COVID-19 vaccines in the WHO's Emergency Use Listing (EUL) Report (9) - 30.11.2021

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Literature screening report

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Abstract

This report focuses on the World Health Organization's (WHO) Emergency Use Listing (EUL) of authorized vaccines as of 26 November 2021. Bharat Biotech's new vaccine **COVAXIN/ BBV152** received WHO EUL authorisation on 3 November 2021 leading to **seven** vaccines being now authorised for emergency use: BNT162b2/COMIRNATY (Pfizer-BioNTech, USA), Spikevax/Moderna COVID-19 Vaccine/ mRNA-1273 (Moderna, USA), Vaxzevria/ChAdOx1 nCoV-19/AZD1222/Covishield (AstraZeneca/Oxford, UK, India), Janssen Covid-19 vaccine/Johnson & Johnson (Janssen, USA), Sinopharm/BBIBP-CorV (China), Sinovac/CoronaVac (China), and COVAXIN/BBV152 (Bharat Biotech, India)]. This report provides a condensed summary concerning vaccine efficacy, 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 observational studies. This report focuses on the latest data on vaccine effectiveness, vaccine induced immunity, breakthrough infections, 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, 53.8% of the world populations, of which only 5.5% of people in low-income countries, have received at least one dose of a marketed COVID-19 vaccine as of 26 November 2021[1]. Currently, seven vaccines [namely, Comirnaty/BNT162b2 (Pfizer-BioNTech, USA), Spikevax/Moderna COVID-19 Vaccine/mRNA-1273 (Moderna, USA), Vaxzevria/ChAdOx1_nCoV-19/AZD1222/Covishield (AstraZeneca/Oxford, UK, India), Janssen Covid-19 vaccine/Johnson & Johnson (Janssen, USA), Sinopharm/BBIBP-CorV (China), Sinovac/CoronaVac (China), and COVAXIN/BBV152 (Bharat Biotech, India)] were assessed and granted an authorization by WHO as of 26 November 2021. **Articles regarding the latest data on vaccine effectiveness, vaccine induced immune response, breakthrough infections and transmission, and booster doses were prioritized during the literature search and are the latest additions to the table. Data from clinical trials and observational studies for the seven EUL-accepted vaccines and the vaccine candidate Novavax regarding these highlighted topics were summarized and can be found in the synoptic table below.**

[1] https://ourworldindata.org/covid-vaccinations (accessed on 26.11.2021).

Methodology

We screened the data for the EUL-accepted vaccines and the vaccine candidate Novavax as of 26 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 seven WHO EUL authorized vaccines, and as the share of fully vaccinated people begin to increase across countries, it is important to assess vaccine effectiveness in real-world conditions, especially in relation to evolving variants of concern (VOC).

Latest Data on Vaccine Effectiveness

No significant updates regarding vaccine effectiveness were identified since the previous synoptic table this month. In a recent study, final analyses of the blinded phase of Moderna's mRNA1273 vaccine efficacy and safety further support existing evidence of its effectiveness against COVID-19 infection and severe disease. From the clinical trial's 30,315 subjects, there were 55 confirmed COVID-19 cases among individuals who received mRNA-1273 compared with 744 COVID-19 cases among individuals in the placebo group; resulting in vaccine efficacy preventing COVID-19 infection **at 93.2% (95% CI, 91.0 to 94.8)**.[3] In terms of prevention against severe disease, vaccine efficacy was **98.2% (95% CI, 92.8 to 99.6)** while vaccine efficacy against asymptomatic infection 14-days after dose completion was 63.0% **(95% CI,**

[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] Efficacy of the mRNA-1273 SARS-CoV-2 Vaccine at Completion of Blinding Phase. *New England Medical Journal of Medicine.* https://www.nejm.org/doi/10.1056/NEJMoa2113017

56.6 to 68.5).[4] Results were consistent across age, ethnicity, and individuals with coexisting conditions.

Alternatively, a national cohort study conducted in Norway from January to September 2021 investigated vaccine effectiveness by age and product-specific vaccine (homologous and heterologous regimens) effectiveness against various COVID-19 disease outcomes. Overall, full vaccine dosages were found to provide better protection when compared with partial doses. Resulting effectiveness against any COVID-19 infection for those fully vaccinated was at **72.1% (95% CI, 71.2-73.0)**, **95.5% (95% CI 92.6-97.2)** against ICU hospitalization, and **88.0% (95% CI 82.5-91.8)** against death.[5] Furthermore, when comparing specific vaccine regimens among fully vaccinated, heterologous mRNA vaccines demonstrated the highest protection with effectiveness against infection at **84.7% (95% CI 83.1-86.1)** followed by homologous regimens; mRNA-1273 and BNT162b2 at **78.3% (95% CI 76.8-79.7)** and **69.7% (95% CI 68.6-70.8)** respectively, and **60.7% (95% CI 57.5-63.6)** for ChADox nCOV-19.[6]

