

Literature screening report

COVID-19 vaccines in the WHO's Emergency Use Listing (EUL) Report (8)

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Abstract

This report focuses on the World Health Organization's (WHO) Emergency Use Listing (EUL) of authorized vaccines as of 11 November 2021. Bharat Biotech's new vaccine **COVAXIN/BBV152** received WHO EUL authorisation on 3 November 2021 leading to **seven** vaccines being now 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), Sinovac/CoronaVac (China), and COVAXIN/BBV152 (Bharat Biotech, India)]. This report provides a condensed summary concerning vaccine efficacy or effectiveness, safety, protection against variants, and further important information for each vaccine in the form of a synoptic table. The data in this synoptic table were extracted from phase III clinical trials and observational studies. This report focuses on the latest data on vaccine effectiveness, breakthrough infections, booster doses, and vaccinations in children.

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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, 51.7% of the world populations, of which only 4.5% of people in low-income countries, have received at least one dose of a marketed COVID-19 vaccine as of 15 November 2021¹. Currently, seven vaccines [namely, Comirnaty/BNT162b2 (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), and COVAXIN/BBV152 (Bharat Biotech, India)] were assessed and granted an authorization by WHO as of 11 November 2021. **Articles regarding the latest data on vaccine effectiveness, breakthrough infections, and mRNA vaccinations in children (5-12) were prioritized during the literature search and are the latest additions to the table. Data from clinical trials and observational studies for the seven 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 15.11.2021).

Methodology

We screened the data for the EUL-accepted vaccines and the vaccine candidate Novavax as of 12 November 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 reports².

Results

As phase III COVID-19 vaccine trials confirmed vaccine efficacy and safety for all seven WHO EUL authorized vaccines, and as the share of fully vaccinated people begin to 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

Given reports of waning vaccine immunity over time and Delta's greater capacity to evade vaccine-induced immunity, it is important to track vaccine effectiveness over time. Recently published studies corroborated past mRNA vaccine effectiveness data. Moderna's mRNA-1273 vaccine continues to demonstrate higher effectiveness against infection^{3,4} than Pfizer-BioNTech's BNT162b2. Regarding duration of protection against hospitalization, Tenforde et al. (2021) reported that mRNA-1273 vaccines (aOR=0.15 (95% CI, 0.09-0.23)) provides greater protection against COVID-19 related hospitalization than BNT162b2 (aOR=0.36 (95% CI, 0.27-0.49; $P<0.001$)) 120 days or more post full (two-dose) vaccination⁵. The Centers for Disease Control

² COVID-19 vaccines: efficacy and safety (Literature Review 1). Swiss School of Public Health. https://www.bag.admin.ch/dam/bag/de/dokumente/mt/k-und-i/aktuelle-ausbrueche-pandemien/2019-nCoV/Literaturrecherchen/literaturrecherchen_covid-19-impfstoffe_20210209.pdf.download.pdf/20210209_Literaturrecherchen_Covid-19-Impfstoffe_EN.pdf

³ Product-specific COVID-19 vaccine effectiveness against secondary infection in close contacts, Navarre, Spain, April to August 2021. *Eurosurveillance Journal*. <https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2021.26.39.2100894>

⁴ SARS-CoV-2 vaccine protection and deaths among US veterans during 2021. *Science*. <https://www.science.org/doi/10.1126/science.abm0620>

⁵ Association between mRNA vaccination and COVID-19 hospitalization and disease severity. *JAMA* <https://jamanetwork.com/journals/jama/fullarticle/2786039>



and Prevention's (CDC) Morbidity and Mortality Weekly Report is calling for all previously COVID-19 infected persons to be vaccinated against SARS-CoV-2 as soon as possible, as the adjusted odds ratio of getting (re)infected with SARS-CoV-2 and becoming hospitalized was **5.49-fold (95% CI, 2.75-10.99)** higher for COVID-19 recovered individuals (90-179 days post recovery) than mRNA-vaccinated persons, (90-179 days post two-dose vaccination or recovery)⁶.

A Finish study conducted over December 2020 and October 2021 demonstrated thT Janssen's Ad26.COv2 waned from **89% (95 CI, 73-95)** 14-90 days after the second dose to **63% (95% CI, -166-95%)** 91-180 days after the second dose⁷. The study did not detect changes in vaccine effectiveness following the emergence of Delta, possibly indicating that the observed declines in vaccine protection against infection could be due to waning vaccine immunity. Similar results have been corroborated by previous studies^{8,9,10}. In Navarre, Spain AstraZeneca's ChAdOx1 nCoV-19's effectiveness against any SARS-CoV-2 infection was **54.0% (95% CI, 48-60)** between the months of April and August while effectiveness against symptomatic infection was **56% (95% CI, 48-63)**¹¹. However, results from the Spanish study was contradicted by a study in India during the same time period which instead showed that vaccine effectiveness of ChAdOx1 against any SARS-CoV-2 infection was **88% (95% CI, 79-94)**.¹²

Further, a prospective cohort study was conducted in China regarding Sinopharm's BBIBP-CorV and the possible influence that timing of inoculation have on vaccine

⁶ Laboratory-confirmed COVID-19 among adults hospitalized with COVID-19-like illness with infection-induced or mRNA vaccine-induced SARS-CoV-2 immunity – Nine States, January-September 2021. *Morbidity and Mortality Weekly Report*. https://www.cdc.gov/mmwr/volumes/70/wr/mm7044e1.htm?s_cid=mm7044e1_w

⁷ Cohort study of COVID-19 vaccine effectiveness among healthcare workers in Finland, December 2020-October 2021. *medRxiv*. <https://www.medrxiv.org/content/10.1101/2021.11.03.21265791v2>

⁸ Effect of Delta variant on viral burden and vaccine effectiveness against new SARS-CoV-2 infections in the UK. *Nature Medicine*. <https://www.nature.com/articles/s41591-021-01548-7>

⁹ Effectiveness of mRNA Covid-19 Vaccine among U.S. Health Care Personnel. *The New England Journal of Medicine*. <https://www.nejm.org/doi/full/10.1056/NEJMoa2106599>

¹⁰ Waning immunity after the BNT162b2 vaccine in Israel. *The New England Journal of Medicine*. <https://www.nejm.org/doi/full/10.1056/NEJMoa2114228>

¹¹ Product-specific COVID-19 vaccine effectiveness against secondary infection in close contacts, Navarre, Spain, April to August 2021. *Eurosurveillance Journal*. <https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2021.26.39.2100894>

¹² Effectiveness of COVID-19 vaccine in preventing infection and disease severity: a case-control study from an Eastern State of India. *Epidemiology & Infection*. <https://www.cambridge.org/core/journals/epidemiology-and-infection/article/effectiveness-of-covid19-vaccine-in-preventing-infection-and-disease-severity-a-casecontrol-study-from-an-eastern-state-of-india/6CAA68CE4E8340FD66EA316DD04A233>

effectiveness. Sixty-three participants received both doses of the inactivated vaccine at either the morning (from 9AM to 11AM) or the afternoon (3PM to 5PM). The resulting serological studies showed evidence that individuals who were vaccinated in the morning had higher (**34.70 AU/mL**) levels of neutralizing antibodies (NAbs) compared with those who received their vaccines during the afternoon (**19.35 AU/mL**)¹³. Overall study results indicated that morning vaccination may be linked to stronger immune responses as participants vaccinated earlier in the day showed stronger B cell and Tfh responses as well as higher percentages of monocytes and dendritic cells¹⁴. While these results show promising evidence of BBIBP-CorV's effectiveness, the study's small sample size and design are limited. Additional studies concerning the 24-hour circadian rhythm cycle and vaccination are necessary for future vaccine protocol recommendations.

Breakthrough Infections

While all WHO EUL authorised vaccines have demonstrated to be effective against severe SARS-CoV-2 infections and hospitalization, the combined effects of low vaccination rates¹⁵, reductions in vaccine effectiveness, and the emergence of the Delta variant has led to increased cases of SARS-CoV-2 breakthrough infections. A SARS-CoV-2 breakthrough infection is defined as testing positive for SARS-CoV-2 14 or more days after having received two doses of an anti-SARS-CoV-2 vaccine¹⁶. The Mayo Clinic, a non-profit American academic medical centre, characterised SARS-CoV-2 breakthrough cases admitted to a health centre in Florida from 3 January 2021 until 28 August 2021. From the 6,161 SARS-CoV-2 positive cases, 18% ($n=1,120$) were SARS-CoV-2 breakthrough infections¹⁷. Interestingly, 97% of the breakthrough

¹³ Time of day influences immune response to an inactivated vaccine against SARS-CoV-2. *Cell Research*. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8326654/>

¹⁴ Time of day influences immune response to an inactivated vaccine against SARS-CoV-2. *Cell Research*. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8326654/>

¹⁵ Community-level evidence for SARS-CoV-2 vaccine protection of unvaccinated individuals. *Nature Medicine*. <https://www.nature.com/articles/s41591-021-01407-5>

¹⁶ The possibility of COVID-19 after vaccination: breakthrough infections. *Centers for Disease Control & Prevention*. <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/effectiveness/why-measure-effectiveness/breakthrough-cases.html>

¹⁷ COVID-19 vaccine-breakthrough infections requiring hospitalization in Mayo Clinic Florida through August 2021. *Clinical Infectious Diseases*. <https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab932/6415962>

cases occurred after 2 May 2021, which corresponds to the emergence of the Delta variant circulation in Florida. Additionally, prior to 2 May 2021, only 2.1% of breakthrough infections resulted in hospitalizations; the percentage of hospitalized breakthrough infections rose to 19.1% after 2 May 2021. The authors did not determine whether the rise in breakthrough infections were due to the more infectious Delta variant, waning vaccine immunity over time, declines in social distancing and protective measures or a combination of all three factors. Breakthrough cases occurred in older people with higher rates of comorbidities¹⁸. Controlling for possible confounders, including age and comorbidities, an Israeli study reported that early BNT162b2 vaccinated individuals (those vaccinated in January and February 2021) had a 1.51-fold (95% CI, 1.38-1.66) increased risk of breakthrough infection compared to persons vaccinated (with the BNT162b2 vaccine) in March and April 2021¹⁹. When further disaggregated, those vaccinated in January 2021 had a 2.26-fold (95% CI, 1.80-3.01) increased risk than those vaccinated in April 2021. While the authors acknowledged that the results could be confounded by differences in individual health behaviours (i.e., mask wearing or social distancing), they concluded that a “possible relative decrease in the long-term protection of BNT162b2 vaccine against the Delta variant” could be driving the rise in breakthrough infections²⁰. Nevertheless, studies have reported that vaccinated individuals with breakthrough infections, including those of the Delta strain, are less likely to develop severe symptoms and require hospitalization and more likely to recover swiftly from illness than unvaccinated persons^{21,22}. Of the few breakthrough cases that require hospitalization, patients often

¹⁸ COVID-19 vaccine-breakthrough infections requiring hospitalization in Mayo Clinic Florida through August 2021. *Clinical Infectious Diseases*. <https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab932/6415962>

¹⁹ Correlation of SARS-CoV-2 breakthrough infections to time-from-vaccine. *Nature Communications*. <https://www.nature.com/articles/s41467-021-26672-3>

²⁰ Correlation of SARS-CoV-2 breakthrough infections to time-from-vaccine. *Nature Communications*. <https://www.nature.com/articles/s41467-021-26672-3>

²¹ Effectiveness of mRNA BNT162b2 COVID-19 vaccine up to 6 months in a large integrated health system in the USA: A retrospective cohort study. *The Lancet*. [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)02183-8/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02183-8/fulltext)

²² Understanding breakthrough infections following mRNA SARS-CoV-2 vaccination. *JAMA*. <https://jamanetwork.com/journals/jama/fullarticle/2786040>

have comorbidities or are immunocompromised^{23,24}. Studies are recommending the continuation of social distancing and non-pharmaceutical measures.

Booster Dose

With the reported waning immunity of vaccines against SARS-CoV-2 and the emergence of more infectious variants, concerns regarding breakthrough infections and the possible increase of cases rose. To overcome the waning immunity, ministries of health and governments started administering booster doses, beginning with immunocompromised, older individuals, and healthcare workers and later expanding the administration to the general population. By now, the booster dose of BNT162b2 has demonstrated to elicit a robust immune response²⁵, and showed to be efficacious against COVID-19 disease regardless of age, sex, race, ethnicity, and comorbid conditions²⁶, and to be effective against hospitalization, severe disease, and any COVID-19 disease²⁷. However, limited information on the immune response, efficacy, or effectiveness of the other six remaining WHO EUL COVID-19 vaccines is available, by the time of writing this report. Recently, a study evaluating the antibody immunity to SARS-CoV-2 elicited by a third dose of the inactivated vaccine BBIBP-CorV was published on bioRxiv²⁸. The study included more than 500 individuals who received two or three doses of the inactivated SARS-CoV-2 vaccine (BBIBP-CorV) and were followed for up to nearly nine months. The kinetics of receptor-binding domain (RBD) antibodies, neutralizing antibodies, and RBD-specific memory B cells against the wild type and the SARS-CoV-2 Beta, Delta, and Lambda variants was analysed and

²³ Understanding breakthrough infections following mRNA SARS-CoV-2 vaccination. *JAMA*.

<https://jamanetwork.com/journals/jama/fullarticle/2786040>

²⁴ Association between mRNA vaccination and COVID-19 hospitalization and disease severity. *JAMA*

<https://jamanetwork.com/journals/jama/fullarticle/2786039>

²⁵ SARS-CoV-2 Neutralization with BNT162b2 Vaccine Dose 3. *NEJM*. <https://www.nejm.org/doi/full/10.1056/NEJMc2113468>

²⁶ Pfizer and BioNTech Announce Phase 3 Trial Data Showing High Efficacy of a Booster Dose of their COVID-19 Vaccine.

[Press Release] Pfizer and BioNTech. <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-phase-3-trial-data-showing>

²⁷ Effectiveness of a third dose of the BNT162b2 mRNA COVID-19 for preventing severe outcomes in Israel: an observational study. *The Lancet*. [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)02249-2/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02249-2/fulltext)

²⁸ Potent antibody immunity to SARS-CoV-2 variants elicited by a third dose of inactivated vaccine. *bioRxiv*.

<https://www.biorxiv.org/content/10.1101/2021.11.10.468037v1>

compared to the immune response of individuals that only received two doses of the vaccine. Based on the results, a third dose of the inactivated vaccine significantly increased and elicited a robust immune response in recipients against the wild type and Beta, Delta, and Lambda variants of SARS-CoV-2.

