Literature screening report

COVID-19 vaccines in the WHO's Emergency Use Listing (EUL) Report (Updated Version 7)

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Abstract

This report focuses on the World Health Organization's (WHO) Emergency Use Listing (EUL) of authorized vaccines as of 02 November 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, mRNA COVID-19 vaccine for children, duration of protection and waning immunity, and booster doses.

Content

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, 49.6% of the world populations, of which only 3.7% of people in low-income countries, have received at least one dose of a marketed COVID-19 vaccine as of 02 November 2021[1]. Currently, six vaccines [namely, Pfizer-BioNTech, USA), Spikevax/Moderna COVID-19 Vaccine/ mRNA-1273 (Moderna, USA), Vaxzevria/ChAdOx1 nCoV-19/AZD1222/Covishield (AstraZeneca/Oxford, UK, India), Janssen Covid-19 vaccine/Johnson & Johnson (Janssen, USA), Sinopharm/BBIBP- CorV (China), and Sinovac/CoronaVac (China)] were assessed and granted an authorization by WHO as of 20 October 2021. **Articles regarding the latest data on vaccine effectiveness, the duration of protection and waning immunity, efficacy and heterologous booster doses, and mRNA vaccines in children (5-15), 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 02.11.2021).

Methodology

We screened the data for the EUL-accepted vaccines and the vaccine candidate Novavax as of 02 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 reports[2].

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 for the Pfizer-BioNTech, Moderna and Janssen vaccines

Studies continue to report waning mRNA vaccine protection over time. The latest data published over the month of October demonstrates that Pfizer-BioNTech's BNT162b2/ Comirnaty vaccine effectiveness steadily declines until approximately four months after the administration of the second dose and then stabilises around the **50%** effectiveness mark (see synoptic table below). A large-scale U.S study reported BNT162b2 effectiveness was **53% (95% CI, 39-65)** and **47% (95% CI, 43-51)** four and five months after the second dose, respectively[3]. A Puerto Rican study additionally corroborates the US data: four months after the second dose, effectiveness waned from **87% (95% CI, 85-89)** to **56% (95% CI, 53-59)**[4]. A similar study that utilised U.S.

[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] 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

[4] Time varying effectiveness of three COVID-19 vaccines in Puerto Rico. *medRxiv.* https://www.medrxiv.org/content/10.1101/2021.10.17.21265101v2

Veterans Health Administration (VHA) data, observed a large decline in vaccine protection from March 2021 [**91% (95% CI, 91-92)]** to August 2021 [**50% (95% CI, 47-52)]** for BNT162b2[5]. These declines in vaccine protection are in part due to the more transmissible and infectious Delta variant and waning vaccine immunity over time[6].

Moderna's mRNA-1273 vaccine also demonstrates waning vaccine immunity over time, however, the vaccine continues to demonstrate higher effectiveness levels (approximately between **60[7] and 70%**[8]) than Pfizer-BioNTech's mRNA vaccine.

Two studies published over the month of October observed large declines in Janssen's single dose Ad26.COV2.S vaccine. In Puerto Rico, Janssen's vaccine effectiveness declined from **58% (95% CI, 51-65)** to **27% (95% CI, 17-37)** four months after the administration of the second dose[9], while a U.S. preprint observed a decline from **88% (95% CI, 98-89)** to **3% (95% CI, -7–12)** in vaccine effectiveness[10]. The authors did not provide an explanation for Janssen's extremely low effectiveness, however it could be impacted by the study's older population demographic (past studies have reported larger declines in vaccine protection over time among older persons (≥65 years) than younger individuals[11,12,13,14]); approximately 50% of the participants (*N*=301,861 out of

[5] Breakthrough SARS-CoV-2 infections in 620,000 U.S. Veterans, February 1, 2021 to August 13, 2021. *medRxiv.* https://www.medrxiv.org/content/10.1101/2021.10.13.21264966v1

[6] See SSPH+ and FOPH Literature Screening Report. COVID-19 vaccines and post-vaccination data: Literature update (10) – October 2021.

[7] mRNA vaccine effectiveness against asymptomatic SARS-CoV-2 infection 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

[8] Time varying effectiveness of three COVID-19 vaccines in Puerto Rico. *medRxiv.* https://www.medrxiv.org/content/10.1101/2021.10.17.21265101v2

[9] Time varying effectiveness of three COVID-19 vaccines in Puerto Rico. *medRxiv.* https://www.medrxiv.org/content/10.1101/2021.10.17.21265101v2

[10] Breakthrough SARS-CoV-2 infections in 620,000 U.S. Veterans, February 1, 2021 to August 13, 2021. *medRxiv.* https://www.medrxiv.org/content/10.1101/2021.10.13.21264966v1

[11] Prior infection and age impacts antibody persistence after SARS-Cov-2 mRNA vaccine. *Clinical Infectious Diseases.* https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab850/6373987

[12] 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

[13] Effectiveness of MRNA-1273 against Delta, Mu, and other emerging variants. *medRxiv*. https://www.medrxiv.org/content/10.1101/2021.09.29.21264199v1.full

[14] 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

619,755) were aged 65 and above[15]. Despite Ad26.COV2.S low effectiveness against SARS-CoV-2 infection, it has been demonstrated to maintain high effectiveness against hospitalization **72.9% (95% CI, 35.1-91.1)** between the months of June and September in a Brazilian population[16]. Unfortunately, the Brazilian study could not assess potential declines in vaccine protection.

Given reports of reduced effectiveness against SARS-Cov-2 infection, it is important to mention that 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.

Vaccine Effectiveness against the Mu variant of concern

The Mu variant is partially resistant to neutralization by mRNA and adenoviral vector-based vaccine-elicited antibodies, however the resistance is similar to the Delta variant's resistance; the authors state that the "Mu variant does not present any additional concerns over Delta with which it is nearly identical"[17]. The authors' statement is corroborated by another study, which reported that the Moderna's (mRNA-1273) two-dose vaccine effectiveness was **86.7% (95% CI, 84.3-88.7)** against Delta infection and **90.4% (95% CI, 73.9-96.5)** against Mu infection[18].

Efficacy of BNT162b2 Booster Dose

Recent studies evaluating and comparing the rate of confirmed SARS-CoV-2 infection and severe COVID-19 among persons, of different age groups, vaccinated during different time periods have demonstrated that the immunity against the Delta variant

[15] Breakthrough SARS-CoV-2 infections in 620,000 U.S. Veterans, February 1, 2021 to August 13, 2021. *medRxiv.* https://www.medrxiv.org/content/10.1101/2021.10.13.21264966v1

[16] Vaccine effectiveness of Ad26.COV2.S against symptomatic COVID-19 and clinical outcomes in Brazil: a test-negative study design. *medRxiv*. https://www.medrxiv.org/content/10.1101/2021.10.15.21265006v1

[17] Neutralization of Mu and C.1.2 SARS-CoV-2 variants by vaccine-elicited antibodies in individuals with and without previous history of infection. *bioRxiv.* https://www.biorxiv.org/content/10.1101/2021.10.19.463727v1.full.pdf

[18] Effectiveness of MRNA-1273 against Delta, Mu, and other emerging variants. *medRxiv*. https://www.medrxiv.org/content/10.1101/2021.09.29.21264199v1.full

wanes in all age groups a few months after receipt of the second vaccine dose. Similar results were highlighted in the recently published Israeli study evaluating the waning immunity of the BNT162b2 vaccine in Israel. Based on the data of 4,791,398 vaccinated individuals aged 16 years old and over, the rate of COVID-19 infection was higher among individuals who became fully vaccinated earlier in the year than among those who were fully vaccinated 2 months later, for all age groups[19]. These concerning results have led countries to expand their booster platforms to include the general populations, such as the Israeli Ministry of Health who has recommended booster vaccinations to all over 12 years of age.

Despite the ongoing administration of booster doses to immunocompromised patients, older populations, and medical personnel and the expansion of booster platforms to include the general population, results from randomized trials on the efficacy and safety of booster doses remain limited. Recently, preliminary results from the first randomized, controlled COVID-19 vaccine booster trial aiming to evaluate the efficacy and safety of a booster dose of the BNT162b2 vaccine in individuals who previously received the full BNT162b2 jab were released[20]. Based on the results, more than 10,000 participants 16 years of age and older who received their BNT162b2 booster dose showed a relative **efficacy of 95.6%** against any COVID-19 disease compared to individuals who did not receive a booster, during a period when Delta was the prevalent strain. Additionally, multiple subgroup analyses demonstrated that the efficacy was consistent irrespective of age, sex, race, ethnicity, or comorbid conditions. Overall, a third 30-µg booster dose of the BNT162b2 vaccine in individuals 16 years of age and older who previously received the full BNT162b2 jab demonstrated to be highly efficacious and safe across various age groups, sexes, races, ethnicities, and comorbid conditions.

[19] Waning Immunity after BNT162b2 Vaccine in Israel. *NEJM.* https://www.nejm.org/doi/full/10.1056/NEJMoa2114228

[20] 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

Effectiveness of BNT162b2 Booster Dose

To overcome the reported waning immunity of the BNT162b2 vaccine, the Israeli Ministry of Health announced a campaign to administer a third dose of the mRNA COVID-19 vaccine (Pfizer-BioNTech) to immunocompromised patients on 13 July 2021, which was later expanded to eventually include the general population over the age of 12 years on 30 August 2021. Based on the data repositories of Israel's health-care organisation, the effectiveness of a third dose of the BNT162b2 mRNA vaccine for preventing severe COVID-19 outcomes was estimated[21]. A total of 728,321 individuals who received the booster dose were matched (1:1) to demographically and clinically similar controls who did not receive a third dose. The effectiveness of the third vaccine dose, compared with two doses only, was estimated to be **93%** (95% CI: 88–97) **against admission to hospital**, **92%** (95% CI: 82–97) **against severe disease**, and **81%** (95% CI: 59–97) **against COVID-19-related death**. The third booster also demonstrated to be effective within different age groups with an estimated **effectiveness against admission to hospital** of **70%** (95% CI: -70-100) **for individuals aged 16 to 39 years**, **92%** (95% CI: 83-97) **for individuals aged 40 to 69 years**, and **93%** (95% CI: 87-97) **for individuals aged 70 years and over**. Additionally, an estimated **effectiveness against severe COVID-19 disease** of **94%** (95% CI: 85-99) for **40 to 69 years** and **92%** (95% CI: 83-98) for **70 years and over** was calculated. Overall, the results suggest that a third dose of the BNT162b2 mRNA vaccine is effective in protecting individuals against severe COVID-19-related outcomes across age groups, compared to individuals who only received two doses.

