

# Weekly COVID-19 Vaccine Updates

Number 11, 27 May 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. 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.
- A very rare clotting disorder with low platelets (Thrombosis with Thrombocytopenia Syndrome – TTS) has been associated with the AstraZeneca and Johnson & Johnson vaccines.<sup>1-3</sup> 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.<sup>4</sup> The risk following the first dose of Johnson & Johnson vaccine has been estimated as 1 in 286,000 in the USA<sup>5</sup> Following the second dose in the UK, 15 cases have been reported out of 9 million second doses administered, with an estimated rate of 1.7 per million second doses.<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
- The US FDA has authorised the Pfizer-BioNTech vaccine for emergency use in adolescents aged 12-15 years<sup>7</sup>
- Strong immunogenicity has been found following first dose AstraZeneca vaccine followed by second dose Pfizer/BioNTech vaccine in Spain<sup>8</sup>

## New updates









Key updates include (*also highlighted in yellow text in the document*):

- Effectiveness of AstraZeneca vaccine against symptomatic infection caused by B.1.617.2 (Indian) variant in England: 59.8% (28.9-77.3) [vs. 66.1% (54.0-75.0) against B.1.1.7] (Page 6)
- Effectiveness of Pfizer/BioNTech vaccine against B.1.617.2 variant 87.9% (78.2-93.2) [vs. 93.4% (90.4-95.5) against B.1.1.7] (Page 6)
- Effectiveness of Pfizer/BioNTech vaccine against any infection in Israel (Pages 5 and 7):
  - Overall: 90% (79-95)
  - Diabetes or cardiovascular disease: 82% (62-92)
  - 65-74 years: 82% (63-92)
  - ≥75 years: 82% (61-91)
- Efficacy of Novavax vaccine for preventing symptomatic infection in UK (Pages 4 and 7):
  - Overall: 89.7% (80.2-94.6)
  - B.1.1.7 variant: 86.3% (71.3-93.5)
  - Wild variant: 96.4% (73.8-99.5)
- Effectiveness of single dose of vaccine against hospitalisation in those aged ≥80 years in the UK (Page 7):
  - AstraZeneca: 80.4% (36.4-94.5)
  - Pfizer/BioNTech: 71.4% (43.1-86.2)
- Transmission following a single dose of vaccine in long-term care facility residents in England:
 

Hazard ratio in vaccinated vs. unvaccinated:

  - AstraZeneca: 0.32 (0.15-0.66)
  - Pfizer/BioNTech: 0.35 (0.17-0.71)
- Efficacy of Moderna vaccine against symptomatic infection in adolescents aged 12-17 years:
  - 93% (1 case in the vaccine arm)
- A table has been added on adverse events following immunisation with WHO EUL vaccines (Page 9)
- The potential risk of TTS following AstraZeneca vaccine in PICs has been updated based on estimates of clotting disorders occurring in approximately 1 in 75,000 vaccinated adults in Australia (20 cases in ~1.5 million doses administered) (Page 11)

