Literature screening report

COVID-19 vaccines in the WHO's Emergency Use Listing (EUL) Report (5)

Report submission date:	30.09.2021

Responsible authors: *Authors contributed equally	Sabina Rodriguez Velásquez* [A,B] Gabriela Guizzo Dri* [A,B]
Co-authors/ collaborators:	Muaamar Al Gobari [B,C] Sara Botero-Mesa [A,B] Olivia Keiser [A]
Affiliation:	[A] Institute of Global Health, University of Geneva, Switzerland [B] Association Actions en Santé Publique (ASP) & The GRAPH Network, [C] Department of Occupational and Environmental Health, Center for Primary Care and Public Health (Unisanté), University of Lausanne, Epalinges-Lausanne, Switzerland.

Coordination contact:	Jorgen Bauwens (SSPH+)

Abstract

This report focuses on the World Health Organization's (WHO) Emergency Use Listing (EUL) of authorized vaccines as of 30 September 2021. Currently six vaccines are authorised for emergency use: BNT162b2/COMIRNATY (Pfizer-BioNTech, USA), Spikevax/Moderna COVID-19 Vaccine/ mRNA-1273 (Moderna, USA), Vaxzevria/ChAdOx1 nCoV-19/AZD1222/Covishield (AstraZeneca/Oxford, UK, India), Janssen Covid-19 vaccine/Johnson & Johnson (Janssen, USA), Sinopharm/BBIBP-CorV (China), and Sinovac/CoronaVac (China). This report provides a condensed summary concerning vaccine efficacy, safety, protection against variants, and further important information for each vaccine, in the form of a synoptic table. The information and data in this synoptic table was extracted from phase III clinical trials and from observational studies. This report particularly focuses on the latest data on vaccine effectiveness, updates on the Janssen COVID-19 vaccine, booster doses, and new

data on the safety and immunogenicity of the Sinopharm and Pfizer and BioNtech vaccine in children.

Content

Abstract	1
Content	2
Preamble	3
Background	3
Methodology	4
Results	4
Latest Data on Vaccine Effectiveness, Duration over Time, and Waning Immunity	4
New Data on Janssen COVID-19 Vaccine	5
Protection of Booster Doses and Heterologous Regimen	6
Safety and Immunogenicity of COVID-19 Vaccines in Children (3-17 & 5-11)	7
Synoptic Table	9
General Vaccine Information	9
Effectiveness	11
Effectiveness Against Variants	14
Safety And Adverse Events	18
Transmission, Prevention & Protection	22
Children Vaccination	26
Heterologous Vaccination	29
Booster Doses	31
Annexes	40
Further Information	40
Efficacy	41
Efficacy Against Variants	42
Phase III Trials Results	45
Phase III Trial Other	46
Vaccine Production Sites	46
References	50

Preamble

A large number of scientific publications become available on a daily basis, reflecting the rapid development of knowledge and progress of science on COVID-19 related issues. Leading authorities should base decisions or policies on this knowledge; hence they need to master the actual state of this knowledge. Due to the large number of publications shared daily, decision makers heavily depend on accurate summaries of these publications, in the different public health domains. Therefore, the authors of this report were mandated by the Swiss School of Public Health plus (SSPH+), upon request of the Federal Office of Public Health (FOPH), to inform the FOPH on recent findings from the literature.

Background

According to the current global data on vaccinations, only 44.5% of the world populations, of which only 2.2% of people in low-income countries, have received at least one dose of a marketed COVID-19 vaccine as of 30 September, 2021[1]. Currently, six vaccines [namely, Pfizer-BioNTech, USA), Spikevax/Moderna COVID-19 Vaccine/ mRNA-1273 (Moderna, USA), Vaxzevria/ChAdOx1 nCoV-19/AZD1222/Covishield (AstraZeneca/Oxford, UK, India), Janssen Covid-19 vaccine/Johnson & Johnson (Janssen, USA), Sinopharm/BBIBP- CorV (China), and Sinovac/CoronaVac (China)] were assessed and granted an authorization by WHO as of 19 August 2021. Articles regarding the latest data on vaccine effectiveness against the delta variant, new data on the Janssen COVID-19 vaccine, booster doses, and new data on the safety and immunogenicity of the Sinopharm and Pfizer-BioNtech vaccine in children were prioritized during the literature search and are the latest additions to the table. Data from clinical trials and observational studies for the six EUL-accepted vaccines and the vaccine candidate Novavax regarding these highlighted topics were summarized and can be found in the synoptic table below.

[1] https://ourworldindata.org/covid-vaccinations (accessed on 27.09.2021).

Methodology

We screened the data for the EUL-accepted vaccines and the vaccine candidate Novavax as of 30 September 2021 from PubMed, Embase, medRxiv, bioRxiv, Cochrane, and clinical trials databases such as ClinicalTrials and WHO Trial Registry. The methods used were reported previously and can be found in prior reports.

Results

As phase III COVID-19 vaccine trials confirmed vaccine efficacy and safety for all six WHO EUL authorized vaccines, and as the share of fully vaccinated people begin to slowly increase across countries, it is important to assess vaccine effectiveness in real-world conditions, especially in relation to evolving variants of concern (VOC).

Latest Data on Vaccine Effectiveness and Waning Immunity

Given the rise of the more infectious and transmissible Delta variant (B.1.617.2) throughout the world[2] and reports of waning vaccine immunity over time[3], it is important to continuously track real-world vaccine effectiveness, particularly to determine the vaccine-induced protection against severe disease, hospitalization, and death. Both mRNA vaccines demonstrated reduced effectiveness against SARS-CoV-2 infection in the Delta predominant period (June-September) than the Alpha-dominant period[4,5,6,7], although Moderna's mRNA-1273 vaccine demonstrated higher

[2] Tracking of variants. *GISAID*. https://www.gisaid.org/hcov19-variants/
[3] COVID vaccine immunity is waning — how much does that matter? *Nature*. https://www.nature.com/articles/d41586-021-02532-4
[4] New COVID-19 Cases and Hospitalizations Among Adults, by Vaccination Status — New York, May 3–July 25, 2021. *Morbidity & Mortality Weekly Report.* https://www.cdc.gov/mmwr/volumes/70/wr/mm7037a7.htm?s_cid=mm7037a7_x
[5] Comparison of two highly-effective mRNA vaccines for COVID-19 during periods of Alpha and Delta variant prevalence. *medRxiv.* https://www.medrxiv.org/content/10.1101/2021.08.06.21261707v3
[6] Effectiveness of Pfizer-BioNTech and Moderna Vaccines in Preventing SARS-CoV-2 Infection Among Nursing Home Residents Before and During Widespread Circulation of the SARS-CoV-2 B.1.617.2 (Delta) Variant — National Healthcare Safety Network, March 1–August 1, 2021. *Morbidity & Mortality Weekly Report*. https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e3.htm?s_cid=mm7034e3_w
[7] Impact of Delta on viral burden and vaccine effectiveness against new SARS-CoV-2 infections in the UK. *medRxiv.* https://www.medrxiv.org/content/10.1101/2021.08.18.21262237v1

effectiveness than Pfizer-BioNTech's BNT162b2 vaccine[8]. While AstraZeneca's ChadOx1 nCoV-19/Vaxzevria demonstrates lower vaccine effectiveness than both mRNA vaccines, studies have observed sustained vaccine effectiveness over time[9,10]. Likewise, Ad26.COV2.S vaccine effectiveness has been reported to be high (**79%** against SARS-CoV-2 infection and **81%** against COVID-19 related hospitalization) and sustained over time[11]. Despite some reports of reduced effectiveness against SARS-Cov-2 infection with the circulating Delta variant, vaccine effectiveness remains high against severe infection, hospitalization, and death for all vaccines. Vaccine effectiveness data can be found in the synoptic table below.

New Data on Janssen COVID-19 Vaccine

The pharmaceutical company Jonhson & Johnson has recently released data from a Phase III clinical trial (ENSEMBLE 2 study) showing that two doses of their Janssen Ad26.CoV2.S COVID-19 vaccine, administered 56 days apart, provides **94% (95% CI, 58-100)** protection against symptomatic (moderate to severe/critical) COVID-19 in the trial from the USA[12], demonstrating similar vaccine efficacy data to those reported by Pfizer-BioNTech and Moderna. When including efficacy data from Janssen's global ENSEMBLE 2 study, however, the second dose only provided **75% (95% CI, 55-87)** protection against symptomatic (moderate to severe/critical) COVID-19. No data thus far has been released explaining the difference in efficacy between the US and global cohorts. Moreover, the study reported that the Ad26.COV2 vaccine provides **100%**

[8] Comparative Effectiveness of Moderna, Pfizer-BioNTech, and Janssen (Johnson & Johnson) Vaccines in Preventing COVID-19 Hospitalizations Among Adults Without Immunocompromising Conditions — United States, March–August 2021. *Morbidity & Mortality Weekly Report*. https://www.cdc.gov/mmwr/volumes/70/wr/mm7038e1.htm?s_cid=mm7038e1_w

[9] Efficacy of vaccination against severe COVID-19 in relation to Delta variant and time since second dose: the REACT-SCOT case-control study. *medRxiv.* https://www.medrxiv.org/content/10.1101/2021.09.12.21263448v1

[10] Impact of Delta on viral burden and vaccine effectiveness against new SARS-CoV-2 infections in the UK. *medRxiv.* https://www.medrxiv.org/content/10.1101/2021.08.18.21262237v1

[11] Effectiveness of the Single-Dose Ad26.COV2.S COVID Vaccine. *medRxiv.* https://www.medrxiv.org/content/10.1101/2021.09.10.21263385v2

[12] Johnson & Johnson Announces Real-World Evidence and Phase 3 Data Confirming Strong and Long-Lasting Protection of Single-Shot COVID-19 Vaccine in the U.S. *Johnson & Johnson*. https://www.jnj.com/johnson-johnson-announces-real-world-evidence-and-phase-3-data-confirming-strong-and-long-lasting-protection-of-single-shot-covid-19-vaccine-in-the-u-s

(95% CI, 33-100) protection against severe/ critical COVID-19 and that antibody levels increased **4- to 6-fold** after the second dose when compared to the single shot. Another phase III trial data demonstrated that a Ad26.COV2 booster dose administered six months after Janssen's single dose increased antibody levels by **factor of 9** one week after the booster up to a **factor of 12** four weeks after the booster. Adverse events following the second dose or booster shot were similar to the ones observed following a single dose[13]. Lastly, real-world effectiveness data confirm that the Janssen vaccine provides **79% (95% CI, 77-80)** effectiveness against SARS-CoV-2 infections and **81% (95% CI,79-84)** against COVID-19 related hospitalizations[14]. These observational data were consistent with Johnson & Johnson's Phase III ENSEMBLE efficacy trials.

Protection of Booster Doses and Heterologous Regimen

Since many countries have started the administration of COVID-19 vaccines booster doses after multiple articles reported a waning immunity against the SARS-CoV-2 virus, data on the prevention of SARS-CoV-2 infections, the rate of severe/critical COVID-19 disease, and potential benefits of heterologous booster doses are needed. New data on the benefits of a third dose of Pfizer-BioNtech (BNT162b2) vaccine on a population aged 60 years and more in Israel demonstrated that the booster dose lowered the rate of confirmed infections by a factor of 11.3 and lowered the rate of severe illness by a factor of 19.5 compared to participants with only two doses of the vaccine[15]. Additionally, the rate of confirmed infection, at least 12 days after receiving the booster dose, was lower than the rate, after 4 to 6 days, by a factor of 5.4. Other data regarding the administration of heterologous booster doses, such as the

[13] Johnson & Johnson Announces Real-World Evidence and Phase 3 Data Confirming Strong and Long-Lasting Protection of Single-Shot COVID-19 Vaccine in the U.S. *Johnson & Johnson*. https://www.jnj.com/johnson-johnson-announces-real-world-evidence-and-phase-3-data-confirming-strong-and-long-lasting-protection-of-single-shot-covid-19-vaccine-in-the-u-s

[14] Johnson & Johnson Announces Real-World Evidence and Phase 3 Data Confirming Strong and Long-Lasting Protection of Single-Shot COVID-19 Vaccine in the U.S. *Johnson & Johnson*. https://www.jnj.com/johnson-johnson-announces-real-world-evidence-and-phase-3-data-confirming-strong-and-long-lasting-protection-of-single-shot-covid-19-vaccine-in-the-u-s

[15] Protection of BNT162b2 Vaccine Booster against Covid-19 in Israel. *New England Journal of Medicine.* https://www.nejm.org/doi/full/10.1056/NEJMoa2114255

administration of third doses of ChAdOx1 or BNT162b2, after immunization with CoronaVac, have been made available after countries such as Thailand and Turkey recommended a booster dose for healthcare workers and elderly people. Results from two different studies showed that a third heterologous dose of either ChAdOx1 or BNT162b2, following full immunization with CoronaVac, elicited a higher neutralizing activity against the SARS-CoV-2 virus compared to a third homologous dose of CoronaVac[16,17].

Safety and Immunogenicity of COVID-19 Vaccines in Children (3-17 & 5-11)

As many countries are slowly beginning to reopen schools and the number of COVID-19 cases among children are starting to weekly increase, the discussion regarding COVID-19 children vaccination has become of importance. Currently, most countries have approved the administration of COVID-19 vaccines in children aged 12-years-old and over as the vaccines showed to be safe, tolerable, and immunogenic in this population. Only few countries have approved the use of Sinopharm and Sinovac vaccines in children aged 3 years and over including the United Arab Emirates and China[18]. Recently, new data and preliminary results on the safety and immunogenicity of BBIBP-CorV/Sinopharm and Pfizer-BioNtech vaccine for children aged less than 12 years old were released and made available to the public. Results of a randomised, double-blind, controlled, phase 1/2 trial of BBIBP-CorV vaccine in participants aged 3-17 years was published[19]. Overall, the vaccine demonstrated to be safe and well tolerated in participants 3-17 years while also eliciting robust humoral response against SARS-CoV-2 infection after two 4 µg doses. Similar preliminary results were

[16] SARS-CoV-2 specific antibody response after third CoronaVac or BNT162b2 vaccine following two-dose CoronaVac vaccine regimen. *Journal of Medical Virology.* https://onlinelibrary.wiley.com/doi/10.1002/jmv.27350

[17] Immunogenicity of a third dose viral-vectored COVID-19 vaccine after receiving two-dose inactivated vaccines in healthy adults. *medRxiv.* https://www.medrxiv.org/content/10.1101/2021.09.16.21263692v1

[18] Which countries are vaccinating children against Covid-19? *The National News UAE.* https://www.thenationalnews.com/uae/health/2021/08/03/which-countries-are-vaccinating-children-against-covid-19/

[19] Safety and immunogenicity of an inactivated COVID-19 vaccine, BBIBP-CorV, in people younger than 18 years; a randomized, double-blind, controlled, phase 1/2 trial. *The Lancet Infectious Diseases.* https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00462-X/fulltext

announced by Pfizer-BioNtech for the phase 2/3 trial of the BNT162b2 vaccine in children aged 5-11 years[20]. The mRNA vaccine showed favourable safety profile and robust neutralizing antibody responses using 10 µg doses, making this smaller dose the preferred one for children 5-11 years old. Although results for the population of 5 years and younger is expected to be released later this year, Pfizer-BioNtech announced their plan to submit these data to the FDA, EMA, and other regulatory agencies around the world[5].

Further (biweekly) updated data on the six WHO EUL vaccines and the vaccine candidate Novavax are synthesized in the synoptic table and new data has been highlighted in yellow.