Heterologous Booster Doses

[21] 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

Although booster vaccinations continue to receive emergency use authorization for certain populations in multiple countries, the authorization is restricted to homologous schedules due to the limited data and information available on the safety, reactogenicity, and immunogenicity of heterologous booster vaccination. The Food and Drug Administration recently announced its plan to offer heterologous COVID-19 vaccine as booster, an announcement that could provide more flexibility to doctors and other vaccinators, especially for Janssen vaccine recipients wanting to receive a booster dose[22]. The announcement was preceded by a recent study presenting preliminary findings on the safety, reactogenicity, and humoral immunogenicity of heterologous SARS-CoV-2 booster vaccinations (focusing on BNT162b2, mRNA1273, and Ad26. COV2.S.)[23]. Based on the study, the reactogenicity for the heterologous schedules was similar to the one reported for the primary vaccine jabs. Injection site pain, malaise, headache, and myalgia occurred in more than half the participants. The booster vaccines **increased** the neutralizing activity by **4.2 to 76-fold** and the binding antibody titers **increased 4.6 to 56-fold** for all combinations. Homologous booster **increased** neutralizing antibody titers **4.2-20-fold** whereas the heterologous boost **increased** titers **6.2 to 76-fold**. Overall, the homologous and heterologous booster vaccinations were well-tolerated and immunogenic.

mRNA Vaccines in Children (5-15)

Pfizer-BioNTech and Moderna COVID-19 vaccine have both been approved for 12–15-year-old people by both the FDA and EMA. Since then, many controlled trials and studies have been conducted to further monitor the vaccine's safety and immunogenicity, however, vaccine effectiveness against COVID-19 in-real world setting for children remained limited. Recent results on the Pfizer-BioNTech COVID-19 vaccine estimated vaccine effectiveness against SARS-CoV-2 among children

[22] F.D.A. to Allow 'Mix and Match' Approach for Covid Booster Shots. *The New York Times.* https://www.nytimes.com/2021/10/18/us/politics/fda-mix-and-match-boosters.html?referringSource=articleShare

[23] Heterologous SARS-CoV-2 Booster Vaccinations – Preliminary Report. *medRxiv.* https://www.medrxiv.org/content/10.1101/2021.10.10.21264827v2.full-text

aged 12 to 15 years old in Israel. Based on the retrospective cohort study, the vaccine was highly effective in this younger population with a reported effectiveness of **91.5%** 8 to 28 days after receiving the second dose against laboratory-confirmed SARS-CoV-2 infection[24]. While the Pfizer-BioNTech and Moderna COVID-19 vaccines have been available for children 12-years and older, vaccination of younger children have yet to be approved. This may soon change as both Pfizer-BioNTech and Moderna have shared promising preliminary results of their vaccines in children younger than 12 years old. Based on Pfizer-BioNTech preliminary results of their phase 2/3 clinical trial, the BNT162b2 vaccine in children aged 5 to 11 years old had an efficacy of **90.7%** against confirmed COVID-19 and demonstrated to be safe and elicit a robust immune response[25]. As for results of the randomized, observer-blind, placebo-controlled phase 2/3 clinical trial of the mRNA-1273 vaccine in healthy children aged 6 to 11 years old, the two 50 µg doses of mRNA-1273 demonstrated to be generally well tolerated in children and showed robust neutralizing antibody titers while meeting the primary immunogenicity endpoints[26].

Myocarditis Data

Reports of myocarditis, pericarditis and myopericarditis cases post COVID-19 vaccinations, particularly in young and adolescent populations, have raised some concerns regarding vaccine safety. Past studies have confirmed the benefits of anti-SARS-CoV-2 vaccine-induced immunity outweigh the risks of developing myocarditis or other cardiovascular related side effects post vaccination. Several studies that quantified the risk of developing myocarditis following mRNA vaccination were published throughout the month of October 2021 and corroborate previously reported

[24] Effectiveness of BNT162b2 Vaccine in Adolescents during Outbreak of SARS-CoV-2 Delta Variant Infection, Israel, 2021. *CDC Emerging Infectious Diseases.* https://wwwnc.cdc.gov/eid/article/27/11/21-1886_article

[25] Vaccines and Related Biological Products Advisory Committee October 26, 2021. *FDA/Pfizer-BioNTech.* https://www.fda.gov/media/153409/download

[26] Moderna Announces Positive Top Line Data from Phase 2/3 Study of COVID-19 Vaccine in Children 6 to 11 years of Age. *Moderna Inc.* https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-positive-top-line-data-phase-23-study-covid-19

myocarditis data: Developing myocarditis complications post-COVID-19 vaccination is rare and most cases are mild and resolve rapidly. Young men (16-29 years) however, do have an increased risk of developing complications compared to older individuals and/or women. Two Israeli studies estimated that the incidence of developing myocarditis for **men of all ages** was **4.12 cases (95% CI, 2.99-5.26)**[27] and **3.19 cases (95% CI, 2.37-4.02)**[28] per 100,000 vaccinated with the BNT162b2 vaccine. The estimated incidence for young males aged between 16 and 29 years were **10.69 cases (95% CI, 6.93-14.46)**[29] and **13.60 cases (95% CI, 9.30-19.20)**[30] per 100,000 vaccinated, respectively. For women of all ages, the estimated incidence rates were **0.23 cases (95% CI, 0-0.49)**[31] and **0.39 cases (95% CI, 0.10-0.68)**[32] per 100,000 vaccinated. Please refer to the synoptic table below for more estimated incidence rates of myocarditis cases. Most studies report myocarditis data per 100,000 vaccinated, however, due to the small number of observed cardiovascular complications in one US study (Simone et al. 2021)[33], this particular study reported cases per 1 million administered mRNA vaccine doses (50% received BNT1262b2 and the other 50% received mRNA-1273) (see synoptic table below for further information).

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.

[27] Myocarditis after COVID-19 vaccination in a large health care organization. *The New England Journal of Medicine.* https://www.nejm.org/doi/10.1056/NEJMoa2110737

[28] Myocarditis after BNT162b2 mRNA vaccine against COVID-19 in Israel. *The New England Journal of Medicine.* *https://www.nejm.org/doi/10.1056/NEJMoa2109730*

[29] Myocarditis after COVID-19 vaccination in a large health care organization. *The New England Journal of Medicine.* https://www.nejm.org/doi/10.1056/NEJMoa2110737

[30] Myocarditis after BNT162b2 mRNA vaccine against COVID-19 in Israel. *The New England Journal of Medicine.* *https://www.nejm.org/doi/10.1056/NEJMoa2109730*

[31] Myocarditis after COVID-19 vaccination in a large health care organization. *The New England Journal of Medicine.* https://www.nejm.org/doi/10.1056/NEJMoa2110737

[32] Myocarditis after BNT162b2 mRNA vaccine against COVID-19 in Israel. *The New England Journal of Medicine.* *https://www.nejm.org/doi/10.1056/NEJMoa2109730*

[33] Acute myocarditis following COVID-19 mRNA vaccination in adults aged 18 years or older. *JAMA Internal Medicine*. https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2784800

Synoptic Table

Synoptic table about SARS-CoV-2 vaccines accepted in the WHO's Emergency Use Listing and Novavax Vaccine (as of 29 October 2021)

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

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

	FDA approves booster for those ages 16 and above, 6 months after the 2nd dose[iii]	for individuals older than 65 and high-risk individuals, 6 months after the 2nd dose[v]					
EFFECTIVENESS AGAINST ANY SARS-COV-2 INFECTION							
Effectiveness single dose	*General population:* 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] *Individuals ≥70:* Symptomatic disease: **58%**[5].	*General population:* Symptomatic disease: **60%** (95% CI, 57-64; >2 weeks after dose)[7].[vii] **88.9%** (95% CI, 78.7-94.2)[3] *Individuals ≥70:* Symptomatic disease: **64%** (95% CI, 46-78;	*General population:* Asymptomatic or symptomatic disease: **64%;** Symptomatic disease: **67%**[8]. *Individuals ≥70:* Symptomatic disease: **58%**[5]. Hospitalization risk reduced by **35-45%**[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]. **79%** (95% CI, 77-80) (when corrected for	Partial protection[15].[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[16]. **18.6%** (95% CI, 17.6-19.6) against SARS-CoV-2	Ongoing studies in South Africa[18] and the United Kingdom[19]

[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.

	Hospitalization risk reduced by 35-**45%**[5]. Risk of death reduced by **54%**[5]. *Individuals ≥50:* ≥14 days after first dose: **54%** (95% CI, 47-61) effectiveness against hospitalization [1 January-22 June[6].[vi]	>2 weeks after dose)[7].[viii] *Individuals ≥50:* ≥14 days after first dose: **54%** (95% CI, 47-61) effectiveness against hospitalization [1 January-22 June[6].[ix]		under-recording, VE was estimated to be **69%** (95% CI, 67-71)[10]. **81%** (95% CI, 79-84) for preventing hospitalization when corrected for under-recording, VE was estimated to be **73%** (95% CI, 69-76)[10]. **75%** (95% CI, 65-82) against severe critical COVID-19[11]. **71%** (95% CI, 56-81) [11 March – 15 August][12]. **61%** (95% CI, 29-84) [January-June][13]		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][17]	

[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).