# 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	WHO EUL, EMA, FDA	Under review by WHO SAGE	WHO EUL, EMA, FDA, TGA, MHRA	Under review by WHO SAGE	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
<b>AstraZeneca</b>	UK: 66.7% (57.4-74.0) <sup>10</sup> USA, Chile, Peru: 76% <sup>9</sup> (not peer-reviewed) Single dose in UK (22-90 days post-vaccination): 76.0% (59.3 to 85.9) <sup>10</sup> Efficacy with different interval between doses in UK: 12+ weeks: 82.4% (2.7-91.7) <6 weeks: 54.9% (32.7-69.7) <sup>10</sup>	-	Severe/critical and hospitalisation in USA, Chile, Peru: 100% <sup>9</sup> (not peer-reviewed) UK: 100% (15 cases in the placebo group) <sup>10</sup>	Hospitalisation in UK: 100% (9 cases in placebo group) <sup>10</sup>
<b>Gamaleya</b>	91.6% (85.6-95.2) <sup>11</sup>	Moderate-severe: 100% (20 cases in the placebo group) <sup>11</sup>	-	-
<b>Johnson &amp; Johnson</b>	-	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) <sup>12</sup>	85.4% (54.2-96.9) <sup>12</sup>	100% (7 deaths in placebo group) <sup>12</sup>
<b>Moderna</b>	USA: 94.1% (89.3-96.8) <sup>13</sup> USA: >90% <sup>16</sup> 12-17 years in USA: 93% (1 case in vaccine arm) <sup>14</sup>	-	USA: 100% (30 cases in placebo group) <sup>13</sup> US: >95% <sup>16</sup>	USA: 100% (1 death in placebo group) <sup>13</sup>
<b>Novavax</b>	UK: 89.7% (80.2-94.6) <sup>15</sup>	-	-	-
<b>Pfizer/BioNTech</b>	Argentina, Brazil, Germany, South Africa, Turkey and the USA: 94.6% (89.9-97.3) <sup>17</sup> 12-15 years in USA: 100% <sup>18</sup>	-	Argentina, Brazil, Germany, South Africa, Turkey and the USA: 88.9% (20.1-99.7) <sup>17</sup>	-
<b>Sinovac</b>	Brazil: 50.7% (35.9-62.0) Chile: 67% (65-69) Indonesia: 65% (20-85) Turkey: 84% (65-92) <sup>20</sup>	Requiring medical assistance in Brazil: 83.7% (58.0-93.7) Moderate-severe: 100% (56.4-100.0) <sup>19</sup>	Brazil: Moderate-severe: 100% (56.4-100.0) <sup>19</sup>	Hospitalisation: Brazil: 100% (56-100) Chile: 85% (83-97) Turkey: 100% (20-100) <sup>20</sup>
<b>Sinopharm</b>	UAE, Bahrain, Egypt and Jordan: 78.1% (64.9-86.3) <sup>20</sup>	-	-	Hospitalisation in UAE, Bahrain, Egypt and Jordan: 78.7% (26.0-93.9) <sup>20</sup>

# COVID-19 Vaccine Effectiveness

VACCINE	SEVERE	HOSPITALISATION / DEATH	OTHER OUTCOMES
AstraZeneca	-	Single dose in Scotland: 94% (73-99) <sup>21</sup> Risk of death in vaccine failures compared to unvaccinated cases in England reduced by: 55% (41-66) <sup>22</sup> (not peer reviewed)	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>23</sup>  Pooled analysis of Pfizer/BioNTech and AstraZeneca vaccines: reduced odds of infection post-second dose: 70% (62-77) <sup>24</sup>
Moderna	-	-	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>25</sup>  Pooled analysis of Moderna and Pfizer/BioNTech vaccines in USA: Fully vaccinated: 90% (68-97) Two weeks after first dose: 80% (59-90) <sup>26</sup>
Pfizer/BioNTech	Israel: 92% (75-100) <sup>27</sup>	Single dose in Scotland: 85% (76-91) <sup>21</sup> Risk of death in vaccine failures compared to unvaccinated cases in England reduced by: Single dose: 44% (32-53) Fully vaccinated: 69% (31-86) <sup>22</sup> (not peer reviewed)	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>25</sup>  Pooled analysis of Moderna and Pfizer/BioNTech vaccines in USA: Fully vaccinated: 90% (68-97) Two weeks after first dose: 80% (59-90) <sup>26</sup> Symptomatic infection in Israel: 94% (87-98) <sup>27</sup> <b>Any infection in Israel: 90% (79-95)<sup>28</sup></b>  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>23</sup>  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 <sup>29</sup>  Pooled analysis of Pfizer/BioNTech and AstraZeneca vaccines: reduced odds of infection post-second dose: 70% (62-77) <sup>24</sup>
Sinovac	-	Chile: Hospital admission: 85% (83-87); ICU admission: 89% (84-92); Death: 80% (73-86) <sup>30</sup> (not peer reviewed)	Symptomatic infection in Chile: 67% (65-69) <sup>30</sup> (not peer reviewed)
Sinopharm	-	-	Symptomatic infection in Bahrain: 90% (88-91) <sup>20</sup>