[20] Pfizer and BioNtech Announce Positive Topline Results from Pivotal Trial of COVID-19 Vaccine in Children 5 to 11 Years. *Pfizer and BioNtech Press Release.* https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-positive-topline-results

Synoptic Table

Synoptic table about SARS-CoV-2 vaccines accepted in the WHO's Emergency Use Listing and Novavax Vaccine (as of 30 September 2021)

							AWAITING APPROVAL FROM WHO EUL
	BNT162b2/ COMIRNATY (Pfizer-BioNTech, USA)	**Spikevax/ Moderna COVID-19 Vaccine/ mRNA-1273 (Moderna, USA)**	**Vaxzevria/ ChAdOx1 nCoV-19/ AZD1222/ Covishield (AstraZeneca/Oxford, UK, India)**	**Janssen COVID-19 vaccine/Johnson & Johnson (Janssen, USA)**	**Sinopharm/BBIBP-CorV, China**	**Sinovac CoronaVac, China**	**Novavax/ NVX-CoV2373**
GENERAL VACCINE INFORMATION							
Platform	mRNA-based vaccine	mRNA-based vaccine	Non-replicating vector-based vaccine	Non-replicating vector-based vaccine	Inactivated virus (Vero cell)	Inactivated virus (Vero cell)	Recombinant protein (nanoparticle) vaccine with Matrix-M adjuvant
Dose and frequency	2 doses, 21 days apart	2 doses, 28 days apart	2 doses, 4-12 weeks apart	1 dose, once [Phase III trials currently testing 2-	2 doses, 21 days apart	2 doses, 14 days apart	2 doses, 21 days apart

				dose regime, 56 days apart][i]			
Target population	12 years old and over	12 years old and over	18 years old and over	18 years old and over	18 years old and over	18 years old and over	18 years old and over
Storage conditions	2°C to 8 °C (for 1 month)	2°C to 8 °C (for 1 month)	2°C until 8 °C	2°C to 8 °C (for 3 months)	2°C until 8 °C	2°C until 8 °C	2°C to 8 °C
Approving authorities	FDA (11.12.20)[ii]; EMA (21.12.20); WHO EUL (31.12.20); and list of countries (including Switzerland – approved on 20.12.20)	FDA (18.12.20); EMA (06.01.21); WHO EUL (30.04.21); and list of 51 countries (including Switzerland – approved 12.01.21)	FDA (awaiting on approval); EMA (29.01.21); WHO EUL (15.02.21); and list of 121 countries (Switzerland awaiting on approval)	FDA (27.02.21); EMA (11.03.21), WHO EUL (12.03.21), and list of 59 countries (including Switzerland – approved 22.03.21)	WHO EUL (07.05.21); and list of 55 countries (e.g., Argentina, Bahrain, Brazil, China, Indonesia, United Arab Emirates, Zimbabwe)	WHO EUL (01.06.21), and list of 33 countries (e.g., Albania, Chile, Egypt, Hong Kong, Malaysia, Tunisia, Turkey, Ukraine)	Waiting on approval (Not-yet-approved by countries or WHO for emergency use)
JOHNSON & JOHNSON 2-DOSE EFFICACY							
Protection against symptomatic (moderate to severe/ critical) SARS-CoV-2 infection	-	-	-	**94%** (95% CI, 58-100) in the US. **75%** (95% CI, 55-87) globally.[1]	-	-	-

[i] Johnson & Johnson Announces Real-World Evidence and Phase 3 Data Confirming Strong and Long-Lasting Protection of Single-Shot COVID-19 Vaccine in the U.S. *Johnson & Johnson*. https://www.jnj.com/johnson-johnson-announces-real-world-evidence-and-phase-3-data-confirming-strong-and-long-lasting-protection-of-single-shot-covid-19-vaccine-in-the-u-s

[ii] Pfizer-BioNTech's Comirnaty Vaccine received full FDA approval on 23 August 2021 for people age 16 and above, moving it beyond emergency use status. https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine

Protection against severe/ critical SARS-CoV-2 infection	-	-	-	**100%** (95% CI, 33-100)[1]	-	-	-
EFFECTIVENESS							
Effectiveness single dose	*General population:* Against infection: **70%**[2]. *Individuals ≥70:* Symptomatic disease: **58%**[3]. Hospitalization risk reduced by 35-**45%**[3]. Risk of death reduced by **54%**[3]. *Individuals ≥50:* ≥14 days after first dose: **54%** (95% CI, 47-61) effectiveness against	*General population:* Symptomatic disease: **60%** (95% CI, 57-64; >2 weeks after dose)[5].[iv] *Individuals ≥70:* Symptomatic disease: **64%** (95% CI, 46-78; >2 weeks after dose)[5].[v] *Individuals ≥50:* ≥14 days after first dose: **54%** (95% CI, 47-61) effectiveness against hospitalization [1	*General population:* Asymptomatic or symptomatic disease: **64%;** Symptomatic disease: **67%**[6]. *Individuals ≥70:* Symptomatic disease: **58%**[3]. Hospitalization risk reduced by **35-45%**[3].	**50.6%** (95% CI, 14.0-74.0) in preventing SARS-CoV-2 infection (<2 weeks after dose); **76.7%** (95% CI, 30.3-95.3) in preventing SARS-CoV-2 infection (>2 weeks after dose)[7]. **79%** (95% CI, 77-80) (when corrected for under-recording, VE was estimated to be **69%** (95% CI, 67-71)[8].	Partial protection[10].[vii]	**15.5%** for preventing COVID-19; **37.4%** for preventing hospitalization; **44.7%** for preventing admission to the ICU; and **45.7%** for preventing of COVID-19 related death[11]. **18.6%** (95% CI, 17.6-19.6) against SARS-CoV-2 infection, **28.1%** (95% CI, 26.3-29.9) against hospitalization, **28.5%** (95% CI, 25.4-31.4) against	Ongoing studies in South Africa[13] and United Kingdom[14]

[iv] mRNA-aggregated data (results do not disaggregate between BNT162b2 and mRNA-1273).
[v] mRNA-aggregated data (results do not disaggregate between BNT162b2 and mRNA-1273).
[vii] Study did not report numerical data on vaccine effectiveness. Further studies are required to validate results.

	hospitalization [1 January-22 June[4]. [iii]	January-22 June[4]. [vi]		**81%** (95% CI, 79-84) for preventing hospitalization when corrected for under-recording, VE was estimated to be **73%** (95% CI, 69-76)[8]. 75% (95% CI, 65-82) against severe critical COVID-19[1]. **71%** (95% CI, 56-81) [11 March – 15 August][9]. *Individuals ≥50:* 68% (95% CI, 50-79)[4].		ICU admission, and **29.4%** (95% CI, 26.7.3-31.9) against death [January-April][12]	
Effectiveness of two doses	*SARS-Cov-2 infection:* **85%**[2]. **94.6%**[15].	*SARS-Cov-2 infection:* **100%**[15].	*SARS-CoV-2 infection*: **85%**; *Symptomatic disease*: **90%**[6].	Not Applicable (one dose schedule)	Partial protection[10]. [xiii]	**65.9%** for preventing COVID-19; **87.5%** for preventing hospitalization; **90.3%** for	Ongoing studies in South Africa[13] and United Kingdom[14]

[iii] mRNA-aggregated data (results do not disaggregate between BNT162b2 and mRNA-1273).
[vi] mRNA-aggregated data (results do not disaggregate between BNT162b2 and mRNA-1273).
[xiii] Study did not report numerical data on vaccine effectiveness. Further studies are required to validate results.

	94.5%[16]. **76%** (95% CI, 69-81) [January-July][17]. *Asymptomatic SARS-CoV-2 infection:* **90.6%**[18].[viii] *Hospitalization:* **85%** (95% CI, 73-93) [January-July][17]. **88%** (95% CI, 85-91) [11 March – 15 August][9]. **89%** (95% CI, 87-91) for individuals ≥50 years [1 January-22 June[4].[ix]	**86%** (95% CI, 81-90.6) [January-July][17]. *Symptomatic disease*: **91%** (95% CI, 89-93; >2 weeks after dose)[5].[x] *Asymptomatic SARS-CoV-2 infection:* **90.6%**[18].[xi] *Hospitalization:* **91.6%** (95% CI, 81-97) [January-July][17]. **93%** (95% CI, 91-95) [11 March – 15 August)[9].				preventing ICU admission; and **86.3%** for preventing COVID-19 related death[11].[xiv] **52.7%** (95% CI, 52.1-53.4) against SARS-CoV-2 infection, **72.8%** (95% CI, 71.8-73.7) against hospitalization, **73.8%** (95% CI, 72.2-75.2) against ICU admission, and **73.7%** (95% CI, 72.3-75.0) against death [January-April][12]	

[viii] Results do not disaggregate between BNT162b2 and mRNA-1273

[ix] mRNA-aggregated data (results do not disaggregate between BNT162b2 and mRNA-1273).

[x] Results do not disaggregate between BNT162b2 and mRNA-1273.

[xi] Results do not disaggregate between BNT162b2 and mRNA-1273

[xiv] Death reports on fully vaccinated doctors (10 cases during June 2021 in Indonesia). It may be related to new variants [media report]. Indonesian Covid deaths add to questions over Sinovac vaccine. *The Guardian* [press release]. https://www.theguardian.com/world/2021/jun/28/indonesian-covid-deaths-add-to-questions-over-sinovac-vaccine

		89% (95% CI, 87-91) for individuals ≥50 years [1 January-22 June[4]. [xii]					
EFFECTIVENESS AGAINST VARIANTS[xv]							
Alpha (B.1.1.7)	*Single dose:* **48.7%** (95% CI, 45.5 to 51.7)[19] **66%** (95% CI,64-68)[20]. **54.5%** (95 CI, 50.4-58.3)[21] *Two doses:* **93.7%** (95% CI, 91.6 to 95.3)[19] **92%** (95% CI, 90-93)[22]. **89%** (95% CI, 86-91)[20]. **78%** (95% CI, 68-84)[23]	*Single dose:* **88.1%** (95% CI, 83.7 to 91.5)[24] **83%** (95% CI, 80-86)[20]. *Two doses:* **100%** (95% CI, 91.8 to 100)[24] **92%** (95% CI, 86-96)[20].	*Single dose:* **48.7%** (95% CI 45.5 to 51.7)[19] 6**4%** (95% CI, 60-68)[20]. *Two doses:* **74.5%** (95% CI, 68.4 to 79.4)[19] **73%** (95% CI, 66-78)[22]. 79% (95% CI, 56-90)[23].	-	No published data	*Two doses:* Equally effective **(~76%)** in neutralizing D614G, B.1.1.7 and B.1.429 as the wild-type strain.	Ongoing studies in South Africa[13] and United Kingdom[14]

[xii] mRNA-aggregated data (results do not disaggregate between BNT162b2 and mRNA-1273).

[xv] Effectiveness data against the latest variant of interest (Mu) will be included in upcoming reports based on data availability.

	84.4% (95 CI, 81.8-86.5)[21]						
Beta (1.351)	*Single dose:* **60%** (95% CI, 52-67)[20]. *Two doses:* **84%** (95% CI, 69-92)[20].	*Single dose:* **61.3%** (95% CI, 56.5 to 65.5)[24] **77%** (95% CI, 69-92)[20]. *Two doses:* **96.4%** (95% CI, 91.9 to 98.7)[24]	*Single dose:* **48%** (95% CI, 28-63)[20].	-	No published data	Neutralization capacity was decreased by factor **5.27**[25].	No available data
Gamma (P.1)	Neutralization activity reduced by **3.3-fold**[26].	-	-	-	No published data	Demonstrated **42%** vaccine effectiveness in a setting with high P.1 transmission, in individuals aged 70 and above[27]. **50.2%** against P.1 (>14 days after 2nd dose)[28]. Neutralization was decreased by factor **3.92**[25].	No available data
Delta (1.617.2)	*Single dose:* **30.7%** (95% CI, 25.2 to 35.7)[19];	*Single dose:* **72%** effective against	*Single dose:* **30.7%** (95% CI 25.2 to 35.7)[19]	**78%** (95% CI, 73-82) against SARS-CoV-2 infection[8].			No available data

	57% (95% CI, 50-63)[23] **22.5%** (95 CI, 17.0-27.4)[21] *Two doses:* **88.0%** (95% CI, 85.3 to 90.1)[19]; **80%** (95% CI, 77-83)[23] **79%** (95% CI,75-82)[22]. **80%** (95% CI, 77-83)[23] **40.5%** (95% CI, 8.7-61.2)[29]. **42%** (95% CI, 13-62)[17]. **89.8%** (95% CI, 89.6-90.0) [2-9 weeks after second dose][30]. **69.7%** (95% CI, 68.7-70.5) [≥20 weeks after second dose][30]. **64.6%** (95 CI, 60.6-68.2)[21] **52.4%** (95% CI, 48.0-56.4) [among nursing home residents][31].	symptomatic SARS-Cov-2 infection[32]. *≥14 days after second dose:* **76%** (95% CI, 58-87)[17]. **94.5%** (95% CI, 94.1-95) [2-9 weeks after second dose][30]. **50.6%** (95% CI, 45.0-55.7) [among nursing home residents][31]. *10-14 weeks after second dose:* **90.3%** (95% CI, 67.2-97.1)[30].	*Two doses:* **67.0%** (95% CI, 61.3 to 71.8)[19] **67%** (95% CI, 62-71)[23]. **60%** (95% CI, 53-66)[22]. **66.7%** (95% CI, 45-49.6) [2-9 weeks after second dose][30]. **47.3%** (95% CI, 66.3-67.0) [≥20 weeks after second dose][30]. Odds ratio of **5.45** (95% CI, 1.39-21.4) to become infected with B.1.167.2 compared to non-B.1.167.2 [33].	*Individuals ≥50:* **83% (**95% CI, 81-85)[8]		*Single dose:* **13.8%** (95% CI, -60.2-54.8)[34]. *Two doses:* **59%** (95% CI, 16-81.6) against SARS-CoV-2 infection and **70.2%** (95% CI, 29.6-89.3) against moderate COVID-19 infection[34].	

Effectiveness against hospitalization and death	***Alpha*** *Against hospitalization:* Single dose: **83%** (95% CI, 62-93) Two doses: **95%** (95% CI, 78-99)[35]. ***Delta*** *Against severe COVID-19*: **91.4%** (95% CI, 82.5-95.7)[29]. *Against hospitalization:* *Single dose*: **94%** (95% CI, 46-99)[35]. **91%** (95% CI, 90-93)[36] *Two doses*: **96%** (95% CI, 86-99)[35].	***Delta*** **96%** against severe COVID-19 infection[32]. *Against hospitalization:* *Single dose:* **81%** (95% CI, 81-90.6)[17]. *Two doses:* **84%** (95% CI, 80-87)[36] *Against ICU admission:* **86%** (95% CI, 79-90)[36]	***Alpha*** *Against hospitalization:* Single dose: **76%** (95% CI, 61-85) Two doses: **86%** (95% CI, 53-96)[35]. ***Delta*** *Against hospitalization:* *Single dose*: **71%** (95% CI, 51-83)[35] **88%** (95% CI, 83-91)[36] *Two doses*: **92%** (95% CI, 75-97)[35]. **95.2%** (95% CI, 94.6-95.6) [2-9 weeks][30]. **77.0%** (95% CI, 70.3-82.3) [≥20 weeks][30].	***Beta*** **67%** effective at preventing hospitalizations[38]. ***Delta*** *Against hospitalization:* **71%** [38] **85%** (95% CI, 73-91)[8]. **91%** (95% CI, 88-94)[36] **85%** effective at preventing severe disease and hospitalization[39]. *Individuals ≥50:* **84% (**95% CI, 81-85)[8]	***Delta*** Single dose: Does not offer clinically meaningful protection against severe illness [40,xvi] Two doses: 88% (95% CI, 55-98) adjusted risk reduction in developing severe illness.[40,xvii]	***Delta*** Single dose: Does not offer clinically meaningful protection against severe illness [40,xviii] Two doses: 88% (95% CI, 55-98) adjusted risk reduction in developing severe illness.[40,xix]	No available data

[xvi] Study does not differentiate between the two inactivated vaccines, BBIBP-CorV and CoronaVac.
[xvii] Study does not differentiate between the two inactivated vaccines, BBIBP-CorV and CoronaVac.
[xviii] Study does not differentiate between the two inactivated vaccines, BBIBP-CorV and CoronaVac.
[xix] Study does not differentiate between the two inactivated vaccines, BBIBP-CorV and CoronaVac.

