

# Weekly COVID-19 Vaccine Updates

Number 7, 29 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. 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
- An EMA investigation reported a possible link between the AstraZeneca vaccine and very rare clotting disorders with low platelets (Thrombosis with Thrombocytopenia Syndrome – TTS) affecting the brain (central venous sinus thrombosis, CVST) and abdomen (splanchnic vein thrombosis). In Australia, there have been 6 reported cases in 1,100,000 adults vaccinated.<sup>1</sup> 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. The EMA confirmed the overall benefits of the vaccine in preventing COVID-19 outweigh the risks of side effects.<sup>2</sup> There are insufficient data yet to assess risk after the second dose of vaccine<sup>3</sup>
- An EMA investigation reported a possible link between the Johnson & Johnson vaccine and TTS – most of 8 cases occurred in women <60 years of age but specific risk factors have not been confirmed.<sup>4</sup> The CDC and FDA have now recommenced the vaccination program in the USA following a thorough safety review<sup>5</sup>
- WHO Global Advisory Committee on Vaccine Safety (GACVS) review of latest evidence of TTS with AstraZeneca vaccine recommends that countries assessing the risk of TTS following COVID-19 vaccination should perform a benefit-risk analysis that takes into account local COVID-19 epidemiology and mortality, age groups targeted for vaccination, and the availability of alternative vaccines<sup>6</sup>
- 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*):

- Effectiveness of Pfizer/BioNTech vaccine in people aged 80-83 in the UK 35-41 days after first vaccination (Page 7):
  - Documented infection: 70.1% (55.1-80.1)
  - Hospital attendance: 78.9% (60.0-89.9)
  - Hospital admission: 75.6% (52.8-87.6)
- Pooled analysis of Pfizer/BioNTech and AstraZeneca vaccines in England: reduced odds of infection post-second dose: 70% (62-77) There was no evidence that these benefits varied between AstraZeneca and Pfizer/BioNTech vaccines (Page 5)
- Pfizer/BioNTech vaccine in Israel: reduction in incidence of infection in vaccinated people aged >60 years and unvaccinated people aged 20-39 years, respectively suggesting herd protection (Page 7):
  - Documented infection: 45% versus 28%
  - Hospitalisation: 68% versus 22%
- Pooled vaccine effectiveness of Moderna and Pfizer vaccines against hospitalisation in those aged ≥65 years in USA: 94% (49-99) (Page 7)
- Six cases of TTS probably linked to the AstraZeneca vaccine have been reported in Australia following 1,100,000 doses administered (Page 9)
- 168 cases of TTS have been reported in 21.2 million people vaccinated with AstraZeneca vaccine in the UK (Page 9)
- 15 cases of TTS have been reported in 7.98 million people vaccinated with Johnson & Johnson vaccine in USA (Page 9)
- Potential risk of TTS following AstraZeneca vaccine in PICs has been updated based on estimates of TTS occurring in 1 in 100,000 vaccinated adults by the EMA and 6 cases in 1,100,000 vaccinated adults in Australia (Page 10)
- The potential risk of TTS following Johnson & Johnson vaccine in PICs has been added to the table based on estimates of TTS occurring in approximately 1 in 532,000 vaccinated adults in USA (Page 10)
- No obvious safety signals among pregnant persons who received Moderna and Pfizer/BioNTech vaccines in USA (product information and WHO SAGE guidelines have not yet been updated) (Page 9)