				50.9% (95% CI, 35.1-63.0) [June-September; Brazil][14] *Individuals ≥50:* 68% (95% CI, 50-79)[6].			
Effectiveness of two doses	*SARS-Cov-2 infection:* **85%**[2]. **94.6%**[20]. **94.5%**[21]. **76%** (95% CI, 69-81) [January-July][22]. **88.8%** (95% CI, 84.6-91.8) [December-May][3] **74%** (95% CI, 72-76) [January-June][13]	*SARS-Cov-2 infection:* **100%**[20]. **86%** (95% CI, 81-90.6) [January-July][22]. **96.3%** (95% CI, 91.3-98.4) [December-May][3] **85%** (95% CI, 80-90) [January-June][13] **71%** (95% CI, 68-74) [4 months	*SARS-CoV-2 infection*: **53%** (95% CI, 12-84) [January-June][13] **27%** (95% CI, 17-37) [4 months after second dose][24] *Symptomatic disease*: **90%**[8].	Not Applicable (one dose schedule)	Partial protection[15].[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[16]. **52.7%** (95% CI, 52.1-53.4) against SARS-CoV-2 infection, **72.8%** (95% CI, 71.8-73.7) against	Ongoing studies in South Africa[18] and the United Kingdom[19]

[xvi] 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

	77.5% (95% CI, 76.4-78.6) [first month after second dose][4] **47%** (95% CI, 43-51) [5 months after second dose][23] **56%** (95% CI, 53-59) [4 months after second dose][24] *Asymptomatic SARS-CoV-2 infection:* **90.6%**[25].[xi] **73.1** (95% CI, 70.3-75.5)[4] *Hospitalization:* **85%** (95% CI, 73-93) [January-July][22]. **88%** (95% CI, 85-91) [11 March – 15 August][12].	after second dose][24] **63%** (95% CI, 44-76) [June-August][26] *Symptomatic disease*: **91%** (95% CI, 89-93; >2 weeks after dose)[7].[xiii] *Asymptomatic SARS-CoV-2 infection:* **90.6%**[25].[xiv] **71%** (95% CI, 61-78) [January-August][26] *Hospitalization:* **91.6%** (95% CI, 81-97) [January-July][22].				hospitalization, **73.8%** (95% CI, 72.2-75.2) against ICU admission, and **73.7%** (95% CI, 72.3-75.0) against death [January-April][17]	

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

	89% (95% CI, 87-91) for individuals ≥50 years [1 January-22 June[6]. [xii] **90%** (95% CI, 89-92) [Dec 2020 – Aug 2021][23] *Individuals ≥65:* **61%** (95% CI, 57-65) against SARS-CoV-2 infection and **86%** (95% CI, 82-88) against hospitalizations[23]	**93%** (95% CI, 91-95) [11 March – 15 August)[12]. **89%** (95% CI, 87-91) for individuals ≥50 years [1 January-22 June[6]. [xv]					
EFFECTIVENESS AGAINST VARIANTS[xvii]							
Alpha (B.1.1.7)	*Single dose:* **48.7%** (95% CI, 45.5 to 51.7)[27] **66%** (95% CI,64-68)[28]. **54.5%** (95 CI, 50.4-58.3)[29]	*Single dose:* **88.1%** (95% CI, 83.7 to 91.5)[32] **83%** (95% CI, 80-86)[28]. *Two doses:*	*Single dose:* **48.7%** (95% CI 45.5 to 51.7)[27] 6**4%** (95% CI, 60-68)[28]. *Two doses:*	-	No published data	*Two doses:* Equally effective **(~76%**) in neutralizing D614G, B.1.1.7 and B.1.429 as the wild-type strain.	Ongoing studies in South Africa[18] and the United Kingdom[19]

[xii] mRNA-aggregated data (results do not disaggregate between BNT162b2 and mRNA-1273).
[xv] mRNA-aggregated data (results do not disaggregate between BNT162b2 and mRNA-1273).
[xvii] Effectiveness data against the latest variant of interest (Mu) will be included in upcoming reports based on data availability.

	Two doses: **93.7%** (95% CI, 91.6 to 95.3)[27] **92%** (95% CI, 90-93)[30]. **89%** (95% CI, 86-91)[28]. **78%** (95% CI, 68-84)[31] **84.4%** (95 CI, 81.8-86.5)[29]	**100%** (95% CI, 91.8 to 100)[32] **92%** (95% CI, 86-96)[28]. **98.4%** (95% CI, 96.9-99.1)[33]	**74.5%** (95% CI, 68.4 to 79.4)[27] **73%** (95% CI, 66-78)[30]. 79% (95% CI, 56-90)[31].				
Beta (1.351)	*Single dose:* **60%** (95% CI, 52-67)[28]. *Two doses:* **84%** (95% CI, 69-92)[28].	*Single dose:* **61.3%** (95% CI, 56.5 to 65.5)[32] **77%** (95% CI, 69-92)[28]. *Two doses:* **96.4%** (95% CI, 91.9 to 98.7)[32]	*Single dose:* **48%** (95% CI, 28-63)[28].	-	No published data	Neutralization capacity was decreased by factor **5.27**[34].	No available data
Gamma (P.1)	Neutralization activity reduced by **3.3-fold**[35].	-	-	-	No published data	Demonstrated **42%** vaccine effectiveness in a setting with high P.1 transmission, in individuals aged 70 and above[36].	No available data

						50.2% against P.1 (>14 days after 2nd dose)[37]. Neutralization was decreased by factor **3.92**[34].	
Delta (1.617.2)	*Single dose:* **30.7%** (95% CI, 25.2 to 35.7)[27]; **57%** (95% CI, 50-63)[31] **22.5%** (95 CI, 17.0-27.4)[29] *Two doses:* **88.0%** (95% CI, 85.3 to 90.1)[27]; **80%** (95% CI, 77-83)[31] **79%** (95% CI,75-82)[30]. **80%** (95% CI, 77-83)[31] **40.5%** (95% CI, 8.7-61.2)[38]. **42%** (95% CI, 13-62)[22]. **89.8%** (95% CI, 89.6-90.0) [2-9 weeks after second dose][39].	*Single dose:* **72%** effective against symptomatic SARS-Cov-2 infection[42]. *≥14 days after second dose:* **76%** (95% CI, 58-87)[22]. **94.5%** (95% CI, 94.1-95) [2-9 weeks after second dose][39]. **50.6%** (95% CI, 45.0-55.7) [among nursing home residents][40]. **86.7%** (95% CI, 84.3-88.7)[33] **56.6%** (95% CI, 42.0-67.5) *against infection*[43] **84.2%** (95% CI, 56.4-94.3) *against*	*Single dose:* **30.7%** (95% CI 25.2 to 35.7)[27] *Two doses:* **67.0%** (95% CI, 61.3 to 71.8)[27] **67%** (95% CI, 62-71)[31]. **60%** (95% CI, 53-66)[30]. **66.7%** (95% CI, 45-49.6) [2-9 weeks after second dose][39]. **47.3%** (95% CI, 66.3-67.0) [≥20 weeks after second dose][39]. Odds ratio of **5.45** (95% CI, 1.39-21.4) to become infected with B.1.167.2	**78%** (95% CI, 73-82) against SARS-CoV-2 infection[10]. **3%** (95% CI, -7-12) [August][41] *Individuals ≥50:* **83% (**95% CI, 81-85)[10]		*Single dose:* **13.8%** (95% CI, -60.2-54.8)[45]. *Two doses:* **59%** (95% CI, 16-81.6) against SARS-CoV-2 infection and **70.2%** (95% CI, 29.6-89.3) against moderate COVID-19 infection[45].	No available data

	69.7% (95% CI, 68.7-70.5) [≥20 weeks after second dose][39]. **64.6%** (95 CI, 60.6-68.2)[29] **52.4%** (95% CI, 48.0-56.4) [among nursing home residents][40]. **53%** (95% CI, 39-65) [4 months after second dose][23] **50%** (95% CI, 47-52) [August; elderly Veteran population][41] *Against severe COVID-19:* **91.4%** (95% CI, 82.5-95.7)[38].	*symptomatic infection*[43] **64%** (95% CI, 62-66) [August; elderly Veteran population][41] *10-14 weeks after second dose:* **90.3%** (95% CI, 67.2-97.1)[39].	compared to non-B.1.167.2 [44].				
Mu (B.1.621)	No available data	*Two doses:* **90.4%** (95% CI, 73.9-96.5)[33] (demonstrated similar protective measures as	No available data	No available data	No available data	No available data	No available data

		against the Alpha variant)					
EFFECTIVENESS AGAINST HOSPITALIZATION							
Alpha	Single dose: **83%** (95% CI, 62-93) Two doses: **95%** (95% CI, 78-99)[46]. *Against death:* **98.2%** (95% CI, 95.9-99.2) [2-9 weeks][39]. **90.4%** (95% CI, 85.1-93.8) [≥20 weeks][39].		Single dose: **76%** (95% CI, 61-85) Two doses: **86%** (95% CI, 53-96)[46]. *Against death:* **94.1%** (95% CI, 91.8-95.8) [2-9 weeks][39]. **78.7%** (95% CI, 52.1-90.4) [≥20 weeks][39].	***Beta*** **67%** effective at preventing hospitalizations[47]. *Against death:* 96% effective at preventing death[47].	-	**-**	No available data
Gamma	-	-	-	**72.9%** (95% CI, 35.1-91.1)[14] *Against ICU admission:* **92.5%** (95% CI, 54.9-99.6)[14] *Against death:* **90.5%** (95% CI, 31.5-99.6)[14]	-	-	No available data