	88% (95% CI, 78.9-93.2)[29]. **75%** (95% CI, 24-93.9)[17]. **84%** (95% CI, 79-89)[37]. **98.4%** (95% CI, 97.9-98.8) [2-9 weeks][30]. **92.7%** (95% CI, 90.3-94.6) [≥20 weeks][30]. **96%** (95% CI, 95-96)[36] *Against death:* **98.2%** (95% CI, 95.9-99.2) [2-9 weeks][30]. **90.4%** (95% CI, 85.1-93.8) [≥20 weeks][30].		**94%** (95% CI, 92-95)[36] *Against ICU admission:* *Single dose:* **92%** (95% CI, 84-96)[36] *Two doses*: **96%** (95% CI, 94-98)[36] *Against death:* **94.1%** (95% CI, 91.8-95.8) [2-9 weeks][30]. **78.7%** (95% CI, 52.1-90.4) [≥20 weeks][30].	*Against ICU admission:* **94%** (95% CI, 88-98)[36] *Against death:* 96% effective at preventing death[38].			
SAFETY AND ADVERSE EVENTS							

Common side effects	Pain at the injection site, fatigue, headache, myalgia, chills and fever.[41] Optimal safety for asthma patients[42]. The vaccine is considered safe for cancer patients undergoing treatments[43].	Pain at injection site, headache, fatigue, myalgia, arthralgia[44], Covid arm (cutaneous hypersensitivity)[45]. The vaccine is considered safe for cancer patients undergoing treatments[43].	Fatigue, myalgia, arthralgia, headache[46], lethargy, fever, & nausea[47].	Headache, fever, chills, fatigue, myalgia, and nausea[48].	Pain at the injection site, dizziness, fever, headache, fatigue, nausea, vomiting, & allergic dermatitis[47,49].	Pain at injection site, headache, fatigue, tremors, & flushing[50], inflammatory reaction, urticaria[51].	Pain at injection-site, headache, muscle pain, fatigue[52]
Phase III clinical trial serious adverse events	Serious adverse events were observed in a similar proportion of vaccine (0.6%) and placebo (0.5%) recipients. These events also occur at a similar frequency within the general population[41,53].	The frequency of grade 3 adverse events was similar in both the vaccine (1.5%) and placebo groups (1.3). Serious adverse events were observed in a similar proportion in both groups (0.6%). 3 Bell's Palsy cases occurred in the vaccine group and one Bell's Palsy case occurred in	Serious adverse events were balanced across the study arms. 79 cases occurred in the vaccine group and 89 cases in the placebo group – 3 cases were considered related to the experimental or control vaccine (out of 11 636 vaccine recipients): transverse myelitis, haemolytic	Serious adverse events were reported in 0.4% of vaccine recipients and 0.4% of placebo recipients. Seven of the serious adverse events were considered to be related to the vaccine: Guillain-Barré syndrome (1), pericarditis (1), brachial radiculitis (1), hypersensitivity (1), Bell's Palsy	A cross-sectional survey collected data on adverse events following vaccination in the UAE - none of the symptoms were of serious nature or required hospitalization[49].	Overall incidence of serious adverse events was 0.5% (31 in placebo group and 33 in vaccine group). All adverse events were determined to be unrelated to the vaccine[50].	<u>Phase II:</u> Nine serious adverse events were reported, only one of which was assessed as related to the vaccine: acute colitis[55].

		the placebo group[44].	anaemia and a case of fever higher than 40°C [46].	(2), & severe generalized weakness, fever & headache (1)[54].			
Rare adverse events	Myocarditis & myopericarditis[56-58], anaphylaxis and swelling of the lips, face, and tongue related to anaphylaxis[59] (11 anaphylaxis cases per million doses administered)[60], axillary lymphadenopathy, paroxysmal ventricular arrhythmia, leg paresthesia[61], pityriasis rosea[62] (lesions improved completely after ~8 weeks)[63], lymphocytic vasculitis[64], varicella-zoster reactivation [65-67],	Myocarditis & myopericarditis [56-58], orofacial swelling & anaphylaxis[59]. Potential risk factor for Bell's palsy (most improve upon follow-up)[78], herpes zoster reactivation[66,79], varicella zoster reactivation[66], herpes zoster ophtalmicus[80], eczema & urticaria[81], transverse myelitis[82], Guillain-Barré syndrome[83].	Transverse myelitis, high fever[46,84], cutaneous hypersensitivity[84], vasculitis[85], cerebral venous sinus thrombosis[86] (higher risk for women)[87], thromboembolism[88], vaccine induced immune thrombotic thrombocytopenia[89,90-92], intracerebral haemorrhage[93], small vessel vasculitis[85,94], psoriasis, rosacea, raynaud's phenomenon[81],	Thrombosis, thrombocytopenia, cerebral venous sinus thrombosis[101], increased risk of developing Guillain-Barré syndrome post vaccination[102], herpes zoster ophtalmicus[80]. 97% of reported reactions after vaccine administration were non-serious[48].	Similar among the vaccine groups and control group within 7 days[103].	Myalgia, fever[50], pityriasis rosea (lesions improved completely after ~8 weeks)[63], reactivation of herpes zoster and herpes simplex[51]. Most reactions improved without treatment within a few weeks[51], Guillain-Barré syndrome[104].	Myocarditis was reported in one vaccine recipient, occurring 3 days after second dose[52]

	Kikuchi-Fujimoto disease[68], thrombotic thrombocytopenic purpura[69], IgA nephropathy flare-up[70], Guillain-Barré syndrome [71,72], pustural psoriasis[73], immunoglobulin A vasculitis[74], immune complex vasculitis[75], Rhabdomyolysis[76], subacute thyroiditis[77].		Ischaemic stroke[95], anaphylaxis[96], recurrent herpes zoster[97,xx], generalized bullous fixed drug eruption[98], Guillain-Barré syndrome[72], pityriasis rosea[99]. Vaccination in individuals with adrenal insufficiency can lead to adrenal crises[100].				
Potential associated adverse events (warrants further analysis as causal links are not yet proven)	Cerebral venous sinus thrombosis and intracranial haemorrhage[105], aseptic meningitis[106], autoimmune hepatitis[107,108], multiple sclerosis relapse[109], myeloperoxidase	Autoimmune hepatitis[107], myocardial infarction[111]. One case developed IgA Nephropathy after receiving the second dose of mRNA-1273	Autoimmune hepatitis[107], Acute hyperglycaemic crisis[113], Facial nerve palsy, cervical myelitis.[95]	Facial Diplegia[114]	-	-	No available data

[xx] All cases occurred in patients with chornic urticaria and were being treated with cyclosporine.

	anti-neutrophil cytoplasmic antibody-positive optic perineuritis[110].	(causal link not yet proven)[112].					
Myocarditis data	Mainly reported in young adults and adolescents [115] Refer to children vaccination section for more details	Mainly reported in young adults and adolescents [115] Refer to children vaccination section for more details	No available data	No available data	No available data	No available data	Myocarditis was reported as viral myocarditis. Participant fully recovered after 2 days of hospitalisation. No episode of anaphylaxis or vaccine-associated enhanced COVID-19 was reported[52]
TRANSMISSION, PREVENTION & PROTECTION							
Immunogenicity	*7-14 days after second dose:* *18-55 years*: GMT ranged from **1.7 to 4.6** times the GMT of the	*14 days after second dose:* *18-55 years*: $PRNT_{80}$ GMT	*28 days after second dose median antibody titres:*	*29 days after vaccination:* *18-55 years:* GMC **586 (95% CI, 445-771**);	*14 days after second dose:* *18-55 years:* GMT ***211.2*** **(95% CI, 158.9-280.6**)[121].	*Single dose (≥4 weeks)*: **37.7±57.08 IU/ml (min: 0, max: 317.25);** 57.02% of participants did not develop	*14 days after second dose (18-84 years):* 5-ug: IgG GMT **44,421 EU/ ml (95% CI,**

	convalescent serum[116]. *65-85 years*: GMT ranged from **1.1 to 2.2** times the GMT of the convalescent serum[116].	**654.3 (95% CI, 460.1-930.5)**[117]. *56-70 years:* $PRNT_{80}$ GMT **878 (95% CI, 516-1494)**[118]. *≥71 years*: $PRNT_{80}$ GMT **317 (95% CI, 181-557)**[118].	*18–55 years*: **20,713 AU/mL [IQR 13,898 - 33,550]**[119] *56–69 years*: 1**6,170 AU/mL [IQR 10,233 - 40,353]**[119]. *≥70 years*: **17,561 AU/mL [IQR 9,705 - 37,796]**[119].	GMT **224 (95% CI, 168-298)**[120]. *≥65 years*: GMC **312 (95% CI, 246-396);** GMT **212 (95% CI, 163-266)**[120]. *57 days after vaccination:* *18-55 years*: **754 (95% CI, 592-961)**; GMT **288 (95% CI, 221-376)**[120].	*≥60 years: GMT **131.5** (95% CI, 108.2-159.7)*[121].	sufficient antibody titres (<25.6 IU ml) *Two doses (≥4 weeks)*: **194.61±174.88 IU/ml (min: 0, max: 677.82);** 11.48% of participants did not develop sufficient antibody titres (<25.6 IU ml)[122].	**37,929-52,024)**[55]. 25-ug: IgG GMT **46,459 EU/ml (95% CI, 40,839-52,853)**[55].
Transmission prevention	*Prior Delta Variant:* Vaccine effectiveness against infectiousness given infections **41.3%**[123] Vaccine effectiveness against transmission **88.5%**[123] *During Delta Variant:*	Limited data	**48%** (limited data) May not be able to block the transmission of the alpha variant as efficiently as the wild type[127].	Limited data	Unknown	Unknown	Unknown

	Similar Ct values (<25) were found in both vaccinated and unvaccinated groups[124] Studies from Scotland and England demonstrated reductions in secondary infections among families of vaccinated individuals compared to families of unvaccinated individuals[125,126].						
Duration of protection	Limited data[128] Median time between second dose and infection: **146 days (IQR, 121-167)**[129]	*Preliminary phase I results:* Antibody activity remained high in all age groups at **day 209** (approximately 6 months)	*Antibody Response:* After single dose, antibody response declined within one year, but remained above baseline levels. Antibody levels	*Neutralizing antibodies:* Remained largely stable for **8-9 months**[134] *Binding antibodies:*	Limited data[128]	A phase I/II clinical trial found that NAbs titres dropped below the seropositive cut-off of 8, **6 months** after the administration of the first dose[136].	Unknown

	Anti-SARS-CoV-2 Antibodies: 1 month after 2nd dose: **1762 KU/L (IQR: 933-3761)** 3 months after 2nd dose: **1086 KU/L (IQR: 629-2155)** 6 months after 2nd dose: **802 KU/L (IQR, 447-1487)**[130] No health worker had antibodies BELOW method-dependent cut-off (0.8 KU/L) VE reduced by 22% (95% CI, 6-41) for every 30 days from the second dose for those aged 18 to 64 years[23].	GMT were lower in ≥56 years old[131] **36.4** (95% CI, 17.1-51.5) reduction of observed incidence rate (SARS-CoV-2 infection) if vaccinated from Dec 2020 – Apr 2021 than Jul 2021 – Dec 2020.[132] **46.0** (95% CI, -52.4-83.2) reduction of observed incidence rate (**severe** SARS-CoV-2 infection) if vaccinated from Dec 2020 – Apr 2021 than Jul 2021 – Dec 2020.[132]	after **day 180**: 0.54 GMR (CI, 0.47-0.61). Antibody levels after **day 320**: 0.30 GMR (CI, 0.24-0.39)[133] *Cellular Immune Response:* **Day 182** after first dose: median of **237 SFUx10^6 PBMC (IQR, 109-520)**[133] **6 months** after second dose: **(median 1240, IQR 432-2002**) in groups with 15-25 week interval between doses[133] VE reduced by 7% (95% CI, -18 - 2) for every 30 days from the second dose for those aged 18 to 64 years[23].	Remained stable **6 months** irrespective of age group[134] *Humoral & Cellular Immune Response:* Antibody responses were detected in all vaccine recipients on **day 239** (stable response for at least 8 months)[135] A study observed sustained and stable vaccine effectiveness starting 14 days post vaccination to a maximum of 152 days after vaccination[8].		**80-90%** of anti-S IgG and Nab titers against wild type waned **6 months** after second vaccination[137]	

CHILDREN VACCINATION							
Efficacy	*Adolescents (12-15):* After one dose had efficacy of **75% (CI, 7.6-95.5)** After second dose efficacy of **100% (CI, 78.1-100)**[138]. *Children (5-11):* Ongoing trials[139] *Children (Under 5 years):* Ongoing trials[139]	*Adolescents (12-17):* After one dose had efficacy of **92.7% (CI, 67.8-99.2)** After second dose efficacy of **93.3% (CI, 47.9-99.9)**[140]. *Children (6month-11):* Ongoing trials[141]	No available data Paused ongoing trials in children aged 6-17 due to concerns over rare blood clots reported in adult population[142].	No available data Announced at begging of April ongoing study in adolescents but paused to investigate blood clots in adult population[142].	*Children (3-17):* Unknown. Ongoing clinical trial only looked at safety, tolerability, and immunogenicity[xxi] * * The study design administered **three doses** of 2 µg, 4 µg, or 8 µg of vaccine	*Children (3-17):* Unknown. Clinical trial only looked at safety, tolerability and immunogenicity[143].	*Adolescents (16-17):* PREVENT-19 clinical trial[xxii] expanded to assess efficacy, safety, and immunogenicity in 12–17-year-old adolescents[144]
Immunogenicity	*Adolescents (12-15) serum-neutralizing titer:* 1 month after 2nd dose had **1283.0 GMN_{50} (CI, 1095.5-1402.5)**[138].	*Adolescents (12-17):* Neutralizing antibody titer after 2nd dose was **1401.7 GMN_{50} (CI, 1276.3-1539.4)**	No available data	No available data	*Children (3-17):* Neutralizing antibodies after 28 days after 2nd dose ranged from **105.3-180.2 GMT** in 3-5 years cohort, **84.1-168.6**	*Children (3-17):* Neutralizing antibody response after 2nd dose **(100%)** with GMT ranging from **45.9-212.6**[143]	Ongoing clinical trial[147]

[xxi] Safety and immunogenicity of an inactivated COVID-19 vaccine, BBIBP-CorV, in people younger than 18 years: a randomised, double-blind, controlled, phase 1/2 trial. *The Lancet Infectious Diseases*. https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00462-X/fulltext

[xxii] A Study to Evaluate the Efficacy, Immune Response, and Safety of a COVID-19 Vaccine in Adults ≥18 Years With a Pediatric Expansion in Adolescents (12 to <18 Years) at Risk for SARS-CoV-2. *ClinicalTrials.gov*. ClinicalTrials.gov Identifier: NCT04611802. https://clinicaltrials.gov/ct2/show/NCT04611802?term=Novavax&cond=Covid19&draw=2

	Adolescents/young adult (16-25) serum-neutralizing titer: 1 month after 2nd dose had **705.1 GMN_{50} (CI, 621.4-800.2)**[138]. *Children (5-11):* 1 month after 2nd dose had **1,197.6 GMT (95% CI, 1106.1-1296.6)** SARS-CoV-2-neutralizing antibody[145] *Children (Under 5):* Ongoing trials[139]	Serological response was **98.8% (CI, 97.0-99.7)** *Children (6month-11):* Ongoing trials[141]			**GMT** in 6-12 years cohort, and **88.0-155.7 GMT** in 13-17 years cohort Neutralizing antibodies after 28 days after 3rd dose ranged from **143.5-224.5 GMT** in 3-5 years cohort, **127-184.8 GMT** in 6-12 years cohort, and **150.7-199 GMT** in 13-17 years cohort[146]		
Safety and Adverse events	*Adolescents (12-15):* Local and systemic events were generally mild to moderate Severe injection-site pain **(1.5%)** Fever **(20%)** High Fever **(0.1%)**	*Adolescents (12-17):* Solicited local reactions after 2nd dose **(93.4%)** Most common solicited adverse reactions were Injection-site pain **(92.7%)**	No available data	No available data	*Children (3-17):* Most common adverse reaction was pain at injection site in 3–5-year group **(4%)**, 6-12-year group **(1.2%)**, and 13-17-year group **(7.9%)**	*Children (3-17):* Adverse reactions in 12–17 year group **(35%)**, 3-5 year group **(26%)**, and 6-11 year group **(18%)** Reported at least one adverse event **(27%)**	Ongoing clinical trial[147]

	Adverse events **(6%)** Severe adverse events **(0.6%)**[138]. *Adolescent/young adults (16-25):* Local and systemic events were generally mild to moderate Severe injection-site pain **(3.4%)** Fever **(17%)** Adverse events **(6%)** Severe adverse events **(1.7%)**[138]. *Children (5-11):* Preliminary results on safety profile are consistent with those observed in older populations [145] *Children (Under 5):* Ongoing trials[139]	Headache **(70.2%)** Fatigue **(67.8%)** Grade 3 adverse events **(6.8%)** Few reported cases of acute myocarditis and pericarditis (mainly in males)[148] *Children (6month-11):* Ongoing trials[141]			Most common systemic reactions in all three age cohorts were mild to moderate **fever** and **cough** Adverse events were mostly mild to moderate in severity[146]	Most reported events were mild and moderate and only **(<1%)** grade 3 events Injection-site pain **(13%)** Fever **(25%)**[143]	

Myocarditis Data	Few reported cases of acute myocarditis and pericarditis in 16-25 year olds (mainly in males)[148]	Few reported cases of acute myocarditis in adolescents and young adults	No available data	No available data	No available data	No available data	No available data
HETEROLOGOUS VACCINATION							
Vaccine Schedule	**BNT162b2/ChAdOx1** Administration of ChAdOx1 as second/booster dose	**ChAdOx1/mRNA-1273** Administration of mRNA-1273 as second/booster dose	**ChAdOx1/BNT162b2** Administration of BNT162b2 as second/booster dose	Not Applicable (one dose schedule) For more information refer to booster section	**BBIBP/BNT162b2**	**CoronaVac/ChAdOx1** Press releases have confirmed that Thailand will use the AstraZeneca vaccine as the second dose for individuals whose first dose was Sinovac[xxiii] **CoronaVac/Convidecia**	Ongoing trial[149] (Com-Cov2)[xxiv]

[xxiii] Malaysia to stop using Sinovac vaccine after supply ends - minister. *Reuters* [press release]. https://www.reuters.com/world/asia-pacific/malaysia-stop-using-sinovac-vaccine-after-supply-ends-minister-2021-07-15/