# 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>	-	USA, Chile, Peru: Severe/critical and hospitalisation: 100% <sup>7</sup> (not peer-reviewed)  UK: 100% (15 cases in the placebo group) <sup>8</sup>	UK: Hospitalisation: 100% (9 cases in placebo group) <sup>8</sup>	Symptomatic infection: 66.7% (57.4-74.0) <sup>8</sup>  Symptomatic infection: 76% <sup>7</sup> (not peer-reviewed)  Symptomatic infection using a SINGLE DOSE (22-90 days post-vaccination): 76.0% (59.3 to 85.9) <sup>8</sup>  Efficacy higher with longer time interval between doses: 12+ weeks: 82.4% (2.7-91.7) <6 weeks: 54.9% (32.7-69.7) <sup>8</sup>
<b>Gamaleya</b>	-	Moderate-severe: 100% (20 cases in the placebo group) <sup>9</sup>	-	Symptomatic infection: 91.6% (85.6-95.2) <sup>9</sup>
<b>Johnson &amp; Johnson</b>	≥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) <sup>10</sup>	85.4% (54.2-96.9) <sup>10</sup>	100% (7 deaths in placebo group) <sup>10</sup>	Preserved for all ages and virus variants including B.1.351 <sup>10</sup>
<b>Moderna</b>	-	100% (30 cases in placebo group) <sup>11</sup>	100% (1 death in placebo group) <sup>11</sup>	Symptomatic infection: 94.1% (89.3-96.8) <sup>11</sup>
<b>Novavax</b>	-	-	-	Symptomatic infection: 89.3% (75.2-95.4) <sup>12</sup> (not peer reviewed)
<b>Pfizer/BioNTech</b>	US COVE study: >90% <sup>13</sup>	88.9% (20.1-99.7) <sup>14</sup>	US COVE study: >95% <sup>13</sup>	Symptomatic infection: 94.6% (89.9-97.3) <sup>14</sup>  USA: 100% against symptomatic infection in adolescents <sup>15</sup>
<b>Sinovac</b>	Brazil: requiring medical assistance: 83.7% (58.0-93.7) Moderate-severe: 100% (56.4-100.0) <sup>16</sup>	Brazil: Moderate-severe: 100% (56.4-100.0) <sup>16</sup>	-	Brazil: Symptomatic infection: 50.7% (36.0-62.0) <sup>16</sup>  Indonesia: Symptomatic infection: 65.3% (not peer reviewed) Turkey: Symptomatic infection: 91.3% (not peer reviewed)

# COVID-19 Vaccine Effectiveness

VACCINE	SEVERE	HOSPITALISATION / DEATH	OTHER OUTCOMES
AstraZeneca	-	SINGLE DOSE in Scotland: 94% (73-99) <sup>17</sup>	<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%<sup>18</sup></p> <p>Pooled analysis of Pfizer/BioNTech and AstraZeneca vaccines: reduced odds of infection post-second dose: 70% (62-77) There was no evidence that these benefits varied between AstraZeneca and Pfizer-BioNTech vaccines<sup>19</sup></p>
Moderna	-	-	<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)<sup>20</sup></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)<sup>21</sup></p>
Pfizer/BioNTech	Israel: 92% (75-100) <sup>22</sup>	SINGLE DOSE in Scotland: 85% (76-91) <sup>17</sup>	<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)<sup>20</sup></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)<sup>21</sup></p> <p>Symptomatic infection in Israel: 94% (87-98)<sup>22</sup></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%<sup>18</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>23</sup></p> <p>Pooled analysis of Pfizer/BioNTech and AstraZeneca vaccines: reduced odds of infection post-second dose: 70% (62-77) There was no evidence that these benefits varied between AstraZeneca and Pfizer-BioNTech vaccines<sup>19</sup></p>
Sinovac	-	Chile: Hospital admission: 85% (83-87); ICU admission: 89% (84-92); Death: 80% (73-86) <sup>24</sup> (not peer reviewed)	Symptomatic infection in Chile: 67% (65-69) <sup>24</sup> (not peer reviewed)

