

Literature screening report

COVID-19 vaccines in the WHO's Emergency Use Listing (EUL) Report (6)

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Abstract

This report focuses on the World Health Organization's (WHO) Emergency Use Listing (EUL) of authorized vaccines as of 15 October 2021. Currently six vaccines are authorised for emergency use: BNT162b2/COMIRNATY (Pfizer-BioNTech, USA), Spikevax/Moderna COVID-19 Vaccine/ mRNA-1273 (Moderna, USA), Vaxzevria/ChAdOx1 nCoV-19/AZD1222/Covishield (AstraZeneca/Oxford, UK, India), Janssen Covid-19 vaccine/Johnson & Johnson (Janssen, USA), Sinopharm/BBIBP-CorV (China), and Sinovac/CoronaVac (China). This report provides a condensed summary concerning vaccine efficacy, safety, protection against variants, and further important information for each vaccine, in the form of a synoptic table. The information and data in this synoptic table was extracted from phase III clinical trials and from observational studies. This report particularly focuses on the latest data on vaccine effectiveness, duration of protection and waning immunity, booster doses, efficacy and safety of NVX-CoV2372, and myocarditis.

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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, 48% of the world populations, of which only 2.5% of people in low-income countries, have received at least one dose of a marketed COVID-19 vaccine as of 15 October 2021¹. Currently, six vaccines [namely, Pfizer-BioNTech, USA), Spikevax/Moderna COVID-19 Vaccine/ mRNA-1273 (Moderna, USA), Vaxzevria/ChAdOx1 nCoV-19/AZD1222/Covishield (AstraZeneca/Oxford, UK, India), Janssen Covid-19 vaccine/Johnson & Johnson (Janssen, USA), Sinopharm/BBIBP- CorV (China), and Sinovac/CoronaVac (China)] were assessed and granted an authorization by WHO as of 29 September 2021. **Articles regarding the latest data on vaccine effectiveness, vaccine effectiveness against hospitalization, booster doses protection across different age groups, new data on the duration of protection and waning immunity, the efficacy and safety of NVX-CoV2373 in adults in the United States and Mexico, and data on myocarditis were prioritized during the literature search and are the latest additions to the table. Data from clinical trials and observational studies for the six EUL-accepted vaccines and the vaccine candidate Novavax regarding these highlighted topics were summarized and can be found in the synoptic table below.**

¹ <https://ourworldindata.org/covid-vaccinations> (accessed on 15.10.2021).

Methodology

We screened the data for the EUL-accepted vaccines and the vaccine candidate Novavax as of 15 October 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 six 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

There have not been substantial updates on vaccine effectiveness studies since the previous synoptic table's (30 September 2021) publication. Recently published studies continue to report waning mRNA vaccine protection over time³ (i.e. **BNT162b2**: VE declined from **93.6%** in May to **65.8%** in July⁴; **mRNA-1273**: VE declined from to **94.1%** 14-60 days after vaccination to **80.0%** 151-180 days after vaccination⁵) and

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 mRNA vaccine effectiveness against asymptomatic SARS-CoV-2 infections over a seven-month period. *Infection Control & Hospital Epidemiology*. <https://www.cambridge.org/core/journals/infection-control-and-hospital-epidemiology/article/mrna-vaccine-effectiveness-against-asymptomatic-sarscov2-infection-over-a-seven-month-period/0B67BE1950C88E93B73C15F75E2FC497>

⁴ COVID-19 vaccine effectiveness by product and timing in New York State. *medRxiv*.

<https://www.medrxiv.org/content/10.1101/2021.10.08.21264595v1.full-text>

⁵ Effectiveness of mRNA-1273 against Delta, Mu, and other emerging variants. *medRxiv*.

<https://www.medrxiv.org/content/10.1101/2021.09.29.21264199v1.full.pdf+html>

against the Delta variant^{6,7}. See summary paragraph and the synoptic table below for more in-depth information on waning vaccine immunity^{8,9,10,11,12}. While both mRNA vaccines demonstrate reduced effectiveness levels, Moderna's mRNA-1273 vaccine has continued to demonstrate higher effectiveness levels¹³ and reduced number of breakthrough infections¹⁴ than Pfizer-BioNTech's BNT162b2 vaccine. However, one Belgian study demonstrated that the BNT162b2 vaccine had higher vaccine effectiveness against onwards transmission (**62%; 95% CI, 57-67**) than the mRNA-1273 vaccine (**52%; 95% CI, 33-69**)¹⁵.

A pre-print reported the mRNA-1273 vaccine demonstrated higher effectiveness levels against the Mu (B.1.621) variant of concern (**90.4%** (95% CI, 73.9-96.5) than the Delta variant (**86.7%** (95% CI, 84.3-88.7)).¹⁶

The latest vaccine effectiveness data on AstraZeneca's ChadOx1 nCoV-19/Vaxzevria (VE of **53%** (95% CI, 12-84) in June)¹⁷ or Ad26.COVS.S Janssen vaccines (VE

⁶ Transmission event of SARS-CoV-2 delta variant reveals multiple vaccine breakthrough infections. *BMC Medicine*. <https://bmcmmedicine.biomedcentral.com/articles/10.1186/s12916-021-02103-4>

⁷ The impact of SARS-CoV-2 vaccination on Alpha & Delta variant transmission. *medRxiv*. <https://www.medrxiv.org/content/10.1101/2021.09.28.21264260v1>

⁸ Waning of BNT162b2 vaccine protection against SARS-CoV-2 infection in Qatar. *New England Journal of Medicine*. https://www.nejm.org/doi/full/10.1056/NEJMoa2114114?query=featured_home

⁹ Effectiveness of mRNA-1273 against Delta, Mu, and other emerging variants. *medRxiv*. <https://www.medrxiv.org/content/10.1101/2021.09.29.21264199v1>

¹⁰ 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)

¹¹ mRNA vaccine effectiveness against asymptomatic SARS-CoV-2 infections over a seven-month period. *Infection Control & Hospital Epidemiology*. <https://www.cambridge.org/core/journals/infection-control-and-hospital-epidemiology/article/mrna-vaccine-effectiveness-against-asymptomatic-sarscov2-infection-over-a-sevenmonth-period/0B67BE1950C88E93B73C15F75E2FC497>

¹² COVID-19 vaccine effectiveness by product and timing in New York State. *medRxiv*. <https://www.medrxiv.org/content/10.1101/2021.10.08.21264595v1>

¹³ 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)

¹⁴ A retrospective analysis of COVID-19 mRNA vaccine breakthrough infections – Risk factors and vaccine effectiveness. *medRxiv*. <https://www.medrxiv.org/content/10.1101/2021.10.05.21264583v1>

¹⁵ Vaccine effectiveness against infection and onwards transmission of COVID-19: Analysis of Belgian contact tracing data, January-June 2021. *Vaccine*. <https://www.sciencedirect.com/science/article/pii/S0264410X21011087?via%3Dihub>

¹⁶ Effectiveness of mRNA-1273 against Delta, Mu, and other emerging variants. *medRxiv*. <https://www.medrxiv.org/content/10.1101/2021.09.29.21264199v1>

¹⁷ Vaccine effectiveness against infection and onwards transmission of COVID-19: Analysis of Belgian contact tracing data, January-June 2021. *Vaccine*. <https://www.sciencedirect.com/science/article/pii/S0264410X21011087?via%3Dihub>

decreased from **89.4%** [1 May] to **51.7%** [10 July])¹⁸ corroborate previously reported data on waning vaccine protection.

Effectiveness data on Sinopharm's BBIBP-CorV and Sinovac's CoronaVac remains scarce. A recent study highlighted that the BBIBP-CorV vaccine induced high levels of IgG anti-spike antibodies (GMC: **377.0 IU/ml**; 95% CI, 324.3-438.3) in SARS-CoV-2 naïve individuals, however antibody (GMC) concentrations reduced to **125.4 IU/ml** (95% CI, 88.2-178.4) three months after receiving the second dose (most individuals received their second dose 54 days after their first dose and not the suggested 21 days apart)¹⁹. The authors did not specify which SARS-CoV-2 lineage was utilised. Another neutralizing antibody titre (NAb) quantification study demonstrated that the CoronaVac vaccine could not effectively neutralise variants of concern, particularly the delta variant, advocating for the administration of a third CoronaVac or heterologous vaccine dose to maintain long-term immunity against SARS-CoV-2²⁰. Although both inactivated virus studies only analysed neutralization level data and not vaccine effectiveness, neutralization levels against SARS-CoV-2 assays have been shown to be highly predictive of immune protection against symptomatic SARS-CoV-2 infection²¹.

Despite reports of reduced effectiveness against SARS-Cov-2 infection, vaccine effectiveness remains high against severe infection, hospitalization, and death for all vaccines. Further vaccine effectiveness data can be found in the synoptic table below.

Duration of Protection and Waning Immunity

The waning immunity of vaccine protection against SARS-CoV-2 infection and COVID-19 disease remains a concern, especially when trying to control and contain

¹⁸ COVID-19 vaccine effectiveness by product and timing in New York State. *medRxiv*.

<https://www.medrxiv.org/content/10.1101/2021.10.08.21264595v1>

¹⁹ Humoral response to the BBIBP-CoRV vaccine over time in healthcare workers with or without exposure to SARS-CoV-2.

medRxiv. <https://www.medrxiv.org/content/10.1101/2021.10.02.21264432v1.full.pdf>

²⁰ CoronaVac induces lower neutralising activity against variants of concern than natural infection. *The Lancet Infectious*

Diseases. <https://www.sciencedirect.com/science/article/pii/S1473309921005685?via%3Dihub>

²¹ Neutralizing antibody levels are highly predictive of immune protection from symptomatic SARS-CoV-2 infection. *Nature*.

<https://www.nature.com/articles/s41591-021-01377-8#citeas>

the ongoing COVID-19 pandemic. Two longitudinal studies examining the waning immunity of the BNT162b2 vaccine provide insightful data on the longitudinal dynamics of the immune response to the vaccine. The first study was conducted over a period of 6 months in which vaccinated health care workers were tested monthly for the presence of anti-spike IgG and neutralizing antibodies²². Based on the results, six months after receipt of the second dose of the BNT162b2 vaccine, humoral response substantially decreased, especially among men, among persons 65 years of age or older, and among persons with immunosuppression. Similar results were reported in the second study in which a test-negative, case-control study design was used to estimate the vaccine effectiveness against any SARS-CoV-2 infection and Covid-19 disease in Qatar²³. The results demonstrated that the BNT162b2-induced protection against SARS-CoV-2 infection appeared to wane rapidly following its peak after second dose, but protection against hospitalization and death persisted at robust level for 6 months after the second dose.