[xxiv] Comparing COVID-19 Vaccine Schedule Combinations. *University of Oxford.* https://comcovstudy.org.uk/about-com-cov2

Vaccine Immunogenicity	*GMCs of SARS-CoV-2 anti-spike IgG at 28 days post booster:* Heterologous **(7133 ELU/mL, CI 6415-7932)** vs. Homologous **(14080 ELU/mL, CI 12491-15871)**[150]. *SFC frequency (T0cell ELISpot):* Heterologous **(99 SFC/10^6 PBMCs)** vs. Homologous **(80 SFC/10^6 PBMCs)**[150]**.**	**Spike-specific IgG antibodies:* Heterologous **(3602 BAU/mL)** vs. Homologous **(4189 BAU/mL)**[48] **Neutralizing antibodies:* Heterlogous **(100%)** vs. Homologous **(100%)**[151]. *Results based on immunosuppressed population	*RBD antibody titres:* Heterologous **(7756.68 BAU/mL, CI 7371.53-8161.96)** vs. Homologous **(99.84 BAU/mL, CI 76.93-129.59)** at day 14[152]. *IgG antibody titres:* Heterologous **(3684 BAU/mL)** vs. Homologous **(101.2 BAU/mL)** at day 14[152]. *Neutralizing antibodies:* Heterologous **(100%)** at day 14 vs. Homologous **(30%)** at day 14[152].	Not Applicable (one dose schedule) For more information refer to booster section	Unknown (on-going clinical trial)[49]	**CoronaVac/ChAdOx1 :** *Anti-S Antibodies:* Heterologous **(797 U/mL; 95% CI, 598.7-1062)** vs. Homologous CoronaVac **(94.4 U/mL; 95% CI : 76.1-122.1)** vs. Homologugous ChAdOx1 **(818 U/mL; 95% CI: 662.5-1010)**[153] **CoronaVac/Convidecia** *Neutralizing antibodies :* Heterologous **54.4 GMT** (95% CI, 37.9-78) vs. Homologous CoronaVac **12.8 GMT** (95% CI, 9.3-17.5)[154]	No available data Ongoing trial[149]
Vaccines Reactogenicity	Observed increase in systemic reactogenicity	*Adverse events in heterologous and homologous vaccination	*Adverse events in heterologous:* Headache **(44%)**, Myalgia **(43%)**,	Not Applicable (one dose schedule)	Unknown (on-going clinical trial)[155]	**CoronaVac/ChAdOx1:** Unknown	No available data Ongoing trial[149]

	after boost in heterologous schedules in comparison with homologous schedules[150] *Adverse events in heterologous:* Adverse events **(90)** Grade 1 **(54.4%)** Grade 2 **(37.8%)** Grade 3 **(7.8%)** Grade 4 **(0%)** Arthralgia, Migraine, Back Pain[150]. *Adverse events in homologous:* Adverse events **(81)** Grade 1 **(59.3%)** Grade 2 **(39.5%)** Grade 3 **(1.2%)** Grade 4 **(0%)**[150].	groups were very similar[151]. *Majority of adverse events self-reported were Pain at injection site, Swelling at injection site, Fever, Headaches, Fatigue, Chills, GI effects, Myalgia, Arthralgia[151]. *Results based on immunosuppressed population	Malaise **(42%)**, Fever **(2%)**, Injection site pain **(88%)**, Induration **(35%)**, Erythema **(31%)**[152]. *Severity of adverse events in heterologous:* Mild **(68%)**, Moderate **(30%)**, Severe **(2%)**[152].	For more information refer to booster section		**CoronaVac/Convidecia:** Convidecia recipients reported more adverse reactions and reported higher occurrence of solicited injection-site pain)[154]	
BOOSTER DOSES							

Vaccine Schedule	*Homologous:* **BNT162b2/BNT162b2**	*Homologous:* **mRNA-1273/mRNA-1273**	*Homologous:* **ChAdOx1/ChAdOX1**	*Homologous:* **Ad26.CoV.2.S/ Ad26.CoV.2.S** *Heterologous:* **BNT162b2/Ad26.CoV.2.S**	*Homologous:* **SinoPharm/SinoPharm** *Heterologous:* **SinoPharm/BNT162b2**	*Homologous:* **CoronaVac/CoronaVac** *Heterologous 1:* **CoronaVac/ChAdOx1** *Heterologous 2 :* **CoronaVac/BNT162b2**	*Homologous:* **NVX-CoV2373/NVX-CoV2373** *Heterologous:* Ongoing trial of heterologous booster shot using NVX-CoV2373[xxv]
Approved Administration	*Israel:* 12-year-old and over can received homologous booster shot 5 months after full jab[xxvi] *United States:* Starting September, adults who received	Phase II booster trial of three booster doses are ongoing[156] Moderna sought FDA approval of its COVID-19 vaccine booster[xxviii] *United States:*	Preliminary results on tolerability and immunogenicity of third dose of ChAdOx1 vaccines showed strong boost to the immune response[157]	Johnson & Johnson has said it will submit all of their new data to the FDA for potential consideration for adding a booster dose and consideration to authorize two-dose regimen[xxix]	*UAE:* Offering booster doses of Pfizer and Sinopharm to people who received full Sinopharm jab ≥6 months ago	**Turkey** and the **United Arab Emirates** began homologous booster shots **Indonesia** and **Thailand** are considering giving homologous	Ongoing phase II trials[158] Results below are based on ongoing phase II trial

[xxv] COV-Boost Evaluating COVID-19 Vaccine Boosters. *University of Southampton & NHS.* https://www.covboost.org.uk/home

[xxvi] Israel offers COVID-19 booster to all vaccinated people. *Reuters* [press release]. https://www.reuters.com/world/middle-east/israel-offers-covid-19-booster-shots-all-vaccinated-people-2021-08-29/

[xxviii] Moderna seeks U.S. authorization for COVID-19 vaccine booster. *Reuters* [press release]. https://www.reuters.com/business/healthcare-pharmaceuticals/moderna-submits-initial-data-covid-19-vaccine-booster-us-fda-2021-09-01/

[xxix] Two dose version of Johnson & Johnson shot 94% effective against Covid-19, study finds. *CNN.* https://edition.cnn.com/2021/09/21/health/johnson-vaccine-two-doses-booster/index.html

	mRNA vaccine 8 months ago are eligible for booster *Europe:* Starting in fall, most European countries are planning on rolling out booster shots to immunocompromised and elder populations[xxvii]	Starting September, adults who received mRNA vaccine 8 months ago are eligible for booster.				booster shot to HCW[xxx]	
Time-to-booster dose	**6 months to 8 months** after initial two-dose regimen Israel offers up to **5 months** after initial two-dose regimen	**6 months to 8 months** after initial two-dose regimen	**6-9 months** after initial two-dose regimen	*Homologous:* **6 months** after one dose regimen[134] *Heterologous:* **4 months** after initial two-dose BNT162b2 regimen[159]	**6 months** after initial two-dose regimen	*Homologous:* **6 months to 12 months** After primary vaccination **8 months** after the primary vaccination to healthy adults ≥60 years *Heterologous 1:*	**6 months** after initial two-dose regimen (**189 days**)[158]

[xxvii] A country-by-country guide to coronavirus vaccine booster plans. *POLITICO* [press reléase]. https://www.politico.eu/article/vaccine-booster-coronavirus-covid-19-europe-delta-varian-who/

[xxx] Indonesia and Thailand consider booster shots amid doubts over Sinovac vaccine. *Reuters* [press release]. https://www.reuters.com/world/china/indonesia-thailand-consider-booster-shots-amid-doubts-over-sinovac-vaccine-2021-07-08/

						21 to 26 days after full jab of CoronaVac *Heterologous 2:* **6 months** after primary vaccination of CoronaVac	
Immunogenicity	*Neutralizing titers:* Elicits **>5-8 more** for wild type after 6 months after 2nd dose[160]	Booster doses (mRNA1273 or mRNA1273.351) increased neutralizing antibody titers against wild-type[161]	*Antibody Levels:* Higher levels after third dose (tIgG EU **3746**; IQR: 2047-6420) [157] *Spike Cellular Immune Response:* Increased from **200 SFUx10^6 PBMC (IQR, 127-389)** after the second dose to **399 SFUx10^6 PBMC (IQR, 314-662)** after the third one[157]	*Homologous:* 5X10^{10} vp booster dose elicited **9-fold** increase at day 7 compared to first dose after 29 days in 18-55-year-olds[134] 1.25X10^{10} vp booster dose elicited **6-7.7-fold** increase at day 28 compared to first dose after 29 days in 18-55 and ≥65-year-old[134] *Heterologous:* **14.8 to 32.4-fold** increase in neutralization titers against wild-type virus[159]	Ongoing trial[155]	*Homologous:* Neutralizing Antibodies: **60%** higher NAbs activity against wild-type compared to 2-doses[137] Anti-S IgG and NAbs: **20-fold** increase 4 weeks post booster vaccination NAbs were maintained **60** to **180 days** post booster[137] *Heterologous 1:* Heterologous vaccination had a **9-fold greater**	*Anti-spike IgG:* Increase of **4.6-fold** compared to peak response after 2nd dose (**Day 217 GMEU = 200408**; 95% CI: 159796-251342)[158] *Wild-type Neutralizing Response:* Increase of **4.3-fold** compared to peak response after 2nd dose **(IC50 = 6231; 95% CI: 4738-8195)** [158]

						GMT (7,947 U/mL) than fully patients fully vaccinated with AZD1222 and the highest antibody response, IgA, and neutralizing antibodies than other groups[162] *Heterologous 2:* Median values of IgG-S titers were higher in group that received BNT162b2 as booster than CoronaVac BNT162b2 boosted IgG-S median titers by **factor of 46.6** but IgG-N titers decreased by **factor of 6.5**[163]	*Older Participants (60-84):* **5.4-fold** increase in antibody response[158] *Younger Participants (18-59):* **3.7-fold** increase in antibody response[158]
Immunogenicity against variants	*Beta (B.1.351):* Elicits **15-21** more neutralizing titers for Beta variant after 6 months after 2nd dose[160]	Preliminary results of booster doses of mRNA-1273 vaccine show robust antibody	Third dose provided higher antibody titters against Alpha, Beta, and Delta variants[157]	*Homologous:* No available data *Heterologous:* **10.9 to 21.2-fold** increase in	Ongoing trial[155]	*Homologous:* **Beta (B.1.351):** **3.0-fold** decrease in neutralizing antibodies	High levels of functional antibodies against Alpha (B.1.1.7), Beta (B.1.351), and

	Delta (B.1.671.2): **>5-fold** increase in neutralizing titers against Delta compared to dose 2 titers in 18–55-year-olds **>11-fold** increase in neutralizing titers against Delta compared to dose 2 titers in 65–85-year-olds[160]	response against Delta variant[156]		pseudovirus neutralization assay (one volunteer did not have any against fB.1.351) [159]		compared to wild type[137] **Gamma (P.1):** **3.1-fold** decrease in neutralizing antibodies compared to wild type[137] **Delta (B.1.671.2):** **2.3-fold** decrease in neutralizing antibodies compared to wild type **2.5-fold** higher neutralizing potency than 2-dose vaccination[137] *Heterologous 1:* Neutralizing activity against the wild type and variant strains showed higher neutralizing activity in the following order: **wild type > B.1.617.2 >**	Delta (B.1.671.2)[158] *Delta (B.1.671.2):* Increase of **6.6-fold** in antibody response compared to Delta response observed with primary vaccination[158]

						B.1.1.7 > B.1.351[162]	
Reactogenicity	Preliminary results show consistent tolerability[160]	Similar safety and tolerability compared to second dose[156] *Common solicited local adverse events:* Injection-site pain **(68.4% for mRNA-1273.351, 90% for mRNA-1273)** fatigue **(36.8% for mRNA-1273.351, 70% for mRNA-1273)** headache **(36.8% for mRNA1273.351, 55.0% for mRNA-1273)** myalgia **(31.6% for mRNA-1273.351, 45.0% for mRNA-1273)** arthralgia **(21.1% for mRNA-1273,**	Lower reactogenicity after third dose compared to first dose[133]	No available data	Ongoing trial[155]	The third shot is considered to be safe[136]. *Common side effects:* Pain at the injection site. *Adverse events:* Unrelated to the vaccination	Booster dose was **well tolerated** Local and systemic **reactogenicity increased** between Dose 1, Dose 2, and Dose 3 **90%** of symptoms were rated as mild or moderate[158]

		50.0% for mRNA-1273)[161]					
Protection against COVID-19	Older population (≥60): **11.3 (95% CI, 10.4-12.3) lower rate** of confirmed infection in booster group[164] **19.5 (95% CI, 12.9-29.5) lower rate** of severe illness in booster group[164]	No available information	No available information	No available information	No available information	No available information	No available information
Other	Detailed report from Pfizer regarding booster doses can be found here: https://www.fda.gov/media/152161/download 14-20 days after booster, marginal					For more detailed information regarding immunogenicity of third dose refer to study[xxxi] Ongoing clinical trial examining the immunogenicity and safety of a	

[xxxi] A third dose of inactivated vaccine augments the potency, breadth, and duration of anamnestic responses against SARS-CoV-2. *medRxiv.* https://www.medrxiv.org/content/10.1101/2021.09.02.21261735v1

	effectiveness increases to **70-84%**[165]					third dose vaccination with ChAdOx1 or BNT162b2 vaccine among adults who received full jab of CoronaVac[xxxii]		

[xxxii] Third Dose Vaccination with AstraZeneca or Pfizer COVID-19 Vaccine Among Adults Received Sinovac COVID-19 Vaccine. *ClinicalTrials.gov.* https://clinicaltrials.gov/ct2/show/NCT05049226

ANNEXES

	BNT162b2/ COMIRNATY (Pfizer-BioNTech, USA)	Spikevax/ Moderna COVID-19 Vaccine/ mRNA-1273 (Moderna, USA)	Vaxzevria/ ChAdOx1 nCoV-19/ AZD1222/ Covishield (AstraZeneca/Oxford, UK, India)	Janssen COVID-19 vaccine/Johnson & Johnson (Janssen, USA)	Sinopharm/BBIBP-CorV, China	Sinovac CoronaVac, China	Novavax/ NVX-CoV2373
FURTHER INFORMATION							
Storage conditions	2°C to 8 °C (for 1 month)	2°C to 8 °C (for 1 month)	2°C until 8 °C	2°C to 8 °C (for 3 months)	2°C until 8 °C	2°C until 8 °C	2°C to 8 °C
Approving authorities	FDA (11.12.20)[xxxiii]; EMA (21.12.20); WHO EUL (31.12.20); and list of countries (including Switzerland –	FDA (18.12.20); EMA (06.01.21); WHO EUL (30.04.21); and list of 51 countries (including Switzerland – approved 12.01.21)	FDA (awaiting on approval); EMA (29.01.21); WHO EUL (15.02.21); and list of 121 countries (Switzerland awaiting on approval)	FDA (27.02.21); EMA (11.03.21), WHO EUL (12.03.21), and list of 59 countries (including Switzerland – approved 22.03.21)	WHO EUL (07.05.21); and list of 55 countries (e.g., Argentina, Bahrain, Brazil, China, Indonesia, United Arab Emirates, Zimbabwe)	WHO EUL (01.06.21), and list of 33 countries (e.g., Albania, Chile, Egypt, Hong Kong, Malaysia, Tunisia, Turkey, Ukraine)	Waiting on approval (Not-yet-approved by countries or WHO for emergency use)

[xxxiii] Pfizer-BioNTech's Comirnaty Vaccine received full FDA approval on 23 August 2021 for people age 16 and above, moving it beyond emergency use status. https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine

	approved on 20.12.20)						
EFFICACY							
Single dose[xxxiv]	**52%** (95% CI, 29.5 to 68.4; starting at 12 days) or 82.2% (75.1 to 87.3; starting at ≥14 days)[166]. **91%** (95% CI, 85-94)[167].	**95.2%** (95% CI, 91.2.8 to 97.4; starting at >14 days)[44].	**72.8%** (starting at 22 days up to 60 days)[168]. **88%** (95% CI, 75-94)[167].[xxxv]	Single dose vaccine	Unknown	**35.1%** (95% CI, -6.6 to -60.5) [conducted in a setting with high P.1 transmission][169].	**83.4%** (95% CI, 73.6-89.5) starting at ≥14 days[52]
Two doses[xxxvi]	**95.0%** (95% CI, 90.3-97.6) starting at ≥7 days in population without prior SARS-CoV-2 infection[61] **94.6%** (95% CI, 89.9-97.3) starting at ≥7 days in	**94.1%** (95% CI, 89.3-96.8) after median follow-up of less than 63 days[44] **93.2%** (95% CI, 91.0-94.8)[170]	**63.1% (**95% CI, 51.8-71.7) starting at ≥14 days for two standard doses[168] **80.7%** (95% CI, 62.1-90.2) starting at ≥14 days for first low dose and	**66.9%** (95% CI 59.0-73.4) after 14 days and **66.1%** (95% CI 55.0-89.1) after 28 days for VE against moderate-severe-critical COVID-19[54]	After 14 days, efficacy against symptomatic cases was **72.8%** (95% CI 58.1-82.4; in WIV04 vaccine) or **78.1%** (95% CI 64.8 to 86.3; in HBO2 vaccine).[103]	After 14 days, efficacy against symptomatic cases was **50.7%** (95% CI 35.9 to 0-62.0).[50] 99.17% of NAb titres were above or equal to the	**89.7%** (95% CI, 80.2-94.6) starting at ≥7 days[52]

[xxxiv] Against SARS-COV-2 infection

[xxxv] Conducted between 8 December 2020 and 8 February 2021. Study sample = ≤1 million participants.