# 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.<sup>31</sup>

VACCINE	VACCINE EFFICACY/EFFECTIVENESS							
	B.1.1.7 (UK) VARIANT		B.1.351 501Y.V2 (SOUTH AFRICA) VARIANT		B.1.1.28.P1 AND B.1.1.28.P2 (BRAZIL) VARIANTS		B.1.617.2 (INDIA) VARIANT	
	ANY INFECTION	SEVERE	ANY INFECTION	SEVERE	ANY INFECTION	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>32</sup> Effectiveness: 66.1% (54.0-75.0) <sup>33</sup>	-	10.4% (-76.8 to 54.8) <sup>34</sup>	Study underway <sup>12</sup>	-	-	Effectiveness: 59.8% (28.9-77.3) <sup>33</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>12</sup>	-	Moderate to severe/critical: 68.1% (48.8-80.7) Severe/critical: 87.6% (7.8-99.7) <sup>12</sup>		
<b>Novavax</b>	86.3% (71.3-93.5) (vs. 96.4% (73.8-99.5) against wild variant in UK) <sup>15</sup>	-	South Africa: 51.0% (-0.6 to 76.2) <sup>35</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>36</sup> Effectiveness in Qatar: 89.5% (85.9-92.3) <sup>37</sup> Effectiveness: 93.4% (90.4-95.5) <sup>33</sup>	Effectiveness in Qatar: 100% (81.7-100) <sup>37</sup>	Israel case-control study: Vaccinees infected at least 1 week after the second dose were disproportionately infected with B.1.351 (odds ratio: 8:1) <sup>36</sup> Effectiveness in Qatar: 75.0% (70.5-78.9) <sup>37</sup>	Effectiveness in Qatar: 100% (73.7-100) <sup>37</sup>	-	-	Effectiveness 87.9% (78.2-93.2) <sup>33</sup>	
<b>Sinovac</b>	Chile: 67% (65-69) <sup>*20</sup>	-	-	-	Brazil: vaccine effectiveness after at least 1 dose: 35.1% (-6.6-60.5) <sup>38</sup> Chile: 67% (65-69) <sup>*20</sup>	-		

\* While it is known P.1. and B.1.1.7 were circulating at the time of the study, the extent is unknown based on available surveillance

# Vaccine Efficacy/Effectiveness in the Elderly and Against Comorbidities

VACCINE	VACCINE EFFICACY UNLESS OTHERWISE STATED			
	DIABETES	OBESITY	AT RISK FOR SEVERE COVID-19	ELDERLY
<b>AstraZeneca</b>	-	-	76% against symptomatic infection in a sample where 60% had comorbidities, including diabetes, severe obesity or cardiac disease <sup>9</sup> (not peer-reviewed)	In ≥65 years: 85% <sup>9</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>21</sup> Effectiveness against symptomatic infection in England: ≥70 years: 60% (41-73) <sup>39</sup> Effectiveness of single dose against hospitalisation in England: ≥80 years: 73% (60-81) <sup>40</sup> Effectiveness in England: Symptomatic infection ≥70 years: 73% (27-90); Hospitalisation ≥80 years: 37% (3-59) <sup>41</sup> <b>Hospitalisation following single dose in the UK: ≥80 years: 80.4% (36.4-94.5)<sup>42</sup></b>
<b>Gamaleya</b>	-	-	-	Against symptomatic infection in >60 years: 91.8% (67.1–98.3) <sup>11</sup>
<b>Johnson &amp; Johnson</b>	Against moderate to severe/critical: 23.0% (-90.1-69.8) <sup>12</sup>	Against moderate to severe/critical: 65.9% (47.8-78.3) <sup>12</sup>	Against moderate to severe/critical: With any comorbidity: 58.6% (40.6-71.6) <sup>12</sup> No comorbidity: 68.8% (59.0-76.6) <sup>12</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>12</sup>
<b>Moderna</b>	-	-	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) <sup>13</sup>	Against symptomatic infection: 18-64 years: 95.6% (90.6-97.9) ≥65 years: 86.4% (61.4-95.2) <sup>13</sup> Pooled Moderna and Pfizer vaccines against hospitalisation ≥65 years: 94% (49-99) <sup>43</sup>
<b>Pfizer/BioNTech</b>	Effectiveness in Israel: Diabetes or cardiovascular disease: 82% (62-92) <sup>28</sup>	-	Against symptomatic infection: With any comorbidity or obesity: 95.3% With no comorbidity: 94.7% <sup>17</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>17</sup> Effectiveness against hospitalisation 28-34 days after a single dose (pooled analysis of AstraZeneca and Pfizer vaccines): 18-64 years: 85% (68-93); 65-79 years: 79% (17-95); ≥80 years: 81% (65-90) <sup>21</sup> Effectiveness against symptomatic infection in England: ≥70 years: 61% (51-69) ≥80 years: 89% (85-93) <sup>39</sup> (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) <sup>44</sup> 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>45</sup> Pooled Moderna and Pfizer vaccines against hospitalisation ≥65 years: 94% (49-99) <sup>43</sup> 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) <sup>41</sup> Effectiveness against hospitalisation in England ≥80 years: Single dose: 81% (76-85) Fully vaccinated: 93% (89-95) <sup>40</sup> (not peer reviewed) <b>Effectiveness in Israel: 65-74 years: 82% (63-92); ≥75 years: 82% (61-91)<sup>28</sup></b> <b>Hospitalisation following single dose in the UK: ≥80 years: 71.4% (43.1-86.2)<sup>42</sup></b>
<b>Sinovac</b>	-	74.9% (53.7-86.4) <sup>20</sup>	Any comorbidity: 48.9% (26.6-64.5) <sup>20</sup>	-
<b>Sinopharm</b>	-	80.7% (56.7-91.4) <sup>20</sup>	-	Effectiveness against symptomatic infection in Bahrain: ≥60 years: 91% (87-94)