Since the roll-out of COVID-19 vaccines such as mRNA (BNT162b2, mRNA-1273), adenoviral virus (ChAdOx1 nCoV-19), and inactivated virus vaccines (CoronaVac, Sinopharm), concerns regarding the duration of protection and waning immunity have emerged, especially when aiming to compare vaccine platforms. A study seeking to address the duration of protection and waning immunity of BNT162b2, ChAdOx1 nCoV-19, and CoronaVac in younger and older age groups, comparatively analysed the spike RBD IgG antibody titers in those three vaccine platforms²⁴. When comparing the three different vaccine types, the BNT162b2 induced the highest overall seropositivity and anti-spike RBD IgG antibody levels in both younger and older age groups, followed by ChAdOx1, and then by CoronaVac vaccine. In regards of the rate

²² Waning Immune Humoral Response to BNT162b2 Covid-19 Vaccine over 6 Months. *NEJM*.

https://www.nejm.org/doi/full/10.1056/NEJMoa2114583?query=featured_home

²³ Waning of BNT162b2 Vaccine Protection against SARS-CoV-2 Infection in Qatar. *NEJM*.

<https://www.nejm.org/doi/full/10.1056/NEJMoa2114114>

²⁴ Longitudinal comparison of SARS-CoV-2 anti-Spike RBD IgG antibody response after CoronaVac, BNT162b2, ChAdOx1 nCoV-19 vaccines and evaluation of a single booster dose of BNT162b2 or CoronaVac after a primary CoronaVac regimen. *SSRN – Preprint*. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3929973

of declining antibodies, the CoronaVac group had the fastest decline followed by ChAdOx1, and then by BNT162b2.

Another study aiming to understand the duration of protection and waning immunity, analysed the humoral response to the BBIBP-CorV (Sinopharm) vaccine over time in healthcare workers with or without exposure to SARS-CoV-2²⁵. Based on those results, three months after the second dose individuals with SARS-CoV-2 exposure prior to vaccination and individuals without prior exposure showed a decline in antibody levels, being more abrupt in unexposed subjects. Overall, the results showed a trend towards lower antibody concentrations over time following BBIBP-CorV vaccination.

Protection of Booster Doses across age groups

Earlier this month of October, the European Medicines Agency (EMA) released their recommendations on extra doses and boosters²⁶. Regarding the administration of extra doses, the EMA concluded that an extra dose of the COVID-19 vaccines Comirnaty (BioNTech/Pfizer) and Spikevax (Moderna) may be given to people with severely weakened immune systems, at least 28 days after their second dose. This conclusion was based on the multiple studies demonstrating the benefits of a third dose in immunocompromised individuals^{27,28}. In terms of their recommendation for booster doses in populations with normal immune systems, the EMA concluded that booster doses of the Comirnaty vaccine may be considered at least 6 months after the second dose for people aged 18 years and older. Their decision only applies for the BioNTech/Pfizer COVID-19 vaccine, as the EMA is currently evaluating data to support a booster for Spikevax. Many of the decision regarding the administration of

²⁵ Humoral response to the BBIBP-CorV vaccine over time in healthcare workers with or without exposure to SARS-CoV-2. *medRxiv*. <https://www.medrxiv.org/content/10.1101/2021.10.02.21264432v1>

²⁶ Comirnaty and Spikevax: EMA recommendations on extra doses and boosters. *EMA*. https://www.ema.europa.eu/en/news/comirnaty-spikevax-ema-recommendations-extra-doses-boosters#_ftnref1

²⁷ Three Doses of an mRNA Covid-19 Vaccine in Solid-Organ Transplant Recipients. *NEJM*. <https://www.nejm.org/doi/full/10.1056/NEJMc2108861>

²⁸ Randomized Trial of a Third Dose of mRNA-1273 Vaccine in Transplant Recipients. *NEJM*. <https://www.nejm.org/doi/full/10.1056/NEJMc2111462>

booster doses rely on data from Israel where boosters started being offered to the whole population early on. One of the first studies to provide data on the protection of BNT162b2 against COVID-19 infections and severe illnesses was their study on the protection of the BNT162b2 vaccine booster against COVID-19 in 60-years-old and over²⁹. The study demonstrated that a booster dose lowered the rate of confirmed infection and severe illness in older populations²¹, and their newest preprint on the protection of BNT162b2 vaccine booster against COVID-19 across age groups shows that the rate of confirmed infection and severe illness were substantially lowered among those who received a booster dose across all age groups³⁰. Overall, the newest results on the protection of BNT162b2 vaccine booster show that confirmed infection rates were approximately **10-fold lower** in the booster group compared to the non-booster group (ranging from **8.8-17.6** for ≥ 12 days post booster administration and **4.8-11.2** for 3-7 days post booster administration across the five different age groups), while the severe illness rates were **18.7 fold** (95% CI, 15.7-22.4) ≥ 12 days post booster administration and **6.5-fold** (95% CI, 5.1-8.3) **lower** 3-7 days post booster administration for ages 60 and over, and **22-fold** (95% CI, 10.3-47.0) ≥ 12 days post booster administration and **3.2-fold** (95% CI, 1.1-9.6) **lower** 3-7 days post booster administration for ages 40-60¹⁰. In terms of COVID-19 associated death rates, for ages 60 and over, the rates were **14.7-fold** (95% CI, 9.4-23.1) ≥ 12 days post booster administration and **4.8-fold** (95% CI, 2.8-8.2) **lower** 3-7 days post booster administration¹⁰.

New Data on Efficacy and Safety of Novavax Vaccine

The Novavax COVID-19 vaccine candidate is an adjuvant, recombinant S protein nanoparticle vaccine that has previously demonstrated clinical efficacy for prevention of COVID-19 in phase 2b/3 trials in the United Kingdom and South Africa. New results

²⁹ Protection of BNT162b2 Vaccine Booster against Covid-19 in Israel. *NEJM*.

<https://www.nejm.org/doi/full/10.1056/NEJMoa2114255>

³⁰ Protection Across Age Groups of BNT162b2 Vaccine Booster against Covid-19. *medRxiv*.

<https://www.medrxiv.org/content/10.1101/2021.10.07.21264626v1>

from a phase 3, randomized, observer-blinded, placebo-controlled trial performed in the United States and Mexico evaluated the efficacy and safety of NVX-CoV2373 in adults over 18-years of age³¹. Based on the results, a vaccine efficacy of **90.4%** (95% CI: 82.9-94.6) and a vaccine efficacy against any variant of concern/interest (i.e., Alpha, Delta, Kappa) of **92.6%** (95% CI: 83.6-96.7) were reported. In terms of reactogenicity, most reported side effects or adverse events were mild-to-moderate and transient and mainly occurring in the NVX-CoV-2373 recipients and after the second dose. Overall, the Novavax COVID-19 vaccine candidate was well tolerated and demonstrated a high overall VE for prevention of COVID-19 where the most sequenced viral genomes were classified as variants of concern or interest.

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

³¹ Efficacy and Safety of NVX-CoV2373 in the United States and Mexico. *medRxiv*.

<https://www.medrxiv.org/content/10.1101/2021.10.05.21264567v1>

Synoptic Table

Synoptic table about SARS-CoV-2 vaccines accepted in the WHO's Emergency Use Listing and Novavax Vaccine (as of 15 October 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) | Sinopharm/BBIB P-CorV, China | Sinovac CoronaVac, China | 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) | Recombinant protein (nanoparticle) vaccine with Matrix-M adjuvant |
| Dose and frequency | 2 doses, 21 days apart | 2 doses, 28 days apart | 2 doses, 4-12 weeks apart | 1 dose, once [Phase III trials currently testing 2- | 2 doses, 21 days apart | 2 doses, 14 days apart | 2 doses, 21 days apart |

| | | | | | | | |
|---|---|--|--|--|---|---|--|
| | | | | dose regime, 56 days apart ⁱ | | | |
| Target population | 12 years old and over | 12 years old and over | 18 years old and over | 18 years old and over | 18 years old and over | 18 years old and over | 18 years old and over |
| Storage conditions | 2°C to 8 °C (for 1 month) | 2°C to 8 °C (for 1 month) | 2°C until 8 °C | 2°C to 8 °C (for 3 months) | 2°C until 8 °C | 2°C until 8 °C | 2°C to 8 °C |
| Approving authorities | FDA (11.12.20) ⁱⁱ ; EMA (21.12.20); WHO EUL (31.12.20); and list of countries (including Switzerland – approved on 20.12.20) | FDA (18.12.20); EMA (06.01.21); WHO EUL (30.04.21); and list of 51 countries (including Switzerland – approved 12.01.21) | FDA (awaiting on approval); EMA (29.01.21); WHO EUL (15.02.21); and list of 121 countries (Switzerland awaiting on approval) | FDA (27.02.21); EMA (11.03.21), WHO EUL (12.03.21), and list of 59 countries (including Switzerland – approved 22.03.21) | WHO EUL (07.05.21); and list of 55 countries (e.g., Argentina, Bahrain, Brazil, China, Indonesia, United Arab Emirates, Zimbabwe) | WHO EUL (01.06.21), and list of 33 countries (e.g., Albania, Chile, Egypt, Hong Kong, Malaysia, Tunisia, Turkey, Ukraine) | Waiting on approval (Not-yet-approved by countries or WHO for emergency use) |
| Booster shot approving authorities | EMA approves booster for those aged 18 and above, 6 months after the 2 nd dose ¹ | EMA authorises booster dose for immunocompromised individuals ^{iv} FDA approves a third booster dose | | | | | |

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

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

^{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>

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|---|---|---|--|--|---|--|--|
| | FDA approves booster for those ages 16 and above, 6 months after the 2 nd dose ⁱⁱⁱ | for individuals older than 65 and high-risk individuals, 6 months after the 2 nd dose ^v | | | | | |
| EFFECTIVENESS AGAINST ANY SARS-COV-2 INFECTION | | | | | | | |
| Effectiveness single dose | <u>General population:</u> Against infection: 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 | <u>General population:</u> Symptomatic disease: 60% (95% CI, 57-64; >2 weeks after dose) ^{7, vii} 88.9% (95% CI, 78.7-94.2) ³ | <u>General population:</u> Asymptomatic or symptomatic disease: 64% ; Symptomatic disease: 67% ⁸ . <u>Individuals ≥ 70:</u> Symptomatic disease: 58% ⁵ . | 50.6% (95% CI, 14.0-74.0) in preventing SARS-CoV-2 infection (<2 weeks after dose); 76.7% (95% CI, 30.3-95.3) in preventing SARS-CoV-2 infection (>2 weeks after dose) ⁹ . | Partial protection ^{14, x} | 15.5% for preventing COVID-19; 37.4% for preventing hospitalization; 44.7% for preventing admission to the ICU; and 45.7% for preventing of COVID-19 related death ¹⁵ . | Ongoing studies in South Africa ¹⁷ and United Kingdom ¹⁸ |
| | <u>Individuals ≥ 70:</u> Symptomatic disease: 58% ⁵ . | <u>Individuals ≥ 70:</u> Symptomatic disease: 64% (95% CI, 46-78; | Hospitalization risk reduced by 35-45% ⁵ . | 79% (95% CI, 77-80) (when corrected for | 18.6% (95% CI, 17.6-19.6) against SARS-CoV-2 | | |

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>

^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>

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

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

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| <p>Hospitalization risk reduced by 35-45%⁵.</p> <p>Risk of death reduced by 54%⁵.</p> <p><u>Individuals ≥50:</u> ≥14 days after first dose: 54% (95% CI, 47-61) effectiveness against hospitalization [1 January-22 June⁶. vi</p> | <p>>2 weeks after dose)⁷.^{viii}</p> <p><u>Individuals ≥50:</u> ≥14 days after first dose: 54% (95% CI, 47-61) effectiveness against hospitalization [1 January-22 June⁶.^{ix}</p> | | <p>under-recording, VE was estimated to be 69% (95% CI, 67-71)¹⁰.</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)¹⁰.</p> <p>75% (95% CI, 65-82) against severe critical COVID-19¹¹.</p> <p>71% (95% CI, 56-81) [11 March – 15 August]¹².</p> <p>61% (95% CI, 29-84) [January-June]¹³</p> <p><u>Individuals ≥50:</u></p> | | <p>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]¹⁶</p> | |
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^{vi} mRNA-aggregated data (results do not disaggregate between BNT162b2 and mRNA-1273).