# 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.

VACCINE	VACCINE EFFICACY/EFFECTIVENESS				
	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	ANY INFECTION	SEVERE
<b>AstraZeneca</b>	70.4% (43.6–84.5) (vs. 81.5% (67.9–89.4) against wild variant in UK) <sup>25</sup>	10.4% (–76.8 to 54.8) <sup>26</sup>	Study underway <sup>10</sup>		-
<b>Johnson &amp; Johnson</b>	-	-	Moderate to severe/critical: 64.0% (41.2-78.7) Severe/critical: 81.7% (46.2-95.4) <sup>10</sup>		Moderate to severe/critical: 68.1% (48.8-80.7) Severe/critical: 87.6% (7.8-99.7) <sup>10</sup>
<b>Novavax</b>	85.6% <sup>12</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>27</sup>	-		-
<b>Pfizer/BioNTech</b>	Case-control study in Israel: Vaccinees infected between 2 weeks after the first dose and 1 week after the second dose, were disproportionately infected with B.1.1.7 (odds ratio of 26:10) <sup>28</sup>	Case-control study in Israel: Vaccinees infected at least 1 week after the second dose were disproportionately infected with B.1.351 (odds ratio of 8:1) <sup>28</sup>			
<b>Sinovac</b>				Brazil: vaccine effectiveness after at least 1 dose: 35.1% (–6.6-60.5) <sup>29</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>7</sup> (not peer-reviewed)	In ≥65 years: 85% <sup>7</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>17</sup> Effectiveness against symptomatic infection in England: ≥70 years: 60% (41-73) <sup>30</sup> (not peer reviewed)
<b>Gamaleya</b>	-	-	-	Against symptomatic infection in >60 years: 91.8% (67.1–98.3) <sup>9</sup>
<b>Johnson &amp; Johnson</b>	Against moderate to severe/critical: 23.0% (-90.1-69.8) <sup>10</sup>	Against moderate to severe/critical: 65.9% (47.8-78.3) <sup>10</sup>	Against moderate to severe/critical: With any comorbidity: 58.6% (40.6-71.6) <sup>10</sup> No comorbidity: 68.8% (59.0-76.6) <sup>10</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>10</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>11</sup>	Against symptomatic infection: 18-64 years: 95.6% (90.6-97.9) ≥65 years: 86.4% (61.4-95.2) <sup>11</sup> <b>Pooled Moderna and Pfizer vaccines against hospitalisation ≥65 years: 94% (49-99)<sup>31</sup></b>
<b>Pfizer/BioNTech</b>	-	-	Against symptomatic infection: With any comorbidity or obesity: 95.3% With no comorbidity: 94.7% <sup>14</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>14</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>17</sup> Effectiveness against symptomatic infection in England: ≥70 years: 61% (51-69) ≥80 years: 89% (85-93) <sup>30</sup> (not peer reviewed) <b>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)<sup>32</sup></b> 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% <sup>33</sup> <b>Pooled Moderna and Pfizer vaccines against hospitalisation ≥65 years: 94% (49-99)<sup>31</sup></b>