[xxxvi] Against SARS-CoV-2 infection.

	population with or without prior infection[61]	Against severe disease: **98.2%** (95% CI, 92.8-99.6)[170]	standard second dose[168] **66.7%** (95% CI, 57.4-74.0) starting at ≥14 days for pooled analysis efficacy[168]	**76.7%** (95% CI 54.6 to 89.1) after 14 days and **85.4%** (95% CI 54.2 to 96.9) after 28 days for VE against severe-critical COVID-19[54]		Nab positivity cut-off (20 units) against wild-type[171].	
Against asymptomatic infection	**90%** (starting at 14 days) regardless of symptom status[172]	**63.0%** (95% CI, 56.6-68.5)[170]	Statistically non-significant **reduction of 22.2%** (95% CI -9.9 to 45.0) for asymptomatic cases	At day 71, vaccine efficacy against asymptomatic infections was **65.5%** (95% CI 39.9 to 81.1)[54].	Efficacy against symptomatic and asymptomatic cases was **64%** (95% CI 48.8 to 74.7; in WIV04 vaccine) or 73.5% (95% CI 60.6 to 82.2; in HBO2 vaccine)[103].	Unknown	Unknown
EFFICACY AGAINST VARIANTS							
Alpha (B.1.1.7)	Two doses of the vaccine **effectively neutralize** the B.1.1.7 variant and the D614G substitution[173].	**NAbs remained high** and consistent with titres of the wildtype for the B.1.1.7 variant[174].	**70.4%** (95% CI, 43.6-84.5) against symptomatic infection with alpha variant (B.1.1.7); **28.9%** (95% CI, -77.1 to 71.4) against asymptomatic infection with B.1.1.7[127].	**3.6-fold** reduction in neutralization capacity when compared to wild-type.	Demonstrated reduced neutralizing capacity. However, there were no differences in the NAbs titres against B.1.351 in vaccinated individuals vs.	**10.4-fold** reduction in neutralization capacity when compared to natural infection sera[171]. **85.83%** of NAb titres were above or equal to the	Two dose efficacy against the B.1.1.7 variant **86.3%** (95% CI, 71.3-93.5)[52]

					those naturally infected, suggesting the vaccine has a similar level of protection against infection as natural infections[175].	Nab positivity cut-off (20 units) against wild-type[171]. Neutralization decreased by **4.1-fold** when compared to wild-type[176].	
Beta (B.1.351)	Neutralization was **diminished by a factor of 5**. Despite this, the BNT162b2 mRNA vaccine still provides some protection against B.1.351[177] **100%** (95% CI, 53.5-100)[178].	NAbs were **6-fold** lower. Nevertheless, NAbs were still found to be protective[174].	Two doses of the vaccine had no efficacy against the B.1.351 (VE = **21.9%;** 95% CI, -49.9 to 59.8)[179].	Efficacy against moderate-severe-critical Covid-19 due to the variant was **52.0%** (>14 days) and **64.0%** (>28 days). Efficacy against severe-critical COVID-19 was **73.1%** (>14 days) and **81.7%** (>28 days)[54]. Demonstrated **3.6-fold** reduction in neutralization sensitivity[180]. Neutralization titres were decreased by **6.7-fold[181]**.	No published data	NT_{GM} **35.03 (95% CI, 27.46-44.68**); **8.75-fold** reduction in neutralization capacity when compared to natural infection sera[171]. **82.5%** of NAb titres were above or equal to the Nab positivity cut-off (20 units) against wild-type[171].	**51.0%** (95% CI, -0.6-76.2) efficacy against B.1.351 variant[182]

Gamma (P.1)	*Single dose:* *≥21 days*: **83%** against hospitalization and death[183]. *Two doses*: *≥14 days*: **98%** against hospitalization and death[183].	**3.2-fold** reduction in neutralization capacity when compared to wild-type[184].	*Single dose:* *≥21 days*: **94%** against hospitalization and death[183].	Demonstrated **3.4-fold** reduction in neutralization sensitivity[180].	No published data	**49.6%** against P.1 (>14 days after 1st dose)[169]. Neutralization decreased by **7.5-fold** when compared to wild-type[176].	No available data
Delta (1.671.2)	**Reduced NAb activity** relative to B.1.1.7 strain[185].	**2.1-fold** reduction in neutralization capacity when compared to wild-type[184].	*Single dose:* *≥21 days*: **90%** against hospitalization and death[183].	Demonstrated **1.6-fold** reduction in neutralization sensitivity[180]. Neutralization titres were decreased by **5.4-fold[181]**.	Demonstrated **reduced neutralizing capacity**. However, there were no differences in the NAbs titres against B.1.617.2 in vaccinated individuals vs. those naturally infected, suggesting the vaccine has a similar level of protection against infection as natural infections[175].	NT_{GM} **24.48** (95% CI,19.2-31.2)[171]. **69.17%** of NAb titres were above or equal to the Nab positivity cut-off (20 units) against wild-type[171].	No available data

PHASE III TRIALS RESULTS[xxxvii]							
Number of participants (vaccine/ placebo)	43,448 (21,720/ 21,728)[61]	30,420 (15,210/15,210)[44]	17,178 (8597/8581)[168]	39,321 (19,630/19,691)[54]	26,917 (13,459/13458); or 26,914 (13,465/13,458)[103]	9,823 (4,953/4,870)[50]	14,039 (7,020/7,019)[52]
Total COVID-19 cases (vaccine/ control)	170(8/162)[61]	196 (11/185)[44]	332 (84/248)[168]	464 (116/348)[54]	121(26/95) or 116(21/95)[103]	253(85/168)[50]	106(10/96)[52]
Efficacy estimates in Phase III trials	Starting from 7 days after 2nd dose: **95.0%** (95% CI, 90.3 to 97.6) in population without prior SARS-CoV-2 infection. Efficacy of **94.6%** (95% CI, 89.9 to 97.3) in population with or without prior infection. **100%** among	After a median follow-up of less than 63 days: Efficacy of **94.1%** (95% CI, 89.3 to 96.8; P<0.001). **100%** among adolescents (12 to <18 years old)[44].	Two standard doses: efficacy was **63·1%** (95% CI 51.8 to 71.7; ≥14 days) while those with first low dose and standard 2nd dose the efficacy was **80.7%** (95% CI 62.1 to 90.2). Pooled analysis efficacy was **66.7%** (95% CI 57.4 to 74.0). For	VE against moderate-severe-critical Covid-19 was **66.9%** (95% CI 59.0 to 73.4) after 14 days post vaccine administration, and **66.1%** (95% CI 55.0 to 89.1) after 28 days. VE against severe-critical COVID-19 cases was **76.7%** (95% CI 54.6 to	After 14 days, efficacy against symptomatic cases was **72.8%** (95% CI 58.1 to 82.4; in WIV04 vaccine) or **78.1%** (95% CI 64.8 to 86.3; in HBO2 vaccine)[103].	After 14 days, efficacy against symptomatic cases was **50.7%** (95% CI 35.9 to 0-62.0).[50]	**83.4%** (95% CI, 73.6-89.5) starting at ≥14 days after first dose[52] **89.7%** (95% CI, 80.2-94.6) starting at ≥7 days after second dose[52]

[xxxvii] Phase III trials were conducted between 27 July and 14 November 2020 for BNT162b2/ COMIRNATY, 27 July and 23 October 2020 for Spikevax/ Moderna, 23 April and 6 December 2020 for Vaxzevria/ ChAdOx1 nCoV-19/ AZD1222/ Covishield, 21 September 2020 and 22 January 2021 for Janssen Covid-19 vaccine/ Johnson & Johnson, 16 July and 20 December 2020 for Sinopharm/ BBIB-CorV, 21 July and 16 December 2020 for the Sinovac/ CoronaVac vaccine, and 28 September 2020 and 28 November 2020 for the Novavax vaccine. All trials were conducted prior to the transmission of the more contagious variant strains, particularly the delta variant (B.1.617.2). Studies are currently ongoing to determine the effectiveness of the vaccines against the delta variant.

	adolescents (12-15 years old)[61].		any nucleic acid amplification test-positive swab: efficacy was 54.1% (95% CI 44.7 to 61.9)[168].	89.1) after 14 days and **85.4%** (95% CI 54.2 to 96.9) after 28 days[54].			
Efficacy against hospitalization and death	**100%** (after 7 days)[61]	**100%** (≥14 days)[44]	**100%** (after 21 days)[168]	**76.7%** (≥14 days) or **85.4%** (≥28 days)[54]	**100%** (>14 days)[103]	**100%** (>14 days)[50]	**100%** (after 7 days)[52].
PHASE III TRIAL OTHER							
Comments	Specific populations were excluded (HIV and immunocompromised patients, and pregnant women).	Calculation of efficacy were not based on the total number of confirmed Covid-19 cases.			Only 2 severe cases occurred in the control group and none in the vaccine group (very few cases to get a reliable estimate).		Novavax is currently awaiting FDA, EMA, and WHO EUL approval. Upcoming information regarding results of clinical trials or approval will be updated in upcoming reports

VACCINE PRODUCTION SITES

	BNT162b2/ COMIRNATY (Pfizer-BioNTech, USA)[xxxviii]	Spikevax/ Moderna COVID-19 Vaccine/ mRNA-1273 (Moderna, USA)[xxxix]	Vaxzevria/ ChAdOx1 nCoV-19/ AZD1222/ Covishield (AstraZeneca/Oxford, UK, India)[xl]	Janssen COVID-19 vaccine/Johnson & Johnson (Janssen, USA)[xli]	Sinopharm/BBIBP-CorV, China[xlii]	Sinovac CoronaVac, China[xliii]	Novavax/ NVX-CoV2373
EUL holder	BioNTech Manufacturing GmbH (Germany)	ModernaTX, Inc. (USA)[1] Moderna Biotech (Spain)[2]	AstraZeneca AB (Sweden)	Janssen-Cilag International NV (Belgium)	Beijing Institute of Biological Products Co., Ltd. (BIBP) (China)	Sinovac Life Sciences Co., Ltd. (China)	Novavax (USA)
Production sites (Drug substance)	BioNTech Manufacturing GmbH (Mainz, Germany) BioNTech Manufacturing Marburg	Lonza Biologics, Inc., (USA)[1] Moderna TX, Inc. (USA)[1] Lonza AG (Switzerland)[2]	Henogen S.A (Belgium) Catalent Maryland, Inc. (USA)	Janssen Vaccines & Prevention B.V. (The Netherlands) Janssen Biologics B.V. (The Netherlands)	Beijing Institute of Biological Products Co., Ltd. (China)	Sinovac Life Sciences Co., Ltd. (China)	Novavax (Bohumil, Czech Republic)

[xxxviii] WHO recommendation BioNTech Tozinameran – COVID-19 mRNA vaccine (nucleoside modified) – COMIRNATY. *WHO.* https://extranet.who.int/pqweb/vaccines/who-recommendation-covid-19-mrna-vaccine-nucleoside-modified-comirnaty

[xxxix] 1. WHO recommendation ModernaTX, Inc/USFDA COVID-19 mRNA vaccine (nucleoside modified). *WHO*. https://extranet.who.int/pqweb/vaccines/who-recommendation-modernatx-incusfda-covid-19-mrna-vaccine-nucleoside-modified

2. WHO recommendation Moderna COVID-19 mRNA Vaccine (nucleoside modified). *WHO*. https://extranet.who.int/pqweb/vaccines/covid-19-mrna-vaccine-nucleoside-modified

[xl] WHO recommendation AstraZeneca/ EU approved sites COVID-19 vaccine (ChAdOx1-S) [recombinant]. *WHO.* https://extranet.who.int/pqweb/vaccines/covid-19-vaccine-chadox1-s-recombinant-0

[xli] WHO recommendation Janssen-Cilag International NV (Belgium) COVID-19 Vaccine (Ad26.COV2-S [recombinant]). *WHO*. https://extranet.who.int/pqweb/vaccines/who-recommendation-janssen-cilag-international-nv-belgium-covid-19-vaccine-ad26cov2-s

[xlii] WHO recommendation COVID-19 vaccine BIBP/Sinopharm. *WHO.* https://extranet.who.int/pqweb/vaccines/who-recommendation-covid-19-vaccine-bibp

[xliii] WHO recommendation of Sinovac COVID-19 vaccine (Vero Cell [Inactivated]) – CoronaVac. *WHO*. https://extranet.who.int/pqweb/vaccines/who-recommendation-sinovac-covid-19-vaccine-vero-cell-inactivated-coronavac

	(Marburg, Germany) Rentschler Biopharma SE (Laupheim, Germany) Wyeth BioPharma Division of Wyeth Pharmaceuticals (USA)		Oxford Biomedica (UK) Ltd. (United Kingdom) SK Bioscience (Republic of Korea) Halix B.V (Netherlands) WuXi Biologics (China)	Emergent Manufacturing Operations Baltimore LLC (USA)			
Production sites (Drug product)	Baxter Oncology GmbH (Halle/ Westfallen, Germany) BioNTech Manufacturing GmbH (Mainz, Germany) Pfizer Manufacturing Belgium NV (Belgium) Novartis Pharma Stein AG (Switzerland) Mibe GmbH Arzneimittel	Baxter Pharmaceutical Solutions, LLC. (USA)[1] Catalent Indiana, LLC. (USA)[1] Rovi Pharma Industrial Services, S.A. (Spain)[2]	Catalent Anagni (Italy) CP Pharmaceuticals (United Kingdom) IDT Biologika (Germany) SK Bioscience (Republic of Korea) Universal Farma, S.L. ("Chemo") (Spain) Amylin Ohio LLC (USA)	Janssen Biologics B.V. (The Netherlands) Janssen Pharmaceutica NV (Belgium) Aspen SVP. (South Africa) Catalent Indiana LLC. (USA) Grand River Aseptic Manufacturing Inc. (USA)	Beijing Institute of Biological Products Co., Ltd. (China)	Sinovac Life Sciences Co., Ltd. (China)	Novavax (Bohumil, Czech Republic)

	(Brehna, Germany)			Catalent Anagni S.R.L. (Italy)			
Diluent suppliers	Pfizer Perth, Australia Fresenius Kabi, USA	-	-	-	-	-	-

References

1. Johnson & Johnson. Johnson & Johnson Announces Real-World Evidence and Phase 3 Data Confirming Strong and Long-Lasting Protection of Single-Shot COVID-19 Vaccine in the U.S. Johnson & Johnson. https://www.jnj.com/johnson-johnson-announces-real-world-evidence-and-phase-3-data-confirming-strong-and-long-lasting-protection-of-single-shot-covid-19-vaccine-in-the-u-s. Published 2021. Updated 21 September. Accessed 21 September, 2021.
2. 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 - Preprint.* 2021. https://doi.org/10.2139/ssrn.3790399
3. Public Health England. *Public Health England vaccine effectiveness report.* 2021. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/989360/PHE_COVID-19_vaccine_effectiveness_report_March_2021_v2.pdf.
4. Thomson EC, Rosen LE, Shepherd JG, et al. Circulating SARS-CoV-2 spike N439K variants maintain fitness while evading antibody-mediated immunity. *Cell.* 2021;184(5):1171-1187.e1120. https://doi.org/10.1016/j.cell.2021.01.037
5. Chung H, He S, Nasreen S, et al. Effectiveness of BNT162b2 and mRNA-1273 covid-19 vaccines against symptomatic SARS-CoV-2 infection and severe covid-19 outcomes in Ontario, Canada: test negative design study. *BMJ.* 2021;374:n1943. https://doi.org/10.1136/bmj.n1943
6. Lumley SF, Rodger G, Constantinides B, et al. An observational cohort study on the incidence of SARS-CoV-2 infection and B.1.1.7 variant infection in healthcare workers by antibody and vaccination status. *Clinical infectious diseases.* 2021. https://doi.org/10.1093/cid/ciab608
7. Corchado-Garcia J, Puyraimond-Zemmour D, Hughes T, et al. Real-World Effectiveness of Ad26.COV2.S Adenoviral Vector Vaccine for COVID-19. *SSRN - Preprint.* 2021. https://doi.org/10.2139/ssrn.3835737
8. Polinski JM, Weckstein AR, Batech M, et al. Effectiveness of the Single-Dose Ad26.COV2.S COVID Vaccine. *medRxiv.* 2021:2021.2009.2010.21263385. https://doi.org/10.1101/2021.09.10.21263385
9. Self WH, Tenforde MW, Rhoads JP, IVY Network. Vaccines in Preventing COVID-19 Hospitalizations Among Adults Without Immunocompromising Conditions. *Morbidity & Mortality Weekly Report.* 2021. https://doi.org/10.15585/mmwr.mm7038e1external
10. Jahromi M, Al Sheikh MH. Partial protection of Sinopharm vaccine against SARS COV2 during recent outbreak in Bahrain. *Microb Pathog.* 2021;158:105086. https://doi.org/10.1016/j.micpath.2021.105086
11. Jara A, Undurraga EA, González C, et al. Effectiveness of an Inactivated SARS-CoV-2 Vaccine in Chile. *New England Journal of Medicine.* 2021. https://doi.org/10.1056/NEJMoa2107715
12. Cerqueira-Silva T, Oliveira VdA, Pescarini J, et al. Influence of age on the effectiveness and duration of protection in Vaxzevria and CoronaVac vaccines. *medRxiv.* 2021:2021.2008.2021.21261501. https://doi.org/10.1101/2021.08.21.21261501