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

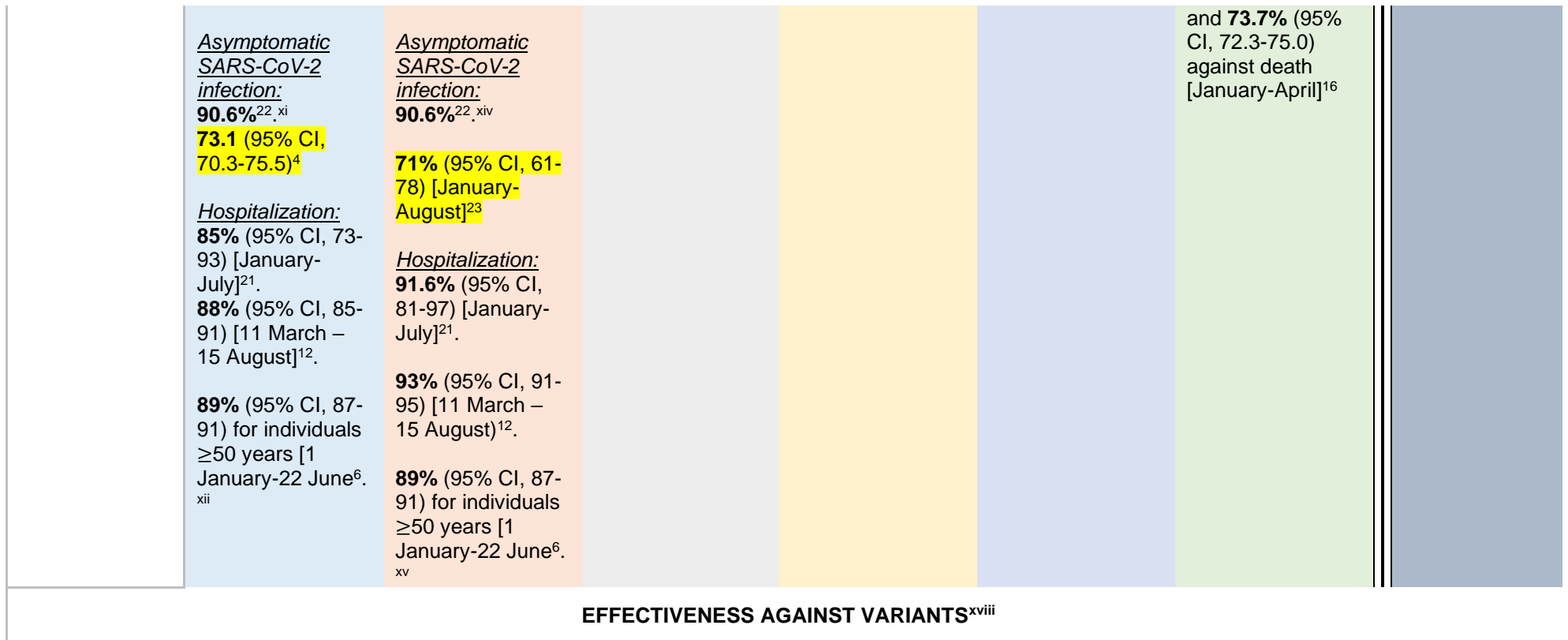
^{ix} mRNA-aggregated data (results do not disaggregate between BNT162b2 and mRNA-1273).

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| | | | | 68% (95% CI, 50-79) ⁶ . | | | |
| Effectiveness of two doses | <u>SARS-Cov-2 infection:</u> 85% ² . | <u>SARS-Cov-2 infection:</u> 100% ¹⁹ . | | | | | |
| | 94.6% ¹⁹ . | 86% (95% CI, 81-90.6) [January-July] ²¹ . | | | | | |
| | 94.5% ²⁰ . | | | | | | |
| | 76% (95% CI, 69-81) [January-July] ²¹ . | 96.3% (95% CI, 91.3-98.4) [December-May] ³ | <u>SARS-CoV-2 infection:</u> 85% ; 53% (95% CI, 12-84) [January-June] ¹³ | Not Applicable (one dose schedule) | Partial protection ^{14, xvi} | 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 death ^{15, xvii} | Ongoing studies in South Africa ¹⁷ and United Kingdom ¹⁸ |
| | 88.8% (95% CI, 84.6-91.8) [December-May] ³ | 85% (95% CI, 80-90) [January-June] ¹³ | <u>Symptomatic disease:</u> 90% ⁸ . | | | 52.7% (95% CI, 52.1-53.4) against SARS-CoV-2 infection, 72.8% (95% CI, 71.8-73.7) against hospitalization, 73.8% (95% CI, 72.2-75.2) against ICU admission, | |
| 74% (95% CI, 72-76) [January-June] ¹³ | | | | | | | |
| 77.5% (95% CI, 76.4-78.6) [first month after second dose] ⁴ | <u>Symptomatic disease:</u> 91% (95% CI, 89-93; >2 weeks after dose) ^{7, xiii} | | | | | | |

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

^{xvi} Study did not report numerical data on vaccine effectiveness. Further studies are required to validate results.

^{xvii} 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>



^{xi} Results do not disaggregate between BNT162b2 and mRNA-1273
^{xii} mRNA-aggregated data (results do not disaggregate between BNT162b2 and mRNA-1273).
^{xiv} Results do not disaggregate between BNT162b2 and mRNA-1273
^{xv} mRNA-aggregated data (results do not disaggregate between BNT162b2 and mRNA-1273).
^{xviii} Effectiveness data against the latest variant of interest (Mu) will be included in upcoming reports based on data availability.



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| <p>Alpha (B.1.1.7)</p> | <p><u>Single dose:</u> 48.7% (95% CI, 45.5 to 51.7)²⁴ 66% (95% CI, 64-68)²⁵. 54.5% (95 CI, 50.4-58.3)²⁶</p> <p><u>Two doses:</u> 93.7% (95% CI, 91.6 to 95.3)²⁴ 92% (95% CI, 90-93)²⁷. 89% (95% CI, 86-91)²⁵. 78% (95% CI, 68-84)²⁸ 84.4% (95 CI, 81.8-86.5)²⁶</p> | <p><u>Single dose:</u> 88.1% (95% CI, 83.7 to 91.5)²⁹</p> <p>83% (95% CI, 80-86)²⁵.</p> <p><u>Two doses:</u> 100% (95% CI, 91.8 to 100)²⁹ 92% (95% CI, 86-96)²⁵. 98.4% (95% CI, 96.9-99.1)³⁰</p> | <p><u>Single dose:</u> 48.7% (95% CI 45.5 to 51.7)²⁴ 64% (95% CI, 60-68)²⁵.</p> <p><u>Two doses:</u> 74.5% (95% CI, 68.4 to 79.4)²⁴ 73% (95% CI, 66-78)²⁷. 79% (95% CI, 56-90)²⁸.</p> | <p>-</p> | <p>No published data</p> | <p><u>Two doses:</u> Equally effective (~76%) in neutralizing D614G, B.1.1.7 and B.1.429 as the wild-type strain.</p> | <p>Ongoing studies in South Africa¹⁷ and United Kingdom¹⁸</p> |
| <p>Beta (1.351)</p> | <p><u>Single dose:</u> 60% (95% CI, 52-67)²⁵.</p> <p><u>Two doses:</u> 84% (95% CI, 69-92)²⁵.</p> | <p><u>Single dose:</u> 61.3% (95% CI, 56.5 to 65.5)²⁹ 77% (95% CI, 69-92)²⁵.</p> <p><u>Two doses:</u> 96.4% (95% CI, 91.9 to 98.7)²⁹</p> | <p><u>Single dose:</u> 48% (95% CI, 28-63)²⁵.</p> | <p>-</p> | <p>No published data</p> | <p>Neutralization capacity was decreased by factor 5.27³¹.</p> | <p>No available data</p> |

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| <p>Gamma (P.1)</p> | <p>Neutralization activity reduced by 3.3-fold³².</p> | <p>-</p> | <p>-</p> | <p>-</p> | <p>No published data</p> | <p>Demonstrated 42% vaccine effectiveness in a setting with high P.1 transmission, in individuals aged 70 and above³³. 50.2% against P.1 (>14 days after 2nd dose)³⁴. Neutralization was decreased by factor 3.92³¹.</p> | <p>No available data</p> |
| <p>Delta (1.617.2)</p> | <p><u>Single dose:</u> 30.7% (95% CI, 25.2 to 35.7)²⁴; 57% (95% CI, 50-63)²⁸ 22.5% (95 CI, 17.0-27.4)²⁶</p> <p><u>Two doses:</u> 88.0% (95% CI, 85.3 to 90.1)²⁴; 80% (95% CI, 77-83)²⁸ 79% (95% CI, 75-82)²⁷. 80% (95% CI, 77-83)²⁸</p> | <p><u>Single dose:</u> 72% effective against symptomatic SARS-Cov-2 infection³⁹.</p> <p><u>≥ 14 days after second dose:</u> 76% (95% CI, 58-87)²¹. 94.5% (95% CI, 94.1-95) [2-9 weeks after second dose]³⁶. 50.6% (95% CI, 45.0-55.7) [among</p> | <p><u>Single dose:</u> 30.7% (95% CI 25.2 to 35.7)²⁴</p> <p><u>Two doses:</u> 67.0% (95% CI, 61.3 to 71.8)²⁴ 67% (95% CI, 62-71)²⁸. 60% (95% CI, 53-66)²⁷. 66.7% (95% CI, 45-49.6) [2-9 weeks after second dose]³⁶. 47.3% (95% CI, 66.3-67.0) [≥20</p> | <p>78% (95% CI, 73-82) against SARS-CoV-2 infection¹⁰.</p> <p><u>Individuals ≥50:</u> 83% (95% CI, 81-85)¹⁰</p> | <p>No published data</p> | <p><u>Single dose:</u> 13.8% (95% CI, -60.2-54.8)⁴¹.</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 infection⁴¹.</p> | <p>No available data</p> |