Children COVID-19 Vaccination (<12 years old)

After careful evaluation of the scientific evidence regarding the vaccination of children aged 5 to 11 years with BNT162b2, the FDA authorized, on 29 October 2021, the emergency use of the Pfizer-BioNTech vaccine for prevention of COVID-19 to include children 5 through 11 years of age²⁹. On the following week, the CDC expanded their vaccine recommendations to include children in this age group, officially commencing the administration of the two 10-µg dose BNT162b2 vaccine in children all over the United States³⁰. The decision was based on the preliminary results made available by Pfizer-BioNTech, now published in the *New England Journal of Medicine*³¹, which demonstrated that the two 10-µg dose BNT162b2 vaccine in children (5-11) were found to be safe, immunogenic, and efficacious. In the previous three months, other countries such as Chile, China, Cuba, and the United Arab Emirates (UAE) started inoculating children younger than 12 years old with various COVID-19 vaccines. For instances, UAE started administering the Sinopharm COVID-19 vaccine to children aged 3 to 17 years during the beginning of August³² and has recently approved the BNT162b2 vaccine for children aged 5 to 11 years. With the expansion of children's COVID-19 vaccination and the reported rates of myocarditis in younger persons vaccinated with mRNA COVID-19 vaccines, many parents may fear the onset of

²⁹ FDA Authorizes Pfizer-BioNTech COVID-19 Vaccine for Emergency Use in Children 5 through 11 Years of Age. *FDA*. <https://www.fda.gov/news-events/press-announcements/fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use-children-5-through-11-years-age>

³⁰ CDC Recommends Pediatric COVID-19 Vaccine for Children 5 to 11 Years. *CDC*. <https://www.cdc.gov/media/releases/2021/s1102-PediatricCOVID-19Vaccine.html>

³¹ Evaluation of the BNT162b2 Covid-19 Vaccine in Children 5 to 11 Years of Age. *NEJM*. <https://www.nejm.org/doi/full/10.1056/NEJMoa2116298>

³² UAE rolls out Sinopharm COVID-19 vaccine to children aged 3-17. [Press Release] *Reuters*. <https://www.reuters.com/world/middle-east/uae-rolls-out-sinopharm-covid-19-vaccine-children-aged-3-17-2021-08-02/>

serious adverse events such as myocarditis. However, multiple studies and reports have argued and demonstrated that the benefits of the COVID-19 vaccine outweigh the very low potential risk of vaccine-associated inflammation of the heart and other adverse events³³.

COVAXIN

On 3 November 2021, the WHO issued an emergency listing for COVAXIN (India's first indigenous COVID-19 vaccine manufactured and developed by Bharat Biotech) by adding it to its validated portfolio of vaccines against SARS-CoV-2³⁴. The COVAXIN vaccine is a two-dose vaccination regimen given 28 days apart developed using whole-virion inactivated Vero cell platform technology. Based on the phase 1/2 clinical trial results, the vaccine generated adequate safety data without any reactogenicity, led to tolerable safety outcomes, induced neutralizing antibody titers against two divergent SARS-CoV-2 strains, and enhanced humoral and cell-mediated immune responses^{35,36}. During the randomised, double-blinded, placebo-controlled, multicentre phase 3 clinical trial, the efficacy, safety, and immunogenicity of COVAXIN was evaluated in individuals aged 18 years and older. Based on those results, the vaccine demonstrated **77.8%** vaccine efficacy against symptomatic COVID-19 disease, **93.4%** efficacy against severe symptomatic COVID-19 disease, and **63.6%** efficacy protection against asymptomatic COVID-19 disease. Additionally, the vaccine demonstrated an efficacy of **65.2%** protection against the SARS-CoV-2 B.1.617.2 Delta variant³⁷. When analysing real world effectiveness data, COVAXIN was

³³ The very low risk of myocarditis and pericarditis after mRNA COVID-19 vaccination should not discourage vaccination. *Swiss Medical Weekly*. <https://smw.ch/article/doi/smw.2021.w30087>

³⁴ WHO issues emergency use listing for eight COVID-19 vaccine. *WHO News*. <https://www.who.int/news/item/03-11-2021-who-issues-emergency-use-listing-for-eighth-covid-19-vaccine>

³⁵ Safety and immunogenicity of an inactivated SARS-CoV-2 vaccine, BBV152: a double-blind randomised, phase 1 trial. *The Lancet Infectious Diseases*. [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(20\)30942-7/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30942-7/fulltext)

³⁶ Safety and immunogenicity of an inactivated SARS-CoV-2 vaccine, BBV152: interim results from a double-blind, randomised, multicentre, phase 2 trial, and 3-month follow-up of a double-blind, randomised phase 1 trial. *The Lancet Infectious Diseases*. [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(21\)00070-0/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00070-0/fulltext)

³⁷ Efficacy, safety, lot to lot immunogenicity of an inactivated SARS-CoV-2 vaccine (BBV152): a double-blind, randomized, controlled phase 3 trial. *medRxiv*. <https://www.medrxiv.org/content/10.1101/2021.06.30.21259439v1>

estimated to have an effectiveness of **71%** against symptomatic disease in individuals who received the two doses³⁸. Other studies evaluating children vaccination, and heterologous vaccines can be found in the synoptic table under the COVAXIN columns.

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

³⁸ Effectiveness of COVID-19 vaccine in preventing infection and disease severity: a case-control study from an Eastern State of India. Cambridge University press. <https://www.cambridge.org/core/journals/epidemiology-and-infection/article/effectiveness-of-covid19-vaccine-in-preventing-infection-and-disease-severity-a-casecontrol-study-from-an-eastern-state-of-india/6CAA68CE4E8340FD66EA316DD04A233>

Synoptic Table

Synoptic table about SARS-CoV-2 vaccines accepted in the WHO's Emergency Use Listing and Novavax Vaccine (as of 12 November 2021)

	BNT162b2/ COMIRNATY (Pfizer-BioNTech, USA)	Spikevax/ Moderna COVID- 19 Vaccine/ mRNA-1273 (Moderna, USA)	Vaxzevria/ ChAdOx1 nCoV- 19/ AZD1222/ Covishield (AstraZeneca/Oxf ord, UK, India)	Janssen COVID- 19 vaccine/Johnson & Johnson (Janssen, USA)	BBIBP-CorV, (Sinopharm, China)	CoronaVac (Sinovac, China)	COVAXIN / BBV152 (Bharat Biotech, India)	AWAITING APPROVAL FROM WHO EUL
								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)	Whole-virion inactivated 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-dose regime, 56 days apart] ⁱ	2 doses, 21 days apart	2 doses, 14 days apart	2 doses, 28 days apart	2 doses, 21 days apart

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>

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	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 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 103 countries (including Switzerland – approved on 20.12.20)	FDA (18.12.20); EMA (06.01.21); WHO EUL (30.04.21); and list of 76 countries (including Switzerland – approved 12.01.21)	FDA (awaiting on approval); EMA (29.01.21); WHO EUL (15.02.21); and list of 124 countries (Switzerland awaiting on approval)	FDA (27.02.21); EMA (11.03.21), WHO EUL (12.03.21), and list of 75 countries (including Switzerland – approved 22.03.21)	WHO EUL (07.05.21); and list of 68 countries (e.g., Argentina, Bahrain, Brazil, China, Indonesia, United Arab Emirates, Zimbabwe)	WHO EUL (01.06.21), and list of 42 countries (e.g., Albania, Chile, Egypt, Hong Kong, Malaysia, Tunisia, Turkey, Ukraine)	WHO EUL (03.11.21) and list of 9 countries (Guyana, India, Iran, Mauritius, Mexico, Nepal, Paraguay, Philippines & Zimbabwe)	Waiting on approval (Not-yet-approved by countries or WHO for emergency use)
Booster shot approving authorities	EMA approved booster for those aged 18 and above, 6 months after the 2 nd dose ¹ FDA approved booster for those ages 16 and above, 6 months after the 2 nd dose ⁱⁱⁱ	EMA authorised booster dose for immunocompromised individuals ^{iv} FDA approved third booster dose for individuals >65 and high-risk individuals, 6 months after the 2 nd dose ^v	-	-	-	-	-	-

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>

ⁱⁱⁱ FDA authorizes booster dose of Pfizer-BioNTech COVID-19 vaccine for certain populations. *FDA News Release*. <https://www.fda.gov/news-events/press-announcements/fda-authorizes-booster-dose-pfizer-biontech-covid-19-vaccine-certain-populations>

^{iv} Comirnaty and Spikevax: EMA recommendations on extra doses and boosters. *European Medicines Agency*. <https://www.ema.europa.eu/en/news/comirnaty-spikevax-ema-recommendations-extra-doses-boosters>

^v F.D.A. Panel recommends booster for many Moderna vaccine recipients. *The New York Times*. <https://www.nytimes.com/2021/10/14/us/politics/fda-moderna-vaccine-boosters.html>

EFFECTIVENESS AGAINST ANY SARS-COV-2 INFECTION

Effectiveness single dose	<p><u>Against any SARS-CoV-2 infection:</u> 70%². 77.6% (95% CI, 70.9-82.7)³ 36.8% (95% CI, 33.2-40.2) [3 weeks after first dose]⁴ 57% (95% CI, 52-61; Spain) [Apr-Aug]⁵ 72% (pooled meta-analysis)⁶ 64% (95% CI, 59%-68%; United States) [May to July 2021]^{7vi}</p>	<p><u>Against symptomatic disease:</u> 60% (95% CI, 57-64; >2 weeks after dose)^{10.viii} 88.9% (95% CI, 78.7-94.2)³ 66% (95% CI, 56-73; Spain) [Apr-Aug]⁵ 69% (pooled meta-analysis)⁶ 64% (95% CI, 59%-68%; United States) [May to July 2021]^{7ix}</p>	<p><u>Against symptomatic or symptomatic disease:</u> 64%</p> <p><u>Symptomatic disease:</u> 67%¹¹ 49% (95% CI, 32.0-62.0; India) [Apr-Jun]¹² 41% (95% CI, 34-48; Spain) [Apr-Aug]⁵ 51% (pooled meta-analysis)⁶ 46% (95% CI, 37-54; Spain) [Apr-Aug]⁵ 66% (95% CI, 58-72; India) [May-Jul 2021]¹³</p>	<p><u>Against SARS-CoV-2 infection:</u> 50.6% (95% CI, 14.0-74.0) [<2 weeks after dose]; 76.7% (95% CI, 30.3-95.3) [>2 weeks after dose]¹⁴; 79% (95% CI, 77-80) (when corrected for under-recording, VE was estimated to be 69% (95% CI, 67-71)¹⁵. 71% (95% CI, 56-81) [11 March – 15 August]¹⁶. 61% (95% CI, 29-84) [January-June]¹⁷ 50.9% (95% CI, 35.1-63.0) [June-September; Brazil]¹⁸</p>	<p>Partial protection^{22.xii}</p>	<p>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 death²³.</p> <p>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 ICU admission, and 29.4% (95% CI, 26.7.3-31.9) against death [January-April]²⁴</p>	<p><u>Against symptomatic disease:</u> 45% (95% CI, 6.0-68.0; India) [Apr-Jun]¹² 40% (95% CI, 4-62; India) [May-Jul 2021]¹³</p>	<p>Ongoing studies in South Africa²⁵ and the United Kingdom²⁶</p>
	<p><u>Against symptomatic disease:</u> 66% (95% CI, 60-71; Spain) [Apr-Aug]⁵</p>	<p><u>Against symptomatic disease:</u> 71% (95% CI, 61-79; Spain) [Apr-Aug]⁵</p> <p><u>Individuals ≥ 70:</u></p>	<p><u>Individuals ≥ 70:</u> Symptomatic disease: 58%⁸.</p>					

vi Results do not disaggregate between mRNA vaccines, BNT162b2 and mRNA-1273.
viii mRNA-aggregated data (results do not disaggregate between BNT162b2 and mRNA-1273).
ix Results do not disaggregate between mRNA vaccines, BNT162b2 and mRNA-1273.
xii Study did not report numerical data on vaccine effectiveness. Further studies are required to validate results.

<p><u>Individuals ≥70:</u> Symptomatic disease: 58%⁸.</p> <p>Hospitalization risk reduced by 35-45%⁸.</p> <p>Risk of death reduced by 54%⁸.</p> <p><u>Individuals ≥50:</u> ≥14 days after first dose: 54% (95% CI, 47-61) effectiveness against hospitalization [1 January-22 June⁹. vii</p>	<p>Symptomatic disease: 64% (95% CI, 46-78; >2 weeks after dose)¹⁰.^x</p> <p><u>Individuals ≥50:</u> ≥14 days after first dose: 54% (95% CI, 47-61) effectiveness against hospitalization [1 January-22 June⁹.^{xi}</p>	<p>Hospitalization risk reduced by 35-45%⁸.</p>	<p>50.0% (95% CI, 42.0-57.0; Spain) [Apr-Aug]⁵</p> <p>73.6% (95% CI, 65.9-79.9; US) [Feb-Jul]¹⁹</p> <p>66.9% (95% CI, 58.4-73.6; pooled meta-analysis)²⁰</p> <p><u>Symptomatic disease:</u> 54% (95% CI, 45-62; Spain) [Apr-Aug]⁵</p> <p>75.7% (95% CI, 69.3-80.8; pooled meta-analysis)²⁰</p> <p>81% (95% CI, 79-84) for preventing hospitalization when corrected for under-recording, VE was estimated to be 73% (95% CI, 69-76)¹⁵.</p>				
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vii mRNA-aggregated data (results do not disaggregate between BNT162b2 and mRNA-1273).

x mRNA-aggregated data (results do not disaggregate between BNT162b2 and mRNA-1273).

xi mRNA-aggregated data (results do not disaggregate between BNT162b2 and mRNA-1273).