# 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
<b>AstraZeneca</b>	<p>Asymptomatic (UK only): 22.2% (-9.9-45.0)</p> <p>Symptomatic and asymptomatic combined (UK, South Africa and Brazil): 54.1% (44.7-61.9)<sup>10</sup></p> <p>Odds ratio for household contacts of vaccinated health workers vs non-vaccinated health workers testing positive in England: 0.53 (0.43-0.63)<sup>46</sup></p> <p>Pooled analysis of AstraZeneca and Pfizer/BioNTech in Scotland: Hazard ratio for household contacts of vaccinated health workers vs non-vaccinated health workers testing positive: 0.70 (0.63-0.78)<sup>47</sup></p> <p><b>Hazard ratio for single dose in vaccinated vs. unvaccinated care facility residents in England: 0.32 (0.15-0.66)<sup>48</sup></b></p>	-
<b>Johnson &amp; Johnson</b>	<p>Asymptomatic: 59.7% (32.8-76.6)<sup>12</sup></p>	-
<b>Moderna</b>	<p>US: Pooled analysis of Pfizer/BioNTech and Moderna vaccines: 88.7% (68.4-97.1)<sup>49</sup></p> <p>Pooled analysis of Pfizer/BioNTech and Moderna vaccines in USA (weekly testing for 13 weeks): 2 weeks after single dose: 80% (59-90); 2 weeks after second dose: 90% (68%-97)<sup>50</sup></p> <p>Pooled analysis of Pfizer/BioNTech and Moderna vaccines in USA: compared to unvaccinated residents, relative risk of infection in asymptomatic pre-surgical patients &gt;10 days after first dose: 0.21 (0.12-0.37)<sup>51</sup></p> <p>Following mRNA vaccination in nursing homes in USA, incident cases in <i>unvaccinated</i> residents decreased from 4.3% within 14 days of the first vaccination clinic to 0.3% after 42 days<sup>52</sup></p>	-
<b>Pfizer/BioNTech</b>	<p>England: 86% (76-97) 7 days after 2 doses; 72% (58-86) 21 days after 1 dose<sup>53</sup></p> <p>Israel: 75% (72-84) 15-28 days after single dose<sup>54</sup>; 92% (88-95)<sup>27</sup></p> <p>USA: Pooled analysis of Pfizer/BioNTech and Moderna vaccines: 88.7% (68.4-97.1)<sup>49</sup></p> <p>UK, single dose: 4-fold decrease in risk amongst HCWs ≥12 days post-vaccination<sup>55</sup></p> <p>Pooled analysis of Pfizer/BioNTech and Moderna vaccines in US (weekly testing for 13 weeks): 2 weeks after single dose: 80% (59-90); 2 weeks after second dose: 90% (68%-97)<sup>50</sup></p> <p>Pooled analysis of Pfizer/BioNTech and Moderna vaccines in USA: compared to unvaccinated residents, relative risk of infection in asymptomatic pre-surgical patients &gt;10 days after first dose: 0.21 (0.12-0.37)<sup>51</sup></p> <p>Following mRNA vaccination in nursing homes in USA, incident cases in <i>unvaccinated</i> residents decreased from 4.3% within 14 days of the first vaccination clinic to 0.3% after 42 days<sup>52</sup></p> <p>Detectable transmission in residents of long-term care facilities in Spain was reduced 90% (76-93)<sup>56</sup></p> <p>Odds ratio for household contacts of vaccinated health workers vs non-vaccinated health workers testing positive in England: 0.51 (0.44-0.59)<sup>46</sup></p> <p>Pooled analysis of AstraZeneca and Pfizer/BioNTech in Scotland: Hazard ratio for household contacts of vaccinated health workers vs non-vaccinated health workers testing positive: 0.70 (0.63-0.78)<sup>47</sup></p> <p><b>Hazard ratio for single dose in vaccinated vs. unvaccinated care facility residents: 0.35 (0.17-0.71)<sup>48</sup></b></p>	<p>Lower viral load in vaccine failure cases 12-37 days after the first dose of vaccine compared to within the first 11 days, indicating potentially lower infectiousness<sup>57</sup></p> <p>Data from 223 communities in Israel: strong correlation between community vaccination rate and a later decline in infection among children under 16 years of age who were unvaccinated<sup>58</sup></p> <p>Substantially decreased viral load for infections occurring 12-37 days after the first dose of vaccine in Israel, indicating likely lower infectiousness<sup>57</sup></p>