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| | <p>40.5% (95% CI, 8.7-61.2)³⁵. 42% (95% CI, 13-62)²¹. 89.8% (95% CI, 89.6-90.0) [2-9 weeks after second dose]³⁶. 69.7% (95% CI, 68.7-70.5) [≥20 weeks after second dose]³⁶. 64.6% (95 CI, 60.6-68.2)²⁶ 52.4% (95% CI, 48.0-56.4) [among nursing home residents]³⁷. 53% (95% CI, 39-65) [4 months after second dose]³⁸</p> | <p>nursing home residents]³⁷. 86.7% (95% CI, 84.3-88.7)³⁰ <u>10-14 weeks after second dose:</u> 90.3% (95% CI, 67.2-97.1)³⁶.</p> | <p>weeks after second dose]³⁶. Odds ratio of 5.45 (95% CI, 1.39-21.4) to become infected with B.1.167.2 compared to non-B.1.167.2⁴⁰.</p> | | | | |
| Mu (B.1.621) | No available data | <p><u>Two doses:</u> 90.4% (95% CI, 73.9-96.5)³⁰ (demonstrated similar protective measures as against the Alpha variant)</p> | No available data | No available data | No available data | No available data | No available data |

EFFECTIVENESS AGAINST HOSPITALIZATION

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| <p>Alpha</p> | <p>Single dose: 83% (95% CI, 62-93) Two doses: 95% (95% CI, 78-99)⁴².</p> <p>Delta <i>Against severe COVID-19:</i> 91.4% (95% CI, 82.5-95.7)³⁵.</p> <p><i>Against death:</i> 98.2% (95% CI, 95.9-99.2) [2-9 weeks]³⁶. 90.4% (95% CI, 85.1-93.8) [≥20 weeks]³⁶.</p> | | <p>Single dose: 76% (95% CI, 61-85) Two doses: 86% (95% CI, 53-96)⁴².</p> <p><i>Against death:</i> 94.1% (95% CI, 91.8-95.8) [2-9 weeks]³⁶. 78.7% (95% CI, 52.1-90.4) [≥20 weeks]³⁶.</p> | <p>Beta 67% effective at preventing hospitalizations⁴³.</p> <p><i>Against death:</i> 96% effective at preventing death⁴³.</p> | - | - | No available data |
| <p>Delta</p> | <p><i>Single dose:</i> 94% (95% CI, 46-99)⁴². 91% (95% CI, 90-93)⁴⁴</p> | <p><i>Single dose:</i> 81% (95% CI, 81-90.6)²¹.</p> <p><i>Two doses:</i></p> | <p><i>Single dose:</i> 71% (95% CI, 51-83)⁴² 88% (95% CI, 83-91)⁴⁴</p> | <p>71%⁴³ 85% (95% CI, 73-91)¹⁰.</p> | <p><i>Single dose:</i> Does not offer clinically meaningful protection against severe illness^{47,xix}</p> | <p><i>Single dose:</i> Does not offer clinically meaningful protection against severe illness^{47,xxi}</p> | |

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

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

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| <p><u>Two doses:</u> 96% (95% CI, 86-99)⁴². 88% (95% CI, 78.9-93.2)³⁵. 75% (95% CI, 24-93.9)²¹. 84% (95% CI, 79-89)⁴⁵. 98.4% (95% CI, 97.9-98.8) [2-9 weeks]³⁶. 92.7% (95% CI, 90.3-94.6) [≥20 weeks]³⁶. 96% (95% CI, 95-96)⁴⁴. 93% (95% CI, 84-96)³⁸. 96.8% (95% CI, 93.9-98.3)[2 months after the second dose]⁴</p> | <p>84% (95% CI, 80-87)⁴⁴ <u>Against ICU admission:</u> 86% (95% CI, 79-90)⁴⁴ 96% against severe COVID-19 infection³⁹.</p> | <p><u>Two doses:</u> 92% (95% CI, 75-97)⁴². 95.2% (95% CI, 94.6-95.6) [2-9 weeks]³⁶. 77.0% (95% CI, 70.3-82.3) [≥20 weeks]³⁶. 94% (95% CI, 92-95)⁴⁴ <u>Against ICU admission:</u> Single dose: 92% (95% CI, 84-96)⁴⁴ Two doses: 96% (95% CI, 94-98)⁴⁴</p> | <p>91% (95% CI, 88-94)⁴⁴ 85% effective at preventing severe disease and hospitalization⁴⁶. <u>Individuals ≥50:</u> 84% (95% CI, 81-85)¹⁰ <u>Against ICU admission:</u> 94% (95% CI, 88-98)⁴⁴</p> | <p><u>Two doses:</u> 88% (95% CI, 55-98) adjusted risk reduction in developing severe illness.^{47,xx}</p> | <p><u>Two doses:</u> 88% (95% CI, 55-98) adjusted risk reduction in developing severe illness.^{47,xxii}</p> | |
| SAFETY AND ADVERSE EVENTS | | | | | | |

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

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

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| <p>Common side effects</p> | <p>Pain at the injection site, fatigue, headache, myalgia, chills and fever.⁴⁸</p> <p>Optimal safety for asthma patients⁴⁹.</p> <p>The vaccine is considered safe for cancer patients undergoing treatments⁵⁰.</p> | <p>Pain at injection site, headache, fatigue, myalgia, arthralgia⁵¹, Covid arm (cutaneous hypersensitivity)⁵².</p> <p>The vaccine is considered safe for cancer patients undergoing treatments⁵⁰.</p> | <p>Fatigue, myalgia, arthralgia, headache⁵³, lethargy, fever, & nausea⁵⁴.</p> | <p>Headache, fever, chills, fatigue, myalgia, and nausea⁵⁵.</p> | <p>Pain at the injection site, dizziness, fever, headache, fatigue, nausea, vomiting, & allergic dermatitis^{54,56}.</p> | <p>Pain at injection site, headache, fatigue, tremors, & flushing⁵⁷, inflammatory reaction, urticaria⁵⁸.</p> | <p>Pain at injection-site, headache, muscle pain, fatigue⁵⁹</p> |
| <p>Rare adverse events</p> | <p>Myocarditis & myopericarditis⁶⁰⁻⁶², anaphylaxis and swelling of the lips, face, and tongue related to anaphylaxis⁶³ (11 anaphylaxis cases per million doses administered)⁶⁴, axillary lymphadenopathy, paroxysmal ventricular arrhythmia, leg paresthesia⁶⁵, pityriasis rosea⁶⁶ (lesions improved completely after</p> | <p>Myocarditis & myopericarditis⁶⁰⁻⁶², orofacial swelling & anaphylaxis⁶³. Potential risk factor for Bell's palsy⁸³ (most improve upon follow-up)⁹¹, herpes zoster reactivation⁷⁰, varicella zoster reactivation⁷⁰, herpes zoster ophtalmicus⁹², eczema & urticaria⁹³, transverse</p> | <p>Transverse myelitis, high fever^{53,100}, cutaneous hypersensitivity¹⁰⁰, vasculitis¹⁰¹, cerebral venous sinus thrombosis¹⁰² (higher risk for women)¹⁰³, thromboembolism¹⁰⁴, vaccine induced immune thrombotic thrombocytopenia^{105,106-108},</p> | <p>Thrombosis, thrombocytopenia, cerebral venous sinus thrombosis¹²⁴, increased risk of developing Guillain-Barré syndrome post vaccination¹²⁵, herpes zoster ophtalmicus⁹².</p> <p>97% of reported reactions after vaccine administration were non-serious⁵⁵.</p> | <p>Rare adverse events were similar among the vaccine groups and control group within 7 days¹²⁶. Pityriasis rosea¹²⁷</p> | <p>Myalgia, fever⁵⁷, pityriasis rosea (lesions improved completely after ~8 weeks)⁶⁷, reactivation of herpes zoster and herpes simplex⁵⁸. Most reactions improved without treatment within a few weeks⁵⁸, Guillain-Barré syndrome¹²⁸, subacute thyroiditis¹²⁹</p> | <p>Myocarditis was reported in one vaccine recipient, occurring 3 days after second dose⁵⁹</p> |

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| <p>~8 weeks)⁶⁷, lymphocytic vasculitis⁶⁸, varicella-zoster reactivation⁶⁹⁻⁷¹, Kikuchi-Fujimoto disease⁷², thrombotic thrombocytopenic purpura^{73,74}, IgA nephropathy flare-up⁷⁵, Guillain-Barré syndrome^{76,77}, pustular psoriasis⁷⁸, immunoglobulin A vasculitis⁷⁹, immune complex vasculitis⁸⁰, Rhabdomyolysis⁸¹, subacute thyroiditis⁸², Bell's Palsy⁸³, erythema multiforme⁸⁴, vaccine induced interstitial lung disease⁸⁵, macular neuroretinopathy⁸⁶, brachial neuritis⁸⁷, thyroid eye disease⁸⁸,</p> | <p>myelitis⁹⁴, Guillain-Barré syndrome^{95,96}, acute generalized exanthematous pustulosis⁹⁷, rhabdomyolysis^{98,99}</p> | <p>intracerebral haemorrhage¹⁰⁹, small vessel vasculitis^{101,110}, psoriasis¹¹¹, rosacea, raynaud's phenomenon⁹³, Ischaemic stroke¹¹², anaphylaxis¹¹³, recurrent herpes zoster^{114,xxiii}, generalized bullous fixed drug eruption¹¹⁵, Guillain-Barré syndrome^{77,116}, pityriasis rosea^{117,118}. Vaccination in individuals with adrenal insufficiency can lead to adrenal crises¹¹⁹, Dariers</p> | | | | |
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xxiii All cases occurred in patients with chornic urticaria and were being treated with cyclosporine.