				<p>75% (95% CI, 65-82) against severe critical COVID-19²¹</p> <p><i>Individuals ≥50:</i> 68% (95% CI, 50-79)⁹.</p>				
Effectiveness of two doses	<p><u>SARS-Cov-2 infection:</u> 85%². 94.6%²⁷. 94.5%²⁸. 76% (95% CI, 69-81) [Jan-Jul]²⁹. 88.8% (95% CI, 84.6-91.8) [Dec 2020-May]³ 74% (95% CI, 72-76) [Jan-Jun]¹⁷ 77.5% (95% CI, 76.4-78.6) [first month after second dose]⁴ 47% (95% CI, 43-51) [5 months after second dose]³⁰</p>	<p><u>SARS-Cov-2 infection:</u> 100%²⁷. 86% (95% CI, 81-90.6) [January-July]²⁹. 96.3% (95% CI, 91.3-98.4) [December-May]³ 85% (95% CI, 80-90) [January-June]¹⁷ 71% (95% CI, 68-74) [4 months after second dose]³¹ 63% (95% CI, 44-76) [June-August]³⁵</p>	<p><u>SARS-CoV-2 infection:</u> 53% (95% CI, 12-84) [January-June]¹⁷ 27% (95% CI, 17-37) [4 months after second dose]³¹ 88% (95% CI, 79.0-94.0; India) [Apr-Jun]¹² 80% (95% CI, 73-86; India) [May-Jul 2021]¹³</p>	<p>Not Applicable (one dose schedule)</p>	<p>Partial protection^{22, xx}</p>	<p>65.9% for preventing COVID-19; 87.5% for preventing hospitalization; 90.3% for preventing ICU admission; and 86.3% for preventing COVID-19 related death²³.</p> <p>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,</p>	<p><u>Against symptomatic disease:</u> 71% (95% CI, 41-85; India) [Apr-Jun]¹² 69% (95% CI, 54-79; India) [May-Jul 2021]¹³</p>	<p>Ongoing studies in South Africa²⁵ and the United Kingdom²⁶</p> <p>89.7% protection against SARS-CoV-2 infection (95% CI, 80.2-94.6; United Kingdom)³⁶</p>

xx Study did not report numerical data on vaccine effectiveness. Further studies are required to validate results. 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>

<p>56% (95% CI, 53-59) [4 months after second dose]³¹</p> <p>69% (95% CI, 66-72; Spain) [Apr-Aug]⁵</p> <p>88% (pooled meta-analysis)⁶</p> <p>84% (95% CI, 40-96; Italy) [27 Dec 2020 – 24 Mar 2021] 14-21 days from the first dose and 95% (95% CI, 62-99; Italy) [27 Dec 2020 – 24 Mar 2021] at least 7 days from the second dose³²</p> <p>95% (95% CI, 93%-96%; United States) [May to July 2021]^{7,xiii}</p> <p>66.9% (95% CI, 58.4-73.6; pooled meta-analysis)²⁰</p> <p><u>Symptomatic disease:</u></p>	<p>82% (95% CI, 78-86; Spain) [Apr-Aug]⁵</p> <p>80% (pooled meta-analysis)⁶</p> <p>95% (95% CI, 93%-96%; United States) [May to July 2021]^{7,xvi}</p> <p>66.9% (95% CI, 58.4-73.6; pooled meta-analysis)²⁰</p> <p><u>Symptomatic disease:</u> 91% (95% CI, 89-93; >2 weeks after dose)^{10, xvii}</p> <p>85% (95% CI, 80-89; Spain) [Apr-Aug]⁵</p> <p>75.7% (95% CI, 69.3-80.8; pooled meta-analysis)²⁰</p> <p><u>Asymptomatic SARS-CoV-2 infection:</u></p>	<p>54.0% (95% CI, 48-60; Spain) [Apr-Aug]⁵</p> <p>66.9% (95% CI, 58.4-73.6; pooled meta-analysis)²⁰</p> <p><u>Symptomatic disease:</u> 90%¹¹.</p> <p>56% (95% CI, 48-63; Spain) [Apr-Aug]⁵</p> <p>75.7% (95% CI, 69.3-80.8; pooled meta-analysis)²⁰</p> <p><u>Asymptomatic SARS-CoV-2 infection</u></p> <p>63.1% (95% CI, 40.9-76.9; pooled meta-analysis)²⁰</p>			<p>72.2-75.2) against ICU admission, and 73.7% (95% CI, 72.3-75.0) against death [January-April]²⁴</p>		
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^{xiii} Results do not disaggregate between mRNA vaccines, BNT162b2 and mRNA-1273.

^{xvi} Results do not disaggregate between mRNA vaccines, BNT162b2 and mRNA-1273.

^{xvii} Results do not disaggregate between BNT162b2 and mRNA-1273.

<p>72% (95% CI, 69-75; Spain) [Apr-Aug]⁵ 75.7% (95% CI, 69.3-80.8; pooled meta-analysis)²⁰</p> <p><u>Asymptomatic SARS-CoV-2 infection:</u> 90.6%^{33, xiv} 73.1% (95% CI, 70.3-75.5)⁴ 63.1% (95% CI, 40.9-76.9; pooled meta-analysis)²⁰</p> <p><u>Hospitalization:</u> 85% (95% CI, 73-93) [January-July]²⁹. 88% (95% CI, 85-91) [11 March – 15 August]¹⁶. 89% (95% CI, 87-91) for individuals ≥50 years [1</p>	<p>90.6%^{33, xviii} 71% (95% CI, 61-78) [January-August]³⁵ 63.1% (95% CI, 40.9-76.9; pooled meta-analysis)²⁰</p> <p><u>Hospitalization:</u> 91.6% (95% CI, 81-97) [January-July]²⁹. 93% (95% CI, 91-95) [11 March – 15 August]¹⁶. 89% (95% CI, 87-91) for individuals ≥50 years [1 January-22 June]^{9, xix}</p>						
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^{xiv} Results do not disaggregate between BNT162b2 and mRNA-1273

^{xviii} Results do not disaggregate between BNT162b2 and mRNA-1273

^{xix} mRNA-aggregated data (results do not disaggregate between BNT162b2 and mRNA-1273).

	<p>January-22 June^{xv} 90% (95% CI, 89-92) [Dec 2020 – Aug 2021]³⁰</p> <p><u>Individuals ≥ 65:</u> 61% (95% CI, 57-65) against SARS-CoV-2 infection and 86% (95% CI, 82-88) against hospitalizations³⁰</p> <p><u>Individuals ≥ 80:</u> VE of 68.3% (95% CI, 65.5-70.9) for infections, 73.2% (95% CI, 65.3-79.3) for hospitalization, 85.1% (95% CI, 80.0-89.0) for mortality [Germany, 09 Jan – 11 Apr 2021]³⁴</p>							
EFFECTIVENESS AGAINST VARIANTS^{xxi}								
Alpha (B.1.1.7)	<u>Single dose:</u> 48.7% (95%	<u>Single dose:</u>	<u>Single dose:</u>			<u>Two doses:</u>	No available data	Ongoing studies in South Africa ²⁵

^{xv} mRNA-aggregated data (results do not disaggregate between BNT162b2 and mRNA-1273).

^{xxi} Effectiveness data against the latest variant of interest (Mu) will be included in upcoming reports based on data availability.

	<p>CI, 45.5 to 51.7)³⁷ 66% (95% CI, 64-68)³⁸. 54.5% (95 CI, 50.4-58.3)³⁹</p> <p><u>Two doses:</u> 93.7% (95% CI, 91.6 to 95.3)³⁷ 92% (95% CI, 90-93)⁴⁰. 89% (95% CI, 86-91)³⁸. 78% (95% CI, 68-84)⁴¹ 84.4% (95 CI, 81.8-86.5)³⁹</p>	<p>88.1% (95% CI, 83.7 to 91.5)⁴² 83% (95% CI, 80-86)³⁸.</p> <p><u>Two doses:</u> 100% (95% CI, 91.8 to 100)⁴² 92% (95% CI, 86-96)³⁸. 98.4% (95% CI, 96.9-99.1)⁴³</p>	<p>48.7% (95% CI 45.5 to 51.7)³⁷ 64% (95% CI, 60-68)³⁸.</p> <p><u>Two doses:</u> 74.5% (95% CI, 68.4 to 79.4)³⁷ 73% (95% CI, 66-78)⁴⁰. 79% (95% CI, 56-90)⁴¹.</p>	-	No published data	Equally effective (~76%) in neutralizing D614G, B.1.1.7 and B.1.429 as the wild-type strain.		and the United Kingdom ²⁶ Post hoc analysis showed efficacy of 86.3% (95% CI, 71.3-93.5; United Kingdom) against B.1.1.7 variants and 96.4% (95% CI, 73.8-99.5; United Kingdom) against non-B.1.1.7 variants . ³⁶
Beta (1.351)	<p><u>Single dose:</u> 60% (95% CI, 52-67)³⁸. <u>Two doses:</u> 84% (95% CI, 69-92)³⁸.</p>	<p><u>Single dose:</u> 61.3% (95% CI, 56.5 to 65.5)⁴² 77% (95% CI, 69-92)³⁸.</p> <p><u>Two doses:</u> 96.4% (95% CI, 91.9 to 98.7)⁴²</p>	<p><u>Single dose:</u> 48% (95% CI, 28-63)³⁸.</p>	-	No published data	Neutralization capacity was decreased by factor 5.27 ⁴⁴ .	No available data	No available data
Gamma (P.1)	Neutralization activity reduced by 3.3-fold ⁴⁵ .	No available data	No available data	No available data	No published data	Demonstrated 42% vaccine effectiveness in a setting with high	No available data	No available data

						<p>P.1 transmission, in individuals aged 70 and above⁴⁶.</p> <p>50.2% against P.1 (>14 days after 2nd dose)⁴⁷.</p> <p>Neutralization was decreased by factor 3.92⁴⁴.</p>		
Delta (1.617.2)	<p><u>Single dose:</u> 30.7% (95% CI, 25.2 to 35.7)³⁷; 57% (95% CI, 50-63)⁴¹ 22.5% (95 CI, 17.0-27.4)³⁹</p> <p><u>Two doses:</u> 88.0% (95% CI, 85.3 to 90.1)³⁷; 80% (95% CI, 77-83)⁴¹ 79% (95% CI, 75-82)⁴⁰. 80% (95% CI, 77-83)⁴¹ 40.5% (95% CI, 8.7-61.2)⁴⁸. 42% (95% CI, 13-62)²⁹. 89.8% (95% CI, 89.6-90.0) [2-9</p>	<p><u>Single dose:</u> 72% effective against symptomatic SARS-Cov-2 infection⁵².</p> <p><u>≥ 14 days after second dose:</u> 76% (95% CI, 58-87)²⁹. 94.5% (95% CI, 94.1-95) [2-9 weeks after second dose]⁴⁹. 50.6% (95% CI, 45.0-55.7) [among nursing home residents]⁵⁰. 86.7% (95% CI, 84.3-88.7)⁴³ 56.6% (95% CI, 42.0-67.5) <i>against infection</i>⁵³</p>	<p><u>Single dose:</u> 30.7% (95% CI 25.2 to 35.7)³⁷ 73% (95% CI, 64-80; India) [May-Jul 2021]¹³</p> <p><u>Two doses:</u> 67.0% (95% CI, 61.3 to 71.8)³⁷ 67% (95% CI, 62-71)⁴¹. 60% (95% CI, 53-66)⁴⁰. 66.7% (95% CI, 45-49.6) [2-9 weeks after second dose]⁴⁹. 47.3% (95% CI, 66.3-67.0) [≥20 weeks after second dose]⁴⁹.</p>	<p>78% (95% CI, 73-82) against SARS-CoV-2 infection¹⁵.</p> <p>3% (95% CI, -7-12) [August]⁵¹</p> <p><u>Individuals ≥50:</u> 83% (95% CI, 81-85)¹⁵</p>	No available data	<p><u>Single dose:</u> 13.8% (95% CI, -60.2-54.8)⁵⁵.</p> <p><u>Two doses:</u> 59% (95% CI, 16-81.6) against SARS-CoV-2 infection and 70.2% (95% CI, 29.6-89.3) against moderate COVID-19 infection⁵⁵.</p>	<p><u>Single dose:</u> 44% (95% CI, 0-71; India) [May-Jul 2021]¹³</p> <p><u>Two doses:</u> 64% (95% CI, 40-79; India) [May-Jul 2021]¹³</p>	No available data

	<p>weeks after second dose]⁴⁹. 69.7% (95% CI, 68.7-70.5) [≥20 weeks after second dose]⁴⁹. 64.6% (95% CI, 60.6-68.2)³⁹ 52.4% (95% CI, 48.0-56.4) [among nursing home residents]⁵⁰. 53% (95% CI, 39-65) [4 months after second dose]³⁰ 50% (95% CI, 47-52) [August; elderly Veteran population]⁵¹</p> <p><u>Against severe COVID-19:</u> 91.4% (95% CI, 82.5-95.7)⁴⁸.</p>	<p>84.2% (95% CI, 56.4-94.3) <i>against symptomatic infection</i>⁵³</p> <p>64% (95% CI, 62-66) [August; elderly Veteran population]⁵¹</p> <p><u>10-14 weeks after second dose:</u> 90.3% (95% CI, 67.2-97.1)⁴⁹.</p>	<p>81% (95% CI, 71-88; India) [May-Jul 2021]¹³</p> <p>Odds ratio of 5.45 (95% CI, 1.39-21.4) to become infected with B.1.167.2 compared to non-B.1.167.2⁵⁴.</p>					
Mu (B.1.621)	<p>Mu variant is 9.1 times more resistant than the wild type strain when vaccinated with BNT162b2⁵⁶</p>	<p><u>Two doses:</u> 90.4% (95% CI, 73.9-96.5)⁴³ (demonstrated similar protective measures as</p>	No available data	No available data	No available data	No available data	No available data	No available data

	against the Alpha variant)							
EFFECTIVENESS AGAINST HOSPITALIZATION								
Any SARS-CoV-2 infection	<p><u>Single dose:</u> 85% (pooled meta-analysis)⁶</p> <p><u>Two doses:</u> 91% (pooled meta-analysis)⁶ 91% (95% CI, 93%-96%; United States) [May to July 2021]^{7xxii} 90.9% (95% CI, 84.5-94.7; pooled meta-analysis)²⁰</p>	<p><u>Single dose:</u> 73% (pooled meta-analysis)⁶</p> <p><u>Two doses:</u> 88% (pooled meta-analysis)⁶ 91% (95% CI, 93%-96%; United States) [May to July 2021]^{7xxiii} 90.9% (95% CI, 84.5-94.7; pooled meta-analysis)²⁰</p>	<p><u>Single dose:</u> 56% (pooled meta-analysis)⁶</p> <p><u>Two doses:</u> 91% (pooled meta-analysis)⁶ 90.9% (95% CI, 84.5-94.7; pooled meta-analysis)²⁰</p>	No available data	No available data	No available data	No available data	No available data
Alpha	<p>Single dose: 83% (95% CI, 62-93) Two doses: 95% (95% CI, 78-99)⁵⁷.</p> <p><u>Against death:</u> 98.2% (95% CI, 95.9-99.2) [2-9 weeks]⁴⁹.</p>	No available data	<p>Single dose: 76% (95% CI, 61-85) Two doses: 86% (95% CI, 53-96)⁵⁷.</p> <p><u>Against death:</u> 94.1% (95% CI, 91.8-95.8) [2-9 weeks]⁴⁹.</p>	<p>Beta 67% effective at preventing hospitalizations⁵⁸.</p> <p><u>Against death:</u> 96% effective at preventing death⁵⁸.</p>	No available data	No available data	No available data	No available data

xxii Results do not disaggregate between mRNA vaccines, BNT162b2 and mRNA-1273.

xxiii Results do not disaggregate between mRNA vaccines, BNT162b2 and mRNA-1273.

	90.4% (95% CI, 85.1-93.8) [≥ 20 weeks] ⁴⁹ .		78.7% (95% CI, 52.1-90.4) [≥ 20 weeks] ⁴⁹ .					
Gamma	No available data	No available data	No available data	72.9% (95% CI, 35.1-91.1) ¹⁸ <u>Against ICU admission:</u> 92.5% (95% CI, 54.9-99.6) ¹⁸ <u>Against death:</u> 90.5% (95% CI, 31.5-99.6) ¹⁸	No available data	No available data	No available data	No available data
Delta	<u>Single dose:</u> 94% (95% CI, 46-99) ⁵⁷ . 91% (95% CI, 90-93) ⁵⁹ <u>Two doses:</u> 96% (95% CI, 86-99) ⁵⁷ . 88% (95% CI, 78.9-93.2) ⁴⁸ . 75% (95% CI, 24-93.9) ²⁹ . 84% (95% CI, 79-89) ⁶⁰ .	<u>Single dose:</u> 81% (95% CI, 81-90.6) ²⁹ . <u>Two doses:</u> 84% (95% CI, 80-87) ⁵⁹ 95% (95% CI, 92-97) [June-August] ⁶¹ <u>Against ICU admission:</u> 86% (95% CI, 79-90) ⁵⁹	<u>Single dose:</u> 71% (95% CI, 51-83) ⁵⁷ 88% (95% CI, 83-91) ⁵⁹ <u>Two doses:</u> 92% (95% CI, 75-97) ⁵⁷ . 95.2% (95% CI, 94.6-95.6) [2-9 weeks] ⁴⁹ . 77.0% (95% CI, 70.3-82.3) [≥ 20 weeks] ⁴⁹ .	71% ⁵⁸ 85% (95% CI, 73-91) ¹⁵ . 91% (95% CI, 88-94) ⁵⁹ 85% effective at preventing severe disease and hospitalization ⁶⁴ . <u>Individuals ≥ 50:</u>	<u>Single dose:</u> Does not offer clinically meaningful protection against severe illness ^{65,xxiv} <u>Two doses:</u> 88% (95% CI, 55-98) adjusted risk reduction in	<u>Single dose:</u> Does not offer clinically meaningful protection against severe illness ^{65,xxvi} <u>Two doses:</u> 88% (95% CI, 55-98) adjusted risk reduction in	No available data	No available data

xxiv Study does not differentiate between the two inactivated vaccines, BBIBP-CorV and CoronaVac.

xxvi Study does not differentiate between the two inactivated vaccines, BBIBP-CorV and CoronaVac.