13. A Study Looking at the Effectiveness and Safety of a COVID-19 Vaccine in South African Adults. In. ClinicalTrials.gov2021. https://clinicaltrials.gov/ct2/show/NCT04533399?term=Novavax&cond=Covid19&draw=2.
14. A Study Looking at the Effectiveness, Immune Response, and Safety of a COVID-19 Vaccine in Adults in the United Kingdom. In. ClinicalTrials.gov2021. https://clinicaltrials.gov/ct2/show/NCT04583995?term=Novavax&cond=Covid19&draw=2&rank=2.
15. Paris C, Perrin S, Hamonic S, et al. Effectiveness of mRNA-BNT162b2, mRNA-1273, and ChAdOx1 nCoV-19 vaccines against COVID-19 in healthcare workers: an observational study using surveillance data. *Clinical Microbiology and Infection.* 2021. https://doi.org/10.1016/j.cmi.2021.06.043
16. Katz MA, Bron Harlev E, Chazan B, et al. Covid-19 Vaccine Effectiveness in Healthcare Personnel in six Israeli Hospitals (CoVEHPI). *medRxiv.* 2021:2021.2008.2030.21262465. https://doi.org/10.1101/2021.08.30.21262465
17. Puranik A, Lenehan PJ, Silvert E, et al. Comparison of two highly-effective mRNA vaccines for COVID-19 during periods of Alpha and Delta variant prevalence. *medRxiv.* 2021:2021.2008.2006.21261707. https://doi.org/10.1101/2021.08.06.21261707
18. Knobel P, Serra C, Grau S, et al. Coronavirus disease 2019 (COVID-19) mRNA vaccine effectiveness in asymptomatic healthcare workers. *Infection Control & Hospital Epidemiology.* 2021:1-2. https://doi.org/10.1017/ice.2021.287
19. Lopez Bernal J, Andrews N, Gower C, et al. Effectiveness of Covid-19 Vaccines against the B.1.617.2 (Delta) Variant. *New England Journal of Medicine.* 2021;385(7):585-594. https://doi.org/10.1056/NEJMoa2108891
20. Nasreen S, Chung H, He S, et al. Effectiveness of COVID-19 vaccines against variants of concern in Ontario, Canada. *medRxiv.* 2021:2021.2006.2028.21259420. https://doi.org/10.1101/2021.06.28.21259420
21. Seppälä E, Veneti L, Starrfelt J, et al. Vaccine effectiveness against infection with the delta (b.1.617.2) variant, norway, april to august 2021. *Eurosurveillance.* 2021;26(35). https://doi.org/10.2807/1560-7917.ES.2021.26.35.2100793
22. Sheikh A, McMenamin J, Taylor B, Robertson C. SARS-CoV-2 Delta VOC in Scotland: demographics, risk of hospital admission, and vaccine effectiveness. *The Lancet.* 2021;397(10293):2461-2462. https://doi.org/10.1016/S0140-6736(21)01358-1
23. Pouwels KB, Pritchard E, Matthews P, et al. Impact of Delta on viral burden and vaccine effectiveness against new SARS-CoV-2 infections in the UK. *medRxiv.* 2021:2021.2008.2018.21262237. https://doi.org/10.1101/2021.08.18.21262237
24. Chemaitelly H, Yassine HM, Benslimane FM, et al. mRNA-1273 COVID-19 vaccine effectiveness against the B.1.1.7 and B.1.351 variants and severe COVID-19 disease in Qatar. *Nature Medicine.* 2021. https://doi.org/10.1038/s41591-021-01446-y
25. Chen Y, Shen H, Huang R, Tong X, Wu C. Serum neutralising activity against SARS-CoV-2 variants elicited by CoronaVac. *The Lancet Infectious Diseases.* 2021;21(8):1071-1072. https://doi.org/10.1016/S1473-3099(21)00287-5
26. Gidari A, Sabbatini S, Bastianelli S, et al. Cross-neutralization of SARS-CoV-2 B.1.1.7 and P.1 variants in vaccinated, convalescent and P.1 infected. *Journal of Infection.* 2021. https://doi.org/10.1016/j.jinf.2021.07.019
27. Ranzani O, Hitchings M, Neto M, et al. Effectiveness of the CoronaVac vaccine in the elderly population during a P.1 variant-associated epidemic of COVID-19 in Brazil: A

test-negative case-control study. *medRxiv preprint.* 2021. https://doi.org/10.1101/2021.05.19.21257472

28. World Health Organization. The Sinovac-CoronaVac COVID-19 vaccine: What you need to know. World Health Organization. https://www.who.int/news-room/feature-stories/detail/the-sinovac-covid-19-vaccine-what-you-need-to-know?gclid=Cj0KCQjw4eaJBhDMARIsANhrQADBYtFm2zMvzbfjthveE2gmCJTRl_jPc4HPlIFSwdZpzTix45gmEM0aAml9EALw_wcB. Published 2021. Updated 2 September 2021. Accessed 8 September, 2021.
29. State of Israel Ministry of Health. Vaccine efficacy among those first vaccinated. https://www.gov.il/BlobFolder/reports/vaccine-efficacy-safety-follow-up-committee/he/files_publications_corona_two-dose-vaccination-data.pdf Published 2021. Accessed 25 August, 2021.
30. Andrews N, Tessier E, Stowe J, et al. Vaccine effectiveness and duration of protection of Comirnaty, Vaxzevria and Spikevax against mild and severe COVID-19 in the UK *Public Health England - Preprint.* 2021. https://khub.net/documents/135939561/338928724/Vaccine+effectiveness+and+duration+of+protection+of+covid+vaccines+against+mild+and+severe+COVID-19+in+the+UK.pdf/10dcd99c-0441-0403-dfd8-11ba2c6f5801.
31. Nanduri S, Pilishvili T, Derado G, Schrag SJ. Effectiveness of Pfizer-BioNTech and Moderna Vaccines in Preventing SARS-CoV-2 Infection Among Nursing Home Residents Before and During Widespread Circulation of the SARS-CoV-2 B.1.617.2 (Delta) Variant - National Healthcare Safety Network, March 1–August 1. *Morbidity & Mortality Weekly Report.* 2021;70(34):163-1166. https://doi.org/10.15585/mmwr.mm7034e3
32. Mayo Foundation for Medical Education and Research (MFMER). Do COVID-19 vaccines protect against the variants? Mayo Clinic. Published 2021. Updated 24 August 2021. Accessed 8 September, 2021.
33. Mlcochova P, Kemp SA, Shanker Dhar M, et al. SARS-CoV-2 B.1.617.2 Delta variant replication, sensitivity to neutralising antibodies and vaccine breakthrough. *bioRxiv.* 2021:2021.2005.2008.443253. https://doi.org/10.1101/2021.05.08.443253
34. Li X-n, Huang Y, Wang W, et al. Efficacy of inactivated SARS-CoV-2 vaccines against the Delta variant infection in Guangzhou: A test-negative case-control real-world study. *Emerging Microbes & Infections.* 2021:1-32. https://doi.org/10.1080/22221751.2021.1969291
35. Stowe J, Andrews N, Gower C, et al. Effectiveness of COVID-19 vaccines against hospital admission with the delta (B.1.617.2) variant *Public Health Enland Publishing - Preprint.* 2021. https://khub.net/web/phe-national/public-library/-/document_library/v2WsRK3ZlEig/view_file/479607329?_com_liferay_document_library_web_portlet_DLPortlet_INSTANCE_v2WsRK3ZlEig_redirect=https%3A%2F%2Fkhub.net%3A443%2Fweb%2Fphe-national%2Fpublic-library%2F-%2Fdocument_library%2Fv2WsRK3ZlEig%2Fview%2F479607266.
36. de Gier B, Andeweg S, Joosten R, et al. Vaccine effectiveness against SARS-CoV-2 transmission and infections among household and other close contacts of confirmed cases, the Netherlands, February to May 2021. *Eurosurveillance.* 2021;26(31). https://doi.org/10.2807/1560-7917.ES.2021.26.31.2100640
37. Tenforde MW, Self WH, Naioti EA, et al. Sustained Effectiveness of Pfizer-BioNTech and Moderna Vaccines Against COVID-19 Associated Hospitalizations Among Adults — United States, March–July 2021. *Morbidity & Mortality Weekly Report.* 2021;70(34):1156-1162. https://doi.org/10.15585/mmwr.mm7034e2

38. Foley KE. J&J shot effective against Delta variant in large South Africa study. Politico. https://www.politico.eu/article/johnson-johnson-coronavirus-vaccine-delta-variant/. Published 2021. Updated 6 August 2021. Accessed 7 September, 2021.
39. Johnson & Johnson. Positive New Data for Johnson & Johnson Single-Shot COVID-19 Vaccine on Activity Against Delta Variant and Long-lasting Durability of Response. Johnson & Johnson. https://www.jnj.com/positive-new-data-for-johnson-johnson-single-shot-covid-19-vaccine-on-activity-against-delta-variant-and-long-lasting-durability-of-response. Published 2021. Updated 1 July 2021. Accessed 8 September, 2021.
40. Hu Z, Tao B, Li Z, et al. Effectiveness of inactive COVID-19 vaccines against severe illness in B.1.617.2 (Delta) variant-infected patients in Jiangsu, China. *medRxiv.* 2021:2021.2009.2002.21263010. https://doi.org/10.1101/2021.09.02.21263010
41. Oliver SE, Gargano JW, Marin M, et al. The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine - United States, December 2020. *MMWR Morbidity and mortality weekly report.* 2020;69(50):1922-1924. https://doi.org/10.15585/mmwr.mm6950e2
42. Caminati M, Guarnieri G, Batani V, et al. Covid-19 vaccination in patients with severe asthma on biologic treatment: Safety, tolerability, and impact on disease control. *Vaccines.* 2021;9(8). https://doi.org/10.3390/vaccines9080853
43. Haroun F, Alharbi M, Hong A. Case series on the safety of mRNA COVID19 vaccines in cancer patients undergoing treatment. *Journal of Clinical Oncology.* 2021;39(15 SUPPL). https://doi.org/10.1200/JCO.2021.39.15_suppl.e14562
44. Baden LR, El Sahly HM, Essink B, et al. Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine. *New England Journal of Medicine.* 2020;384(5):403-416. https://doi.org/10.1056/NEJMoa2035389
45. Wei N, Fishman M, Wattenberg D, Gordon M, Lebwohl M. "COVID arm": A reaction to the Moderna vaccine. *JAAD case reports.* 2021;10:92-95. https://doi.org/10.1016/j.jdcr.2021.02.014
46. Voysey M, Costa Clemens SA, Madhi SA, et al. Safety and efficacy of the ChAdOx1 nCoV-19 vaccine (AZD1222) against SARS-CoV-2: an interim analysis of four randomised controlled trials in Brazil, South Africa, and the UK. *The Lancet.* 2021;397(10269):99-111. https://doi.org/10.1016/S0140-6736(20)32661-1
47. Ghiasi N, Valizadeh R, Arabsorkhi M, et al. Efficacy and side effects of Sputnik V, Sinopharm and AstraZeneca vaccines to stop COVID-19; a review and discussion. 2021. https://doi.org/http://immunopathol.com/PDF/ipp-7-e31.pdf
48. Shay DK, Gee J, Su JR, et al. Safety Monitoring of the Janssen (Johnson & Johnson) COVID-19 Vaccine - United States, March–April 2021. *Morbidity and Mortality Weekly Report.* 2021;70(18):680–684. https://doi.org/http://dx.doi.org/10.15585/mmwr.mm7018e2external
49. Saeed BQ, Al-Shahrabi R, Alhaj SS, Alkokhardi ZM, Adrees AO. Side Effects and Perceptions Following Sinopharm COVID-19 Vaccination. *Int J Infect Dis.* 2021. https://doi.org/10.1016/j.ijid.2021.08.013
50. Palacios R, Batista AP, Santos Nascimento Albuquerque C, et al. Efficacy and Safety of a COVID-19 Inactivated Vaccine in Healthcare Professionals in Brazil: The PROFISCOV Study. *SSRN - Preprint.* 2021. https://doi.org/http://dx.doi.org/10.2139/ssrn.3822780
51. Durmaz K, Temiz SA, Zuhal K, Dursun R, Abdelmaksoud A. Allergic and Cutaneous reactions following Inactivated SARS-CoV-2 vaccine (CoronaVac®) in Healthcare workers. *Clin Exp Dermatol.* 2021. https://doi.org/10.1111/ced.14896

52. Heath PT, Galiza EP, Baxter DN, et al. Safety and Efficacy of NVX-CoV2373 Covid-19 Vaccine. *New England Journal of Medicine.* 2021. https://doi.org/10.1056/NEJMoa2107659
53. Chagla Z. The BNT162b2 (BioNTech/Pfizer) vaccine had 95% efficacy against COVID-19 ≥7 days after the 2nd dose. *Annals of Internal Medicine.* 2021;174(2):JC15. https://doi.org/10.7326/ACPJ202102160-015
54. Sadoff J, Gray G, Vandebosch A, et al. Safety and Efficacy of Single-Dose Ad26.COV2.S Vaccine against Covid-19. *N Engl J Med.* 2021;384(23):2187-2201. https://doi.org/10.1056/NEJMoa2101544
55. Formica N, Mallory R, Albert G, et al. Evaluation of a SARS-CoV-2 Vaccine NVX-CoV2373 in Younger and Older Adults. *medRxiv.* 2021:2021.2002.2026.21252482. https://doi.org/10.1101/2021.02.26.21252482
56. Kim HW, Jenista ER, Wendell DC, et al. Patients With Acute Myocarditis Following mRNA COVID-19 Vaccination. *JAMA Cardiology.* 2021. https://doi.org/10.1001/jamacardio.2021.2828
57. Bozkurt B, Kamat I, Hotez PJ. Myocarditis With COVID-19 mRNA Vaccines. *Circulation.* 2021;144(6):471-484. https://doi.org/doi:10.1161/CIRCULATIONAHA.121.056135
58. Kafil T, Lamacie MM, Chenier S, et al. mRNA COVID-19 Vaccination and Development of CMR-confirmed Myopericarditis. *medRxiv.* 2021:2021.2009.2013.21262182. https://doi.org/10.1101/2021.09.13.21262182
59. Cirillo N. Reported orofacial adverse effects of COVID-19 vaccines: The knowns and the unknowns. *Journal of Oral Pathology & Medicine.* 2021;50(4):424-427. https://doi.org/10.1111/jop.13165
60. Shimabukuro T. Allergic reactions including anaphylaxis after receipt of the first dose of Pfizer-BioNTech COVID-19 vaccine - United States, December 14-23, 2020. *American journal of transplantation : official journal of the American Society of Transplantation and the American Society of Transplant Surgeons.* 2021;21(3):1332-1337. https://doi.org/10.1111/ajt.16516
61. Polack FP, Thomas SJ, Kitchin N, et al. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. *New England Journal of Medicine.* 2020;383(27):2603-2615. https://doi.org/10.1056/NEJMoa2034577
62. Cohen OG, Clark AK, Milbar H, Tarlow M. Pityriasis rosea after administration of Pfizer-BioNTech COVID-19 vaccine. *Hum Vaccin Immunother.* 2021:1-2. https://doi.org/10.1080/21645515.2021.1963173
63. Temiz SA, Abdelmaksoud A, Dursun R, Durmaz K, Sadoughifar R, Hasan A. Pityriasis rosea following SARS-CoV-2 vaccination: A case series. *Journal of Cosmetic Dermatology.* 2021. https://doi.org/10.1111/jocd.14372
64. Vassallo C, Boveri E, Brazzelli V, et al. Cutaneous lymphocytic vasculitis after administration of COVID-19 mRNA vaccine. *Dermatol Ther.* 2021:e15076. https://doi.org/10.1111/dth.15076
65. Santovito LS, Pinna G. A case of reactivation of varicella-zoster virus after BNT162b2 vaccine second dose? *Inflamm Res.* 2021:1-3. https://doi.org/10.1007/s00011-021-01491-w
66. Fathy RA, McMahon DE, Lee C, et al. Varicella Zoster and Herpes Simplex Virus Reactivation Post-COVID-19 Vaccination: A Review of 40 Cases in an International Dermatology Registry. *J Eur Acad Dermatol Venereol.* 2021. https://doi.org/10.1111/jdv.17646