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| | exacerbation of subclinical hyperthyroidism ⁸⁹ , rhabdomyolysis ⁹⁰ | | disease ¹²⁰ , vaccine induced acute localized exanthematous pustulosis ¹²¹ , Henoch-Schönlein Purpura ¹²² , rhabdomyolysis ¹²³ | | | | |
| Potential associated adverse events (causal links not yet proven) | Cerebral venous sinus thrombosis and intracranial haemorrhage ¹³⁰ , aseptic meningitis ¹³¹ , autoimmune hepatitis ^{132,133} , multiple sclerosis relapse ¹³⁴ , myeloperoxidase anti-neutrophil cytoplasmic antibody-positive optic perineuritis ¹³⁵ , central retinal vein occlusion ¹³⁶ , paracentral acute middle maculopathy & | Autoimmune hepatitis ¹³² , myocardial infarction ¹⁴⁰ , autoimmune haemolytic anaemia ¹⁴¹ , hypophysitis & panhypopituitarism ¹⁴² One case developed IgA Nephropathy after receiving the second dose of mRNA-1273 (causal link not yet proven) ¹⁴³ . | Autoimmune hepatitis ¹³² , Acute hyperglycaemic crisis ¹⁴⁴ , Facial nerve palsy, cervical myelitis ¹¹² , alopecia areata ¹⁴⁵ | Facial Diplegia ¹⁴⁶ | - | - | No available data |

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| | acute macular neurotinopathy ¹³⁷ , Stevens-Johnson syndrome/ toxic epidermal necrolysis ^{138,139} | | | | | | |
| Myocarditis data | <p>Mainly reported in young adults and adolescents ¹⁴⁷</p> <p>Israeli study: 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)¹⁴⁸</p> <p>Male patients Incidence of 4.12 (95% CI, 2.99-5.26) per 100,000 vaccinated¹⁴⁸</p> <p>Male patients (16-29 years)</p> | Mainly reported in young adults and adolescents ¹⁴⁷ | No available data | No available data | No available data | No available data | Myocarditis was reported as viral myocarditis. Participant fully recovered after 2 days of hospitalisation. No episode of anaphylaxis or vaccine-associated enhanced COVID-19 was reported ⁵⁹ |



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| Risk per 100,000 persons | | | | | | | |
| 1 st dose (male): 0.64 | | | | | | | |
| 2 nd dose (male): 3.83 | | | | | | | |
| 1 st dose (female): 0.07 | | | | | | | |
| 2 nd dose (female): 0.46 | | | | | | | |
| 1 st dose (male 16-19): 1.34 | | | | | | | |
| 2 nd dose (male 16-19): 15.07 ¹⁴⁹ | | | | | | | |

TRANSMISSION, PREVENTION & PROTECTION

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| Immunogenicity | <u>7-14 days after second dose:</u> 18-55 years: GMT ranged from 1.7 to 4.6 times the GMT of the convalescent serum ¹⁵⁰ . 65-85 years: GMT ranged from 1.1 to 2.2 times the GMT of the convalescent serum ¹⁵⁰ . | <u>14 days after second dose:</u> 18-55 years: PRNT ₈₀ GMT 654.3 (95% CI, 460.1-930.5) ¹⁵¹ . 56-70 years: PRNT ₈₀ GMT 878 (95% CI, 516-1494) ¹⁵² . ≥71 years: PRNT ₈₀ GMT 317 | <u>28 days after second dose median antibody titres:</u> 18-55 years: 20,713 AU/mL [IQR 13,898 - 33,550] ¹⁵³ 56-69 years: 16,170 AU/mL [IQR 10,233 - 40,353] ¹⁵³ . | <u>29 days after vaccination:</u> 18-55 years: GMC 586 (95% CI, 445-771) ; GMT 224 (95% CI, 168-298) ¹⁵⁴ . ≥65 years: GMC 312 (95% CI, 246-396) ; GMT 212 (95% CI, 163-266) ¹⁵⁴ . | <u>14 days after second dose:</u> 18-55 years: GMT 211.2 (95% CI, 158.9-280.6) ¹⁵⁵ . ≥60 years: GMT 131.5 (95% CI, 108.2-159.7) ¹⁵⁵ . | <u>Single dose (≥4 weeks):</u> 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) <u>Two doses (≥4 weeks):</u> 194.61±174.88 IU/ml (min: 0, max: 677.82) ; | <u>14 days after second dose (18-84 years):</u> 5-ug: IgG GMT 44,421 EU/ ml (95% CI, 37,929-52,024) ¹⁵⁷ . 25-ug: IgG GMT 46,459 EU/ml (95% CI, 40,839-52,853) ¹⁵⁷ . |
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| | | (95% CI, 181-557) ¹⁵² . | ≥70 years: 17,561 AU/mL [IQR 9,705 - 37,796] ¹⁵³ . | 57 days after vaccination: 18-55 years: 754 (95% CI, 592-961); GMT 288 (95% CI, 221-376) ¹⁵⁴ . | | 11.48% of participants did not develop sufficient antibody titres (<25.6 IU ml) ¹⁵⁶ . | |
| Transmission prevention | <p><u>Prior Delta Variant:</u> Vaccine effectiveness against infectiousness given infections 41.3%¹⁵⁸</p> <p>Vaccine effectiveness against transmission 88.5%¹⁵⁸</p> <p><u>During Delta Variant:</u> Similar Ct values (<25) were found in both vaccinated and unvaccinated groups¹⁵⁹</p> <p>Studies from Scotland and England</p> | <p>VE against onwards transmission: 52% (95% CI, 33-69)¹³</p> | <p>48% (limited data)</p> <p>May not be able to block the transmission of the alpha variant as efficiently as the wild type¹⁶².</p> | Limited data | Unknown | Unknown | Unknown |

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| | <p>demonstrated reductions in secondary infections among families of vaccinated individuals compared to families of unvaccinated individuals^{160,161}.</p> <p>VE against onwards transmission: 62% (95% CI, 57-67)¹³</p> | | | | | | |
| <p>Duration of protection</p> | <p>Median time between second dose and infection: 146 days (IQR, 121-167)¹⁶³</p> <p><u>Anti-SARS-CoV-2 Antibodies:</u> 1 month after 2nd dose: 1762 KU/L (IQR: 933-3761)</p> | <p><u>Preliminary phase I results:</u> Antibody activity remained high in all age groups at day 209 (approximately 6 months) GMT were lower in ≥56 years old¹⁶⁸</p> <p>36.4 (95% CI, 17.1-51.5) reduction of</p> | <p><u>Antibody Response:</u> 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:</p> | <p><u>Neutralizing antibodies:</u> Remained largely stable for 8-9 months¹⁷¹</p> <p><u>Binding antibodies:</u> Remained stable 6 months irrespective of age group¹⁷¹</p> | <p><u>Antibody Response:</u> 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)¹⁷³</p> | <p>A phase I/II clinical trial found that NAbs titres dropped below the seropositive cut-off of 8, 6 months after the administration of the first dose¹⁷⁴.</p> <p>80-90% of anti-S IgG and Nab titers against wild type waned 6 months</p> | <p>Unknown</p> |

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| <p>3 months after 2nd dose: 1086 KU/L (IQR: 629-2155) 6 months after 2nd dose: 802 KU/L (IQR, 447-1487)¹⁶⁴</p> <p>No health worker had antibodies BELOW method-dependent cut-off (0.8 KU/L)</p> <p>VE reduced by 22% (95% CI, 6-41) for every 30 days from the second dose for those aged 18 to 64 years²⁸.</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 dose¹⁶⁵</p> | <p>observed incidence rate (SARS-CoV-2 infection) if vaccinated from Dec 2020 – Apr 2021 than Jul 2021 – Dec 2020.¹⁶⁹</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 2021 than Jul 2021 – Dec 2020.¹⁶⁹</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-</p> | <p>0.30 GMR (CI, 0.24-0.39)¹⁷⁰</p> <p><u>Cellular Immune Response:</u> Day 182 after first dose: median of 237 SFUx10⁶ PBMC (IQR, 109-520)¹⁷⁰</p> <p>6 months after second dose: (median 1240, IQR 432-2002) in groups with 15-25 week interval between doses¹⁷⁰</p> <p>VE reduced by 7% (95% CI, -18 - 2) for every 30 days from the second dose for those aged 18 to 64 years²⁸.</p> <p><u>Anti-spike Protein RBD IgG Antibodies:</u> Younger age groups (<60):</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)¹⁷²</p> <p>A study observed sustained and stable vaccine effectiveness starting 14 days post vaccination to a maximum of 152 days after vaccination¹⁰.</p> <p>VE decreased from 89.4% in May to 51.7% in July²³</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)¹⁷³</p> | <p>after second vaccination¹⁷⁵</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)¹⁶⁶</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% seropositivity, 1.3 (IQR, 0.5-3.3)¹⁶⁶</p> |
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| <p>Effectiveness against Hospitalization and Death: 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 cases¹⁶⁵</p> | <p>180 days after vaccination.³⁰</p> <p>91% [January-March]</p> <p>71% (95% CI, 53-83) [April-May]</p> <p>63% (95% CI, 44-76)²³</p> | <p>1 month after 2nd dose: 100% seropositivity, 17.1 (IQR, 9.9-23.6)</p> <p>3 months after 2nd dose: 97% seropositivity, 6.5 (IQR, 3.5-9.3)¹⁶⁶</p> <p>Older age groups (≥60): 1 month after 2nd dose: 96% seropositivity, 13.3 (IQR, 6.9-27.7)</p> <p>3 months after 2nd dose: 90% seropositivity, 3.9 (IQR, 1.9-8.4)¹⁶⁶</p> | | | | |
| <p>Anti-spike Protein RBD IgG Antibodies: Younger age groups (<60): 1 month after 2nd dose: 100% seropositivity, 35.3 (IQR, 27.6-40.0)</p> <p>3 months after 2nd dose: 100% seropositivity, 19.2 (IQR, 8.2-23.1)¹⁶⁶</p> | | | | | | |
| <p>Older age groups (≥60): 1 month after 2nd dose: 100%</p> | | | | | | |

seropositivity, **29.4**
(IQR, 22.5-33.3)
3 months after 2nd
dose: 100%
seropositivity, **14.8**
(IQR, 7.4-18.7)¹⁶⁶

Sub-populations:

Older age (≥65):
38% to 42%
decrease of
humoral
antibodies
compared to 18-
to 45-year-old¹⁶⁷

Older age (≥65)
AND men:
37% to 46%
decrease
compared to 18-
to 45-year-old
women¹⁶⁷

Immunosuppress
ion:
65% to 70%
decrease
compared to non-
immunosuppressed¹⁶⁷

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| | Obesity (BMI ≥30): 31% increase in neutralizing antibody compared with nonobese ¹⁶⁷ | | | | | | |
| 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)¹⁷⁶.</p> <p><u>Children (5-11):</u> Ongoing trials¹⁷⁷</p> <p><u>Children (Under 5 years):</u> Ongoing trials¹⁷⁷</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)¹⁷⁸.</p> <p><u>Children (6month-11):</u> Ongoing trials¹⁷⁹</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 population¹⁸⁰.</p> | <p>No available data</p> <p>Announced at begging of April ongoing study in adolescents but paused to investigate blood clots in adult population¹⁸⁰.</p> | <p><u>Children (3-17):</u> Unknown. Ongoing clinical trial only looked at safety, tolerability, and immunogenicity^{xxiv} *</p> <p>* The study design administered three doses of 2 µg, 4 µg, or 8 µg of vaccine</p> | <p><u>Children (3-17):</u> Unknown. Clinical trial only looked at safety, tolerability and immunogenicity¹⁸¹.</p> | <p><u>Adolescents (16-17):</u> PREVENT-19 clinical trial^{xxv} expanded to assess efficacy, safety, and immunogenicity in 12–17-year-old adolescents¹⁸²</p> |