	<p>98.4% (95% CI, 97.9-98.8) [2-9 weeks]⁴⁹.</p> <p>92.7% (95% CI, 90.3-94.6) [\geq20 weeks]⁴⁹.</p> <p>96% (95% CI, 95-96)⁵⁹</p> <p>80% (95% CI, 73-85) [June-August]⁶¹</p> <p>93% (95% CI, 84-96)⁶²</p> <p>96.8% (95% CI, 93.9-98.3)[2 months after the second dose]⁴</p> <p>93% (95% CI, 84-96)³⁰</p> <p><u>Against death:</u> 90% (95% CI, 83-94) [\geq2 weeks after second dose]⁶³</p>	<p>96% against severe COVID-19 infection⁵².</p>	<p>94% (95% CI, 92-95)⁵⁹</p> <p><u>Against ICU admission:</u> Single dose: 92% (95% CI, 84-96)⁵⁹ Two doses: 96% (95% CI, 94-98)⁵⁹</p> <p><u>Against death:</u> 91% (95% CI, 86-94) [\geq2 weeks after second dose]⁶³</p>	<p>84% (95% CI, 81-85)¹⁵</p> <p><u>Against ICU admission:</u> 94% (95% CI, 88-98)⁵⁹</p>	<p>developing severe illness.^{65,xxv}</p>	<p>developing severe illness.^{65,xxvii}</p>			
DURATION OF PROTECTION, TRANSMISSION & BREAKTHROUGH INFECTIONS									
Duration of protection (antibodies)	Median time between second	<u>Preliminary phase I results:</u>	<u>Antibody Response:</u>	<u>Neutralizing antibodies:</u>	<u>Antibody Response:</u>	A phase I/II clinical trial found that NAbs titres dropped below the	No available data	No available data	No available data

^{xxv} Study does not differentiate between the two inactivated vaccines, BBIBP-CorV and CoronaVac.

^{xxvii} Study does not differentiate between the two inactivated vaccines, BBIBP-CorV and CoronaVac.

<p>dose and infection: 146 days (IQR, 121-167)⁶⁶</p> <p><u>Anti-SARS-CoV-2 Antibodies:</u> 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)⁶⁷</p> <p>No health worker had antibodies BELOW method-dependent cut-off (0.8 KU/L)</p> <p><u>Anti-spike Protein RBD IgG Antibodies:</u> Younger age groups (<60): 1 month after 2nd dose: 100% seropositivity, 35.3 (IQR, 27.6-40.0) 3 months after 2nd dose: 100%</p>	<p>Antibody activity remained high in all age groups at day 209 (approximately 6 months) GMT were lower in ≥56 years old⁷⁰</p>	<p>After single dose, antibody response declined within one year, but remained above baseline levels. Antibody levels after day 180: 0.54 GMR (CI, 0.47-0.61). Antibody levels after day 320: 0.30 GMR (CI, 0.24-0.39)⁷¹</p> <p><u>Cellular Immune Response:</u> Day 182 after first dose: median of 237 SFUx10⁶ PBMC (IQR, 109-520)⁷¹</p> <p>6 months after second dose: (median 1240, IQR 432-2002) in groups with 15-25 week interval between doses⁷¹</p> <p><u>Anti-spike Protein RBD IgG Antibodies:</u></p>	<p>Remained largely stable for 8-9 months⁷²</p> <p><u>Binding antibodies:</u> Remained stable 6 months irrespective of age group⁷²</p> <p><u>Humoral & Cellular Immune Response:</u> Antibody responses were detected in all vaccine recipients on day 239 (stable response for at least 8 months)⁷³</p>	<p>Unexposed subjects: After 1st dose: 43.6 IU/mL (95% CI, 30.3-62.8) After 2nd dose: 377.0 IU/mL (95% CI: 324.3-438.3) 3 months after 2nd dose: 125.4 IU/mL (95% CI: 88.2-178.4)⁷⁴</p> <p>Exposed subjects: Before 1st dose: 203.2 UI/mL (95% CI: 42.9-962.4) After 1st dose: 761.7 UI/mL (95% CI: 381.1-1522) After 2nd dose: 719.9 UI/mL (95% CI : 264.6-1959) 3 months after 2nd dose: 484.4 IU/mL (95% CI: 147.3-1593)⁷⁴</p> <p>Anti-RBD IgG: Decreased up to 41.8% 2 months after second dose and dropped to</p>	<p>seropositive cut-off of 8, 6 months after the administration of the first dose⁷⁶.</p> <p>80-90% of anti-S IgG and Nab titers against wild type waned 6 months after second vaccination⁷⁷</p> <p><u>Anti-spike Protein RBD IgG Antibodies:</u> Younger age groups (<60): 1 month after 2nd dose: 97% seropositivity, 11.3 (IQR, 6.2-20.7) 3 months after 2nd dose: 76% seropositivity, 2.4 (IQR, 1.0-5.0)⁶⁸</p> <p>Older age groups (≥60): 1 month after 2nd dose: 88% seropositivity, 6.4 (IQR, 2.5-13.6) 3 months after 2nd dose: 60%</p>		
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<p>seropositivity, 19.2 (IQR, 8.2-23.1)⁶⁸</p> <p>Older age groups (≥60): 1 month after 2nd dose: 100% seropositivity, 29.4 (IQR, 22.5-33.3) 3 months after 2nd dose: 100% seropositivity, 14.8 (IQR, 7.4-18.7)⁶⁸</p> <p><u>Sub-populations:</u> Older age (≥65): 38% to 42% decrease of humoral antibodies compared to 18- to 45-year-old⁶⁹</p> <p>Older age (≥65) AND men: 37% to 46% decrease compared to 18- to 45-year-old women⁶⁹</p> <p>Immunosuppression: 65% to 70% decrease</p>		<p>Younger age groups (<60): 1 month after 2nd dose: 100% seropositivity, 17.1 (IQR, 9.9-23.6) 3 months after 2nd dose: 97% seropositivity, 6.5 (IQR, 3.5-9.3)⁶⁸</p> <p>Older age groups (≥60): 1 month after 2nd dose: 96% seropositivity, 13.3 (IQR, 6.9-27.7) 3 months after 2nd dose: 90% seropositivity, 3.9 (IQR, 1.9-8.4)⁶⁸</p>		<p>42.9% decrease after 7 months⁷⁵</p> <p><u>Binding Antibodies:</u> Decreased 82.1% 7 months after second dose⁷⁵</p>	<p>seropositivity, 1.3 (IQR, 0.5-3.3)⁶⁸</p>		
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	<p>compared to non-immunosuppressed⁶⁹</p> <p>Obesity (BMI ≥30): 31% increase in neutralizing antibody compared with nonobese⁶⁹</p>							
<p>Duration of protection (vaccine effectiveness)</p>	<p><u>Effectiveness against any SARS-CoV-2 Infection:</u> After reaching peak VE (77.5%) 1 month after 2nd dose, VE dropped to 20% in months 5-7 after 2nd dose⁷⁸</p> <p>VE reduced from 87% (95% CI, 85-89) to 56% (95% CI, 53-59) after 4 months.³¹</p> <p>VE reduced from 91% (95% CI, 91-92) in March to</p>	<p>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 2020.⁸²</p> <p>46.0 (95% CI, -52.4-83.2) reduction of observed incidence rate (severe SARS-CoV-2 infection) if vaccinated from Dec 2020 – Apr</p>	<p>VE reduced by 7% (95% CI, -18 - 2) for every 30 days from the second dose for those aged 18 to 64 years⁴¹.</p> <p>VE reduced from 58% (95% CI, 51-65) to 27% (95% CI, 17-37) after 4 months.³¹</p> <p>VE reduced from 88% (95% CI, 87-89) in March to 3% (95% CI, -7-12) in August⁵¹</p> <p>VE was 10-20% lower against</p>	<p>A study observed sustained and stable vaccine effectiveness starting 14 days post vaccination to a maximum of 152 days after vaccination¹⁵.</p> <p>VE decreased from 89.4% in May to 51.7% in July³⁵</p> <p>VE decreased from 86.4% (95% CI, 85.2-87.6) in March 2021 to 13.1% (95% CI, 9.2-16.8) in September 2021⁸⁰</p>	<p>No available data</p>	<p>No available data</p>	<p>No available data</p>	<p>No available data</p>

<p>50% (95% CI, 47-52) in August⁵¹</p> <p><u>Effectiveness against Hospitalization and Death:</u> After reaching peak VE (96.8%) 2 months after 2nd dose, VE did not decline over time, except for 7th months (VE 55.6%) with very few cases⁷⁸</p> <p>VE reduced by 22% (95% CI, 6-41) for every 30 days from the second dose for those aged 18 to 64 years⁴¹.</p> <p>VE against infection was 82% (95% CI, 79-85) 14-90 days after the second dose and appeared to wane over time and was 63% (95% CI, 55-68) 91-180 days after</p>	<p>2021 than Jul 2021 – Dec 2020.⁸²</p> <p>VE against the Delta variant declined from 94.1% (95% CI, 90.5-96.3) 14-60 days after vaccination to 80.0% (95% CI, 70.2-86.6) 151-180 days after vaccination.⁴³</p> <p>91% [January-March] 71% (95% CI, 53-83) [April-May] 63% (95% CI, 44-76)³⁵</p> <p>VE reduced from 90% (95% CI, 88-91) to 71% (95% CI, 68-74) after 4 months³¹</p> <p>VE reduced from 91% (95% CI, 72-98) in January-March to 71% (95% CI, 53-83) in April-May to 63%</p>	<p>delta than against the alpha variant (pooled meta-analysis)²⁰</p>					
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<p>the second dose [27 Dec 2020 – 26 Oct 2021; Finland]^{79xxviii}</p>	<p>(95% CI, 44-76) in June-August³⁵</p>						
<p>VE decreased from 86.9% (95% CI, 86.5-87.3) in March 2021 to 43.3% (95% CI, 41.9-44.6) in September 2021⁸⁰</p>	<p>VE reduced from 92% (95% CI, 92-93) in March to 64% (95% CI, 62-66) in August⁵¹</p>						
<p><u>Following the Delta Variant:</u> VE decreased from 94% to 64% [Israel]⁸¹</p>	<p>VE against infection was 82% (95% CI, 79-85) 14-90 days after the second dose and appeared to wane over time and was 63% (95% CI, 55-68) 91-180 days after the second dose [27 Dec 2020 – 26 Oct 2021; Finland]^{79xxix}</p>						
<p>VE was 10-20% lower against delta than against the alpha variant (pooled meta-analysis)²⁰</p>	<p>VE decreased from 89.2% (95% CI, 88.8-89.6) in March 2021 to 58.0% (95% CI, 56.9-59.1) in September 2021⁸⁰</p>						

xxviii Study does not differentiate between COMIRNATY/BNT162b2 and SPIKEVAX/ mRNA-1273.

xxix Study does not differentiate between COMIRNATY/BNT162b2 and SPIKEVAX/ mRNA-1273.

		VE was 10-20% lower against delta than against the alpha variant (pooled meta-analysis) ²⁰						
Transmission prevention	<p><u>Prior Delta Variant:</u> Vaccine effectiveness against infectiousness given infections 41.3%⁸³</p> <p>Vaccine effectiveness against transmission 88.5%⁸³</p> <p><u>During Delta Variant:</u> Similar Ct values (<25) were found in both vaccinated and unvaccinated groups⁸⁴</p>	<p>VE against onwards transmission: 52% (95% CI, 33-69)¹⁷</p> <p>VE against transmission from vaccinated index case to unvaccinated contact is 63% (95% CI, 46-75) and 40% (95% CI, 20-54) to a vaccinated contact.^{87xxxii}</p>	<p>48% (limited data)</p> <p>May not be able to block the transmission of the alpha variant as efficiently as the wild type⁸⁸.</p> <p>VE against transmission from vaccinated index case to unvaccinated contact is 63% (95% CI, 46-75) and 40% (95% CI, 20-54) to a vaccinated contact.^{87xxxii}</p>	Limited data	Unknown	Unknown	No available data	No available data

^{xxxii} Study does not differentiate between Comirnaty/BNT162b2, Spikevax/ mRNA-1273, and Vaxzevria/ ChAdOz1 nCOV-19.

^{xxxii} Study does not differentiate between Comirnaty/BNT162b2, Spikevax/ mRNA-1273, and Vaxzevria/ ChAdOz1 nCOV-19.

Studies from Scotland and England demonstrated reductions in secondary infections among families of vaccinated individuals compared to families of unvaccinated individuals^{85,86}.

VE against onwards transmission: **62%** (95% CI, 57-67)¹⁷

VE against transmission from vaccinated index case to unvaccinated contact is **63%** (95% CI, 46-75) and **40%** (95% CI, 20-54) to a vaccinated contact.^{87,xxx}

xxx Study does not differentiate between Comirnaty/BNT162b2, Spikevax/ mRNA-1273, and Vaxzevria/ ChAdOz1 nCoV-19.