67. Papasavvas I, de Courten C, Herbort CP, Jr. Varicella-zoster virus reactivation causing herpes zoster ophthalmicus (HZO) after SARS-CoV-2 vaccination - report of three cases. *J Ophthalmic Inflamm Infect.* 2021;11(1):28. https://doi.org/10.1186/s12348-021-00260-4
68. Soub HA, Ibrahim W, Maslamani MA, A. Ali G, Ummer W, Abu-Dayeh A. Kikuchi-Fujimoto disease following SARS CoV2 vaccination: Case report. *IDCases.* 2021;25. https://doi.org/10.1016/j.idcr.2021.e01253
69. Chamarti K, Dar K, Reddy A, Gundlapalli A, Mourning D, Bajaj K. Thrombotic Thrombocytopenic Purpura Presentation in an Elderly Gentleman Following COVID Vaccine Circumstances. *Cureus.* 2021;13(7):e16619. https://doi.org/10.7759/cureus.16619
70. Horino T. IgA nephropathy flare-up following SARS-CoV-2 vaccination. *QJM : monthly journal of the Association of Physicians.* 2021. https://doi.org/10.1093/qjmed/hcab223
71. Hughes DL, Brunn JA, Jacobs J, Todd PK, Askari FK, Fontana RJ. Guillain-Barré syndrome after COVID-19 mRNA vaccination in a liver transplant recipient with favorable treatment response. *Liver Transpl.* 2021. https://doi.org/10.1002/lt.26279
72. Osowicki J, Morgan H, Harris A, Crawford NW, Buttery JP, Kiers L. Guillain-Barré Syndrome in an Australian state using both mRNA and adenovirus-vector SARS-CoV-2 vaccines. *Ann Neurol.* 2021. https://doi.org/10.1002/ana.26218
73. Perna D, Jones J, Schadt CR. Acute generalized pustular psoriasis exacerbated by the COVID-19 vaccine. *JAAD Case Rep.* 2021. https://doi.org/10.1016/j.jdcr.2021.08.035
74. Iwata H, Kamiya K, Kado S, et al. Case of immunoglobulin A vasculitis following coronavirus disease 2019 vaccination. *J Dermatol.* 2021. https://doi.org/10.1111/1346-8138.16167
75. Mücke VT, Knop V, Mücke MM, Ochsendorf F, Zeuzem S. First description of immune complex vasculitis after COVID-19 vaccination with BNT162b2: a case report. *BMC Infect Dis.* 2021;21(1):958. https://doi.org/10.1186/s12879-021-06655-x
76. Elias C, Cardoso P, Gonçalves D, Vaz I, Cardoso L. Rhabdomyolysis Following Administration of Comirnaty(®). *Eur J Case Rep Intern Med.* 2021;8(8):002796. https://doi.org/10.12890/2021_002796
77. Franquemont S, Galvez J. Subacute Thyroiditis After mRNA Vaccine for Covid-19. *Journal of the Endocrine Society.* 2021;5(Suppl 1):A956-A957. https://doi.org/10.1210/jendso/bvab048.1954
78. Iftikhar H, Noor SMU, Masood M, Bashir K. Bell's Palsy After 24 Hours of mRNA-1273 SARS-CoV-2 Vaccine. *Cureus.* 2021;13(6):e15935-e15935. https://doi.org/10.7759/cureus.15935
79. Channa L, Torre K, Rothe M. Herpes zoster reactivation after mRNA-1273 (Moderna) SARS-CoV-2 vaccination. *JAAD Case Reports.* 2021;15:60-61. https://doi.org/10.1016/j.jdcr.2021.05.042
80. Thimmanagari K, Veeraballi S, Roach D, Al Omour B, Slim J. Ipsilateral Zoster Ophthalmicus Post COVID-19 Vaccine in Healthy Young Adults. *Cureus.* 2021;13(7):e16725. https://doi.org/10.7759/cureus.16725
81. Drerup KA, Gläser R. SARS-CoV-2—update on skin manifestations, predictive markers and cutaneous reactions after vaccination. *Hautarzt.* 2021. https://doi.org/10.1007/s00105-021-04881-7

82. Khan E, Shrestha AK, Colantonio MA, Liberio RN, Sriwastava S. Acute transverse myelitis following SARS-CoV-2 vaccination: a case report and review of literature. *Journal of Neurology.* 2021. https://doi.org/10.1007/s00415-021-10785-2
83. Christensen SK, Ballegaard M, Boesen MS. Guillian Barré syndromeafter mRNA-1273 vaccination against COVID-19. *Ugeskr Laeger.* 2021;183(35). Published 2021/09/04.
84. Català A, Muñoz-Santos C, Galván-Casas C, et al. Cutaneous reactions after SARS-COV-2 vaccination: A cross-sectional Spanish nationwide study of 405 cases. *The British journal of dermatology.* 2021. https://doi.org/10.1111/bjd.20639
85. Guzmán-Pérez L, Puerta-Peña M, Falkenhain-López D, et al. Small-vessel vasculitis following Oxford-AstraZeneca vaccination against SARS-CoV-2. *Journal of the European Academy of Dermatology and Venereology.* 2021. https://doi.org/10.1111/jdv.17547
86. Wolf ME, Luz B, Niehaus L, Bhogal P, Bäzner H, Henkes H. Thrombocytopenia and Intracranial Venous Sinus Thrombosis after "COVID-19 Vaccine AstraZeneca" Exposure. *Journal of Clinical Medicine.* 2021;10(8):1599. https://www.mdpi.com/2077-0383/10/8/1599.
87. Schulz JB, Berlit P, Diener HC, et al. COVID-19 vaccine-associated cerebral venous thrombosis in Germany. *Annals of neurology.* 2021. https://doi.org/10.1002/ana.26172
88. Perera R, Fletcher J. Thromboembolism and the Oxford-AstraZeneca vaccine. *BMJ.* 2021;373:n1159. https://doi.org/10.1136/bmj.n1159
89. Althaus K, Möller P, Uzun G, et al. Antibody-mediated procoagulant platelets in SARS-CoV-2-vaccination associated immune thrombotic thrombocytopenia. *Haematologica.* 2021;106(8):2170-2179. https://doi.org/10.3324/haematol.2021.279000
90. Al Rawahi B, BaTaher H, Jaffer Z, Al-Balushi A, Al-Mazrouqi A, Al-Balushi N. Vaccine-induced immune thrombotic thrombocytopenia following AstraZeneca (ChAdOx1 nCOV19) vaccine-A case report. *Res Pract Thromb Haemost.* 2021;5(6):e12578. https://doi.org/10.1002/rth2.12578
91. Asmat H, Fayeye F, Alshakaty H, Patel J. A rare case of COVID-19 vaccine-induced thrombotic thrombocytopaenia (VITT) involving the veno-splanchnic and pulmonary arterial circulation, from a UK district general hospital. *BMJ Case Rep.* 2021;14(9). https://doi.org/10.1136/bcr-2021-244223
92. Alalwan AA, Abou Trabeh A, Premchandran D, Razeem M. COVID-19 Vaccine-Induced Thrombotic Thrombocytopenia: A Case Series. *Cureus.* 2021;13(9):e17862. https://doi.org/10.7759/cureus.17862
93. Wolthers SA, Stenberg J, Nielsen HB, Stensballe J, Pedersen HP. Intracerebral haemorrhage twelve days after vaccination with ChAdOx1 nCoV-19. *Ugeskr Laeger.* 2021;183(35). Published 2021/09/04.
94. Kar BR, Singh BS, Mohapatra L, Agrawal I. Cutaneous small-vessel vasculitis following COVID-19 vaccine. *J Cosmet Dermatol.* 2021. https://doi.org/10.1111/jocd.14452
95. Corrêa DG, Cañete LAQ, dos Santos GAC, de Oliveira RV, Brandão CO, da Cruz LCH. Neurological symptoms and neuroimaging alterations related with COVID-19 vaccine: Cause or coincidence? *Clinical Imaging.* 2021;80:348-352. https://doi.org/10.1016/j.clinimag.2021.08.021

96. Oh HK, Kim EK, Hwang I, et al. COVID-19 vaccine safety monitoring in the Republic of Korea: February 26, 2021 to April 30, 2021. *Osong Public Health Res Perspect.* 2021;12(4):264-268. https://doi.org/10.24171/j.phrp.2021.0157
97. Mohta A, Arora A, Srinivasa R, Mehta RD. Recurrent herpes zoster after COVID-19 vaccination in patients with chronic urticaria being treated with cyclosporine—A report of 3 cases. *Journal of Cosmetic Dermatology.* 2021. https://doi.org/10.1111/jocd.14437
98. Wantavornprasert K, Noppakun N, Klaewsongkram J, Rerknimitr P. Generalized Bullous Fixed Drug Eruption after ChAdOx1 nCoV-19 Vaccination. *Clin Exp Dermatol.* 2021. https://doi.org/10.1111/ced.14926
99. Pedrazini MC, da Silva MH. "Pityriasis Rosea-like cutaneous eruption as a possible dermatological manifestation after Oxford-AstraZeneca vaccine: case report and brief literature review.". *Dermatol Ther.* 2021:e15129. https://doi.org/10.1111/dth.15129
100. Maguire D, McLaren DS, Rasool I, Shah PM, Lynch J, Murray RD. ChAdOx1 SARS-CoV-2 vaccination: A putative precipitant of adrenal crises. *Clinical Endocrinology.* 2021. https://doi.org/10.1111/cen.14566
101. MacNeil JR, Su JR, Broder KR, et al. Updated Recommendations from the Advisory Committee on Immunization Practices for Use of the Janssen (Johnson & Johnson) COVID-19 Vaccine After Reports of Thrombosis with Thrombocytopenia Syndrome Among Vaccine Recipients - United States, April 2021. *MMWR Morbidity and mortality weekly report.* 2021;70(17):651-656. https://doi.org/10.15585/mmwr.mm7017e4
102. U.S. Food & Drug Administration. Coronavirus (COVID-19) Update: July 13, 2021. U.S Food & Drug Administration. Published 2021. Updated 13 July 2021. Accessed 18 August, 2021.
103. Al Kaabi N, Zhang Y, Xia S, et al. Effect of 2 Inactivated SARS-CoV-2 Vaccines on Symptomatic COVID-19 Infection in Adults: A Randomized Clinical Trial. *JAMA.* 2021;326(1):35-45. https://doi.org/10.1001/jama.2021.8565
104. Tutar NK, EyigÜRbÜZ T, Yildirim Z, Kale N. A variant of guillain-barre syndrome after sars-cov-2 vaccination: Amsan. *Ideggyogyaszati Szemle.* 2021;74(7-8):286-288. https://doi.org/10.18071/ISZ.74.0286
105. Shimazawa R, Ikeda M. Potential adverse events in Japanese women who received tozinameran (BNT162b2, Pfizer-BioNTech). *Journal of Pharmaceutical Policy and Practice.* 2021;14(1):46. https://doi.org/10.1186/s40545-021-00326-7
106. Saito K, Shimizu T, Suzuki-Inoue K, Ishida T, Wada Y. Aseptic meningitis after vaccination of the BNT162b2 mRNA COVID-19 vaccine. *Neurol Sci.* 2021:1-3. https://doi.org/10.1007/s10072-021-05543-1
107. Bril F, Fettig DM. Reply to: "Comment on "Autoimmune hepatitis developing after coronavirus disease 2019 (COVID-19) vaccine: Causality or casualty?"". *Journal of Hepatology.* 2021. https://doi.org/10.1016/j.jhep.2021.06.008
108. Palla P, Vergadis C, Sakellariou S, Androutsakos T. Letter to the editor: Autoimmune hepatitis after COVID-19 vaccination. A rare adverse effect? *Hepatology.* 2021. https://doi.org/10.1002/hep.32156
109. Maniscalco GT, Manzo V, Di Battista ME, et al. Severe Multiple Sclerosis Relapse After COVID-19 Vaccination: A Case Report. *Front Neurol.* 2021;12:721502. https://doi.org/10.3389/fneur.2021.721502
110. Takenaka T, Matsuzaki M, Fujiwara S, Hayashida M, Suyama H, Kawamoto M. Myeloperoxidase Anti-neutrophil Cytoplasmic Antibody Positive Optic Perineuritis

after mRNA Coronavirus Disease-19 Vaccine: A Case Report. *Qjm.* 2021. https://doi.org/10.1093/qjmed/hcab227
111. Sung JG, Sobieszczyk PS, Bhatt DL. Acute Myocardial Infarction Within 24 Hours After COVID-19 Vaccination. *Am J Cardiol.* 2021;156:129-131. https://doi.org/10.1016/j.amjcard.2021.06.047
112. Abramson M, Mon-Wei Yu S, Campbell KN, Chung M, Salem F. IgA Nephropathy After SARS-CoV-2 Vaccination. *Kidney Medicine.* 2021. https://doi.org/10.1016/j.xkme.2021.05.002
113. Edwards AE, Vathenen R, Henson SM, Finer S, Gunganah K. Acute hyperglycaemic crisis after vaccination against COVID-19: A case series. *Diabet Med.* 2021:e14631. https://doi.org/10.1111/dme.14631
114. Jain E, Pandav K, Regmi P, Michel G, Altshuler I. Facial Diplegia: A Rare, Atypical Variant of Guillain-Barré Syndrome and Ad26.COV2.S Vaccine. *Cureus.* 2021;13(7):e16612. https://doi.org/10.7759/cureus.16612
115. Lane S, Shakir S. Reports of myocarditis and pericarditis following mRNA COVID-19 vaccines: A review of spontaneously reported data from the UK, Europe, and the US. *medRxiv.* 2021:2021.2009.2009.21263342. https://doi.org/10.1101/2021.09.09.21263342
116. Walsh EE, Frenck RW, Falsey AR, et al. Safety and Immunogenicity of Two RNA-Based Covid-19 Vaccine Candidates. *New England Journal of Medicine.* 2020;383(25):2439-2450. https://doi.org/10.1056/NEJMoa2027906
117. Jackson LA, Anderson EJ, Rouphael NG, et al. An mRNA vaccine against SARS-CoV-2—preliminary report. *New England Journal of Medicine.* 2020.
118. Anderson EJ, Rouphael NG, Widge AT, et al. Safety and Immunogenicity of SARS-CoV-2 mRNA-1273 Vaccine in Older Adults. *New England Journal of Medicine.* 2020;383(25):2427-2438. https://doi.org/10.1056/NEJMoa2028436
119. Ramasamy MN, Minassian AM, Ewer KJ, et al. Safety and immunogenicity of ChAdOx1 nCoV-19 vaccine administered in a prime-boost regimen in young and old adults (COV002): a single-blind, randomised, controlled, phase 2/3 trial. *The Lancet.* 2020;396(10267):1979-1993. https://doi.org/10.1016/S0140-6736(20)32466-1
120. Sadoff J, Le Gars M, Shukarev G, et al. Interim results of a phase 1–2a trial of Ad26. COV2. S Covid-19 vaccine. *New England Journal of Medicine.* 2021;384(19):1824-1835.
121. Xia S, Zhang Y, Wang Y, et al. Safety and immunogenicity of an inactivated SARS-CoV-2 vaccine, BBIBP-CorV: a randomised, double-blind, placebo-controlled, phase 1/2 trial. *The Lancet Infectious Diseases.* 2021;21(1):39-51. https://doi.org/10.1016/S1473-3099(20)30831-8
122. Karamese M, Tutuncu EE. The effectiveness of inactivated SARS-CoV-2 vaccine (CoronaVac) on antibody response in participants aged 65 years and older. *Journal of Medical Virology.* 2021. https://doi.org/10.1002/jmv.27289
123. Prunas O, Warren JL, Crawford FW, et al. Vaccination with BNT162b2 reduces transmission of SARS-CoV-2 to household contacts in Israel. *medRxiv.* 2021:2021.2007.2013.21260393. https://doi.org/10.1101/2021.07.13.21260393
124. Riemersma KK, Grogan BE, Kita-Yarbro A, et al. Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent - Wisconsin, July 2021. *medRxiv.* 2021:2021.2007.2031.21261387. https://doi.org/10.1101/2021.07.31.21261387