^{xxiv} 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)

^{xxv} 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>

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| <p>Immunogenicity</p> | <p><u>Adolescents (12-15) serum-neutralizing titer:</u> 1 month after 2nd dose had 1283.0 GMN₅₀ (CI, 1095.5-1402.5)¹⁷⁶.</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)¹⁷⁶.</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 antibody¹⁸³</p> <p><u>Children (Under 5):</u> Ongoing trials¹⁷⁷</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 (6month-11):</u> Ongoing trials¹⁷⁹</p> | <p>No available data</p> | <p>No available data</p> | <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 cohort¹⁸⁴</p> | <p><u>Children (3-17):</u> Neutralizing antibody response after 2nd dose (100%) with GMT ranging from 45.9-212.6¹⁸¹</p> | <p>Ongoing clinical trial¹⁸⁵</p> |

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| <p>Safety and Adverse events</p> | <p><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%)¹⁷⁶.</p> <p><u>Adolescent/young adults (16-25):</u> 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%)¹⁷⁶.</p> <p><u>Children (5-11):</u> Preliminary results on safety profile</p> | <p><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%)</p> <p>Few reported cases of acute myocarditis and pericarditis (mainly in males)¹⁸⁶</p> <p><u>Children (6month-11):</u> Ongoing trials¹⁷⁹</p> | <p>No available data</p> | <p>No available data</p> | <p><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%)</p> <p>Most common systemic reactions in all three age cohorts were mild to moderate fever and cough</p> <p>Adverse events were mostly mild to moderate in severity¹⁸⁴</p> | <p><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%) Fever (25%)¹⁸¹</p> | <p>Ongoing clinical trial¹⁸⁵</p> |
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| | are consistent with those observed in older populations ¹⁸³ | | | | | | |
| | <u>Children (Under 5):</u> Ongoing trials ¹⁷⁷ | | | | | | |
| Myocarditis Data | Few reported cases of acute myocarditis and pericarditis in 16-25 year olds (mainly in males) ¹⁸⁶ | Few reported cases of acute myocarditis in adolescents and young adults | No available data | No available data | No available data | No available data | No available data |
| HETEROLOGOUS VACCINATION | | | | | | | |
| Vaccine Schedule | BNT162b2/ChAd Ox1 Administration of ChAdOx1 as second/booster dose | ChAdOx1/mRNA-1273 Administration of mRNA-1273 as second/booster dose | ChAdOx1/BNT162b2 Administration of BNT162b2 as second/booster dose | Not Applicable (one dose schedule) For more information refer to booster section | BBIBP/BNT162b2 | CoronaVac/ChAd Ox1 Press releases have confirmed that Thailand will use the AstraZeneca vaccine as the | Ongoing trial ¹⁸⁷ (Com-Cov2) ^{xxvii} |

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

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| | | | | | | second dose for individuals whose first dose was Sinovac ^{xxvi} | |
| Vaccine 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)¹⁸⁸.</p> <p><u>SFC frequency (T0cell ELISpot):</u> Heterologous (99 SFC/10⁶ PBMCs) vs. Homologous (80 SFC/10⁶ PBMCs)¹⁸⁸.</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%)¹⁸⁹.</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 14¹⁹⁰.</p> <p><u>IgG antibody titres:</u> Heterologous (3684 BAU/mL) vs. Homologous (101.2 BAU/mL) at day 14¹⁹⁰.</p> | <p>Not Applicable (one dose schedule)</p> <p>For more information refer to booster section</p> | <p>Unknown (ongoing clinical trial)⁴⁹</p> | <p>CoronaVac/Conv idecia</p> <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)¹⁹¹</p> <p>CoronaVac/Conv idecia <u>Neutralizing antibodies :</u> Heterologous</p> | <p>No available data</p> <p>Ongoing trial¹⁸⁷</p> |

^{xxvi} 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/>

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| | | *Results based on immunosuppressed population | <u>Neutralizing antibodies:</u> Heterologous (100%) at day 14 vs. Homologous (30%) at day 14 ¹⁹⁰ . | | | 54.4 GMT (95% CI, 37.9-78) vs. Homologous CoronaVac 12.8 GMT (95% CI, 9.3-17.5) ¹⁹² | |
| Vaccines Reactogenicity | Observed increase in systemic reactogenicity after boost in heterologous schedules in comparison with homologous schedules ¹⁸⁸ | *Adverse events in heterologous and homologous vaccination groups were very similar ¹⁸⁹ . *Majority of adverse events self-reported were Pain at injection site, Swelling at injection site, Fever, Headaches, Fatigue, Chills, GI effects, Myalgia, Arthralgia ¹⁸⁹ . | <u>Adverse events in heterologous:</u> Headache (44%) , Myalgia (43%) , Malaise (42%) , Fever (2%) , Injection site pain (88%) , Induration (35%) , Erythema (31%) ¹⁹⁰ . <u>Severity of adverse events in heterologous:</u> Mild (68%) , Moderate (30%) , Severe (2%) ¹⁹⁰ . | Not Applicable (one dose schedule) For more information refer to booster section | Unknown (ongoing clinical trial) ¹⁹³ | CoronaVac/ChAd Ox1: Unknown CoronaVac/Conv idecia: Conv idecia recipients reported more adverse reactions and reported higher occurrence of solicited injection-site pain) ¹⁹² | No available data Ongoing trial ¹⁸⁷ |
| | <u>Adverse events in heterologous:</u> Adverse events (90) Grade 1 (54.4%) Grade 2 (37.8%) Grade 3 (7.8%) Grade 4 (0%) Arthralgia, Migraine, Back Pain ¹⁸⁸ . | *Results based on immunosuppressed population | | | | | |
| | <u>Adverse events in homologous:</u> | | | | | | |

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| | Adverse events (81) Grade 1 (59.3%) Grade 2 (39.5%) Grade 3 (1.2%) Grade 4 (0%) ¹⁸⁸ . | | | | | | |
| BOOSTER DOSES | | | | | | | |
| Vaccine Schedule | <i>Homologous:</i> BNT162b2/BNT162b2 | <i>Homologous:</i> mRNA-1273/mRNA-1273 | <i>Homologous:</i> ChAdOx1/ChAdOx1 | <i>Homologous:</i> Ad26.CoV.2.S/Ad26.CoV.2.S <i>Heterologous:</i> BNT162b2/Ad26.CoV.2.S | <i>Homologous:</i> SinoPharm/SinoPharm <i>Heterologous:</i> SinoPharm/BNT162b2 | <i>Homologous:</i> CoronaVac/CoronaVac <i>Heterologous 1:</i> CoronaVac/ChAdOx1 <i>Heterologous 2:</i> CoronaVac/BNT162b2 | <i>Homologous:</i> NVX-CoV2373/NVX-CoV2373 <i>Heterologous:</i> Ongoing trial of heterologous booster shot using NVX-CoV2373 ^{xxviii} |
| Approved Administration | <i>Israel:</i> 12-year-old and over can received homologous booster shot 5 months after full jab ^{xxix} | Phase II booster trial of three booster doses are ongoing ¹⁹⁴ Moderna sought FDA approval of | Preliminary results on tolerability and immunogenicity of third dose of ChAdOx1 vaccines showed strong boost to the | Johnson & Johnson has said it will submit all of their new data to the FDA for potential consideration for | <i>UAE:</i> Offering booster doses of Pfizer and Sinopharm to people who received full | Turkey and the United Arab Emirates began homologous booster shots | Ongoing phase II trials ¹⁹⁶ Results below are based on |

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

^{xxix} 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/>

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| | <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^{xxx}</p> | <p>its COVID-19 vaccine booster^{xxxi}</p> <p><u>United States:</u> Starting September, adults who received mRNA vaccine 8 months ago are eligible for booster.</p> | <p>immune response¹⁹⁵</p> | <p>adding a booster dose and consideration to authorize two-dose regimen^{xxxii}</p> | <p>Sinopharm jab ≥6 months ago</p> | <p>Indonesia and Thailand are considering giving homologous booster shot to HCW^{xxxiii}</p> | <p>ongoing phase II trial</p> |
| Time-to-booster dose | 6 months to 8 months after | 6 months to 8 months after | 6-9 months after initial two-dose regimen | <u>Homologous:</u> | 6 months after initial two-dose regimen | <u>Homologous:</u> 6 months to 12 months | 6 months after initial two-dose |

^{xxx} 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/>

^{xxxi} 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/>

^{xxxii} 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>

^{xxxiii} 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/>

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| | initial two-dose regimen Israel offers up to 5 months after initial two-dose regimen | initial two-dose regimen | | 6 months after one dose regimen ¹⁷¹ <u>Heterologous:</u> 4 months after initial two-dose BNT162b2 regimen ¹⁹⁷ | | After primary vaccination 8 months after the primary vaccination to healthy adults ≥ 60 years <u>Heterologous 1:</u> 21 to 26 days after full jab of CoronaVac <u>Heterologous 2:</u> 6 months after primary vaccination of CoronaVac | regimen (189 days) ¹⁹⁶ |
| Immunogenicity | <u>Neutralizing titers:</u> Elicits >5-8 more for wild type after 6 months after 2 nd dose ¹⁹⁸ | Booster doses (mRNA1273 or mRNA1273.351) increased neutralizing antibody titers against wild-type ¹⁹⁹ | <u>Antibody Levels:</u> Higher levels after third dose (tIgG EU 3746 ; IQR: 2047-6420) ¹⁹⁵ <u>Spike Cellular Immune Response:</u> Increased from 200 SFUx10⁶ PBMC (IQR, 127-389) after the second dose to | <u>Homologous:</u> 5X10 ¹⁰ vp booster dose elicited 9-fold increase at day 7 compared to first dose after 29 days in 18-55-year-olds ¹⁷¹ 1.25X10 ¹⁰ vp booster dose elicited 6-7.7-fold increase at day 28 compared to first | Ongoing trial ¹⁹³ | <u>Homologous:</u> Neutralizing Antibodies: 60% higher NAbs activity against wild-type compared to 2-doses ¹⁷⁵ Anti-S IgG and NAbs: 20-fold increase 4 weeks post | <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) ¹⁹⁶ <u>Wild-type Neutralizing Response:</u> |