# 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) <sup>9</sup> Symptomatic and asymptomatic combined (UK, South Africa and Brazil): 54.1% (44.7-61.9) <sup>8</sup>	-
Johnson & Johnson	Asymptomatic: 59.7% (32.8-76.6) <sup>10</sup>	-
Moderna	US: Pooled analysis of Pfizer and Moderna vaccines: 88.7% (68.4-97.1) <sup>34</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>35</sup>	-
Pfizer/BioNTech	England: 86% (76-97) 7 days after 2 doses 72% (58-86) 21 days after 1 dose <sup>36</sup> Israel: 75% (72-84) 15-28 days after single dose <sup>37</sup> Israel: 92% (88-95) <sup>22</sup> USA: Pooled analysis of Pfizer and Moderna vaccines: 88.7% (68.4-97.1) <sup>34</sup> UK, following single dose: 4-fold decrease in risk amongst HCWs ≥12 days post-vaccination <sup>38</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>35</sup>	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 <sup>39</sup>  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 <sup>40</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>8</sup></p> <p>US Phase III study: No serious safety concerns involving 32,449 participants<sup>7</sup> (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 effects<sup>2</sup></p> <p><b>Australia: 6 cases of TTS reported in 1,100,000 people vaccinated<sup>1</sup></b></p> <p>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<sup>41-43</sup>)</p> <p>EMA has started a review of reports of capillary leak syndrome following 5 cases of this very rare disorder post vaccination<sup>44</sup></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>9</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>10</sup></p> <p>EMA investigation of 8 reports of TTS: possible link between the Johnson &amp; Johnson vaccine and TTS. Most cases occurred in women &lt;60 years of age but specific risk factors have not been confirmed<sup>4</sup></p> <p>The CDC and FDA have now recommenced the vaccination program in the USA following a thorough safety review<sup>5</sup></p> <p><b>15 cases of TTS have been reported in 7.98 million people vaccinated in USA<sup>45</sup></b></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>11</sup></p> <p>Anaphylaxis reported in the US at a rate of 2.5 per million doses<sup>46</sup></p> <p><b>No obvious safety signals among pregnant women who received mRNA COVID-19 vaccines in USA<sup>47</sup></b></p>
Novavax	<p>SAEs at low levels and similar between vaccine and placebo groups<sup>12</sup></p>
Pfizer/BioNTech	<p>SAEs and deaths were low and comparable between vaccine and placebo groups (total 37,586 participants)<sup>14</sup>                      Anaphylaxis reported in the US at a rate of 4.7 per million doses<sup>46</sup></p> <p><b>No obvious safety signals among pregnant women who received mRNA COVID-19 vaccines in USA<sup>47</sup></b></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	<1	<1
Fiji	867,000	520,200	2.8-5.2	1.0
French Polynesia	275,918	165,551	0.9-1.7	<1
Guam	159,358	95,615	<1	<1
Kiribati	113,400	68,040	<1	<1
Marshall Islands	54,900	32,940	<1	<1
Nauru	10,900	6,540	<1	<1
New Caledonia	271,407	162,844	0.9-1.6	<1
Niue	1,611	967	<1	<1
Northern Mariana Islands	53,883	32,330	<1	<1
Palau	18,000	10,800	<1	<1
Papua New Guinea	7,744,700	4,646,820	25.4-46.5	8.7
Samoa	195,979	117,587	<1	<1
Solomon Islands	642,000	385,200	2.1-3.9	<1
Tokelau	1,160	696	<1	<1
Tonga	99,419	59,651	<1	<1
Tuvalu	10,507	6,304	<1	<1
Vanuatu	272,173	163,304	0.9-1.6	<1
Wallis and Futuna	11,558	6,935	<1	<1
<b>All Pacific Island Countries</b>	<b>10,976,992</b>	<b>6,586,195</b>	<b>36.0-65.9</b>	<b>12.4</b>

\* Based on estimate of 60% of population aged ≥18 years<sup>48</sup>

\*\* Based on estimates of TTS occurring in approximately 1 in 100,000 vaccinated adults by the European Medicines Agency and 6 cases in 1,100,000 vaccinated adults in Australia<sup>1,3</sup>

\*\*\* Based on estimates of TTS occurring in approximately 1 in 532,000 vaccinated adults in USA<sup>45</sup>

# 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	26	7	2	2	2 (Pfizer/BioNTech, Moderna)
DNA	17	8	2	0	0
Vector (non-replicating)	27	8	3	2	4 (CanSino, Gamaleya, Johnson & Johnson, AstraZeneca)
Vector (replicating)	18	6	0	0	0
Inactivated	9	5	7	1	5 (Sinopharm/BIBP, Sinopharm/WIBP, Bharat, Chumakov, Sinovac)
Live-attenuated	2	1	0	0	0
Protein subunit	73	19	7	1	2 (Vector institute; Anhui Zhifei Longcom Biopharmaceutical Chinese Academy of sciences)
Virus-like particle	19	4	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: 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	End-April 2021
Sinovac	SARS-CoV-2 Vaccine (Vero Cell), Inactivated	Inactivated	In progress	Early May 2021
Moderna	mRNA-1273	mRNA	In progress (to use abridged procedure relying on EMA)	End-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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## References