<p>Breakthrough infections</p>	<p>From 6,161 patients with a positive nasopharyngeal SARS-CoV-2 PCR, 1,120 (18%) were breakthrough infections – 97% of these occurred after 2 May (emergence of Delta variant). Of the 1,120 cases, 126 (12%) were hospitalized. Of the 126 breakthrough admissions, 59 were vaccinated with BNT162b2⁸⁹.</p> <p>Individuals vaccinated in January and February had a 51% (95% CI, 40-68) increased risk for breakthrough infections compared to individuals vaccinated in March and April⁹⁰</p>	<p>From 6,161 patients with a positive nasopharyngeal SARS-CoV-2 PCR, 1,120 (18%) were breakthrough infections – 97% of these occurred after 2 May (emergence of Delta variant). Of the 1,120 cases, 126 (12%) were hospitalized. Of the 126 breakthrough admissions, 36 were vaccinated with mRNA-1273.</p>	<p>As of 10 June, 1.5 million individuals have been fully vaccinated with Covishield in Odisha Province, India. Between 1 March to 10 June, 239 breakthrough infections (SARS-CoV-2 positive after having received two doses of Covishield) were identified. Of these, 199 (83.3%) were symptomatic, 24 (10.0%) were hospitalized - 59 individuals had comorbidities⁹²</p> <p>Median antibody titer: 647.5 AU/ml⁹²</p> <p>Among 8678 fully vaccinated healthcare workers, 4 breakthrough infections were identified. Three</p>	<p>From 6,161 patients with a positive nasopharyngeal SARS-CoV-2 PCR, 1,120 (18%) were breakthrough infections – 97% of these occurred after 2 May (emergence of Delta variant). Of the 1,120 cases, 126 (12%) were hospitalized. Of the 126 breakthrough admissions, 10 were vaccinated with Ad26.COV2.S⁸⁹.</p>	<p>No available data</p>	<p>No available data</p>	<p>As of 10 June, 380,000 individuals have been fully vaccinated with Covaxin in Odisha Province, India. Between 1 March to 10 June, 35 breakthrough infections (SARS-CoV-2 positive after having received two doses of Covishield) were identified. Of these, 29 (82.9%) were symptomatic, 3 (8.6%) were hospitalized. 5 individuals had comorbidities⁹²</p> <p>Median antibody titer: 213.5 AU/ml⁹²</p>	<p>No available data</p>
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	Among 1497 fully vaccinated healthcare workers, 39 breakthrough infections were identified. The Alpha variant was found in 85% of samples tested. ⁹¹		were infected by unvaccinated household members and the remaining breakthrough case was infected by another vaccinated HCW ⁹³ .					
Breakthrough infections (regardless of vaccine type)	<p>Among 4,438 SARS-COV-2 samples collected between October 2020 and August 2021 in Florida, 109 vaccine breakthrough cases were identified, of which 58 were Delta variant infections. Breakthrough cases occurred on average 3 months (101.6 ±57 days) after full immunization. Majority of breakthrough infections occurred in July, coinciding with the emergence of the Delta variant⁹⁴.</p> <p>The secondary attack rate in household contacts exposed to the Delta variant was 25% (95% CI, 18-33) for fully vaccinated individuals compared with 38% (95% CI, 24-53) in unvaccinated individuals.</p>							
SAFETY AND ADVERSE EVENTS								
Common side effects	<p>Pain at the injection site, fatigue, headache, myalgia, chills and fever.⁹⁵</p> <p>Optimal safety for asthma patients⁹⁶.</p> <p>The vaccine is considered safe for cancer patients undergoing treatments⁹⁷.</p>	<p>Pain at injection site, headache, fatigue, myalgia, arthralgia⁹⁸, Covid arm (cutaneous hypersensitivity)⁹⁹.</p> <p>The vaccine is considered safe for cancer patients undergoing treatments⁹⁷.</p>	<p>Fatigue, myalgia, arthralgia, headache¹⁰⁰, lethargy, fever, & nausea¹⁰¹.</p>	<p>Headache, fever, chills, fatigue, myalgia, and nausea¹⁰².</p>	<p>Pain at the injection site, dizziness, fever, headache, fatigue, nausea, vomiting, & allergic dermatitis^{101,103}.</p>	<p>Pain at injection site, headache, fatigue, tremors, & flushing¹⁰⁴, inflammatory reaction, urticaria¹⁰⁵.</p>	<p>Pain at injection site, headache, pyrexia, fatigue, myalgia¹⁰⁶</p>	<p>Pain at injection-site, headache, muscle pain, fatigue³⁶</p>

<p>Rare adverse events</p>	<p>Myocarditis & myopericarditis¹⁰⁷⁻¹⁰⁹, anaphylaxis and swelling of the lips, face, and tongue related to anaphylaxis¹¹⁰ (11 anaphylaxis cases per million doses administered)¹¹¹, axillary lymphadenopathy, paroxysmal ventricular arrhythmia, leg paresthesia¹¹², pityriasis rosea¹¹³ (lesions improved completely after ~8 weeks)¹¹⁴, lymphocytic vasculitis¹¹⁵, varicella-zoster reactivation¹¹⁶⁻¹¹⁸, Kikuchi-Fujimoto disease¹¹⁹, thrombotic thrombocytopenic purpura^{120,121}, IgA nephropathy flare-up¹²², Guillain-Barré syndrome^{123,124}, pustural</p>	<p>Myocarditis & myopericarditis¹⁰⁷⁻¹⁰⁹, orofacial swelling & anaphylaxis¹¹⁰. Potential risk factor for Bell's palsy¹³⁰ (most improve upon follow-up)¹⁴⁷, herpes zoster reactivation¹¹⁷, varicella zoster reactivation¹¹⁷, herpes zoster ophthalmicus¹⁴⁸, eczema & urticaria¹⁴⁹, transverse myelitis¹⁵⁰, Guillain-Barré syndrome^{151,152}, acute generalized exanthematous pustulosis¹⁵³, rhabdomyolysis^{154,155}, herpes zoster ophthalmicus¹⁴⁸, eczema & urticaria¹⁴⁹, transverse myelitis¹⁵⁰, Guillain-Barré</p>	<p>Transverse myelitis, high fever^{100,158}, cutaneous hypersensitivity¹⁵⁸, vasculitis¹⁵⁹, cerebral venous sinus thrombosis¹⁶⁰ (higher risk for women)¹⁶¹, thromboembolism⁶², vaccine induced immune thrombotic thrombocytopenia^{63, 164-166}, intracerebral haemorrhage¹⁶⁷, small vessel vasculitis^{159,168}, psoriasis¹⁶⁹, rosacea, raynaud's phenomenon¹⁴⁹, Ischaemic stroke¹⁷⁰, anaphylaxis¹⁷¹, recurrent herpes zoster^{172,xxxiii}, generalized bullous fixed drug eruption¹⁷³,</p>	<p>Thrombosis, thrombocytopenia, cerebral venous sinus thrombosis¹⁸⁷, increased risk of developing Guillain-Barré syndrome post vaccination¹⁸⁸, herpes zoster ophthalmicus¹⁴⁸, pseudothrombocytopenia¹⁸⁹, vaccine induced thrombotic thrombocytopenia¹⁹⁰</p> <p>97% of reported reactions after vaccine administration were non-serious¹⁰².</p>	<p>Rare adverse events were similar among the vaccine groups and control group within 7 days¹⁹¹. Pityriasis rosea¹⁹², uveitis¹⁹³</p>	<p>Myalgia, fever¹⁰⁴, pityriasis rosea (lesions improved completely after ~8 weeks)¹¹⁴, reactivation of herpes zoster and herpes simplex¹⁰⁵. Most reactions improved without treatment within a few weeks¹⁰⁵, Guillain-Barré syndrome¹⁹⁴, subacute thyroiditis¹⁹⁵, erythema multiforme¹⁹⁶, uveitis¹⁹³, reactive polyarthritis (not persistent, patients treated with short-term steroid therapy)¹⁹⁷</p>	<p>No available data</p>	<p>Myocarditis was reported in one vaccine recipient, occurring 3 days after second dose³⁶</p>
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xxxiii All cases occurred in patients with chronic urticaria and were being treated with cyclosporine.

<p>psoriasis¹²⁵, immunoglobulin A vasculitis¹²⁶, immune complex vasculitis¹²⁷, Rhabdomyolysis¹²⁸, subacute thyroiditis¹²⁹, Bell's Palsy¹³⁰, erythema multiforme¹³¹, vaccine induced interstitial lung disease¹³², macular neuroretinopathy¹³³, brachial neuritis¹³⁴, thyroid eye disease¹³⁵, exacerbation of subclinical hyperthyroidism¹³⁶, rhabdomyolysis¹³⁷, internal jugular vein thrombosis¹³⁸, herpes simplex virus keratitis¹³⁹, cervical lymphadenopathy¹⁴⁰, glomerulonephritis¹⁴¹, Ramsay-Hunt syndrome¹⁴², Sweet's syndrome¹⁴³,</p>	<p>syndrome^{151,152}, acute generalized exanthematous pustulosis¹⁵³, rhabdomyolysis^{154,155}, cervical lymphadenopathy¹⁵⁶, glomerulonephritis¹⁴¹, Behçet's disease¹⁵⁷, neurological autoimmune disease¹⁴⁴</p>	<p>Guillain-Barré syndrome^{124,174}, pityriasis rosea^{175,176}. Vaccination in individuals with adrenal insufficiency can lead to adrenal crises¹⁷⁷, Darier's disease¹⁷⁸, vaccine induced acute localized exanthematous pustulosis¹⁷⁹, Henoch-Schönlein Purpura¹⁸⁰, rhabdomyolysis¹⁸¹, Grave's disease¹⁸², acute demyelinating polyradiculoneuropathy¹⁸³, erythema nodosum¹⁸⁴, polyarthralgia¹⁸⁵, recurrence of cutaneous T-cell lymphoma¹⁸⁶, neurological autoimmune disease¹⁴⁴</p>					
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	neurological autoimmune disease ¹⁴⁴ , non-specific sensory symptoms ¹⁴⁵ , bilateral cell arteritis with skin necrosis ¹⁴⁶							
Potential associated adverse events (causal links not yet proven)	Cerebral venous sinus thrombosis and intracranial haemorrhage ¹⁹⁸ , aseptic meningitis ¹⁹⁹ , autoimmune hepatitis ^{200,201} , multiple sclerosis relapse ²⁰² , myeloperoxidase anti-neutrophil cytoplasmic antibody-positive optic perineuritis ²⁰³ , central retinal vein occlusion ²⁰⁴ , paracentral acute middle maculopathy & acute macular neurotinopathy ²⁰⁵ , Stevens-Johnson syndrome/ toxic	Autoimmune hepatitis ²⁰⁰ , myocardial infarction ²¹⁰ , autoimmune haemolytic anaemia ²¹¹ , hypophysitis & panhypopituitarism ²¹² , erythema nodosum-like rash ²¹³ , pulmonary embolism ²¹⁴ One case developed IgA Nephropathy after receiving the second dose of mRNA-1273 (causal link not yet proven) ²¹⁵ .	Autoimmune hepatitis ^{200,216,217} , Acute hyperglycaemic crisis ²¹⁸ , Facial nerve palsy, cervical myelitis ¹⁷⁰ , alopecia areata ²¹⁹ , takotsubo (stress) cardiomyopathy ²²⁰ , acute disseminated encephalomyelitis ²¹ , ischemic stroke ²²²	Facial Diplegia ²²³ , acute macular neurotinopathy ²²⁴	No available data	Likely vaccine associated disease enhancement (VADE) ²²⁵	No available data	No available data

	epidermal necrolysis ^{206,207} , lichenoid cutaneous skin eruption ²⁰⁸ , acute mania and psychotic features ²⁰⁹ , transient sensory symptoms ¹⁴⁵							
Myocarditis data	<p>Mainly reported in young adults and adolescents ²²⁶</p> <p><u>Israeli study:</u> Estimated incidence within 42 days after receipt of first dose per 100,000 vaccinated persons was 2.13 cases (95% CI, 1.56-2.7)²²⁷</p> <p><u>Male patients</u> Incidence of 4.12 (95% CI, 2.99-5.26) per 100,000 vaccinated²²⁷</p> <p>3.19 cases (95% CI, 2.37-4.02) per 100,000 vaccinated²²⁸</p>	<p>Mainly reported in young adults and adolescents ²²⁶</p> <p>5.8 cases per 1 million second dose administrations²²⁹</p> <p><u>UK MHRA's Yellow Card Scheme</u> 56.67 cases of myocarditis and 40.77 cases of pericarditis per million vaccinees who had received at least one dose ²³¹</p> <p><u>European Economic Area</u></p>	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 ³⁶				

<p><u>Female patients</u> Incidence of 0.23 (95% CI, 0-0.49) per 100,000 vaccinated²²⁷</p> <p>0.39 cases (95% CI, 0.10-0.68) per 100,000 vaccinated²²⁸</p> <p><u>≥30 years</u> Incidence of 1.13 (95% CI, 0.66-1.60) per 100,00 vaccinated²²⁷</p> <p>5.8 cases per 1 million second dose administrations²²⁹</p> <p>5.07 cases per 100,000²³⁰</p> <p><u>Disease severity</u> Mild: 1.62 (95% CI, 1.12-2.11) Intermediate: 0.47 (95% CI, 0.21-0.74) Fulminant: 0.04 (95% CI, 0-0.12)²²⁷</p>	<p>17.62 cases of myocarditis and 8.15 cases of pericarditis per million vaccinees who had received at least one dose²³¹</p> <p><u>US Vaccine Adverse Events Reporting System (VAERS)</u></p> <p>8.92 cases of myocarditis and 6.51 cases of pericarditis per million vaccinees who had received at least one dose²³¹</p>						
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Risk per 100,000 persons
 1st dose (male): **0.64**
 2nd dose (male); **3.83**
 1st dose (female): **0.07**
 2nd dose (female): **0.46**
 1st dose (male 16-19): **1.34**
 2nd dose (male 16-19): **15.07**²²⁸

UK MHRA's Yellow Card Scheme
15.09 cases of myocarditis and **11.81** cases of pericarditis per million vaccinees who had received at least one dose²³¹

European Economic Area
8.30 cases of myocarditis and **5.72** cases of pericarditis per million vaccinees who had received

	<p>at least one dose²³¹</p> <p>US Vaccine Adverse Events Reporting System (VAERS)</p> <p>12.52 cases of myocarditis and 7.78 cases of pericarditis per million vaccinees who had received at least one dose²³¹</p>							
CHILDREN VACCINATION								
Efficacy	<p><u>Adolescents (12-15):</u> After one dose had efficacy of 75% (CI, 7.6-95.5) After second dose efficacy of 100% (CI, 78.1-100)²³².</p> <p><u>Children (5-11):</u></p>	<p><u>Adolescents (12-17):</u> 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)²³⁵.</p> <p><u>Children (6month-11):</u> Ongoing trials²³⁶</p>	<p>No available data</p> <p>Paused ongoing trials in children aged 6-17 due to concerns over rare blood clots reported in adult population²³⁷.</p>	<p>No available data</p> <p>Announced at beginning of April ongoing study in adolescents but paused to investigate blood clots in adult population²³⁷.</p>	<p><u>Children (3-17):</u> Unknown. Ongoing clinical trial only looked at safety, tolerability, and immunogenicity^{xxxiv *}</p>	<p><u>Children (3-17):</u> Unknown. Clinical trial only looked at safety, tolerability and immunogenicity²³⁸.</p>	<p>No available data</p>	<p><u>Adolescents (16-17):</u> PREVENT-19 clinical trial^{xxxv} expanded to assess efficacy, safety, and immunogenicity in 12–17-year-old adolescents²³⁹</p>

^{xxxiv} 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](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00462-X/fulltext)