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| | | <p>399 SFUx10⁶ PBMC (IQR, 314-662) after the third one¹⁹⁵</p> | <p>dose after 29 days in 18-55 and ≥65-year-old¹⁷¹</p> <p><u>Heterologous:</u> 14.8 to 32.4-fold increase in neutralization titers against wild-type virus¹⁹⁷</p> | | <p>booster vaccination NAbs were maintained 60 to 180 days post booster¹⁷⁵</p> <p><u>Heterologous 1:</u> Heterologous vaccination had a 9-fold greater GMT (7,947 U/mL) than fully vaccinated with AZD1222 and the highest antibody response, IgA, and neutralizing antibodies than other groups²⁰⁰</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</p> | <p>Increase of 4.3-fold compared to peak response after 2nd dose (IC50 = 6231; 95% CI: 4738-8195)¹⁹⁶</p> <p><u>Older Participants (60-84):</u> 5.4-fold increase in antibody response¹⁹⁶</p> <p><u>Younger Participants (18-59):</u> 3.7-fold increase in antibody response¹⁹⁶</p> |
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| | | | | | | <p>factor of 46.6 but IgG-N titers decreased by factor of 6.5²⁰¹</p> <p>Single booster dose of BNT162b2 induced higher anti-spike RBD IgG antibody levels, compared to single booster dose of CoronaVac¹⁶⁶</p> | |
| Immunogenicity against variants | <p><u>Beta (B.1.351):</u> Elicits 15-21 more neutralizing titers for Beta variant after 6 months after 2nd dose¹⁹⁸</p> <p><u>Delta (B.1.671.2):</u> >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</p> | <p>Preliminary results of booster doses of mRNA-1273 vaccine show robust antibody response against Delta variant¹⁹⁴</p> | <p>Third dose provided higher antibody titers against Alpha, Beta, and Delta variants¹⁹⁵</p> | <p><u>Homologous:</u> No available data</p> <p><u>Heterologous:</u> 10.9 to 21.2-fold increase in pseudovirus neutralization assay (one volunteer did not have any against fB.1.351)¹⁹⁷</p> | Ongoing trial ¹⁹³ | <p><u>Homologous:</u> Beta (B.1.351): 3.0-fold decrease in neutralizing antibodies compared to wild type¹⁷⁵</p> <p>Gamma (P.1): 3.1-fold decrease in neutralizing antibodies compared to wild type¹⁷⁵</p> <p>Delta (B.1.671.2):</p> | <p>High levels of functional antibodies against Alpha (B.1.1.7), Beta (B.1.351), and Delta (B.1.671.2)¹⁹⁶</p> <p><u>Delta (B.1.671.2):</u> Increase of 6.6-fold in antibody response compared to Delta response observed with</p> |

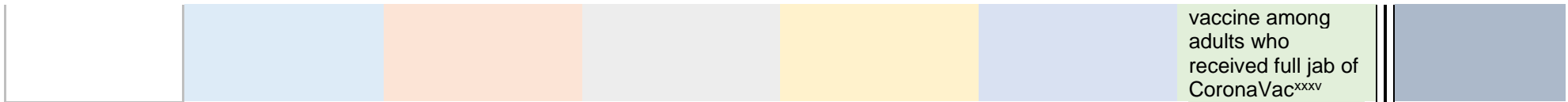
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| | compared to dose 2 titers in 65–85-year-olds ¹⁹⁸ | | | | | <p>2.3-fold decrease in neutralizing antibodies compared to wild type</p> <p>2.5-fold higher neutralizing potency than 2-dose vaccination¹⁷⁵</p> <p><u>Heterologous 1:</u> Neutralizing activity 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.1.351²⁰⁰</p> | primary vaccination ¹⁹⁶ |
| Reactogenicity | Preliminary results show consistent tolerability ¹⁹⁸ | Similar safety and tolerability compared to second dose ¹⁹⁴ <u>Common solicited local adverse events:</u> | Lower reactogenicity after third dose compared to first dose ¹⁷⁰ | No available data | Ongoing trial ¹⁹³ | <p>The third shot is considered to be safe¹⁷⁴.</p> <p><u>Common side effects:</u> Pain at the injection site.</p> | <p>Booster dose was well tolerated</p> <p>Local and systemic reactogenicity increased between Dose</p> |

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| | | <p>Injection-site pain (68.4% for mRNA-1273.351, 90% for mRNA-1273)</p> <p>fatigue (36.8% for mRNA-1273.351, 70% for mRNA-1273)</p> <p>headache (36.8% for mRNA1273.351, 55.0% for mRNA-1273)</p> <p>myalgia (31.6% for mRNA-1273.351, 45.0% for mRNA-1273)</p> <p>arthralgia (21.1% for mRNA-1273, 50.0% for mRNA-1273)¹⁹⁹</p> | | | | <p><u>Adverse events:</u> Unrelated to the vaccination</p> | <p>1, Dose 2, and Dose 3</p> <p>90% of symptoms were rated as mild or moderate¹⁹⁶</p> |
| <p>Protection against COVID-19</p> | <p><u>Confirmed Infection:</u></p> <p>Youngest age group (16-29): 17.6 (95% CI, 15.6-19.9) lower rate in booster group²⁰²</p> <p>30-39 age group:</p> | No available information | No available information | No available information | No available information | No available information | No available information |



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| | <p>rate in booster group²⁰²</p> <p>Older population (≥60): 19.5 (95% CI, 12.9-29.5) lower rate in booster group²⁰³</p> <p>18.7 (95% CI, 15.7-22.4) lower rate in booster group²⁰²</p> | | | | | | |
| Other | <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%²⁰⁴</p> | | | | | <p>For more detailed information regarding immunogenicity of third dose refer to study^{xxxiv}</p> <p>Ongoing clinical trial examining the immunogenicity and safety of a third dose vaccination with ChAdOx1 or BNT162b2</p> | |

^{xxxiv} 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>



^{xxxv} 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 | Novavax/ NVX-CoV2373 |
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| | FURTHER INFORMATION | | | | | | |
| Storage conditions | 2°C to 8 °C (for 1 month) | 2°C to 8 °C (for 1 month) | 2°C until 8 °C | 2°C to 8 °C (for 3 months) | 2°C until 8 °C | 2°C until 8 °C | 2°C to 8 °C |
| Approving authorities | FDA (11.12.20) ^{xxxvi} ; EMA (21.12.20); WHO EUL (31.12.20); and list of countries (including Switzerland – | FDA (18.12.20); EMA (06.01.21); WHO EUL (30.04.21); and list of 51 countries (including Switzerland – approved 12.01.21) | FDA (awaiting on approval); EMA (29.01.21); WHO EUL (15.02.21); and list of 121 countries (Switzerland | FDA (27.02.21); EMA (11.03.21), WHO EUL (12.03.21), and list of 59 countries (including Switzerland – approved 22.03.21) | WHO EUL (07.05.21); and list of 55 countries (e.g., Argentina, Bahrain, Brazil, China, Indonesia, United Arab Emirates, Zimbabwe) | WHO EUL (01.06.21), and list of 33 countries (e.g., Albania, Chile, Egypt, Hong Kong, Malaysia, Tunisia, Turkey, Ukraine) | Waiting on approval (Not-yet-approved by countries or WHO for emergency use) |

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

| | approved on 20.12.20) | | awaiting on approval) | | | | |
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| EFFICACY | | | | | | | |
| Single dose^{xxxvii} | 52% (95% CI, 29.5 to 68.4; starting at 12 days) or 82.2% (75.1 to 87.3; starting at ≥14 days) ²⁰⁵ . 91% (95% CI, 85-94) ²⁰⁶ . | 95.2% (95% CI, 91.2.8 to 97.4; starting at >14 days) ⁵¹ . | 72.8% (starting at 22 days up to 60 days) ²⁰⁷ . 88% (95% CI, 75-94) ^{206, xxxviii} | Single dose vaccine | Unknown | 35.1% (95% CI, -6.6 to -60.5) [conducted in a setting with high P.1 transmission] ²⁰⁸ . | 83.4% (95% CI, 73.6-89.5) starting at ≥14 days ⁵⁹ |
| Two doses^{xxxix} | 95.0% (95% CI, 90.3-97.6) starting at ≥7 days in population without prior SARS-CoV-2 infection ⁶⁵ 94.6% (95% CI, 89.9-97.3) starting at ≥7 days in | 94.1% (95% CI, 89.3-96.8) after median follow-up of less than 63 days ⁵¹ 93.2% (95% CI, 91.0-94.8) ²⁰⁹ | 63.1% (95% CI, 51.8-71.7) starting at ≥14 days for two standard doses ²⁰⁷ 80.7% (95% CI, 62.1-90.2) starting at ≥14 days for first low dose and | 66.9% (95% CI 59.0-73.4) after 14 days and 66.1% (95% CI 55.0-89.1) after 28 days for VE against moderate-severe-critical COVID-19 ²¹⁰ | 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). ¹²⁶ | After 14 days, efficacy against symptomatic cases was 50.7% (95% CI 35.9 to 62.0). ⁵⁷ 99.17% of NAb titres were above or equal to the | 89.7% (95% CI, 80.2-94.6) starting at ≥7 days ⁵⁹ 90.4% (95% CI, 82.9-94.6) ²¹² 100% (95% CI, 87-100) against moderate-to- |

^{xxxvii} Against SARS-COV-2 infection

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

^{xxxix} Against SARS-CoV-2 infection.

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| | population with or without prior infection ⁶⁵ | <u>Against severe disease:</u> 98.2% (95% CI, 92.8-99.6) ²⁰⁹ | standard second dose ²⁰⁷ 66.7% (95% CI, 57.4-74.0) starting at ≥14 days for pooled analysis efficacy ²⁰⁷ | 76.7% (95% CI 54.6 to 89.1) after 14 days and 85.4% (95% CI 54.2 to 96.9) after 28 days for VE against severe-critical COVID-19 ²¹⁰ | | Nab positivity cut-off (20 units) against wild-type ²¹¹ . | severe COVID-19 ²¹² 100% (95% CI, 34.6-100) against severe COVID-19 ²¹² |
| Against asymptomatic infection | 90% (starting at 14 days) regardless of symptom status ²¹³ | 63.0% (95% CI, 56.6-68.5) ²⁰⁹ | 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) ²¹⁰ . | 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) ¹²⁶ . | Unknown | Unknown |
| EFFICACY AGAINST VARIANTS | | | | | | | |
| Alpha (B.1.1.7) | Two doses of the vaccine effectively neutralize the B.1.1.7 variant and the D614G substitution ²¹⁴ . | NAbs remained high and consistent with titres of the wildtype for the B.1.1.7 variant ²¹⁵ . | 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.1.1.7 ¹⁶² . | 3.6-fold reduction in neutralization capacity when compared to wild-type. | Demonstrated reduced neutralizing capacity. However, there were no differences in the NAbs titres against B.1.351 in vaccinated individuals vs. | 10.4-fold reduction in neutralization capacity when compared to natural infection sera ²¹¹ . 85.83% of NAb titres were above or equal to the | Two dose efficacy against the B.1.1.7 variant 86.3% (95% CI, 71.3-93.5) ⁵⁹ 93.6% (95% CI, 81.7-97.8) against the Alpha variant ²¹² |