Delta	*Single dose:* **94%** (95% CI, 46-99)[46]. **91%** (95% CI, 90-93)[48] *Two doses*: **96%** (95% CI, 86-99)[46]. **88%** (95% CI, 78.9-93.2)[38]. **75%** (95% CI, 24-93.9)[22]. **84%** (95% CI, 79-89)[49]. **98.4%** (95% CI, 97.9-98.8) [2-9 weeks][39]. **92.7%** (95% CI, 90.3-94.6) [≥20 weeks][39]. **96%** (95% CI, 95-96)[48] **80%** (95% CI, 73-85) [June-August][50]	*Single dose:* **81%** (95% CI, 81-90.6)[22]. *Two doses:* **84%** (95% CI, 80-87)[48] **95%** (95% CI, 92-97) [June-August][50] *Against ICU admission:* **86%** (95% CI, 79-90)[48] **96%** against severe COVID-19 infection[42].	*Single dose*: **71%** (95% CI, 51-83)[46] **88%** (95% CI, 83-91)[48] *Two doses*: **92%** (95% CI, 75-97)[46]. **95.2%** (95% CI, 94.6-95.6) [2-9 weeks][39]. **77.0%** (95% CI, 70.3-82.3) [≥20 weeks][39]. **94%** (95% CI, 92-95)[48] *Against ICU admission:* *Single dose:* **92%** (95% CI, 84-96)[48] *Two doses*: **96%** (95% CI, 94-98)[48] *Against death:*	**71%** [47] **85%** (95% CI, 73-91)[10]. **91%** (95% CI, 88-94)[48] **85%** effective at preventing severe disease and hospitalization[53]. *Individuals ≥50:* **84% (**95% CI, 81-85)[10] *Against ICU admission:* **94%** (95% CI, 88-98)[48]	*Single dose:* Does not offer clinically meaningful protection against severe illness [54,xviii] *Two doses:* **88%** (95% CI, 55-98) adjusted risk reduction in developing severe illness.[54,xix]	*Single dose:* Does not offer clinically meaningful protection against severe illness [54,xx] *Two doses:* **88%** (95% CI, 55-98) adjusted risk reduction in developing severe illness.[54,xxi]	

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

	93% (95% CI, 84-96)[51] **96.8%** (95% CI, 93.9-98.3)[2 months after the second dose][4] **93%** (95% CI, 84-96)[23] *Against death:* **90%** (95% CI, 83-94) [≥2 weeks after second dose][52]		**91%** (95% CI, 86-94) [≥2 weeks after second dose][52]				
DURATION OF PROTECTION & TRANSMISSION							
Duration of protection (antibodies)	Median time between second dose and infection: **146 days (IQR, 121-167)**[55] *Anti-SARS-CoV-2 Antibodies:* 1 month after 2nd dose: **1762 KU/L (IQR: 933-3761)** 3 months after 2nd dose: **1086 KU/L (IQR: 629-2155)**	*Preliminary phase I results:* Antibody activity remained high in all age groups at **day 209** (approximately 6 months) GMT were lower in ≥56 years old[59]	*Antibody Response:* 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**:	*Neutralizing antibodies:* Remained largely stable for **8-9 months**[61] *Binding antibodies:* Remained stable **6 months** irrespective of age group[61]	*Antibody Response:* **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)[63]	A phase I/II clinical trial found that NAbs titres dropped below the seropositive cut-off of 8, **6 months** after the administration of the first dose[64]. **80-90%** of anti-S IgG and Nab titers against wild type waned **6 months** after second vaccination[65]	

	6 months after 2nd dose: **802 KU/L (IQR, 447-1487)**[56] No health worker had antibodies BELOW method-dependent cut-off (0.8 KU/L) *Anti-spike Protein RBD IgG Antibodies:* **Younger age groups (<60):** 1 month after 2nd dose: 100% seropositivity, **35.3** (IQR, 27.6-40.0) 3 months after 2nd dose: 100% seropositivity, **19.2** (IQR, 8.2-23.1)[57] **Older age groups (≥60)**: 1 month after 2nd dose: 100% seropositivity, **29.4** (IQR, 22.5-33.3) 3 months after 2nd dose: 100%		0.30 GMR (CI, 0.24-0.39)[60] *Cellular Immune Response:* **Day 182** after first dose: median of **237 SFUx10^6 PBMC (IQR, 109-520)**[60] **6 months** after second dose: **(median 1240, IQR 432-2002**) in groups with 15-25 week interval between doses[60] *Anti-spike Protein RBD IgG Antibodies:* **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)[57]	*Humoral & Cellular Immune Response:* Antibody responses were detected in all vaccine recipients on **day 239** (stable response for at least 8 months)[62]	**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)[63]	*Anti-spike Protein RBD IgG Antibodies:* **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)[57] **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)[57]	

	seropositivity, **14.8** (IQR, 7.4-18.7)[57] *Sub-populations:* **Older age (≥65):** **38%** to **42%** decrease of humoral antibodies compared to 18- to 45-year-old[58] **Older age (≥65) AND men:** **37%** to **46%** decrease compared to 18- to 45-year-old women[58] **Immunosuppression:** **65% to 70%** decrease compared to non-immunosuppressed[58] **Obesity (BMI ≥30):** **31%** increase in neutralizing antibody		**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)[57]				

	compared with nonobese[58]						
Duration of protection (vaccine effectiveness)	*Effectiveness against any SARS-CoV-2 Infection:* After reaching peak VE (77.5%) 1 month after 2nd dose, VE dropped to **20%** in **months 5-7** after 2nd dose[66] VE reduced from **87%** (95% CI, 85-89) to **56%** (95% CI, 53-59) after 4 months.[24] VE reduced from **91%** (95% CI, 91-92) in March to **50%** (95% CI, 47-52) in August[41] *Effectiveness against Hospitalization and Death:*	**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.[67] **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.[67] VE against the Delta variant declined from	VE reduced by 7% (95% CI, -18 - 2) for every 30 days from the second dose for those aged 18 to 64 years[31]. VE reduced from **58%** (95% CI, 51-65) to **27%** (95% CI, 17-37) after 4 months.[24] VE reduced from **88%** (95% CI, 87-89) in March to **3%** (95% CI, -7-12) in August[41]	A study observed sustained and stable vaccine effectiveness starting 14 days post vaccination to a maximum of **152** days after vaccination[10]. VE decreased from **89.4%** in May to **51.7%** in July[26]			

	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 cases[66] VE reduced by 22% (95% CI, 6-41) for every 30 days from the second dose for those aged 18 to 64 years[31].	**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.[33] **91%** [January-March] **71%** (95% CI, 53-83) [April-May] **63%** (95% CI, 44-76)[26] VE reduced from **90%** (95% CI, 88-91) to **71%** (95% CI, 68-74) after 4 months[24] VE reduced from **91%** (95% CI, 72-98) in January-March to **71%** (95% CI, 53-83) in April-May to **63%** (95% CI, 44-76) in June-August[26]						

		VE reduced from **92%** (95% CI, 92-93) in March to **64%** (95% CI, 62-66) in August[41]					
Transmission prevention	*Prior Delta Variant:* Vaccine effectiveness against infectiousness given infections **41.3%**[68] Vaccine effectiveness against transmission **88.5%**[68] *During Delta Variant:* Similar Ct values (<25) were found in both vaccinated and unvaccinated groups[69] Studies from Scotland and England demonstrated reductions in	VE against onwards transmission: **52%** (95% CI, 33-69)[13]	**48%** (limited data) May not be able to block the transmission of the alpha variant as efficiently as the wild type[72].	Limited data	Unknown	Unknown	

	secondary infections among families of vaccinated individuals compared to families of unvaccinated individuals[70,71]. VE against onwards transmission: **62%** (95% CI, 57-67)[13]						
SAFETY AND ADVERSE EVENTS							
Common side effects	Pain at the injection site, fatigue, headache, myalgia, chills and fever.[73] Optimal safety for asthma patients[74]. The vaccine is considered safe for cancer patients undergoing treatments[75].	Pain at injection site, headache, fatigue, myalgia, arthralgia[76], Covid arm (cutaneous hypersensitivity)[77]. The vaccine is considered safe for cancer patients undergoing treatments[75].	Fatigue, myalgia, arthralgia, headache[78], lethargy, fever, & nausea[79].	Headache, fever, chills, fatigue, myalgia, and nausea[80].	Pain at the injection site, dizziness, fever, headache, fatigue, nausea, vomiting, & allergic dermatitis[79,81].	Pain at injection site, headache, fatigue, tremors, & flushing[82], inflammatory reaction, urticaria[83].	Pain at injection-site, headache, muscle pain, fatigue[84]

Rare adverse events	Myocarditis & myopericarditis[85-87], anaphylaxis and swelling of the lips, face, and tongue related to anaphylaxis[88] (11 anaphylaxis cases per million doses administered)[89], axillary lymphadenopathy, paroxysmal ventricular arrhythmia, leg paresthesia[90], pityriasis rosea[91] (lesions improved completely after ~8 weeks)[92], lymphocytic vasculitis[93], varicella-zoster reactivation [94-96], Kikuchi-Fujimoto disease[97], thrombotic thrombocytopenic purpura[98,99], IgA nephropathy flare-up[100], Guillain-	Myocarditis & myopericarditis [85-87], orofacial swelling & anaphylaxis[88]. Potential risk factor for Bell's palsy[108] (most improve upon follow-up)[121], herpes zoster reactivation[95], varicella zoster reactivation[95], herpes zoster ophtalmicus[122], eczema & urticaria[123], transverse myelitis[124], Guillain-Barré syndrome[125,126], acute generalized exanthematous pustulosis[127], rhabdomyolysis[128, 129], herpes zoster ophtalmicus[122], eczema & urticaria[123], transverse	Transverse myelitis, high fever[78,131], cutaneous hypersensitivity[131], vasculitis[132], cerebral venous sinus thrombosis[133] (higher risk for women)[134], thromboembolism[135], vaccine induced immune thrombotic thrombocytopenia[136, 137-139], intracerebral haemorrhage[140], small vessel vasculitis[132,141], psoriasis[142], rosacea, raynaud's phenomenon[123], Ischaemic stroke[143], anaphylaxis[144], recurrent herpes zoster[145,xxii], generalized	Thrombosis, thrombocytopenia, cerebral venous sinus thrombosis[158], increased risk of developing Guillain-Barré syndrome post vaccination[159], herpes zoster ophtalmicus[122], pseudothrombocytopenia[160], vaccine induced thrombocytopic thrombosis[161] 97% of reported reactions after vaccine administration were non-serious[80].	Rare adverse events were similar among the vaccine groups and control group within 7 days[162]. Pityriasis rosea[163], uveitis[164]	Myalgia, fever[82], pityriasis rosea (lesions improved completely after ~8 weeks)[92], reactivation of herpes zoster and herpes simplex[83]. Most reactions improved without treatment within a few weeks[83], Guillain-Barré syndrome[165], subacute thyroiditis[166], erythema multiforme[167], uveitis[164]	Myocarditis was reported in one vaccine recipient, occurring 3 days after second dose[84]

[xxii] All cases occurred in patients with chronic urticaria and were being treated with cyclosporine.