125. Harris RJ, Hall JA, Zaidi A, Andrews NJ, Dunbar JK, Dabrera G. Effect of vaccination on household transmission of sars-cov-2 in england. *New England Journal of Medicine.* 2021;385(8):759-760. https://doi.org/10.1056/NEJMc2107717
126. Shah ASV, Gribben C, Bishop J, et al. Effect of vaccination on transmission of COVID-19: an observational study in healthcare workers and their households. *medRxiv.* 2021:2021.2003.2011.21253275. https://doi.org/10.1101/2021.03.11.21253275
127. 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.* 2021;397(10282):1351-1362. https://doi.org/10.1016/s0140-6736(21)00628-0
128. Swiss National COVID-19 Task Force. *Protection Duration After Vaccination or Infection.* Swiss National COVID-19 Task Force; 10 August 2021 2021. https://sciencetaskforce.ch/wp-content/uploads/2021/06/Protection_Duration16Jun2021_EN.pdf.
129. Israel A, Merzon E, Schäffer AA, et al. Elapsed time since BNT162b2 vaccine and risk of SARS-CoV-2 infection in a large cohort. *medRxiv.* 2021:2021.2008.2003.21261496. https://doi.org/10.1101/2021.08.03.21261496
130. Salvagno GL, Henry B, Pighi L, De Nitto S, Lippi G. Total Anti-SARS-CoV-2 Antibodies Measured 6 Months After Pfizer-BioNTech COVID-19 Vaccination in Healthcare Workers. *SSRN- Preprint.* 2021. https://doi.org/10.2139/ssrn.3915349
131. Doria-Rose N, Suthar MS, Makowski M, et al. Antibody Persistence through 6 Months after the Second Dose of mRNA-1273 Vaccine for Covid-19. *New England Journal of Medicine.* 2021;384(23):2259-2261. https://doi.org/10.1056/NEJMc2103916
132. Baden LR, ElSahly HM, Essink B, et al. Covid-19 in the Phase 3 Trial of mRNA-1273 During the Delta-variant Surge. *medRxiv.* 2021:2021.2009.2017.21263624. https://doi.org/10.1101/2021.09.17.21263624
133. Flaxman A, Marchevsky N, Jenkin D, et al. Tolerability and Immunogenicity After a Late Second Dose or a Third Dose of ChAdOx1 nCoV-19 (AZD1222). *SSRN - Preprint.* 2021. https://doi.org/10.2139/ssrn.3873839
134. Sadoff J, Le Gars M, Cardenas V, et al. Durability of antibody responses elicited by a single dose of Ad26.COV2.S and substantial increase following late boosting. *medRxiv.* 2021:2021.2008.2025.21262569. https://doi.org/10.1101/2021.08.25.21262569
135. Barouch DH, Stephenson KE, Sadoff J, et al. Durable Humoral and Cellular Immune Responses 8 Months after Ad26.COV2.S Vaccination. *New England Journal of Medicine.* 2021. https://doi.org/http://doi.org/10.1056/NEJMc2108829
136. Li M, Yang J, Wang L, et al. A booster dose is immunogenic and will be needed for older adults who have completed two doses vaccination with CoronaVac: a randomised, double-blind, placebo-controlled, phase 1/2 clinical trial. *medRxiv.* 2021:2021.2008.2003.21261544. https://doi.org/10.1101/2021.08.03.21261544
137. Wang K, Cao YR, Zhou Y, et al. A third dose of inactivated vaccine augments the potency, breadth, and duration of anamnestic responses against SARS-CoV-2. *medRxiv.* 2021:2021.2009.2002.21261735. https://doi.org/10.1101/2021.09.02.21261735
138. Frenck RW, Klein NP, Kitchin N, et al. Safety, Immunogenicity, and Efficacy of the BNT162b2 Covid-19 Vaccine in Adolescents. *New England Journal of Medicine.* 2021;385(3):239-250. https://doi.org/10.1056/NEJMoa2107456

139. Study to Evaluate the Safety, Tolerability, and Immunogenicity of an RNA Vaccine Candidate Against COVID-19 in Healthy Children <12 Years of Age. In: https://ClinicalTrials.gov/show/NCT04816643;
140. Ali K, Berman G, Zhou H, et al. Evaluation of mRNA-1273 SARS-CoV-2 Vaccine in Adolescents. *N Engl J Med.* 2021. https://doi.org/10.1056/NEJMoa2109522
141. A Study to Evaluate Safety and Effectiveness of mRNA-1273 COVID-19 Vaccine in Healthy Children Between 6 Months of Age and Less Than 12 Years of Age. In: https://ClinicalTrials.gov/show/NCT04796896;
142. Ewen Callaway. COVID vaccines and kids: five questions as trials begin. https://www.nature.com/articles/d41586-021-01061-4. Published 2021. Accessed August 11, 2021, 2021.
143. Han B, Song Y, Li C, et al. Safety, tolerability, and immunogenicity of an inactivated SARS-CoV-2 vaccine (CoronaVac) in healthy children and adolescents: a double-blind, randomised, controlled, phase 1/2 clinical trial. *The Lancet Infectious Diseases.* 2021. https://doi.org/10.1016/S1473-3099(21)00319-4
144. Novavax Initiates Pediatric Expansion for Phase 3 Clinical Trial of COVID-19 Vaccine [press release]. May 3, 2021 2021. https://ir.novavax.com/2021-05-03-Novavax-Initiates-Pediatric-Expansion-for-Phase-3-Clinical-Trial-of-COVID-19-Vaccine.
145. Pfizer and BioNtech Announce Positive Topline Results from Pivotal Trial of COVID-19 Vaccine in Children 5 to 11 Years [press release]. September 20, 2021 2021. https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-positive-topline-results.
146. Xia S, Zhang Y, Wang Y, et al. Safety and immunogenicity of an inactivated COVID-19 vaccine, BBIBP-CorV, in people younger than 18 years: a randomised, double-blind, controlled, phase 1/2 trial. *Lancet Infect Dis.* 2021. https://doi.org/10.1016/s1473-3099(21)00462-x
147. A Study to Evaluate the Efficacy, Immune Response, and Safety of a COVID-19 Vaccine in Adults ≥ 18 Years With a Pediatric Expansion in Adolescents (12 to < 18 Years) at Risk for SARS-CoV-2. In. ClinicalTrials.gov2021. https://clinicaltrials.gov/ct2/show/NCT04611802?id=NCT04917523+OR+NCT05003466+OR+NCT05003479+OR+NCT04998240+OR+NCT04611802&draw=2&rank=5&load=cart.
148. Das BB, Moskowitz WB, Taylor MB, Palmer A. Myocarditis and Pericarditis Following mRNA COVID-19 Vaccination: What Do We Know So Far? *Children.* 2021;8(7). https://doi.org/10.3390/children8070607
149. University of Oxford. Comparing COVID-19 Vaccine Schedule Combinations. https://comcovstudy.org.uk/about-com-cov2. Published 2021. Accessed September 2, 2021.
150. Liu X, Shaw RH, Stuart ASV, et al. Safety and immunogenicity of heterologous versus homologous prime-boost schedules with an adenoviral vectored and mRNA COVID-19 vaccine (Com-COV): a single-blind, randomised, non-inferiority trial. *Lancet.* 2021. https://doi.org/10.1016/S0140-6736(21)01694-9
151. Schmidt T, Klemis V, Schub D, et al. Immunogenicity and reactogenicity of a heterologous COVID-19 prime-boost vaccination compared with homologous vaccine regimens. *medRxiv.* 2021:2021.2006.2013.21258859. https://doi.org/10.1101/2021.06.13.21258859
152. Borobia AM, Carcas AJ, Pérez-Olmeda M, et al. Immunogenicity and reactogenicity of BNT162b2 booster in ChAdOx1-S-primed participants (CombiVacS): a multicentre,

open-label, randomised, controlled, phase 2 trial. *The Lancet.* 2021;398(10295):121-130. https://doi.org/10.1016/S0140-6736(21)01420-3

153. Yorsaeng R, Vichaiwattana P, Klinfueng S, et al. Immune response elicited from heterologous SARS-CoV-2 vaccination: Sinovac (CoronaVac) followed by AstraZeneca (Vaxzevria). *medRxiv.* 2021:2021.2009.2001.21262955. https://doi.org/10.1101/2021.09.01.21262955
154. Li J, Hou L, Guo X, et al. Heterologous prime-boost immunization with CoronaVac and Convidecia. *medRxiv.* 2021:2021.2009.2003.21263062. https://doi.org/10.1101/2021.09.03.21263062
155. Safety and Efficacy of COVID-19 Prime-boost Vaccine in Bahrain. In: https://ClinicalTrials.gov/show/NCT04993560;
156. Moderna Announces Positive Initial Booster Data Against SARS-CoV-2 Variants of Concern [press release]. Cambridge, Massachusetts, May 5 2021. https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-positive-initial-booster-data-against-sars-cov.
157. Flaxman A, Marchevsky NG, Jenkin D, et al. Reactogenicity and immunogenicity after a late second dose or a third dose of ChAdOx1 nCoV-19 in the UK: a substudy of two randomised controlled trials (COV001 and COV002). *Lancet.* 2021. https://doi.org/10.1016/s0140-6736(21)01699-8
158. Novavax Announces COVID-19 Vaccine Booster Data Demonstrating Four-Fold Increase in Neutralizing Antibody Levels Versus Peak Responses After Primary Vaccination [press release]. Novavax, August 5, 2021 2021. https://ir.novavax.com/2021-08-05-Novavax-Announces-COVID-19-Vaccine-Booster-Data-Demonstrating-Four-Fold-Increase-in-Neutralizing-Antibody-Levels-Versus-Peak-Responses-After-Primary-Vaccination.
159. Iketani S, Liu L, Nair MS, et al. A third COVID-19 vaccine shot markedly boosts neutralizing antibody potency and breadth. *medRxiv.* 2021:2021.2008.2011.21261670. https://doi.org/10.1101/2021.08.11.21261670
160. PFIZER AND BIONTECH ANNOUNCE SUBMISSION OF INITIAL DATA TO U.S. FDA TO SUPPORT BOOSTER DOSE OF COVID-19 VACCINE [press release]. NEW YORK & MAINZ, Germany2021. https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-submission-initial-data-us-fda.
161. Wu K, Choi A, Koch M, et al. Preliminary Analysis of Safety and Immunogenicity of a SARS-CoV-2 Variant Vaccine Booster. *medRxiv.* 2021:2021.2005.2005.21256716. https://doi.org/10.1101/2021.05.05.21256716
162. Yorsaeng R, Suntronwong N, Phowatthanasathian H, et al. Immunogenicity of a third dose viral-vectored COVID-19 vaccine after receiving two-dose inactivated vaccines in healthy adults. *medRxiv.* 2021:2021.2009.2016.21263692. https://doi.org/10.1101/2021.09.16.21263692
163. Keskin AU, Bolukcu S, Ciragil P, Topkaya AE. SARS-CoV-2 specific antibody responses after third CoronaVac or BNT162b2 vaccine following two-dose CoronaVac vaccine regimen. *J Med Virol.* 2021. https://doi.org/10.1002/jmv.27350
164. Bar-On YM, Goldberg Y, Mandel M, et al. Protection of BNT162b2 Vaccine Booster against Covid-19 in Israel. *New England Journal of Medicine.* 2021. https://doi.org/10.1056/NEJMoa2114255
165. Patalon T, Gazit S, Pitzer VE, Prunas O, Warren JL, Weinberger DM. Short Term Reduction in the Odds of Testing Positive for SARS-CoV-2; a Comparison Between

Two Doses and Three doses of the BNT162b2 Vaccine. *medRxiv.* 2021:2021.2008.2029.21262792. https://doi.org/10.1101/2021.08.29.21262792

166. Pilishvili T, Fleming-Dutra KE, Farrar JL, et al. Interim Estimates of Vaccine Effectiveness of Pfizer-BioNTech and Moderna COVID-19 Vaccines Among Health Care Personnel — 33 U.S. Sites, January–March 2021. *MMWR Morbidity and mortality weekly report.* 2021;70(20):753–758. https://doi.org/http://dx.doi.org/10.15585/mmwr.mm7020e2external
167. Vasileiou E, Simpson CR, Shi T, et al. Interim findings from first-dose mass COVID-19 vaccination roll-out and COVID-19 hospital admissions in Scotland: a national prospective cohort study. *The Lancet.* 2021;397(10285):1646-1657. https://doi.org/10.1016/S0140-6736(21)00677-2
168. 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. *The Lancet.* 2021;397(10277):881-891. https://doi.org/10.1016/S0140-6736(21)00432-3
169. 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.* 2021:2021.2004.2007.21255081. https://doi.org/10.1101/2021.04.07.21255081
170. El Sahly HM, Baden LR, Essink B, et al. Efficacy of the mRNA-1273 SARS-CoV-2 Vaccine at Completion of Blinded Phase. *New England Journal of Medicine.* 2021. https://doi.org/10.1056/NEJMoa2113017
171. Vacharathit V, Aiewsakun P, Manopwisedjaroen S, et al. SARS-CoV-2 variants of concern exhibit reduced sensitivity to live-virus neutralization in sera from CoronaVac vaccinees and naturally infected COVID-19 patients. *medRxiv.* 2021:2021.2007.2010.21260232. https://doi.org/10.1101/2021.07.10.21260232
172. 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 2021. *MMWR Morbidity and mortality weekly report.* 2021;70(13):495-500. https://doi.org/10.15585/mmwr.mm7013e3external
173. Jalkanen P, Kolehmainen P, Häkkinen HK, et al. COVID-19 mRNA vaccine induced antibody responses against three SARS-CoV-2 variants. *Nat Commun.* 2021;12(1):3991. https://doi.org/10.1038/s41467-021-24285-4
174. Moderna. *Moderna COVID-19 Vaccine Retains Neutralizing Activity Against Emerging Variants First Identified in the U.K. and the Republic of South Africa.* 2021. https://investors.modernatx.com/node/10841/pdf.
175. Jeewandara C, Aberathna IS, Pushpakumara PD, et al. Antibody and T cell responses to Sinopharm/BBIBP-CorV in naïve and previously infected individuals in Sri Lanka. *medRxiv.* 2021:2021.2007.2015.21260621. https://doi.org/10.1101/2021.07.15.21260621
176. Fernández J, Bruneau N, Fasce R, et al. Neutralization of alpha, gamma, and D614G SARS-CoV-2 variants by CoronaVac vaccine-induced antibodies. *Journal of Medical Virology.* 2021. https://doi.org/10.1002/jmv.27310
177. Jalkanen P, Kolehmainen P, Häkkinen HK, et al. COVID-19 mRNA vaccine induced antibody responses against three SARS-CoV-2 variants. *Nature Communications.* 2021;12(1). https://doi.org/10.1038/s41467-021-24285-4

178. Thomas SJ, Moreira ED, Kitchin N, et al. Six Month Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine. *medRxiv.* 2021:2021.2007.2028.21261159. https://doi.org/10.1101/2021.07.28.21261159
179. Madhi SA, Baillie V, Cutland CL, et al. Efficacy of the ChAdOx1 nCoV-19 Covid-19 Vaccine against the B.1.351 Variant. *New England Journal of Medicine.* 2021;384(20):1885-1898. https://doi.org/10.1056/NEJMoa2102214
180. Jongeneelen M, Kaszas K, Veldman D, et al. Ad26.COV2.S elicited neutralizing activity against Delta and other SARS-CoV-2 variants of concern. *bioRxiv.* 2021:2021.2007.2001.450707. https://doi.org/10.1101/2021.07.01.450707
181. Tada T, Zhou H, Samanovic MI, et al. Comparison of Neutralizing Antibody Titers Elicited by mRNA and Adenoviral Vector Vaccine against SARS-CoV-2 Variants. *bioRxiv.* 2021:2021.2007.2019.452771. https://doi.org/10.1101/2021.07.19.452771
182. Shinde V, Bhikha S, Hoosain Z, et al. Efficacy of NVX-CoV2373 Covid-19 Vaccine against the B.1.351 Variant. *New England Journal of Medicine.* 2021;384(20):1899-1909. https://doi.org/10.1056/NEJMoa2103055
183. Buntz B. AstraZeneca, Pfizer Moderna vaccines fare well against Beta, Gamma and Delta variants in study. Drug Discovery & Development. https://www.drugdiscoverytrends.com/astrazeneca-pfizer-moderna-vaccines-fare-well-against-beta-gamma-and-delta-variants-in-study/. Published 2021. Updated 23 July 2021. Accessed 9 September 2021.
184. Choi A, Koch M, Wu K, et al. Serum Neutralizing Activity of mRNA-1273 against SARS-CoV-2 Variants. *bioRxiv.* 2021:2021.2006.2028.449914. https://doi.org/10.1101/2021.06.28.449914
185. Wall EC, Wu M, Harvey R, et al. Neutralising antibody activity against SARS-CoV-2 VOCs B.1.617.2 and B.1.351 by BNT162b2 vaccination. *The Lancet.* 2021;397(10292):2331-2333. https://doi.org/10.1016/S0140-6736(21)01290-3