^{xxxv} 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>

	<p>After second dose efficacy of 90.7% (CI, 67.7-98.3)²³³</p> <p><u>Children (Under 5 years):</u> Ongoing trials²³⁴</p>				<p>* The study design administered three doses of 2 µg, 4 µg, or 8 µg of vaccine</p>			
Immunogenicity	<p><u>Adolescents (12-15) serum-neutralizing titer:</u> 1 month after 2nd dose had 1283.0 GMN₅₀ (CI, 1095.5-1402.5)²³².</p> <p><u>Adolescents/young adult (16-25) serum-neutralizing titer:</u> 1 month after 2nd dose had 705.1 GMN₅₀ (CI, 621.4-800.2)²³².</p> <p><u>Children (5-11):</u> 1 month after 2nd dose had 1,197.6 GMT (95% CI, 1106.1-1296.6) SARS-CoV-2-neutralizing antibody²³³</p>	<p><u>Adolescents (12-17):</u> Neutralizing antibody titer after 2nd dose was 1401.7 GMN₅₀ (CI, 1276.3-1539.4)</p> <p>Serological response was 98.8% (CI, 97.0-99.7)</p> <p><u>Children (6-11):</u> Seroreponse of 99.3%²⁴⁰</p> <p><u>Children (6month-11):</u> Ongoing trials²³⁶</p>	No available data	No available data	<p><u>Children (3-17):</u> Neutralizing antibodies after 28 days after 2nd dose ranged from 105.3-180.2 GMT in 3-5 years cohort, 84.1-168.6 GMT in 6-12 years cohort, and 88.0-155.7 GMT in 13-17 years cohort</p> <p>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 cohort²⁴¹</p>	<p><u>Children (3-17):</u> Neutralizing antibody response after 2nd dose (100%) with GMT ranging from 45.9-212.6²³⁸</p>	Ongoing clinical trial ²⁴²	Ongoing clinical trial ²⁴³

	<u>Children (Under 5):</u> Ongoing trials ²³⁴							
Effectiveness	<u>Against SARS-CoV-2 infection:</u> 91.5% (95% CI, 88.2-93.9) ²⁴⁴ 91% (95% CI, 88-93) ²⁴⁵ <u>Against hospitalization:</u> 81% (95% CI, -55-98) ²⁴⁵ 93% (95% CI, 83-97) ²⁴⁶	No available data	No available data	No available data	No available data	No available data	No available data	No available data
Safety and Adverse events	<u>Adolescents (12-15):</u> Local and systemic events were generally mild to moderate Severe injection-site pain (1.5%) Fever (20%) High Fever (0.1%) Adverse events (6%) Severe adverse events (0.6%) ²³² . <u>Adolescent/young adults (16-25):</u>	<u>Adolescents (12-17):</u> Solicited local reactions after 2nd dose (93.4%) Most common solicited adverse reactions were Injection-site pain (92.7%) Headache (70.2%) Fatigue (67.8%) Grade 3 adverse events (6.8%)	No available data	No available data	<u>Children (3-17):</u> 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%) Most common systemic reactions in all three age cohorts were mild to moderate fever and cough	<u>Children (3-17):</u> 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%) Most reported events were mild and moderate and only (< 1%) grade 3 events Injection-site pain (13%)	Ongoing clinical trial ²⁴²	Ongoing clinical trial ²⁴³

	<p>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%)²³².</p> <p><u>Children (5-11):</u> Pain at injection site, fatigue, headache, chills were reported. Overall, the vaccine is safe and tolerable²³³</p> <p><u>Children (Under 5):</u> Ongoing trials²³⁴</p> <p>Multisystem inflammatory syndrome (causal link not yet proven)²⁴⁷</p>	<p>Few reported cases of acute myocarditis and pericarditis (mainly in males)²⁴⁸</p> <p><u>Children (6-11):</u> Vaccine was generally well tolerated²⁴⁰</p> <p><u>Children (6month-11):</u> Ongoing trials²³⁶</p>			<p>Adverse events were mostly mild to moderate in severity²⁴¹</p>	<p>Fever (25%)²³⁸</p>		
Myocarditis Data	Few reported cases of acute myocarditis and	Few reported cases of acute myocarditis in	No available data	No available data	No available data	No available data	No available data	No available data

	<p>pericarditis in 16-25 year olds (mainly in males)²⁴⁸</p> <p><u>16-29 years</u> Incidence of 5.49 (95% CI, 3.59-7.39) per 100,00 vaccinated²²⁷</p> <p><u>Male patients (16-29 years)</u> Incidence of 10.69 (95% CI, 6.93-14.46) per 100,000 vaccinated²²⁷</p> <p>Incidence of 13.6 cases (95% CI, 9.30-19.20) per 100,000 vaccinated²²⁸</p>	adolescents and young adults						
HETEROLOGOUS VACCINATION								
Vaccine Schedule	BNT162b2/ChAdOx1 Administration of ChAdOx1 as	ChAdOx1/mRNA-1273 Administration of mRNA-1273 as	ChAdOx1/BNT162b2 Administration of BNT162b2 as	Not Applicable (one dose schedule)	BBIBP/BNT162b2	CoronaVac/ChAdOx1	ChAdOx1/BBV15 2 Administration of Covaxin as	Ongoing trial ²⁴⁹ (Com-Cov2) ^{xxxvii}

xxxvii Comparing COVID-19 Vaccine Schedule Combinations. University of Oxford. <https://comcovstudy.org.uk/about-com-cov2>

	second/booster dose	second/booster dose	second/booster dose	For more information refer to booster section		Press releases have confirmed that Thailand will use the AstraZeneca vaccine as the second dose for individuals whose first dose was Sinovac ^{xxxvi}	second/booster dose	
Immunogenicity	<p><u>GMCs of SARS-CoV-2 anti-spike IgG at 28 days post booster:</u> Heterologous (7133 ELU/mL, CI 6415-7932) vs. Homologous (14080 ELU/mL, CI 12491-15871)²⁵⁰.</p> <p><u>SFC frequency (T0cell ELISpot):</u> Heterologous (99 SFC/10⁶ PBMCs) vs.</p>	<p><u>*Spike-specific IgG antibodies:</u> Heterologous (3602 BAU/mL) vs. Homologous (4189 BAU/mL)⁴⁸</p> <p><u>*Neutralizing antibodies:</u> Heterologous (100%) vs. Homologous (100%)²⁵¹.</p>	<p><u>RBD antibody titres:</u> Heterologous (7756.68 BAU/mL, CI 7371.53-8161.96) vs. Homologous (99.84 BAU/mL, CI 76.93-129.59) at day 14²⁵².</p> <p><u>IgG antibody titres:</u> Heterologous (3684 BAU/mL) vs.</p>	<p>Not Applicable (one dose schedule)</p> <p>For more information refer to booster section</p>	Unknown (ongoing clinical trial) ⁴⁹	<p>CoronaVac/ChAd Ox1 : <u>Anti-S Antibodies:</u> Heterologous (797 U/mL; 95% CI, 598.7-1062) vs. Homologous CoronaVac (94.4 U/mL; 95% CI : 76.1-122.1) vs. Homologous ChAdOx1 (818 U/mL; 95% CI: 662.5-1010)²⁵⁴</p> <p>CoronaVac/Conv idecia</p>	<p><u>RBD antibody titres:</u> Heterologous (1866 GMT; 95% CI, 1003-3472) vs. Homologous Covishield (2260 GMT; 95% CI, 1881-2716) vs. Homologous Covaxin (710 GMT, 95% CI, 461-1092)²⁵⁶</p> <p><u>N-protein IgG:</u></p>	<p>No available data</p> <p>Ongoing trial²⁴⁹</p>

^{xxxvi} 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/>

	Homologous (80 SFC/10 ⁶ PBMCs) ²⁵⁰ .	*Results based on immunosuppressed population	Homologous (101.2 BAU/mL) at day 14 ²⁵² . <u>Neutralizing antibodies:</u> Heterologous (100%) at day 14 vs. Homologous (30%) at day 14 ²⁵² . Heterologous (median 99%) vs. Homologous (BNT162b2/BNT162b2) (median 62%) ²⁵³			<u>Neutralizing antibodies:</u> Heterologous 54.4 GMT (95% CI, 37.9-78) vs. Homologous CoronaVac 12.8 GMT (95% CI, 9.3-17.5) ²⁵⁵	Heterologous (1145 GMT; 95% CI, 520.7-2520) vs. Homologous Covishield (353.7 GMT; 95% CI, 219.9-568.9) vs. Homologous Covaxin (742.4 GMT; 95% CI, 485.8-1134) ²⁵⁶ <u>Neutralizing antibody titres:</u> Heterologous (171.4 GMT; 95% CI, 121.3-242.3) vs. Homologous Covishield (111 GMT; 95% CI, 98.59-124.9) vs. Homologous Covaxin (86 GMT; 95% CI, 138.2-252.0) ²⁵⁶	
Immunogenicity against variants	No available data	No available data	<u>Neutralizing Antibodies for Alpha, Beta, Gamma, and Delta:</u>	No available data	No available data	No available data	<u>Neutralizing antibody titres B.1:</u> 539.4 GMT (95% CI, 263.9-1103) ²⁵⁶	No available data

			Heterologous 2.3-fold to 3.6-fold higher neutralizing antibodies than homologous ²⁵³				<p><u>Neutralizing antibody titres</u> Alpha: 396.1 GMT (95% CI, 199.1-788)²⁵⁶</p> <p><u>Neutralizing antibody titres</u> Beta: 151 GMT (95% CI, 80.21-284.3)²⁵⁶</p> <p><u>Neutralizing antibody titres</u> Delta: 241.2 GMT (95% CI, 74.99-775.9)²⁵⁶</p>	
Reactogenicity	<p>Observed increase in systemic reactogenicity after boost in heterologous schedules in comparison with homologous schedules²⁵⁰</p> <p><u>Adverse events in heterologous:</u> Adverse events (90) Grade 1 (54.4%)</p>	<p>*Adverse events in heterologous and homologous vaccination groups were very similar²⁵¹.</p> <p>*Majority of adverse events self-reported were Pain at injection site, Swelling at injection site, Fever, Headaches, Fatigue, Chills, GI</p>	<p><u>Adverse events in heterologous:</u> Headache (44%), Myalgia (43%), Malaise (42%), Fever (2%), Injection site pain (88%), Induration (35%), Erythema (31%)²⁵².</p> <p><u>Severity of adverse events in heterologous:</u></p>	<p>Not Applicable (one dose schedule)</p> <p>For more information refer to booster section</p>	<p>Unknown (ongoing clinical trial)²⁵⁷</p>	<p>CoronaVac/ChAd Ox1: Unknown</p> <p>CoronaVac/Convidecia: Convidecia recipients reported more adverse reactions and reported higher occurrence of solicited injection-site pain)²⁵⁵</p>	<p><u>Most common local adverse events:</u> Pain at injection site (11.1%)²⁵⁶</p> <p><u>Most common systemic adverse events:</u> Pyrexia (27.77%, 11.1%) after 1st and 2nd dose Malaise (33.3%, 5.5%) after 1st and 2nd dose²⁵⁶</p>	<p>No available data</p> <p>Ongoing trial²⁴⁹</p>

	<p>Grade 2 (37.8%) Grade 3 (7.8%) Grade 4 (0%) Arthralgia, Migraine, Back Pain²⁵⁰.</p> <p><i>Adverse events in homologous:</i> Adverse events (81) Grade 1 (59.3%) Grade 2 (39.5%) Grade 3 (1.2%) Grade 4 (0%)²⁵⁰.</p>	<p>effects, Myalgia, Arthralgia²⁵¹.</p> <p>*Results based on immunosuppressed population</p>	<p>Mild (68%), Moderate (30%), Severe (2%)²⁵².</p>					
BOOSTER DOSES								
Vaccine Schedule	BNT162b2/BNT162b2	mRNA-1273/mRNA-1273	ChAdOx1/ChAdOx1	Ad26.CoV.2.S/Ad26.CoV.2.S	SinoPharm/SinoPharm	CoronaVac/CoronaVac	Covaxin/Covaxin	NVX-CoV2373/NVX-CoV2373
Approved Administration	<p><i>Israel:</i> 12-year-old and over can received homologous booster shot 5 months after full jab^{xxxviii}</p>	<p>Phase II booster trial of three booster doses are ongoing²⁵⁸</p> <p>Moderna sought FDA approval of</p>	<p>Preliminary results on tolerability and immunogenicity of third dose of ChAdOx1 vaccines showed strong boost to the</p>	<p>Johnson & Johnson has said it will submit all of their new data to the FDA for potential consideration for adding a booster</p>	<p><i>UAE:</i> Offering booster doses of Pfizer and Sinopharm to people who received full Sinopharm jab ≥6 months ago</p>	<p>Turkey and the United Arab Emirates began homologous booster shots</p>	<p>Ongoing clinical trials^{xliii}</p>	<p>Ongoing phase II trials²⁶⁰</p> <p>Results below are based on ongoing phase II trial</p>

^{xxxviii} 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/>

^{xliii} Bharat Biotech to initiate trials of booster dose of Covid-19 vaccine. *Clinical Trials Arena*. <https://www.clinicaltrialsarena.com/news/bharat-biotech-booster-dose/>

	<p><u>United States:</u> Starting September, adults who received mRNA vaccine 8 months ago are eligible for booster</p> <p><u>Europe:</u> Starting in fall, most European countries are planning on rolling out booster shots to immunocompromised and elder populations^{xxxix}</p>	<p>its COVID-19 vaccine booster^{xi}</p> <p><u>United States:</u> Starting September, adults who received mRNA vaccine 8 months ago are eligible for booster.</p>	<p>immune response²⁵⁹</p>	<p>dose and consideration to authorize two-dose regimen^{xii}</p>		<p>Indonesia and Thailand are considering giving homologous booster shot to HCW^{xiii}</p>		
<p>Time-to-booster dose</p>	<p>6 months to 8 months after initial two-dose regimen</p> <p>Israel offers up to 5 months after initial two-dose regimen</p>	<p>6 months to 8 months after initial two-dose regimen</p>	<p>6-9 months after initial two-dose regimen</p>	<p>6 months after one dose regimen⁷²</p>	<p>6 months after initial two-dose regimen</p>	<p>6 months to 12 months After primary vaccination</p> <p>8 months after the primary vaccination to</p>	<p>Ongoing clinical trials^{xxxvii}</p>	<p>6 months after initial two-dose regimen (189 days)²⁶⁰</p>

^{xxxix} A country-by-country guide to coronavirus vaccine booster plans. *POLITICO* [press release]. <https://www.politico.eu/article/vaccine-booster-coronavirus-covid-19-europe-delta-varian-who/>