# 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 may get sick – this does not mean 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
Adverse events following immunisation (AEFIs)*	<p>Very common (more than 1 in 10 people): headache, nausea, muscle pain, joint pain, injection site tenderness/pain/ warmth/ itch, fatigue, malaise, fever, chills</p> <p>Common (between 1 in 10 and 1 in 100 people): injection site swelling/ redness<sup>59</sup></p>	<p>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%)<sup>60</sup></p>	<p>Very common: headache, muscle pain, joint pain, injection site pain/ swelling, fatigue, fever, chills;</p> <p>Common: nausea, injection site redness<sup>59</sup></p> <p>Uncommon (between 1 in 100 and 1 in 1000 people): lymphadenopathy, insomnia, pain in extremity of vaccinated arm, malaise, injection site itch;</p> <p>Rare: (between 1 in 1000 and 1 in 10,000): acute peripheral facial paralysis<sup>61</sup></p>	<p>Injection site pain/ redness/ swelling, headache, fatigue, muscle pain, nausea, fever<sup>62</sup></p>	<p>Injection site pain (16%)/ itch (1%)/ swelling (2%)/ redness (1%), fever (4%), fatigue (3%), nausea (1%), headache (1%), diarrhoea (1%), muscle pain (&lt;1%), itch (non-injection site) (1%)<sup>63</sup></p>
Adverse events of special interest (AESIs)	<p>Thrombosis with thrombocytopaenia syndrome (TTS) (see page 11 for estimated risk); Guillain-Barre syndrome<sup>64</sup></p>	<p>Myocarditis;<sup>65</sup> Immune thrombocytopaenia (ITP)**<sup>66</sup></p>	<p>Myocarditis;<sup>65</sup> ITP**<sup>66</sup></p>	<p>TTS (see page 11 for estimated risk)</p>	<p>-</p>

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

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

# Serious Adverse Events

Caution is required when comparing safety profiles as definitions and reporting systems vary in trials and in particular phase IV studies

VACCINE	VACCINE SAFETY
<b>AstraZeneca</b>	<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>10</sup></p> <p>US Phase III study: No serious safety concerns involving 32,449 participants<sup>9</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>Australia: 20 cases of TTS reported in 1,500,000 people vaccinated<sup>67</sup></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>68-70</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>71</sup></p>
<b>Gamaleya</b>	<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>11</sup></p>
<b>Johnson &amp; Johnson</b>	<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>12</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>3</sup></p> <p>The CDC and FDA have now recommenced the vaccination program in the USA following a thorough safety review<sup>72</sup></p> <p>15 cases of TTS have been reported in 7.98 million people vaccinated in USA<sup>1</sup></p>
<b>Moderna</b>	<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>13</sup></p> <p>Anaphylaxis reported in the US at a rate of 2.5 per million doses<sup>73</sup></p> <p>No obvious safety signals among pregnant women who received mRNA COVID-19 vaccines in USA<sup>74</sup></p>
<b>Novavax</b>	<p>SAEs at low levels and similar between vaccine and placebo groups<sup>75</sup></p>
<b>Pfizer/BioNTech</b>	<p>SAEs and deaths were low and comparable between vaccine and placebo groups (total 37,586 participants)<sup>17</sup>                      Anaphylaxis reported in the US at a rate of 4.7 per million doses<sup>73</sup>                      No obvious safety signals among pregnant women who received mRNA COVID-19 vaccines in USA<sup>74</sup></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	5.2-6.9	1.8
French Polynesia	275,918	165,551	1.7-2.2	<1
Guam	159,358	95,615	1.0-1.3	<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	1.6-2.2	<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	46.5-62.0	16.2
Samoa	195,979	117,587	1.2-1.6	<1
Solomon Islands	642,000	385,200	3.9-5.1	1.3
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	1.6-2.2	<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>65.9-87.8</b>	<b>23.0</b>