1. Australian Government Therapeutic Goods Administration (TGA). Three additional Australian cases of TTS likely linked to AstraZeneca vaccine 23 April 2021. Available at: <https://www.tga.gov.au/alert/astrazeneca-chadox1-s-covid-19-vaccine-3>.
2. European Medicines Agency (EMA). AstraZeneca's COVID-19 vaccine: EMA finds possible link to very rare cases of unusual blood clots with low blood platelets 7 April 2021. Available at: <https://www.ema.europa.eu/en/news/astrazenecas-covid-19-vaccine-ema-fin>.
3. European Medicines Agency (EMA) press release. AstraZeneca's COVID-19 vaccine: benefits and risks in context 23 April 2021. Available at: <https://www.ema.europa.eu/en/news/astrazenecas-covid-19-vaccine-benefits-risks-context>.
4. European Medicines Agency (EMA). COVID-19 Vaccine Janssen: EMA finds possible link to very rare cases of unusual blood clots with low blood platelets 20 April 2021. Available at: <https://www.ema.europa.eu/en/news/covid-19-vaccine-janssen-ema-finds-possibl>.
5. US Food and Drug Administration (FDA) press release. FDA and CDC Lift Recommended Pause on Johnson & Johnson (Janssen) COVID-19 Vaccine Use Following Thorough Safety Review 23 April 2021. Available at: <https://www.fda.gov/news-events/press-announcements/f>.
6. WHO Global Advisory Committee on Vaccine Safety (GACVS) review of latest evidence of rare adverse blood coagulation events with AstraZeneca COVID-19 Vaccine (Vaxzevria and Covishield) 16 April 2021.
7. AstraZeneca press release. AZD1222 US Phase III primary analysis confirms safety and efficacy 25 March 2021.
8. Voysey M, Costa Clemens SA, Madhi SA, et al. Single-dose administration and the influence of the timing of the booster dose on immunogenicity and efficacy of ChAdOx1 nCoV-19 (AZD1222) vaccine: a pooled analysis of four randomised trials. *Lancet*. 2021;397(10277):881-891. doi:10.1016/S0140-6736(21)00432-3
9. Logunov DY, Dolzhikova I V, Shcheblyakov D V, et al. Safety and efficacy of an rAd26 and rAd5 vector-based heterologous prime-boost COVID-19 vaccine. *Lancet*. 2021.
10. FDA Briefing Document Janssen Ad26.COV2.S Vaccine for the Prevention of COVID-19. Vaccines and Related Biological Products Advisory Committee Meeting February 26, 2021.
11. Baden LR, El Sahly HM, Essink B, et al. Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine. *N Engl J Med*. 2021. doi:10.1056/nejmoa2035389
12. Novavax COVID-19 Vaccine Demonstrates 89.3% Efficacy in UK Phase 3 Trial. Novavax press release 28 January 2021.
13. Moderna press release. Moderna Provides Clinical and Supply Updates on COVID-19 Vaccine Program Ahead of 2nd Annual Vaccines Day 13 April 2021. Available at: <https://investors.modernatx.com/news-releases/news-release-details/moderna-provides-clinical-and->.
14. World Health Organisation (WHO). *Background Document on the MRNA Vaccine BNT162b2 (Pfizer-BioNTech) against COVID-19.*; 2021. [https://www.who.int/publications/i/item/background-document-on-mrna-vaccine-bnt162b2-\(pfizer-biontech\)-against-covid-19](https://www.who.int/publications/i/item/background-document-on-mrna-vaccine-bnt162b2-(pfizer-biontech)-against-covid-19).
15. Mahase E. Covid-19: Pfizer reports 100% vaccine efficacy in children aged 12 to 15. *BMJ*. April 2021:n881. doi:10.1136/bmj.n881