^{xi} 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/>

^{xii} 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>

^{xiii} 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/>

						healthy adults ≥60 years		
Efficacy	95.6% against disease during Delta prevalent period ²⁶¹	No available data	No available data	No available data	No available data	No available data	Ongoing clinical trials ^{xxxvii}	No available data
Immunogenicity	<u>Neutralizing titers:</u> Elicits >5-8 more for wild type after 6 months after 2 nd dose ²⁶²	Booster doses (mRNA1273 or mRNA1273.351) increased neutralizing antibody titers against wild-type ²⁶³	<u>Antibody Levels:</u> Higher levels after third dose (tIgG EU 3746 ; IQR: 2047-6420) ²⁵⁹ <u>Spike Cellular Immune Response:</u> Increased from 200 SFUx10⁶ PBMC (IQR, 127-389) after the second dose to 399 SFUx10⁶ PBMC (IQR, 314-662) after the third one ²⁵⁹	5X10 ¹⁰ vp booster dose elicited 9-fold increase at day 7 compared to first dose after 29 days in 18-55-year-olds ⁷² 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 ⁷²	Ongoing trial ²⁵⁷ <u>IgG Seroconversion:</u> 175/176 vaccinees were seropositive for IgG 14 days after receiving third dose ⁷⁵ <u>Mean IgG value</u> increased 8.00-fold compared to before third vaccination ⁷⁵ <u>Anti-RBD IgG:</u> Increased by 8.14-fold higher than before third vaccine ⁷⁵ <u>Memory B cells:</u> Third dose increased the percentage of	Neutralizing Antibodies: 60% higher NAb activity against wild-type compared to 2-doses ⁷⁷ Anti-S IgG and NABs: 20-fold increase 4 weeks post booster vaccination NABs were maintained 60 to 180 days post booster ⁷⁷	Ongoing clinical trials ^{xxxvii}	<u>Anti-spike IgG:</u> Increase of 4.6-fold compared to peak response after 2 nd dose (Day 217 GMEU = 200408 ; 95% CI: 159796-251342) ²⁶⁰ <u>Wild-type Neutralizing Response:</u> Increase of 4.3-fold compared to peak response after 2 nd dose (IC50 = 6231 ; 95% CI: 4738-8195) ²⁶⁰ <u>Older Participants (60-84):</u> 5.4-fold increase in

					RBD-specific memory B cells (0.96%) ⁷⁵			antibody response ²⁶⁰ <i>Younger Participants (18-59):</i> 3.7-fold increase in antibody response ²⁶⁰
Immunogenicity against variants	<p>Beta (B.1.351): Elicits 15-21 more neutralizing titers for Beta variant after 6 months after 2nd dose²⁶²</p> <p>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-olds²⁶²</p>	Preliminary results of booster doses of mRNA-1273 vaccine show robust antibody response against Delta variant ²⁵⁸	Third dose provided higher antibody titers against Alpha, Beta, and Delta variants ²⁵⁹	No available data	<p>Ongoing trial²⁵⁷</p> <p>Beta (B.1.351): 71.6% plasma inhibitions against Beta variant⁷⁵</p> <p>Delta (B.1.671.2): 83.4% plasma inhibitions against Delta variant⁷⁵</p> <p>Lambda: 89.0% plasma inhibitions against Lambda variant⁷⁵</p>	<p>Beta (B.1.351): 3.0-fold decrease in neutralizing antibodies compared to wild type⁷⁷</p> <p>Gamma (P.1): 3.1-fold decrease in neutralizing antibodies compared to wild type⁷⁷</p> <p>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 vaccination⁷⁷</p>	Ongoing clinical trials ^{xxxvii}	<p>High levels of functional antibodies against Alpha (B.1.1.7), Beta (B.1.351), and Delta (B.1.671.2)²⁶⁰</p> <p>Delta (B.1.671.2): Increase of 6.6-fold in antibody response compared to Delta response observed with primary vaccination²⁶⁰</p>

<p>Reactogenicity</p>	<p>Preliminary results show consistent tolerability²⁶²</p>	<p>Similar safety and tolerability compared to second dose²⁵⁸</p> <p><u>Common solicited local adverse events:</u> 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, 50.0% for mRNA-1273)²⁶³</p>	<p>Lower reactogenicity after third dose compared to first dose⁷¹</p>	<p>No available data</p>	<p>Ongoing trial²⁵⁷</p>	<p>The third shot is considered to be safe⁷⁶.</p> <p><u>Common side effects:</u> Pain at the injection site.</p> <p><u>Adverse events:</u> Unrelated to the vaccination</p>	<p>Ongoing clinical trials^{xxxvii}</p>	<p>Booster dose was well tolerated</p> <p>Local and systemic reactogenicity increased between Dose 1, Dose 2, and Dose 3</p> <p>90% of symptoms were rated as mild or moderate²⁶⁰</p>
<p>Protection against COVID-19</p>	<p><u>Confirmed Infection:</u> Youngest age group (16-29):</p>	<p>No available information</p>	<p>No available information</p>	<p>No available information</p>	<p>No available information</p>	<p>No available information</p>	<p>Ongoing clinical trials^{xxxvii}</p>	<p>No available information</p>



	<p>40-59 age group: 22.0 (95% CI, 10.3-47.0) lower rate in booster group²⁶⁴</p> <p>Older population (≥60): 19.5 (95% CI, 12.9-29.5) lower rate in booster group²⁶⁵ 18.7 (95% CI, 15.7-22.4) lower rate in booster group²⁶⁴</p>							
<p>Other</p>	<p>Detailed report from Pfizer regarding booster doses can be found here: https://www.fda.gov/media/152161/download</p> <p>14-20 days after booster, marginal effectiveness increases to 70-84%²⁶⁶</p>					<p>For more detailed information regarding immunogenicity of third dose refer to study^{xliv}</p>		

^{xliv} 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>

HETEROLOGOUS BOOSTER DOSES								
Vaccine Schedule	<p><u>Heterologous 1:</u> mRNA1273/BNT162b2</p> <p><u>Heterologous 2:</u> Ad26.CoV.2.S/BN T162b2</p> <p>*Received BNT162b2 as booster dose</p>	<p><u>Heterologous 1:</u> BNT162b2/mRNA 1273</p> <p><u>Heterologous 2:</u> Ad26.CoV.2.S/m RNA1272</p> <p>*Received mRNA1273 as booster dose</p>	No available data	<p><u>Heterologous 1:</u> BNT162b2/Ad26. CoV.2.S</p> <p><u>Heterologous 2:</u> mRNA1273/Ad26. CoV.2.S</p> <p>*Received Ad26.CoV.2 as booster dose</p>	<p><u>Heterologous:</u> SinoPharm/BNT1 62b2</p>	<p><u>Heterologous 1:</u> CoronaVac/ChAd Ox1</p> <p><u>Heterologous 2 :</u> CoronaVac/BNT1 62b2</p>	No available data	<p><u>Heterologous:</u> Ongoing trial of heterologous booster shot using NVX-CoV2373^{xlv}</p>
Time-to-booster dose	At least 3 months after receiving two dose regimen	At least 3 months after receiving two dose regimen	No available data	<p>4 months after initial two-dose BNT162b2 regimen²⁶⁷</p> <p>At least 3 months after receiving two dose regimen</p>	6 months after initial two-dose regimen	<p><u>Heterologous 1:</u> 21 to 26 days after full jab of CoronaVac</p> <p><u>Heterologous 2:</u> 6 months after primary vaccination of CoronaVac</p>	No available data	No available data
Immunogenicity	<p><u>Binding Antibody Responses:</u> 2-fold or greater rise in bAb noted in 98-100% of BNT162b2 recipients²⁶⁸</p>	<p><u>Binding Antibody Responses:</u> 2-fold or greater rise in bAb noted in 96-100% of mRNA1273 recipients²⁶⁸</p>	No available data	<p><u>Heterologous 1:</u> 14.8 to 32.4-fold increase in neutralization titers against wild-type virus²⁶⁷</p>	No available data	<p><u>Heterologous 1:</u> Heterologous vaccination had a 9-fold greater GMT (7,947 U/mL) than fully vaccinated with</p>	No available data	No available data

^{xlv} COV-Boost Evaluating COVID-19 Vaccine Boosters. University of Southampton & NHS. <https://www.covboost.org.uk/home>

<p><u>Neutralizing Antibody Responses:</u> 341.3-677.9 IU50/mL 15 days after booster with BNT162b2²⁶⁸</p> <p>Participants who received mRNA-based booster vaccination had four-fold increase compared to Ad26.COV2.S. ²⁶⁸</p>	<p><u>Neutralizing Antibody Responses:</u> 676.1-901.8 IU50/mL 15 days after booster with mRNA1273²⁶⁸</p> <p>Participants who received mRNA-based booster vaccination had four-fold increase compared to Ad26.COV2.S. ²⁶⁸</p>		<p><u>Binding Antibody Responses (bAb):</u> 2-fold or greater rise in bAb noted in 98-100% of Ad26.COV2.S. recipients²⁶⁸</p> <p><u>Neutralizing Antibody Responses:</u> 31.2-382.2 IU50/mL 15 days after booster with Ad26.COV2.S. ²⁶⁸</p>		<p>AZD1222 and the highest antibody response, IgA, and neutralizing antibodies than other groups²⁶⁹</p> <p><u>Heterologous 2:</u> 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 6.5²⁷⁰</p> <p>Single booster dose of BNT162b2 induced higher anti-spike RBD IgG antibody levels, compared to single booster dose of CoronaVac⁶⁸</p>		
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<p>Immunogenicity against variants</p>	<p><u>Binding Antibody Responses:</u> Baseline bAb levels for Delta were 34-45% lower compared to Wa-1 strain²⁶⁸</p> <p>Following boost, bAB levels for Delta were 15-36% lower compared to Wa-1 strain²⁶⁸</p>	<p><u>Binding Antibody Responses:</u> Baseline bAb levels for Delta were 34-45% lower compared to Wa-1 strain²⁶⁸</p> <p>Following boost, bAB levels for Delta were 15-36% lower compared to Wa-1 strain²⁶⁸</p> <p><u>Neutralizing Antibody Responses:</u> Delta and Beta variants were only available in those boosted with mRNA-1273²⁶⁸</p>	<p>No available data</p>	<p><u>Heterologous 1:</u> 10.9 to 21.2-fold increase in pseudo virus neutralization assay (one volunteer did not have any against B.1.351)²⁶⁷</p> <p><u>Binding Antibody Responses:</u> Baseline bAb levels for Delta were 34-45% lower compared to Wa-1 strain²⁶⁸</p> <p>Following boost, bAB levels for Delta were 15-36% lower compared to Wa-1 strain²⁶⁸</p>	<p>No available data</p>	<p><u>Heterologous 1:</u> Neutralizing activity against the wild type and variant strains showed higher neutralizing activity in the following order: wild type > B.1.617.2 > B.1.1.7 > B.1.351²⁶⁹</p>	<p>No available data</p>	<p>No available data</p>
<p>Reactogenicity</p>	<p><u>Adverse Events:</u> 72-92% participants reported local pain or tenderness²⁶⁸</p>	<p><u>Adverse Events:</u> 75-86% participants reported local pain or tenderness²⁶⁸</p>	<p>No available data</p>	<p><u>Adverse Events:</u> 71-84% participants reported local pain or tenderness²⁶⁸</p>	<p>No available data</p>	<p>Similar results to homologous booster administration</p>	<p>No available data</p>	<p>No available data</p>

	<p>Malaise, myalgias, and headaches were commonly reported²⁶⁸</p> <p>14.4% of the participants reported unsolicited adverse events²⁶⁸</p>	<p>Malaise, myalgias, and headaches were commonly reported²⁶⁸</p> <p>15.6% of participants reported unsolicited adverse events²⁶⁸</p>		<p>Malaise, myalgias, and headaches were commonly reported²⁶⁸</p> <p>12% of participants reported unsolicited adverse events²⁶⁸</p>				
Other						<p>Ongoing clinical trial examining immunogenicity and safety of third dose vaccination with ChAdOx1 or BNT162b2 vaccine among adults who received full jab of CoronaVac^{xlvi}</p>		

^{xlvi} 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/Ox ford, UK, India)	Janssen COVID- 19 vaccine/Johnson & Johnson (Janssen, USA)	Sinopharm/BBIB P-CorV, China	Sinovac CoronaVac, China	COVAXIN/ BBV152 (Bharat Biotech, India)	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 until 8 °C	2°C to 8 °C
Approving authorities	FDA (11.12.20) ^{xlvii} ; 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)	WHO EUL (03.11.21) and list of 9 countries (Guyana, India, Iran, Mauritius, Mexico, Nepal, Paraguay, Philippines & Zimbabwe)	Waiting on approval (Not-yet- approved by countries or WHO for emergency use)

^{xlvii} 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>

IMMUNOGENICITY

Immunogenicity	<p><u>7-14 days after second dose:</u></p> <p>18-55 years: GMT ranged from 1.7 to 4.6 times the GMT of the convalescent serum²⁷¹.</p> <p>65-85 years: GMT ranged from 1.1 to 2.2 times the GMT of the convalescent serum²⁷¹.</p>	<p><u>14 days after second dose:</u></p> <p>18-55 years: PRNT₈₀ GMT 654.3 (95% CI, 460.1-930.5)²⁷².</p> <p>56-70 years: PRNT₈₀ GMT 878 (95% CI, 516-1494)²⁷³.</p> <p>≥ 71 years: PRNT₈₀ GMT 317 (95% CI, 181-557)²⁷³.</p>	<p><u>28 days after second dose median antibody titres:</u></p> <p>18-55 years: 20,713 AU/mL [IQR 13,898 - 33,550]²⁷⁴</p> <p>56-69 years: 16,170 AU/mL [IQR 10,233 - 40,353]²⁷⁴.</p> <p>≥70 years: 17,561 AU/mL [IQR 9,705 - 37,796]²⁷⁴.</p>	<p><u>29 days after vaccination:</u></p> <p>18-55 years: GMC 586 (95% CI, 445-771); GMT 224 (95% CI, 168-298)²⁷⁵.</p> <p>≥ 65 years: GMC 312 (95% CI, 246-396); GMT 212 (95% CI, 163-266)²⁷⁵.</p> <p><u>57 days after vaccination:</u></p> <p>18-55 years: 754 (95% CI, 592-961); GMT 288 (95% CI, 221-376)²⁷⁵.</p>	<p><u>14 days after second dose:</u></p> <p>18-55 years: GMT 211.2 (95% CI, 158.9-280.6)²⁷⁶.</p> <p>≥60 years: GMT 131.5 (95% CI, 108.2-159.7)²⁷⁶.</p>	<p><u>Single dose (≥4 weeks):</u></p> <p>37.7±57.08 IU/ml (min: 0, max: 317.25); 57.02% of participants did not develop sufficient antibody titres (<25.6 IU/ml)</p> <p><u>Two doses (≥4 weeks):</u></p> <p>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)²⁷⁷.</p> <p><u>2 weeks after second dose:</u></p> <p>164.4 BAU/ mL²⁷⁸</p> <p><u>4 weeks after second dose:</u></p> <p>94.8 BAU/ mL²⁷⁸</p> <p><u>8-12 weeks after second dose:</u></p>	<p><u>Single dose (≥4 weeks):</u></p> <p>43.8% seropositive for anti-spike antibody > 15 AU/mL²⁷⁹</p> <p>GMT 16.8 (95% CI, 15.80-17.88) for SARS-CoV-2 spike antibody titre²⁷⁹</p> <p><u>Two doses (≥4 weeks):</u></p> <p>80.0% seropositive for anti-spike antibody > 15 AU/mL²⁷⁹</p> <p>GMT 48.3 (95% CI, 47.46-48.92) for SARS-CoV-2 spike antibody titre²⁷⁹</p>
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						34.7 BAU/ mL ²⁷⁸		
Immunogenicity against the Mu variant	6.8-fold decrease in neutralizing titres when compared to convalescent sera ²⁸⁰	Neutralizing titre similar to that of BNT162b2 sera ²⁸⁰	Neutralizing titre similar to that of BNT162b2 sera ²⁸⁰	No available data	No available data	No available data	No available data	No available data
EFFICACY								
Single dose^{xlviii}	<p>52% (95% CI, 29.5 to 68.4; starting at 12 days) or 82.2% (75.1 to 87.3; starting at ≥14 days)²⁸¹.</p> <p>91% (95% CI, 85-94)²⁸².</p> <p>≥80 years : 71.4% (95% CI, 46.5-90.6) vaccine efficacy for symptomatic disease 14 days after one dose</p>	<p>95.2% (95% CI, 91.2.8 to 97.4; starting at >14 days)⁹⁸.</p>	<p>72.8% (starting at 22 days up to 60 days)²⁸⁴.</p> <p>88% (95% CI, 75-94)²⁸².</p> <p>≥80 years : 80.4% (95% CI, 36.4-94.5) vaccine efficacy for symptomatic disease 14 days after one dose [United Kingdom, 18 Dec 2020 – 26 Feb 2021]²⁸³</p> <p>≥65 years :</p>	Single dose vaccine	Unknown	<p>35.1% (95% CI, -6.6 to -60.5) [conducted in a setting with high P.1 transmission]²⁸⁵.</p>	No available data	<p>83.4% (95% CI, 73.6-89.5) starting at ≥14 days³⁶</p>

^{xlviii} Against SARS-COV-2 infection

^l Conducted between 8 December 2020 and 8 February 2021. Study sample = ≤1 million participants.