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| | | | | | those naturally infected, suggesting the vaccine has a similar level of protection against infection as natural infections ²¹⁶ . | Nab positivity cut-off (20 units) against wild-type ²¹¹ . Neutralization decreased by 4.1-fold when compared to wild-type ²¹⁷ . | |
| Beta (B.1.351) | Neutralization was diminished by a factor of 5 . Despite this, the BNT162b2 mRNA vaccine still provides some protection against B.1.351 ²¹⁸ . 100% (95% CI, 53.5-100) ²¹⁹ . | NAbs were 6-fold lower. Nevertheless, NAbs were still found to be protective ²¹⁵ . | Two doses of the vaccine had no efficacy against the B.1.351 (VE = 21.9% ; 95% CI, -49.9 to 59.8) ²²⁰ . | 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) ²¹⁰ . Demonstrated 3.6-fold reduction in neutralization sensitivity ²²¹ . Neutralization titres were decreased by 6.7-fold ²²² . | 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 ²¹¹ . 82.5% of Nab titres were above or equal to the Nab positivity cut-off (20 units) against wild-type ²¹¹ . | 51.0% (95% CI, -0.6-76.2) efficacy against B.1.351 variant ²²³ |

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| <p>Gamma (P.1)</p> | <p><u>Single dose:</u> ≥21 days: 83% against hospitalization and death²²⁴.</p> <p><u>Two doses:</u> ≥14 days: 98% against hospitalization and death²²⁴.</p> | <p>3.2-fold reduction in neutralization capacity when compared to wild-type²²⁵.</p> | <p><u>Single dose:</u> ≥21 days: 94% against hospitalization and death²²⁴.</p> <p><u>Two doses:</u> 64% (95% CI, -2-87) [n=18]²²⁶</p> <p><u>Efficacy against Zeta (P.2) [2 doses]:</u> 69% (95% CI, 55-78)²²⁶</p> | <p>Demonstrated 3.4-fold reduction in neutralization sensitivity²²¹.</p> | <p>No published data</p> | <p>49.6% against P.1 (>14 days after 1st dose)²⁰⁸.</p> <p>Neutralization decreased by 7.5-fold when compared to wild-type²¹⁷.</p> | <p>No available data</p> |
| <p>Delta (1.671.2)</p> | <p>Reduced NAb activity relative to B.1.1.7 strain²²⁷.</p> | <p>2.1-fold reduction in neutralization capacity when compared to wild-type²²⁵.</p> | <p><u>Single dose:</u> ≥21 days: 90% against hospitalization and death²²⁴.</p> | <p>Demonstrated 1.6-fold reduction in neutralization sensitivity²²¹.</p> <p>Neutralization titres were decreased by 5.4-fold²²².</p> | <p>Demonstrated reduced neutralizing capacity. However, there were no differences in the NAb 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</p> | <p>NT_{GM} 24.48 (95% CI, 19.2-31.2)²¹¹.</p> <p>69.17% of NAb titres were above or equal to the NAb positivity cut-off (20 units) against wild-type²¹¹.</p> | <p>No available data</p> |

| | | | | | natural infections ²¹⁶ . | | |
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| PHASE III TRIALS RESULTS^{x1} | | | | | | | |
| Number of participants (vaccine/ placebo) | 43,448 (21,720/ 21,728) ⁶⁵ | 30,420 (15,210/15,210) ⁵¹ | 17,178 (8597/8581) ²⁰⁷ | 39,321 (19,630/19,691) ²¹⁰ | 26,917 (13,459/13,458); or 26,914 (13,465/13,458) ¹²⁶ | 9,823 (4,953/4,870) ⁵⁷ | 14,039 (7,020/7,019) ⁵⁹ |
| Total COVID-19 cases (vaccine/ control) | 170(8/162) ⁶⁵ | 196 (11/185) ⁵¹ | 332 (84/248) ²⁰⁷ | 464 (116/348) ²¹⁰ | 121(26/95) or 116(21/95) ¹²⁶ | 253(85/168) ⁵⁷ | 106(10/96) ⁵⁹ |
| 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% | 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) ⁵¹ . | 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 | 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% | 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 | After 14 days, efficacy against symptomatic cases was 50.7% (95% CI 35.9 to 0-62.0). ⁵⁷ | 83.4% (95% CI, 73.6-89.5) starting at ≥14 days after first dose ⁵⁹ 89.7% (95% CI, 80.2-94.6) starting at ≥7 days after second dose ⁵⁹ |

^{x1} Phase III trials were conducted between 27 July and 14 November 2020 for BNT162b2/ COMIRNATY, 27 July and 23 October 2020 for Spikevax/ Moderna, 23 April and 6 December 2020 for Vaxzevria/ ChAdOx1 nCoV-19/ AZD1222/ Covishield, 21 September 2020 and 22 January 2021 for Janssen Covid-19 vaccine/ Johnson & Johnson, 16 July and 20 December 2020 for Sinopharm/ BBIB-CorV, 21 July and 16 December 2020 for the Sinovac/ CoronaVac vaccine, and 28 September 2020 and 28 November 2020 for the Novavax vaccine. All trials were conducted prior to the transmission of the more contagious variant strains, particularly the delta variant (B.1.617.2). Studies are currently ongoing to determine the effectiveness of the vaccines against the delta variant.

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| | (95% CI, 89.9 to 97.3) in population with or without prior infection. 100% among adolescents (12-15 years old) ⁶⁵ . | | was 80.7% (95% CI 62.1 to 90.2). Pooled analysis efficacy was 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) ²⁰⁷ . | CI 55.0 to 89.1) after 28 days. VE against severe-critical COVID-19 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 ²¹⁰ . | 86.3; in HBO2 vaccine) ¹²⁶ . | | |
| Efficacy against hospitalization and death | 100% (after 7 days) ⁶⁵ | 100% (≥14 days) ⁵¹ | 100% (after 21 days) ²⁰⁷ | 76.7% (≥14 days) or 85.4% (≥28 days) ²¹⁰ | 100% (>14 days) ¹²⁶ | 100% (>14 days) ⁵⁷ | 100% (after 7 days) ⁵⁹ . |
| 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 ^{48,228} . | 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 | 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): | 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), | 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 ⁵⁶ . | 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 ⁵⁷ . | <u>Phase II:</u> Nine serious adverse events were reported, only one of which was assessed as related to the vaccine: acute colitis ¹⁵⁷ . |

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| | | case occurred in the placebo group ⁵¹ . | transverse myelitis, haemolytic anaemia and a case of fever higher than 40°C ⁵³ . | hypersensitivity (1), Bell's Palsy (2), & severe generalized weakness, fever & headache (1) ²¹⁰ . | | | |
| 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><u>2-DOSE EFFICACY</u></p> <p><u>Efficacy against symptomatic (moderate to severe/ critical) SARS-CoV-2 infection</u></p> <p>94% (95% CI, 58-100) in the US.</p> <p>75% (95% CI, 55-87) globally.¹¹</p> <p><u>Efficacy against severe/ critical SARS-CoV-2 infection</u></p> <p>100% (95% CI, 33-100)¹¹</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)^{xli} | Spikevax/ Moderna COVID-19 Vaccine/ mRNA-1273 (Moderna, USA)^{xlii} | Vaxzevria/ ChAdOx1 nCoV-19/ AZD1222/ Covishield (AstraZeneca/Oxford, UK, India)^{xliii} | Janssen COVID-19 vaccine/Johnson & Johnson (Janssen, USA)^{xliv} | Sinopharm/BBIB P-CorV, China^{xlv} | Sinovac CoronaVac, China^{xlvi} | Novavax/ NVX-CoV2373 |
| EUL holder | BioNTech Manufacturing GmbH (Germany) | ModernaTX, Inc. (USA) ¹ Moderna Biotech (Spain) ² | AstraZeneca AB (Sweden) | Janssen-Cilag International NV (Belgium) | Beijing Institute of Biological Products Co., Ltd. (BIBP) (China) | Sinovac Life Sciences Co., Ltd. (China) | Novavax (USA) |

^{xli} 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>

^{xlii} 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>

^{xliii} 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>

^{xliv} 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>

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

^{xlvi} 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>

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| Production sites (Drug substance) | <p>BioNTech Manufacturing GmbH (Mainz, Germany)</p> <p>BioNTech Manufacturing Marburg (Marburg, Germany)</p> <p>Rentschler Biopharma SE (Laupheim, Germany)</p> <p>Wyeth BioPharma Division of Wyeth Pharmaceuticals (USA)</p> | <p>Lonza Biologics, Inc., (USA)¹</p> <p>Moderna TX, Inc. (USA)¹</p> <p>Lonza AG (Switzerland)²</p> | <p>Henogen S.A (Belgium)</p> <p>Catalent Maryland, Inc. (USA)</p> <p>Oxford Biomedica (UK) Ltd. (United Kingdom)</p> <p>SK Bioscience (Republic of Korea)</p> <p>Halix B.V (Netherlands)</p> <p>WuXi Biologics (China)</p> | <p>Janssen Vaccines & Prevention B.V. (The Netherlands)</p> <p>Janssen Biologics B.V. (The Netherlands)</p> <p>Emergent Manufacturing Operations Baltimore LLC (USA)</p> | <p>Beijing Institute of Biological Products Co., Ltd. (China)</p> | <p>Sinovac Life Sciences Co., Ltd. (China)</p> | <p>Novavax (Bohumil, Czech Republic)</p> |
| Production sites (Drug product) | <p>Baxter Oncology GmbH (Halle/Westfallen, Germany)</p> <p>BioNTech Manufacturing GmbH (Mainz, Germany)</p> <p>Pfizer Manufacturing Belgium NV</p> | <p>Baxter Pharmaceutical Solutions, LLC. (USA)¹</p> <p>Catalent Indiana, LLC. (USA)¹</p> <p>Rovi Pharma Industrial Services, S.A. (Spain)²</p> | <p>Catalent Anagni (Italy)</p> <p>CP Pharmaceuticals (United Kingdom)</p> <p>IDT Biologika (Germany)</p> <p>SK Bioscience (Republic of Korea)</p> | <p>Janssen Biologics B.V. (The Netherlands)</p> <p>Janssen Pharmaceutica NV (Belgium)</p> <p>Aspen SVP. (South Africa)</p> <p>Catalent Indiana LLC. (USA)</p> | <p>Beijing Institute of Biological Products Co., Ltd. (China)</p> | <p>Sinovac Life Sciences Co., Ltd. (China)</p> | <p>Novavax (Bohumil, Czech Republic)</p> |

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|------------------------------|---|---|---|---|---|---|---|
| | (Belgium) Novartis Pharma Stein AG (Switzerland) | | Universal Farma, S.L. ("Chemo") (Spain) | Grand River Aseptic Manufacturing Inc. (USA) | | | |
| | Mibe GmbH Arzneimittel (Brehna, Germany) | | Amylin Ohio LLC (USA) | Catalent Anagni S.R.L. (Italy) | | | |
| Diluent suppliers | Pfizer Perth, Australia | - | - | - | - | - | - |
| | Fresenius Kabi, USA | | | | | | |

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