	Barré syndrome [101,102], pustural psoriasis[103], immunoglobulin A vasculitis[104], immune complex vasculitis[105], Rhabdomyolysis[106], subacute thyroiditis[107], Bell's Palsy[108], erythema multiforme[109], vaccine induced interstitial lung disease[110], macular neuroretinopathy[111], brachial neuritis[112], thyroid eye disease[113], exacerbation of subclinical hyperthyroidism[114], rhabdomyolysis[115], internal jugular vein thrombosis[116], herpes simplex virus keratitis[117], cervical lymphadenopathy[118],glomerulonephri	myelitis[124], Guillain-Barré syndrome[125,126], acute generalized exanthematous pustulosis[127], rhabdomyolysis[128, 129], cervical lymphadenopathy[130], glomerulonephritis[119]	bullous fixed drug eruption[146], Guillain-Barré syndrome[102,147], pityriasis rosea[148,149]. Vaccination in individuals with adrenal insufficiency can lead to adrenal crises[150], Dariers disease[151], vaccine induced acute localized exanthematous pustulosis[152], Henoch-Schönlein Purpura[153], rhabdomyolysis[154], Grave's disease[155], acute demyelinating polyradiculoneuropathy[156], erythema nodosum [157]				

	tis[119], Ramsay-Hunt syndrome[120]						
Potential associated adverse events (causal links not yet proven)	Cerebral venous sinus thrombosis and intracranial haemorrhage[168], aseptic meningitis[169], autoimmune hepatitis[170,171], multiple sclerosis relapse[172], myeloperoxidase anti-neutrophil cytoplasmic antibody-positive optic perineuritis[173], central retinal vein occlusion[174], paracentral acute middle maculopathy & acute macular neurotinopathy[175],	Autoimmune hepatitis[170], myocardial infarction[180], autoimmune haemolytic anaemia[181], hypophysitis & panhypopituitarism[182], erythema nodosum-like rash[183], pulmonary embolism[184] One case developed IgA Nephropathy after receiving the second dose of mRNA-1273 (causal link not yet proven)[185].	Autoimmune hepatitis[170,186,187], Acute hyperglycaemic crisis[188], Facial nerve palsy, cervical myelitis[143], alopecia areata[189], takotsubo (stress) cardiomyopathy[190], acute disseminated encephalomyelitis[191]	Facial Diplegia[192]	-	-	No available data

	Stevens-Johnson syndrome/ toxic epidermal necrolysis[176,177], lichenoid cutaneous skin eruption[178], acute mania and psychotic features[179]					
Myocarditis data	Mainly reported in young adults and adolescents [193] <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)[194] <u>Male patients</u> Incidence of **4.12** (95% CI, 2.99-5.26) per 100,000 vaccinated[194] **3.19** cases (95% CI, 2.37-4.02) per	Mainly reported in young adults and adolescents [193] 5.8 cases per 1 million second dose administrations[196]	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[84]

	100,000 vaccinated[195] <u>Female patients</u> Incidence of **0.23** (95% CI, 0-0.49) per 100,000 vaccinated[194] **0.39** cases (95% CI, 0.10-0.68) per 100,000 vaccinated[195] <u>≥30 years</u> Incidence of **1.13** (95% CI, 0.66-1.60) per 100,00 vaccinated[194] 5.8 cases per 1 million second dose administrations[196] 5.07 cases per 100,000[197] <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)[194] <u>Risk per 100,000 persons</u> 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**[195]						
CHILDREN VACCINATION							
Efficacy	*<u>Adolescents (12-15):</u>* After one dose had efficacy of **75% (CI, 7.6-95.5)**	*<u>Adolescents (12-17):</u>* After one dose had efficacy of **92.7% (CI, 67.8-99.2)**	No available data Paused ongoing trials in children aged 6-17 due to concerns over	No available data Announced at begging of April ongoing study in adolescents but	*<u>Children (3-17):</u>* Unknown. Ongoing clinical trial only looked at safety, tolerability,	*<u>Children (3-17):</u>* Unknown. Clinical trial only looked at safety, tolerability	*<u>Adolescents (16-17):</u>* PREVENT-19 clinical trial[xxiv] expanded to

[xxiv] 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

	After second dose efficacy of **100% (CI, 78.1-100)**[198]. *Children (5-11):* After second dose efficacy of **90.7% (CI, 67.7-98.3)**[199] *Children (Under 5 years):* Ongoing trials[200]	After second dose efficacy of **93.3% (CI, 47.9-99.9)**[201]. *Children (6month-11):* Ongoing trials[202]	rare blood clots reported in adult population[203].	paused to investigate blood clots in adult population[203].	and immunogenicity[xxiii] * * The study design administered **three doses** of 2 µg, 4 µg, or 8 µg of vaccine	and immunogenicity[204].	assess efficacy, safety, and immunogenicity in 12–17-year-old adolescents[205]
Immunogenicity	*Adolescents (12-15) serum-neutralizing titer:* 1 month after 2nd dose had **1283.0 GMN_{50} (CI, 1095.5-1402.5)**[198]. *Adolescents/young adult (16-25) serum-neutralizing titer:* 1 month after 2nd dose had **705.1 GMN_{50} (CI, 621.4-800.2)**[198].	*Adolescents (12-17):* Neutralizing antibody titer after 2nd dose was **1401.7 GMN_{50} (CI, 1276.3-1539.4)** Serological response was **98.8% (CI, 97.0-99.7)** *Children (6-11):* Seroreponse of **99.3%**[207]	No available data	No available data	*Children (3-17):* Neutralizing antibodies after 28 days after 2nd dose ranged from **105.3-180.2 GMT** in 3-5 years cohort, **84.1-168.6 GMT** in 6-12 years cohort, and **88.0-155.7 GMT** in 13-17 years cohort Neutralizing antibodies after 28 days after 3rd dose ranged from	*Children (3-17):* Neutralizing antibody response after 2nd dose **(100%)** with GMT ranging from **45.9-212.6**[204]	Ongoing clinical trial[209]

[xxiii] 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

	Children (5-11): 1 month after 2nd dose had **1,197.6 GMT (95% CI, 1106.1-1296.6)** SARS-CoV-2-neutralizing antibody[206] *Children (Under 5):* Ongoing trials[200]	*Children (6month-11):* Ongoing trials[202]			**143.5-224.5 GMT** in 3-5 years cohort, **127-184.8 GMT** in 6-12 years cohort, and **150.7-199 GMT** in 13-17 years cohort[208]		
Effectiveness	*Against SARS-CoV-2 infection:* **91.5%** (95% CI, 88.2-93.9)[210] **91%** (95% CI, 88-93)[211] *Against hospitalization:* **81%** (95% CI, -55-98)[211] **93%** (95% CI,83-97)[212]	No available data	No available data	No available data	No available data	No available data	No available data
Safety and Adverse events	*Adolescents (12-15):* Local and systemic events	*Adolescents (12-17):* Solicited local reactions after 2nd dose **(93.4%)**	No available data	No available data	*Children (3-17):* Most common adverse reaction was pain at injection site in 3–	*Children (3-17):* Adverse reactions in 12–17 year group **(35%)**, 3-5 year group **(26%)**,	Ongoing clinical trial[209]

	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%)**[198]. *Adolescent/young adults (16-25):* Local and systemic events were generally mild to moderate Severe injection-site pain **(3.4%)** Fever **(17%)** Adverse events **(6%)** Severe adverse events **(1.7%)**[198]. *Children (5-11):* Preliminary results on safety profile are consistent with those observed in older populations [206]	Most common solicited adverse reactions were Injection-site pain **(92.7%)** Headache **(70.2%)** Fatigue **(67.8%)** Grade 3 adverse events **(6.8%)** Few reported cases of acute myocarditis and pericarditis (mainly in males)[214] *Children (6-11):* Vaccine was generally well tolerated[207] *Children (6month-11):* Ongoing trials[202]			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** Adverse events were mostly mild to moderate in severity[208]	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%)**[204]	

	Children (Under 5): Ongoing trials[200] Multisystem inflammatory syndrome (causal link not yet proven)[213]						
Myocarditis Data	Few reported cases of acute myocarditis and pericarditis in 16-25 year olds (mainly in males)[214] 16-29 years Incidence of **5.49** (95% CI, 3.59-7.39) per 100,00 vaccinated[194] Male patients (16-29 years) Incidence of **10.69** (95% CI, 6.93-14.46) per 100,000 vaccinated[194]	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

	Incidence of **13.6 cases** (95% CI, 9.30-19.20) per 100,000 vaccinated[195]						
HETEROLOGOUS VACCINATION							
Vaccine Schedule	**BNT162b2/ChAdOx1** Administration of ChAdOx1 as second/booster dose	**ChAdOx1/mRNA-1273** Administration of mRNA-1273 as second/booster dose	**ChAdOx1/BNT162b2** Administration of BNT162b2 as second/booster dose	Not Applicable (one dose schedule) For more information refer to booster section	**BBIBP/BNT162b2**	**CoronaVac/ChAdOx1** Press releases have confirmed that Thailand will use the AstraZeneca vaccine as the second dose for individuals whose first dose was Sinovac[xxv] **CoronaVac/Convidecia**	Ongoing trial[215] (Com-Cov2)[xxvi]