16. Palacios R, Batista AP, Albuquerque CSN, et al. Efficacy and Safety of a COVID-19 Inactivated Vaccine in Healthcare Professionals in Brazil: The PROFISCOV Study. *SSRN Electron J*. 2021.
17. Vasileiou E, Simpson CR, Robertson C, et al. Effectiveness of First Dose of COVID-19 Vaccines Against Hospital Admissions in Scotland: National Prospective Cohort Study of 5.4 Million People. *SSRN Electron J*. 2021. doi:10.2139/ssrn.3789264
18. University College London press release. Covid-19 vaccine: care home residents gain 62% protection from one dose. 29 March 2021.
19. Pritchard E, Matthews PC, Stoesser N, et al. Impact of vaccination on SARS-CoV-2 cases in the community: a population-based study using the UK's COVID-19 Infection Survey. *medRxiv*. January 2021:2021.04.22.21255913. doi:10.1101/2021.04.22.21255913
20. Daniel W, Nivet M, Warner J, Podolsky DK. Early Evidence of the Effect of SARS-CoV-2 Vaccine at One Medical Center. *N Engl J Med*. March 2021:NEJMc2102153. doi:10.1056/NEJMc2102153
21. Thompson MG, Burgess JL, Naleway AL, et al. Interim Estimates of Vaccine Effectiveness of BNT162b2 and mRNA-1273 COVID-19 Vaccines in Preventing SARS-CoV-2 Infection Among Health Care Personnel, First Responders, and Other Essential and Frontline Workers — Eight U.S. Locations, December 2020–March . *MMWR Morb Mortal Wkly Rep*. 2021;70(13):495-500. doi:10.15585/mmwr.mm7013e3
22. Dagan N, Barda N, Kepten E, et al. BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Mass Vaccination Setting. *N Engl J Med*. February 2021:NEJMoa2101765. doi:10.1056/NEJMoa2101765
23. Benenson S, Oster Y, Cohen MJ, Nir-Paz R. BNT162b2 mRNA Covid-19 Vaccine Effectiveness among Health Care Workers. *N Engl J Med*. March 2021:NEJMc2101951. doi:10.1056/NEJMc2101951
24. Government of Chile Ministry of Health. Effectiveness of the inactivated CoronaVac vaccine against SARSCoV-2 in Chile Preliminary report April 16 2021.
25. Emary KRW, Golubchik T, Aley PK, et al. Efficacy of ChAdOx1 nCoV-19 (AZD1222) vaccine against SARS-CoV-2 variant of concern 202012/01 (B.1.1.7): an exploratory analysis of a randomised controlled trial. *Lancet*. March 2021. doi:10.1016/S0140-6736(21)00628-0
26. Madhi SA, Baillie V, Cutland CL, et al. Safety and efficacy of the ChAdOx1 nCoV-19 (AZD1222) Covid-19 vaccine against the B.1.351 variant in South Africa. *Alex Sigal*. 2021.
27. Shinde V, Bhikha S, Hoosain Z, et al. Preliminary Efficacy of the NVX-CoV2373 Covid-19 Vaccine Against the B.1.351 Variant. *medRxiv*. January 2021:2021.02.25.21252477. doi:10.1101/2021.02.25.21252477
28. Kustin T, Harel N, Finkel U, et al. Evidence for increased breakthrough rates of SARS-CoV-2 variants of concern in BNT162b2 mRNA vaccinated individuals. *medRxiv*. January 2021:2021.04.06.21254882. doi:10.1101/2021.04.06.21254882
29. Hitchings MDT, Ranzani OT, Scaramuzzini Torres MS, et al. Effectiveness of CoronaVac in the setting of high SARS-CoV-2 P.1 variant transmission in Brazil: A test-negative case-control study. *medRxiv*. January 2021:2021.04.07.21255081. doi:10.1101/2021.04.07.21255081
30. Bernal JL, Andrews N, Gower C, et al. Early effectiveness of COVID-19 vaccination with BNT162b2 mRNA vaccine and ChAdOx1 adenovirus vector vaccine on symptomatic disease, hospitalisations and mortality in older adults in England. *medRxiv*. January 2021:2021.03.01.21252652. doi:10.1101/2021.03.01.21252652