\* Based on estimate of 60% of population aged ≥18 years<sup>76</sup>

\*\* Based on estimates of TTS occurring in ~1 in 100,000 vaccinated adults by the European Medicines Agency and ~1 in 75,000 in Australia<sup>4,67</sup>

\*\*\* Based on estimates of TTS occurring in ~1 in 286,000 vaccinated adults in USA (may be an underestimate as only cerebral venous sinus thrombosis are reported)<sup>5</sup>

# 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
<b>Minumum Age</b>	18 years	18 years	16 years	18 years	18 years
<b>Maximum Age (SAGE WHO)</b>	None	None	None	None	None
<b>Pregnancy</b>	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
<b>Breastfeeding</b>	Yes if high priority group	Yes if high priority group	Yes if high priority group	Yes if high priority group	Yes if high priority group
<b>Immunocompromised Including HIV</b>	✓	✓	✓	✓	✓
<b>People Previously Infected by SARS-CoV-2 (PCR Confirmed)</b>	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
<b>History of Anaphylaxis (Severe Allergy)</b>	Yes (unless the allergy is to the vaccine or its components)	Yes (unless the allergy is to the vaccine or its components)	Yes (unless the allergy is to the vaccine or its components)	Yes (unless the allergy is to the vaccine or its components)	Yes (unless the allergy is to the vaccine or its components)

# Vaccine Development Pipeline

WHO has recommended that vaccines adopted by countries have WHO SAGE EUL and/or Stringent Regulatory Approval.

VACCINE TYPE	NUMBER OF VACCINE CANDIDATES AT EACH PHASE OF DEVELOPMENT				
	PRE-CLINICAL	PHASE I/II	PHASE III	PHASE IV	IN USE*
RNA	25	9	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	7	0	0	0
Inactivated	8	7	7	2	6 (Sinopharm/BIBP, Sinopharm/WIBP, Sinovac, Bharat, Chumakov, Research Institute for Biological Safety Problems)
Live-attenuated	2	1	0	0	0
Protein subunit	73	19	8	1	3 (Vector institute; Anhui Zhifei Longcom Biopharmaceutical Chinese Academy of sciences, Center for Genetic Engineering and Biotechnology)
Virus-like particle	20	4	1	0	0
Other/unknown	33	4	0	0	0

\*Not all vaccines in use have SRA (as recognised by WHO) approval (see Vaccine specifications table and WHO SAGE Emergency Use Listing and prequalification timeline for approval status of vaccines).

Source: London School of Hygiene and Tropical Medicine COVID-19 vaccine tracker.

# WHO SAGE Emergency Use Listing and Prequalification Timeline

MANUFACTURER	NAME OF VACCINE	PLATFORM	STATUS OF ASSESSMENT	ANTICIPATED DECISION DATE
Pfizer/BioNTech	BNT162b2/COMIRNATY Tozinameran (INN)	mRNA	Final decision made	Authorised 31/12/20
AstraZeneca	AZD1222	Adenoviral vector	Final decision made	SK Bio: Authorised 15/02/21 EU nodes: Authorised 16/04/21
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	May 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	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 starting May 2021	-
Novavax	NVX-CoV2373	Protein subunit	Expression of interest submitted 23/02/21; Pre-submission meeting to be planned in April	-
CureVac	Zorecimeran	mRNA	Expression of interest submitted 12/04/21	-

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>

Weekly COVID-19 Vaccine Updates  
Number 11, 27 May 2021



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Compiled by Dr John Hart

Technical leads: Professor Fiona Russell and Professor Kim Mulholland

Quality checks: Professor Julie Bines, Associate Professor Nigel Crawford and Associate Professor Margie Danchin

## 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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Murdoch Children's Research Institute  
50 Flemington Rd, Parkville  
Victoria 3052 Australia  
ABN 21 006 566 972

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