[xxv] 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/

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

Immunogenicity	*GMCs of SARS-CoV-2 anti-spike IgG at 28 days post booster:* Heterologous **(7133 ELU/mL, CI 6415-7932)** vs. Homologous **(14080 ELU/mL, CI 12491-15871)**[216]. *SFC frequency (T0cell ELISpot):* Heterologous **(99 SFC/10^6 PBMCs)** vs. Homologous **(80 SFC/10^6 PBMCs)**[216]**.**	**Spike-specific IgG antibodies:* Heterologous **(3602 BAU/mL)** vs. Homologous **(4189 BAU/mL)**[48] **Neutralizing antibodies:* Heterlogous **(100%)** vs. Homologous **(100%)**[217]. *Results based on immunosuppressed population	*RBD antibody titres:* Heterologous **(7756.68 BAU/mL, CI 7371.53-8161.96)** vs. Homologous **(99.84 BAU/mL, CI 76.93-129.59)** at day 14[218]. *IgG antibody titres:* Heterologous **(3684 BAU/mL)** vs. Homologous **(101.2 BAU/mL)** at day 14[218]. *Neutralizing antibodies:* Heterologous **(100%)** at day 14 vs. Homologous **(30%)** at day 14[218]. Heterologous **(median 99%)** vs.	Not Applicable (one dose schedule) For more information refer to booster section	Unknown (on-going clinical trial)[49]	**CoronaVac/ChAdOx1 :** *Anti-S Antibodies:* Heterologous **(797 U/mL; 95% CI, 598.7-1062)** vs. Homologous CoronaVac **(94.4 U/mL; 95% CI : 76.1-122.1)** vs. Homologugous ChAdOx1 **(818 U/mL; 95% CI: 662.5-1010)**[220] **CoronaVac/Convidecia** *Neutralizing antibodies :* Heterologous **54.4 GMT** (95% CI, 37.9-78) vs. Homologous CoronaVac **12.8 GMT** (95% CI, 9.3-17.5)[221]	No available data Ongoing trial[215]

			Homologous (BNT162b2/BNT162b2) **(median 62%)**[219]				
Immunogenicity against variants	No available data	No available data	*Neutralizing Antibodies for Alpha, Beta, Gamma, and Delta:* Heterologous **2.3-fold to 3.6-fold** higher neutralizing antibodies than homologous[219]	No available data	No available data	No available data	No available data
Reactogenicity	Observed increase in systemic reactogenicity after boost in heterologous schedules in comparison with homologous schedules[216] *Adverse events in heterologous:* Adverse events **(90)** Grade 1 **(54.4%)**	*Adverse events in heterologous and homologous vaccination groups were very similar[217]. *Majority of adverse events self-reported were Pain at injection site, Swelling at injection site, Fever, Headaches, Fatigue, Chills, GI	*Adverse events in heterologous:* Headache **(44%)**, Myalgia **(43%)**, Malaise **(42%)**, Fever **(2%)**, Injection site pain **(88%)**, Induration **(35%)**, Erythema **(31%)**[218]. *Severity of adverse events in heterologous:*	Not Applicable (one dose schedule) For more information refer to booster section	Unknown (on-going clinical trial)[222]	**CoronaVac/ChAdOx1:** Unknown **CoronaVac/Convidecia:** Convidecia recipients reported more adverse reactions and reported higher occurrence of solicited injection-site pain)[221]	No available data Ongoing trial[215]

	Grade 2 **(37.8%)** Grade 3 **(7.8%)** Grade 4 **(0%)** Arthralgia, Migraine, Back Pain[216]. *Adverse events in homologous:* Adverse events **(81)** Grade 1 **(59.3%)** Grade 2 **(39.5%)** Grade 3 **(1.2%)** Grade 4 **(0%)**[216].	effects, Myalgia, Arthralgia[217]. *Results based on immunosuppressed population	Mild **(68%)**, Moderate **(30%)**, Severe **(2%)**[218].				
BOOSTER DOSES							
Vaccine Schedule	**BNT162b2/BNT162b2**	**mRNA-1273/mRNA-1273**	**ChAdOx1/ChAdOX1**	**Ad26.CoV.2.S/ Ad26.CoV.2.S**	**SinoPharm/SinoPharm**	**CoronaVac/CoronaVac**	**NVX-CoV2373/NVX-CoV2373**
Approved Administration	*Israel:* 12-year-old and over can received homologous booster shot 5 months after full jab[xxvii]	Phase II booster trial of three booster doses are ongoing[223] 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 adding a booster	*UAE:* Offering booster doses of Pfizer and Sinopharm to people who received full Sinopharm jab ≥6 months ago	**Turkey** and the **United Arab Emirates** began homologous booster shots	Ongoing phase II trials[225] Results below are based on ongoing phase II trial

[xxvii] 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/

	United States: Starting September, adults who received mRNA vaccine 8 months ago are eligible for booster *Europe:* Starting in fall, most European countries are planning on rolling out booster shots to immunocompromised and elder populations[xxviii]	its COVID-19 vaccine booster[xxix] *United States:* Starting September, adults who received mRNA vaccine 8 months ago are eligible for booster.	immune response[224]	dose and consideration to authorize two-dose regimen[xxx]		**Indonesia** and **Thailand** are considering giving homologous booster shot to HCW[xxxi]	
Time-to-booster dose	**6 months to 8 months** after initial two-dose regimen	**6 months to 8 months** after initial two-dose regimen	**6-9 months** after initial two-dose regimen	**6 months** after one dose regimen[61]	**6 months** after initial two-dose regimen	**6 months to 12 months** After primary vaccination	**6 months** after initial two-dose regimen (**189 days**)[225]

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

[xxix] 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/

[xxx] 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

[xxxi] 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/

	Israel offers up to **5 months** after initial two-dose regimen					**8 months** after the primary vaccination to healthy adults ≥60 years	
Efficacy	**95.6%** against disease during Delta prevalent period[226]	No available data	No available data	No available data	No available data	No available data	No available data
Effectiveness	*Overall:* **93%** (95% CI: 88-97) against admission to hospital **92%** (95% CI: 82-97) against severe disease **81%** (95% CI: 59-97) against COVID-19-related death[227] *16-39 years old:* **70%** (95% CI: -70-100) against admission to hospital[227] *40-69 years old:*	No available data	No available data	No available data	No available data	No available data	No available data

	92% (95% CI: 83-97) against admission to hospital **94%** (95% CI: 85-97) against severe COVID-19 disease[227] *≥70 years old:* **93%** (95% CI: 87-97) against admission to hospital **92%** (95% CI: 83-98) against severe COVID-19 disease[227]						
Immunogenicity	*Neutralizing titers:* Elicits **>5-8 more** for wild type after 6 months after 2nd dose[228]	Booster doses (mRNA1273 or mRNA1273.351) increased neutralizing antibody titers against wild-type[229]	*Antibody Levels:* Higher levels after third dose (tIgG EU **3746**; IQR: 2047-6420) [224] *Spike Cellular Immune Response:* Increased from **200 SFUx10^6 PBMC (IQR, 127-**	5X10^{10} vp booster dose elicited **9-fold** increase at day 7 compared to first dose after 29 days in 18-55-year-olds[61] 1.25X10^{10} vp booster dose elicited **6-7.7-fold** increase at day 28	Ongoing trial[222]	Neutralizing Antibodies: **60%** higher NAbs activity against wild-type compared to 2-doses[65] Anti-S IgG and NAbs: **20-fold** increase 4 weeks post	*Anti-spike IgG:* Increase of **4.6-fold** compared to peak response after 2nd dose (**Day 217 GMEU = 200408**; 95% CI: 159796-251342)[225]

			389) after the second dose to **399 SFUx10^6 PBMC (IQR, 314-662)** after the third one[224]	compared to first dose after 29 days in 18-55 and ≥65-year-old[61]		booster vaccination NAbs were maintained **60** to **180 days** post booster[65]	*Wild-type Neutralizing Response:* Increase of **4.3-fold** compared to peak response after 2nd dose **(IC50 = 6231; 95% CI: 4738-8195)** [225] *Older Participants (60-84):* **5.4-fold** increase in antibody response[225] *Younger Participants (18-59):* **3.7-fold** increase in antibody response[225]
Immunogenicity against variants	*Beta (B.1.351):* Elicits **15-21** more neutralizing titers for Beta variant after 6 months after 2nd dose[228]	Preliminary results of booster doses of mRNA-1273 vaccine show robust antibody response against Delta variant[223]	Third dose provided higher antibody titters against Alpha, Beta, and Delta variants[224]	No available data	Ongoing trial[222]	**Beta (B.1.351): 3.0-fold** decrease in neutralizing antibodies compared to wild type[65]	High levels of functional antibodies against Alpha (B.1.1.7), Beta (B.1.351), and

	Delta (B.1.671.2): **>5-fold** increase in neutralizing titers against Delta compared to dose 2 titers in 18–55-year-olds **>11-fold** increase in neutralizing titers against Delta compared to dose 2 titers in 65–85-year-olds[228]					**Gamma (P.1):** **3.1-fold** decrease in neutralizing antibodies compared to wild type[65] **Delta (B.1.671.2):** **2.3-fold** decrease in neutralizing antibodies compared to wild type **2.5-fold** higher neutralizing potency than 2-dose vaccination[65]	Delta (B.1.671.2)[225] *Delta (B.1.671.2):* Increase of **6.6-fold** in antibody response compared to Delta response observed with primary vaccination[225]
Reactogenicity	Preliminary results show consistent tolerability[228]	Similar safety and tolerability compared to second dose[223] *Common solicited local adverse events:* Injection-site pain **(68.4% for mRNA-1273.351, 90% for mRNA-1273)** fatigue **(36.8% for mRNA-1273.351,**	Lower reactogenicity after third dose compared to first dose[60]	No available data	Ongoing trial[222]	The third shot is considered to be safe[64]. *Common side effects:* Pain at the injection site. *Adverse events:* Unrelated to the vaccination	Booster dose was **well tolerated** Local and systemic **reactogenicity increased** between Dose 1, Dose 2, and Dose 3 **90%** of symptoms were

		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)**[229]					rated as mild or moderate[225]
Protection against COVID-19	***Confirmed Infection:*** Youngest age group (16-29): **17.6 (95% CI, 15.6-19.9) lower rate** in booster group[230] 30-39 age group: **8.8 (95% CI, 8.2-9.5) lower rate** in booster group[230] 40-49 age group:	No available information	No available information	No available information	No available information	No available information	No available information

	9.7 (95% CI, 9.2-10.4) lower rate in booster group[230] <u>50-59 age group:</u> **12.2 (95% CI, 11.4-13.1) lower rate** in booster group[230] <u>Oldest age group (≥60):</u> **11.3 (95% CI, 10.4-12.3) lower rate** in booster group [231] **12.4 (95% CI, 11.9-12.9) lower rate** in booster group[230] ***<u>Severe Illness:</u>*** <u>40-59 age group:</u> **22.0 (95% CI, 10.3-47.0) lower rate** in booster group[230] <u>Older population (≥60):</u>							