31. Tenforde MW, Olson SM, Self WH, et al. Effectiveness of Pfizer-BioNTech and Moderna Vaccines Against COVID-19 Among Hospitalized Adults Aged  $\geq 65$  Years — United States, January–March 2021. *MMWR Morb Mortal Wkly Rep.* 2021;70(18). doi:10.15585/mmwr.mm7018e1
32. Mason T, Whitston M, Hodgson J, et al. Effects of BNT162b2 mRNA vaccine on Covid-19 infection and hospitalisation among older people: matched case control study for England. *medRxiv.* January 2021:2021.04.19.21255461. doi:10.1101/2021.04.19.21255461
33. Rossman H, Shilo S, Meir T, Gorfine M, Shalit U, Segal E. COVID-19 dynamics after a national immunization program in Israel. *Nat Med.* April 2021. doi:10.1038/s41591-021-01337-2
34. Pawlowski C, Lenehan P, Puranik A, et al. FDA-authorized COVID-19 vaccines are effective per real-world evidence synthesized across a multi-state health system. *medRxiv.* January 2021:2021.02.15.21251623. doi:10.1101/2021.02.15.21251623
35. Thompson MG, Burgess JL, Naleway AL, et al. Interim Estimates of Vaccine Effectiveness of BNT162b2 and mRNA-1273 COVID-19 Vaccines in Preventing SARS-CoV-2 Infection Among Health Care Personnel, First Responders, and Other Essential and Frontline Workers .
36. Hall VJ, Foulkes S, Saei A, et al. Effectiveness of BNT162b2 mRNA Vaccine Against Infection and COVID-19 Vaccine Coverage in Healthcare Workers in England, Multicentre Prospective Cohort Study (the SIREN Study). *SSRN Electron J.* 2021. doi:10.2139/ssrn.3790399
37. Amit S, Regev-Yochay G, Afek A, Kreiss Y, Leshem E. Early rate reductions of SARS-CoV-2 infection and COVID-19 in BNT162b2 vaccine recipients. *Lancet.* 2021;397(10277):875-877. doi:10.1016/S0140-6736(21)00448-7
38. Michael Weekes, Nick K Jones, Lucy Rivett, et al. Single-dose BNT162b2 vaccine protects against asymptomatic SARS-CoV-2 infection. *Authorea.* February 24, 2021. doi:10.22541/au.161420511
39. Levine-Tiefenbrun M, Yelin I, Katz R, et al. Initial report of decreased SARS-CoV-2 viral load after inoculation with the BNT162b2 vaccine. *Nat Med.* March 2021. doi:10.1038/s41591-021-01316-7
40. Milman O, Yelin I, Aharony N, et al. SARS-CoV-2 infection risk among unvaccinated is negatively associated with community-level vaccination rates. *medRxiv.* January 2021:2021.03.26.21254394. doi:10.1101/2021.03.26.21254394
41. Government of Canada National Advisory Committee on Immunization (NACI) statement. NACI rapid response: Recommended use of AstraZeneca COVID-19 vaccine in younger adults.
42. UK Government Department of Health and Social Care. Joint Committee on Vaccination and Immunisation (JCVI) statement on use of the AstraZeneca COVID-19 vaccine: 7 April 2021.
43. Australian Technical Advisory Group on Immunisation (ATAGI). ATAGI reinforce recommendations on use of COVID-19 vaccines following review of vaccine safety data and benefits 23 April 2021. Available at: <https://www.health.gov.au/news/atagi-reinforce-recom>.
44. European Medicines Agency (EMA). Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 6-9 April 2021. Available at: <https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-6-9-april-2>.



45. Center for Disease Control (CDC) Advisory Committee on Immunization Practices (ACIP). Thrombosis with thrombocytopenia syndrome (TTS) following Janssen COVID-19 vaccine 23 April 2021. Available at: <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides>.
46. Shimabukuro TT, Cole M, Su JR. Reports of Anaphylaxis After Receipt of mRNA COVID-19 Vaccines in the US—December 14, 2020-January 18, 2021. *JAMA*. 2021;325(11):1101. doi:10.1001/jama.2021.1967
47. Shimabukuro TT, Kim SY, Myers TR, et al. Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons. *N Engl J Med*. April 2021:NEJMoa2104983. doi:10.1056/NEJMoa2104983
48. United Nations Children’s Fund (UNICEF), Pacific Office. Situation Analysis of Children in the Pacific Island Countries. December 2017.

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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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