	[United Kingdom, 18 Dec 2020 – 26 Feb 2021] ²⁸³ ≥65 years : 56% (95% CI 19-76) at 28-34 days and 62% (95% CI 23-81) at 35-48 days post-vaccination [United Kingdom, 8 Dec 2020 – 15 Mar 2021] ²⁸³ xlix		56% (95% CI 19-76) at 28-34 days and 62% (95% CI 23-81) at 35-48 days post-vaccination [United Kingdom, 8 Dec 2020 – 15 Mar 2021] ²⁸³ li					
Two doses ^{lii}	95.0% (95% CI, 90.3-97.6) starting at ≥7 days in population without prior SARS-CoV-2 infection ¹¹² 94.6% (95% CI, 89.9-97.3) starting at ≥7 days in population with or without prior infection ¹¹²	94.1% (95% CI, 89.3-96.8) after median follow-up of less than 63 days ⁹⁸ 93.2% (95% CI, 91.0-94.8) ²⁸⁶ <u>Against severe disease:</u> 98.2% (95% CI, 92.8-99.6) ²⁸⁶	63.1% (95% CI, 51.8-71.7) starting at ≥14 days for two standard doses ²⁸⁴ 80.7% (95% CI, 62.1-90.2) starting at ≥14 days for first low dose and standard second dose ²⁸⁴ 66.7% (95% CI, 57.4-74.0) starting at ≥14 days for	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-19 ²⁸⁷ 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	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). ¹⁹¹	After 14 days, efficacy against symptomatic cases was 50.7% (95% CI 35.9 to 62.0). ¹⁰⁴ 99.17% of NAb titres were above or equal to the NAb positivity cut-off (20 units) against wild-type ²⁸⁸ .	<u>Against severe symptomatic SARS-CoV-2 infection:</u> 93.4 (95% CI, 57.1-99.8) ¹⁰⁶ <u>≥60 years old:</u> 67.8% (95% CI, 65.2-86.4) against symptomatic COVID-19 ¹⁰⁶ <u>18-59 years old:</u> 79.4% (95% CI, 66.0-88.2) against	89.7% (95% CI, 80.2-94.6) starting at ≥7 days ³⁶ 90.4% (95% CI, 82.9-94.6) ²⁸⁹ 100% (95% CI, 87-100) against moderate-to-severe COVID-19 ²⁸⁹ 100% (95% CI, 34.6-100)

xlix Does not differentiate between BNT162b2 and ChAdOx1 nCoV-19.

li Does not differentiate between BNT162b2 and ChAdOx1 nCoV-19.

lii Against SARS-CoV-2 infection.

			pooled analysis efficacy ²⁸⁴	against severe-critical COVID-19 ²⁸⁷			symptomatic COVID-19 ¹⁰⁶	against severe COVID-19 ²⁸⁹
								90% (95% CI, 80-95) (≥7 days after second dose) ²⁹⁰
Against asymptomatic infection	90% (starting at 14 days) regardless of symptom status ²⁹¹	63.0% (95% CI, 56.6-68.5) ²⁸⁶	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) ²⁸⁷ .	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) ¹⁹¹ .	Unknown	63.6 (95% CI, 29.0-82.4) efficacy against asymptomatic cases ¹⁰⁶	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 ²⁹² .	NAbs remained high and consistent with titres of the wildtype for the B.1.1.7 variant ²⁹³ .	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 ⁸⁸ .	3.6-fold reduction in neutralization capacity when compared to wild-type.	Demonstrated reduced neutralizing capacity. However, there were no differences in the NAb titres against B.1.351 in vaccinated individuals vs. those naturally infected, suggesting the	10.4-fold reduction in neutralization capacity when compared to natural infection sera ²⁸⁸ . 85.83% of NAb titres were above or equal to the Nab positivity cut-off (20 units)	PRNT₅₀ 0.8 when compared with wild type against Alpha (no significant difference in neutralization capacity) ²⁹⁶	Two dose efficacy against the B.1.1.7 variant 86.3% (95% CI, 71.3-93.5) ³⁶ 93.6% (95% CI, 81.7-97.8) against the Alpha variant ²⁸⁹ Against non-B.1.1.7 variant

				vaccine has a similar level of protection against infection as natural infections ²⁹⁴ .	against wild-type ²⁸⁸ . Neutralization decreased by 4.1-fold when compared to wild-type ²⁹⁵ .		96% (95% CI, 74-99.5) (≥ 7 days after second dose) ²⁹⁰ <i>Against B.1.1.7 variant</i> 86% (95% CI, 71-94) (≥ 7 days after second dose) ²⁹⁰	
Beta (B.1.351)	Neutralization was diminished by a factor of 5 . Despite this, the BNT162b2 mRNA vaccine still provides some protection against B.1.351 ²⁹⁷ 100% (95% CI, 53.5-100) ²⁹⁸ .	NAbs were 6-fold lower. Nevertheless, NAbs were still found to be protective ²⁹³ .	Two doses of the vaccine had no efficacy against the B.1.351 (VE = 21.9% ; 95% CI, -49.9 to 59.8) ²⁹⁹ .	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) ²⁸⁷ . Demonstrated 3.6-fold reduction in neutralization sensitivity ³⁰⁰ . Neutralization titres were decreased by 6.7-fold ³⁰¹ .	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 ²⁸⁸ . 82.5% of NAb titres were above or equal to the Nab positivity cut-off (20 units) against wild-type ²⁸⁸ .	GMT 61.57 (95% CI, 36.34-104.3) against Beta variant with significant reduction in neutralization titre ³⁰²	51.0% (95% CI, -0.6-76.2) efficacy against B.1.351 variant ³⁰³

<p>Gamma (P.1)</p>	<p><u>Single dose:</u> ≥21 days: 83% against hospitalization and death³⁰⁴.</p> <p><u>Two doses:</u> ≥ 14 days: 98% against hospitalization and death³⁰⁴.</p>	<p>3.2-fold reduction in neutralization capacity when compared to wild-type³⁰⁵.</p>	<p><u>Single dose:</u> ≥21 days: 94% against hospitalization and death³⁰⁴.</p> <p><u>Two doses:</u> 64% (95% CI, -2-87) [n=18]³⁰⁶</p> <p>Efficacy against Zeta (P.2) [2 doses]: 69% (95% CI, 55-78)³⁰⁶</p>	<p>Demonstrated 3.4-fold reduction in neutralization sensitivity³⁰⁰.</p> <p>No published data</p>	<p>49.6% against P.1 (>14 days after 1st dose)²⁸⁵.</p> <p>Neutralization decreased by 7.5-fold when compared to wild-type²⁹⁵.</p>	<p>No available data</p>	<p>No available data</p>
<p>Delta (1.671.2)</p>	<p>Reduced NAb activity relative to B.1.1.7 strain³⁰⁷.</p>	<p>2.1-fold reduction in neutralization capacity when compared to wild-type³⁰⁵.</p>	<p><u>Single dose:</u> ≥21 days: 90% against hospitalization and death³⁰⁴.</p> <p>Demonstrated 1.6-fold reduction in neutralization sensitivity³⁰⁰.</p> <p>Neutralization titres were decreased by 5.4-fold³⁰¹.</p>	<p>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 infections²⁹⁴.</p>	<p>NT_{GM} 24.48 (95% CI, 19.2-31.2)²⁸⁸.</p> <p>69.17% of NAb titres were above or equal to the Nab positivity cut-off (20 units) against wild-type²⁸⁸.</p>	<p>65.2 (95% CI, 33.1-83.0) estimated efficacy¹⁰⁶</p> <p>GMT 68.97 (95% CI, 24.72-192.4) against Delta variant with significant reduction in neutralization titre³⁰²</p>	<p>No available data</p>

PHASE III TRIALS RESULTS ^{liii}								
Number of participants (vaccine/ placebo)	43,448 (21,720/ 21,728) ¹¹²	30,420 (15,210/15,210) ⁹⁸	17,178 (8597/8581) ²⁸⁴	39,321 (19,630/19,691) ²⁸⁷	26,917 (13,459/13458); or 26,914 (13,465/13,458) ¹⁹¹	9,823 (4,953/4,870) ¹⁰⁴	25,798 (12,899/12899)¹⁰⁶	14,039 (7,020/7,019) ³⁶
Total COVID-19 cases (vaccine/ control)	170(8/162) ¹¹²	196 (11/185) ⁹⁸	332 (84/248) ²⁸⁴	464 (116/348) ²⁸⁷	121(26/95) or 116(21/95) ¹⁹¹	253(85/168) ¹⁰⁴	130 (24/106)¹⁰⁶	106(10/96) ³⁶
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) ⁹⁸ .	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	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	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) ¹⁹¹ .	After 14 days, efficacy against symptomatic cases was 50.7% (95% CI 35.9 to 0-62.0). ¹⁰⁴	77.8% (95% CI, 65.2-86.4) against symptomatic COVID-19 starting at ≥14 days after second dose ¹⁰⁶	83.4% (95% CI, 73.6-89.5) starting at ≥14 days after first dose ³⁶ 89.7% (95% CI, 80.2-94.6) starting at ≥7 days after second dose ³⁶

^{liii} 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, **16 November 2020 and 7 January 2021 for the COVAXIN 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) ¹¹² .		66.7% (95% CI 57.4 to 74.0). For any nucleic acid amplification test-positive swab: efficacy was 54.1% (95% CI 44.7 to 61.9) ²⁸⁴ .	cases was 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 ²⁸⁷ .				
Efficacy against hospitalization and death	100% (after 7 days) ¹¹²	100% (≥14 days) ⁹⁸	100% (after 21 days) ²⁸⁴	76.7% (≥14 days) or 85.4% (≥28 days) ²⁸⁷	100% (>14 days) ¹⁹¹	100% (>14 days) ¹⁰⁴	93.4% (>14 days) against severe COVID-19 ¹⁰⁶	100% (after 7 days) ³⁶ .
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 ^{95,308} .	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 the placebo group ⁹⁸ .	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 anaemia and a case of fever higher than 40°C ¹⁰⁰ .	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 (2), & severe generalized weakness, fever & headache (1) ²⁸⁷ .	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 ¹⁰³ .	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 ¹⁰⁴ .	Rates of local and systemic AEs reported in the BBV152 group as mild (11.2%), moderate (0.8%), or severe (0.3%) were comparable to the placebo group¹⁰⁶ 15 deaths, none considered related to the vaccine or placebo¹⁰⁶	Phase II: Nine serious adverse events were reported, only one of which was assessed as related to the vaccine: acute colitis ³⁰⁹ .

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.		<p>2-DOSE EFFICACY</p> <p><i>Efficacy against symptomatic (moderate to severe/critical) SARS-CoV-2 infection</i></p> <p>94% (95% CI, 58-100) in the US.</p> <p>75% (95% CI, 55-87) globally.²¹</p> <p><i>Efficacy against severe/critical SARS-CoV-2 infection</i></p> <p>100% (95% CI, 33-100)²¹</p>	Only 2 severe cases occurred in the control group and none in the vaccine group (very few cases to get a reliable estimate).	-	-	<p>Novavax is currently awaiting FDA, EMA, and WHO EUL approval.</p> <p>Upcoming information regarding results of clinical trials or approval will be updated in upcoming reports</p>

VACCINE PRODUCTION SITES



	BNT162b2/ COMIRNATY (Pfizer-BioNTech, USA)^{liv}	Spikevax/ Moderna COVID-19 Vaccine/ mRNA-1273 (Moderna, USA)^{lv}	Vaxzevria/ ChAdOx1 nCoV-19/ AZD1222/ Covishield (AstraZeneca/Oxford, UK, India)^{lvi}	Janssen COVID-19 vaccine/Johnson & Johnson (Janssen, USA)^{lvii}	Sinopharm/BBIB P-CorV, China^{lviii}	Sinovac CoronaVac, China^{lix}	COVAXIN / BBV152 (Bharat Biotech, India)	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)	Bharat Biotech International Limited (India)	Novavax (USA)
Production sites (Drug substance)	BioNTech Manufacturing GmbH (Mainz, Germany) BioNTech Manufacturing Marburg (Marburg, Germany) Rentschler Biopharma SE	Lonza Biologics, Inc., (USA) ¹ Moderna TX, Inc. (USA) ¹ Lonza AG (Switzerland) ²	Henogen S.A (Belgium) Catalent Maryland, Inc. (USA) Oxford Biomedica (UK) Ltd. (United Kingdom)	Janssen Vaccines & Prevention B.V. (The Netherlands) Janssen Biologics B.V. (The Netherlands) Emergent Manufacturing Operations Baltimore LLC (USA)	Beijing Institute of Biological Products Co., Ltd. (China)	Sinovac Life Sciences Co., Ltd. (China)	-	Novavax (Bohumil, Czech Republic)

^{liv} 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>

^{lv} 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>

^{lvi} 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>

^{lvii} 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>

^{lviii} WHO recommendation COVID-19 vaccine BIBP/Sinopharm. WHO. <https://extranet.who.int/pqweb/vaccines/who-recommendation-covid-19-vaccine-bibp>

^{lix} 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>

	(Laupheim, Germany) Wyeth BioPharma Division of Wyeth Pharmaceuticals (USA)		SK Bioscience (Republic of Korea) Halix B.V (Netherlands) WuXi Biologics (China)					
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 (Brehna, Germany) Delpharm Saint-Remy	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) Catalent Anagni S.R.L. (Italy)	Beijing Institute of Biological Products Co., Ltd. (China)	Sinovac Life Sciences Co., Ltd. (China)	-	Novavax (Bohumil, Czech Republic)



	(France) Sanofi-Aventis Deutschland GmbH (Germany)							
Diluent suppliers	Pfizer Perth, Australia Fresenius Kabi, USA	-	-	-	-	-	-	-

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