	19.5 (95% CI, 12.9-29.5) lower rate in booster group[231] **18.7 (95% CI, 15.7-22.4) lower rate** in booster group[230]						
Other	Detailed report from Pfizer regarding booster doses can be found here: https://www.fda.gov/media/152161/download 14-20 days after booster, marginal effectiveness increases to **70-84%**[232]					For more detailed information regarding immunogenicity of third dose refer to study[xxxii]	
HETEROLOGOUS BOOSTER DOSES							
Vaccine Schedule	*Heterologous 1:* **mRNA1273/BNT162b2**	*Heterologous 1:* **BNT162b2/mRNA1273**	No available data	*Heterologous 1:* **BNT162b2/Ad26.CoV.2.S**	*Heterologous:* **SinoPharm/BNT162b2**	*Heterologous 1:* **CoronaVac/ChAdOx1**	*Heterologous:* Ongoing trial of heterologous booster shot

[xxxii] 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 2: **Ad26.CoV.2.S/BNT162b2** ***Received BNT162b2 as booster dose	*Heterologous 2:* **Ad26.CoV.2.S/mRNA1272** ***Received mRNA1273 as booster dose		*Heterologous 2:* **mRNA1273/Ad26.CoV.2.S** ***Received Ad26.CoV.2 as booster dose		*Heterologous 2 :* **CoronaVac/BNT162b2**	using NVX-CoV2373[xxxiii]
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	**4 months** after initial two-dose BNT162b2 regimen[233] At least **3 months** after receiving two dose regimen	**6 months** after initial two-dose regimen	*Heterologous 1:* **21 to 26 days** after full jab of CoronaVac *Heterologous 2:* **6 months** after primary vaccination of CoronaVac	
Immunogenicity	*Binding Antibody Responses:* **2-fold or greater rise** in bAb noted in **98-100%** of BNT162b2 recipients[234] *Neutralizing Antibody Responses:*	*Binding Antibody Responses:* **2-fold or greater rise** in bAb noted in **96-100%** of mRNA1273 recipients[234] *Neutralizing Antibody Responses:*	No available data	*Heterologous 1:* **14.8 to 32.4-fold** increase in neutralization titers against wild-type virus[233] *Binding Antibody Responses (bAb):* **2-fold or greater rise** in bAb noted in **98-100%** of	No available data	*Heterologous 1:* Heterologous vaccination had a **9-fold greater GMT** (7,947 U/mL) than fully patients fully vaccinated with AZD1222 and the highest antibody response, IgA, and neutralizing	

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

	341.3-677.9 IU50/mL 15 days after booster with BNT162b2[234] Participants who received mRNA-based booster vaccination had four-fold increase compared to Ad26.COV2.S. [234]	**676.1-901.8 IU50/mL** 15 days after booster with mRNA1273[234] Participants who received mRNA-based booster vaccination had four-fold increase compared to Ad26.COV2.S. [234]		Ad26.COV2.S. recipients[234] *Neutralizing Antibody Responses:* **31.2-382.2 IU50/mL** 15 days after booster with Ad26.COV2.S. [234]		antibodies than other groups[235] *Heterologous 2:* Median values of IgG-S titers were higher in group that received BNT162b2 as booster than CoronaVac BNT162b2 boosted IgG-S median titers by **factor of 46.6** but IgG-N titers decreased by **factor of 6.5**[236] Single booster dose of BNT162b2 induced higher anti-spike RBD IgG antibody levels, compared to single booster dose of CoronaVac[57]	

Immunogenicity against variants	*Binding Antibody Responses:* Baseline bAb levels for **Delta** were **34-45% lower** compared to Wa-1 strain[234] Following boost, bAB levels for **Delta** were **15-36% lowe**r compared to Wa-1 strain[234]	*Binding Antibody Responses:* Baseline bAb levels for **Delta were 34-45% lower** compared to Wa-1 strain[234] Following boost, bAB levels for **Delta** were **15-36% lower** compared to Wa-1 strain[234] *Neutralizing Antibody Responses:* **Delta and Beta** variants were only available in those boosted with mRNA-1273[234]	No available data	*Heterologous 1:* **10.9 to 21.2-fold** increase in pseudo virus neutralization assay (one volunteer did not have any against B.1.351) [233] *Binding Antibody Responses:* Baseline bAb levels for **Delta** were **34-45% lower** compared to Wa-1 strain[234] Following boost, bAB levels for **Delta** were **15-36% lower** compared to Wa-1 strain[234]	No available data	*Heterologous 1:* Neutralizing activity against the wild type and variant strains showed higher neutralizing activity in the following order: **wild type > B.1.617.2 > B.1.1.7 > B.1.351**[235]	
Reactogenicity	*Adverse Events:* **72-92%** participants reported local pain or tenderness[234]	*Adverse Events:* **75-86%** participants reported local pain or tenderness[234]	No available data	*Adverse Events:* **71-84%** participants reported local pain or tenderness[234]	No available data	Similar results to homologous booster administration	

	Malaise, myalgias, and headaches were commonly reported[234] **14.4%** of the participants reported unsolicited adverse events[234]	Malaise, myalgias, and headaches were commonly reported[234] **15.6%** of participants reported unsolicited adverse events[234]		Malaise, myalgias, and headaches were commonly reported[234] **12%** of participants reported unsolicited adverse events[234]			
Other						Ongoing clinical trial examining the immunogenicity and safety of a third dose vaccination with ChAdOx1 or BNT162b2 vaccine among adults who received full jab of CoronaVac[xxxiv]	

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

ANNEXES

	BNT162b2/ COMIRNATY (Pfizer-BioNTech, USA)	Spikevax/ Moderna COVID-19 Vaccine/ mRNA-1273 (Moderna, USA)	Vaxzevria/ ChAdOx1 nCoV-19/ AZD1222/ Covishield (AstraZeneca/Oxford, UK, India)	Janssen COVID-19 vaccine/Johnson & Johnson (Janssen, USA)	Sinopharm/BBIBP-CorV, China	Sinovac CoronaVac, China	Novavax/ NVX-CoV2373
FURTHER INFORMATION							
Storage conditions	2°C to 8 °C (for 1 month)	2°C to 8 °C (for 1 month)	2°C until 8 °C	2°C to 8 °C (for 3 months)	2°C until 8 °C	2°C until 8 °C	2°C to 8 °C
Approving authorities	FDA (11.12.20)[xxxv]; 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)

[xxxv] 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)				
IMMUNOGENICITY							
Immunogenicity	*7-14 days after second dose:* *18-55 years*: GMT ranged from **1.7 to 4.6** times the GMT of the convalescent serum[237]. *65-85 years*: GMT ranged from **1.1 to 2.2** times the GMT of the convalescent serum[237].	*14 days after second dose:* *18-55 years*: $PRNT_{80}$ GMT **654.3 (95% CI, 460.1-930.5**)[238]. *56-70 years:* $PRNT_{80}$ GMT **878 (95% CI, 516-1494**)[239]. *≥71 years*: $PRNT_{80}$ GMT **317 (95% CI, 181-557**)[239].	*28 days after second dose median antibody titres:* *18–55 years*: **20,713 AU/mL [IQR 13,898 - 33,550**][240] *56–69 years*: 1**6,170 AU/mL [IQR 10,233 - 40,353]**[240]. *≥70 years*: **17,561 AU/mL [IQR 9,705 - 37,796]**[240].	*29 days after vaccination:* *18-55 years:* GMC **586 (95% CI, 445-771**); GMT **224 (95% CI, 168-298**)[241]. *≥65 years*: GMC **312 (95% CI, 246-396); GMT 212 (95% CI, 163-266**)[241]. *57 days after vaccination:* *18-55 years*: **754 (95% CI, 592-961**); GMT **288 (95% CI, 221-376**)[241].	*14 days after second dose:* *18-55 years:* GMT ***211.2*** **(95% CI, 158.9-280.6**)[242]. *≥60 years: GMT **131.5** (95% CI, 108.2-159.7*)[242].	*Single dose (≥4 weeks)*: **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) *Two doses (≥4 weeks)*: **194.61±174.88 IU/ml (min: 0, max: 677.82);** 11.48% of participants did not develop sufficient antibody titres (<25.6 IU ml)[243]. *2 weeks after second dose:*	

						164.4 BAU/ mL[244] *4 weeks after second dose:* 94.8 BAU/ mL[244] *8-12 weeks after second dose:* 34.7 BAU/ mL[244]	
Immunogenicity against the Mu variant	6.8-fold decrease in neutralizing titres when compared to convalescent sera[245]	Neutralizing titre similar to that of BNT162b2 sera[245]	Neutralizing titre similar to that of BNT162b2 sera[245]				
EFFICACY							
Single dose[xxxvi]	**52%** (95% CI, 29.5 to 68.4; starting at 12 days) or 82.2% (75.1 to 87.3; starting at ≥14 days)[246].	**95.2%** (95% CI, 91.2.8 to 97.4; starting at >14 days)[76].	**72.8%** (starting at 22 days up to 60 days)[248]. **88%** (95% CI, 75-94)[247].[xxxvii]	Single dose vaccine	Unknown	**35.1%** (95% CI, -6.6 to -60.5) [conducted in a setting with high P.1 transmission][249].	**83.4%** (95% CI, 73.6-89.5) starting at ≥14 days[84]

[xxxvi] Against SARS-COV-2 infection

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

	91% (95% CI, 85-94)[247].						
Two doses[xxxviii]	**95.0%** (95% CI, 90.3-97.6) starting at ≥7 days in population without prior SARS-CoV-2 infection[90] **94.6%** (95% CI, 89.9-97.3) starting at ≥7 days in population with or without prior infection[90]	**94.1%** (95% CI, 89.3-96.8) after median follow-up of less than 63 days[76] **93.2%** (95% CI, 91.0-94.8)[250] Against severe disease: **98.2%** (95% CI, 92.8-99.6)[250]	**63.1% (**95% CI, 51.8-71.7) starting at ≥14 days for two standard doses[248] **80.7%** (95% CI, 62.1-90.2) starting at ≥14 days for first low dose and standard second dose[248] **66.7%** (95% CI, 57.4-74.0) starting at ≥14 days for pooled analysis efficacy[248]	**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[251] **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[251]	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).[162]	After 14 days, efficacy against symptomatic cases was **50.7%** (95% CI 35.9 to 0-62.0).[82] 99.17% of NAb titres were above or equal to the Nab positivity cut-off (20 units) against wild-type[252].	**89.7%** (95% CI, 80.2-94.6) starting at ≥7 days[84] **90.4%** (95% CI, 82.9-94.6)[253] **100%** (95% CI, 87-100) against moderate-to-severe COVID-19[253] **100%** (95% CI, 34.6-100) against severe COVID-19[253]
Against asymptomatic infection	**90%** (starting at 14 days) regardless of symptom status[254]	**63.0%** (95% CI, 56.6-68.5)[250]	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)[251].	Efficacy against symptomatic and asymptomatic cases was **64%** (95% CI 48.8 to 74.7; in WIV04 vaccine) or 73.5%	Unknown	Unknown

[xxxviii] Against SARS-CoV-2 infection.

					(95% CI 60.6 to 82.2; in HBO2 vaccine)[162].		
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[255].	**NAbs remained high** and consistent with titres of the wildtype for the B.1.1.7 variant[256].	**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[72].	**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. those naturally infected, suggesting the vaccine has a similar level of protection against infection as natural infections[257].	**10.4-fold** reduction in neutralization capacity when compared to natural infection sera[252]. **85.83%** of NAb titres were above or equal to the Nab positivity cut-off (20 units) against wild-type[252]. Neutralization decreased by **4.1-fold** when compared to wild-type[258].	Two dose efficacy against the B.1.1.7 variant **86.3%** (95% CI, 71.3-93.5)[84] **93.6%** (95% CI, 81.7-97.8) against the Alpha variant[253]
Beta (B.1.351)	Neutralization was **diminished by a factor of 5**. Despite this, the	NAbs were **6-fold** lower. Nevertheless, NAbs were still	Two doses of the vaccine had no efficacy against the B.1.351 (VE =	Efficacy against moderate-severe-critical Covid-19 due to the variant		NT_{GM} **35.03 (95% CI, 27.46-44.68**); **8.75-fold** reduction in	**51.0%** (95% CI, -0.6-76.2) efficacy against B.1.351 variant[264]

	BNT162b2 mRNA vaccine still provides some protection against B.1.351[259] **100%** (95% CI, 53.5-100)[260].	found to be protective[256].	**21.9%;** 95% CI, -49.9 to 59.8)[261].	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)[251]. Demonstrated **3.6-fold** reduction in neutralization sensitivity[262]. Neutralization titres were decreased by **6.7-fold[263]**.	No published data	neutralization capacity when compared to natural infection sera[252]. **82.5%** of NAb titres were above or equal to the Nab positivity cut-off (20 units) against wild-type[252].	
Gamma (P.1)	*Single dose:* *≥21 days*: **83%** against hospitalization and death[265]. *Two doses*: *≥14 days*: **98%** against hospitalization and death[265].	**3.2-fold** reduction in neutralization capacity when compared to wild-type[266].	*Single dose:* *≥21 days*: **94%** against hospitalization and death[265]. *Two doses:* **64%** (95% CI, -2-87) [n=18][267] Efficacy against Zeta (P.2) [2 doses]: **69%** (95% CI, 55-78)[267]	Demonstrated **3.4-fold** reduction in neutralization sensitivity[262].	No published data	**49.6%** against P.1 (>14 days after 1st dose)[249]. Neutralization decreased by **7.5-fold** when compared to wild-type[258].	No available data

Delta (1.671.2)	**Reduced NAb activity** relative to B.1.1.7 strain[268].	**2.1-fold** reduction in neutralization capacity when compared to wild-type[266].	*Single dose:* *≥21 days*: **90%** against hospitalization and death[265].	Demonstrated **1.6-fold** reduction in neutralization sensitivity[262]. Neutralization titres were decreased by **5.4-fold**[263].	Demonstrated **reduced neutralizing capacity**. However, there were no differences in the NAbs titres against B.1.617.2 in vaccinated individuals vs. those naturally infected, suggesting the vaccine has a similar level of protection against infection as natural infections[257].	NT_{GM} **24.48** (95% CI,19.2-31.2)[252]. **69.17%** of NAb titres were above or equal to the Nab positivity cut-off (20 units) against wild-type[252].	No available data
PHASE III TRIALS RESULTS[xxxix]							

[xxxix] 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.

Number of participants (vaccine/ placebo)	43,448 (21,720/ 21,728)[90]	30,420 (15,210/15,210)[76]	17,178 (8597/8581)[248]	39,321 (19,630/19,691)[251]	26,917 (13,459/13458); or 26,914 (13,465/13,458)[162]	9,823 (4,953/4,870)[82]	14,039 (7,020/7,019)[84]
Total COVID-19 cases (vaccine/ control)	170(8/162)[90]	196 (11/185)[76]	332 (84/248)[248]	464 (116/348)[251]	121(26/95) or 116(21/95)[162]	253(85/168)[82]	106(10/96)[84]
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 adolescents (12-15 years old)[90].	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)[76].	Two standard doses: efficacy was **63·1%** (95% CI 51.8 to 71.7; ≥14 days) while those with first low dose and standard 2nd dose the efficacy was **80.7%** (95% CI 62.1 to 90.2). Pooled analysis efficacy was **66.7%** (95% CI 57.4 to 74.0). For any nucleic acid amplification test-positive swab: efficacy was 54.1% (95% CI 44.7 to 61.9)[248].	VE against moderate-severe-critical Covid-19 was **66.9%** (95% CI 59.0 to 73.4) after 14 days post vaccine administration, and **66.1%** (95% CI 55.0 to 89.1) after 28 days. VE against severe-critical COVID-19 cases was **76.7%** (95% CI 54.6 to 89.1) after 14 days and **85.4%** (95% CI 54.2 to 96.9) after 28 days[251].	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)[162].	After 14 days, efficacy against symptomatic cases was **50.7%** (95% CI 35.9 to 0-62.0).[82]	**83.4%** (95% CI, 73.6-89.5) starting at ≥14 days after first dose[84] **89.7%** (95% CI, 80.2-94.6) starting at ≥7 days after second dose[84]
Efficacy against hospitalization and death	**100%** (after 7 days)[90]	**100%** (≥14 days)[76]	**100%** (after 21 days)[248]	**76.7%** (≥14 days) or **85.4%** (≥28 days)[251]	**100%** (>14 days)[162]	**100%** (>14 days)[82]	**100%** (after 7 days)[84].

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[73,269].	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[76].	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 [78].	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)[251].	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[81].	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[82].	<u>Phase II:</u> Nine serious adverse events were reported, only one of which was assessed as related to the vaccine: acute colitis[270].
PHASE III TRIAL OTHER							
Comments	Specific populations were excluded (HIV and immunocompromi	Calculation of efficacy were not based on the total number of		**<u>2-DOSE EFFICACY</u>** *<u>Efficacy against symptomatic (moderate to severe/ critical)</u>*	Only 2 severe cases occurred in the control group and none in the vaccine group		Novavax is currently awaiting FDA, EMA, and WHO EUL approval.

	sed patients, and pregnant women).	confirmed Covid-19 cases.		*SARS-CoV-2 infection* **94%** (95% CI, 58-100) in the US. **75%** (95% CI, 55-87) globally.[11] *Efficacy against severe/ critical SARS-CoV-2 infection* **100%** (95% CI, 33-100)[11]	(very few cases to get a reliable estimate).		Upcoming information regarding results of clinical trials or approval will be updated in upcoming reports

VACCINE PRODUCTION SITES							
	BNT162b2/ COMIRNATY	**Spikevax/ Moderna COVID-19 Vaccine/**	**Vaxzevria/ ChAdOx1 nCoV-19/ AZD1222/ Covishield**	**Janssen COVID-19 vaccine/Johnson & Johnson**	**Sinopharm/BBIBP-CorV, China[xliv]**	**Sinovac CoronaVac, China[xlv]**	**Novavax/ NVX-CoV2373**

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

[xlv] 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

	(Pfizer-BioNTech, USA)[xl]	mRNA-1273 (Moderna, USA)[xli]	(AstraZeneca/Oxford, UK, India)[xlii]	(Janssen, USA)[xliii]			
EUL holder	BioNTech Manufacturing GmbH (Germany)	ModernaTX, Inc. (USA)[1] Moderna Biotech (Spain)[2]	AstraZeneca AB (Sweden)	Janssen-Cilag International NV (Belgium)	Beijing Institute of Biological Products Co., Ltd. (BIBP) (China)	Sinovac Life Sciences Co., Ltd. (China)	Novavax (USA)
Production sites (Drug substance)	BioNTech Manufacturing GmbH (Mainz, Germany) BioNTech Manufacturing Marburg (Marburg, Germany)	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	Beijing Institute of Biological Products Co., Ltd. (China)	Sinovac Life Sciences Co., Ltd. (China)	Novavax (Bohumil, Czech Republic)

[xl] 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

[xli] 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

[xlii] 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

[xliii] 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

	Rentschler Biopharma SE (Laupheim, Germany) Wyeth BioPharma Division of Wyeth Pharmaceuticals (USA)		SK Bioscience (Republic of Korea) Halix B.V (Netherlands) WuXi Biologics (China)	Operations Baltimore LLC (USA)			
Production sites (Drug product)	Baxter Oncology GmbH (Halle/ Westfallen, Germany) BioNTech Manufacturing GmbH (Mainz, Germany) Pfizer Manufacturing Belgium NV (Belgium) Novartis Pharma Stein AG (Switzerland) Mibe GmbH Arzneimittel (Brehna, Germany)	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)

Diluent suppliers	Pfizer Perth, Australia Fresenius Kabi, USA	-	-	-	-	-	-

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