With regard to the newly WHO EUL approved vaccine BBV152/Covaxin, data in a recent preprint from *The Lancet* show that during dominance of the Delta variant, Covaxin demonstrated, statistically, relatively good effectiveness against severe COVID-19 in India. In this multi-centric, hospital-based case-control study conducted on Covaxin and Covishield effectiveness, results of the investigation illustrated that full dose Covaxin effectiveness was at **69% (95% CI, 54.0-79.0)** for the Delta variant plus its sub-lineages, while Covishield had an effectiveness **of 80% (95% CI, 73.0-86.0)**.[7]

[4] Efficacy of the mRNA-1273 SARS-CoV-2 Vaccine at Completion of Blinding Phase. *New England Medical Journal of Medicine.* https://www.nejm.org/doi/10.1056/NEJMoa2113017

[5] Age and product dependent vaccine effectiveness against SARS-CoV-2 infection and hospitalization among adults in Norway: a national cohort study, January – September 2021. *medRxiv.* https://www.medrxiv.org/content/10.1101/2021.11.24.21266401v1

[6] Age and product dependent vaccine effectiveness against SARS-CoV-2 infection and hospitalization among adults in Norway: a national cohort study, January – September 2021. *medRxiv.* https://www.medrxiv.org/content/10.1101/2021.11.24.21266401v1

[7] Effectiveness of BBV152/Covaxin and AZD1222/Covishield Vaccines Against Severe COVID-19 and B.1.617.2/Delta Variant in India, 2021: A Multi-Centric Hospital-Based Case-Control Study. *Preprint with The Lancet.* https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3955739

Vaccine Induced Immune Responses

A recent study compared the kinetic of humoral and cellular immune responses elicited by Pfizer-BioNTech's BNT162b2 vaccine (2-dose schedule), Moderna's mRNA-1273 vaccine (2-dose schedule), and Janssen's Ad26.COV2.S vaccine (1-dose schedule). The study followed participants from peak immunity (2-4 weeks post full immunization) until to 8 months post-vaccination[8]. Similar to vaccine effectiveness data outcomes, Moderna's mRNA-1273 vaccine demonstrated higher median neutralizing antibody (NAb) titres (**5,848**), pseudovirus neutralizing antibody tires (**1,569**), and receptor-binding domain (RBD) specific binding antibody titre (**25,677**) than recipients of the BNT162b2 vaccine (NAb titre: **1,789**; pseudovirus NAb titre: **700**; RBD titre: **21,564**) at peak immunity. Janssen's Ad26.COV2 induced significantly lower median titres compared to both mRNA vaccines (NAb titre: 146; pseudovirus NAb titre: 391; RBD titre: 1,361). While both mRNA vaccines' titres decreased over time, Ad26.COV2's titres did not. mRNA-1273 titres declined by a factor of **44** (NAb titre), **6** (pseudovirus NAb titre), and **17** (RBD titre), while BNT162b2 titres decreased by a factor of **34, 4, and 29**, respectively[9]. All three vaccines demonstrated "broad cross-reactivity against SARS-CoV-2 variants" and had CD8+ T cell responses of **0.017%**, **0.016%**, and **0.12%** 8 months after full immunization for the mRNA-1273, BNT162b2, and Ad26.COV2 vaccines, respectively[10].

A Colombian surveillance study evaluated the sensitivity of Pfizer-BioNTech's BNT162b2 vaccine to neutralize three SARS-CoV-2 strains in Colombia: Mu (B.1.621; Variant of Interest), Gamma (P1; Variant of Concern) and the B.1.111 lineage ("lacks genetic markers associated with greater virulence")[11]. While the BNT162b2 vaccine demonstrated robust neutralization against both the B.1.111 lineage and P.1 strain, albeit the Gamma variant titre (**GMT 65.2 $TCID_{50}$**) was **3.4-fold lower** than the geometric mean titre of the B.1.111 lineage (**GMT 224.2 $TCID_{50}$**), the Mu variant escaped BNT162b2-elicited neutralization (**11/14 (78.5%) of serum**

[8] Differential kinetics of immune responses elicited by COVID-19 vaccines. *New England Journal of Medicine.* https://www.nejm.org/doi/full/10.1056/NEJMc2115596

[9] Differential kinetics of immune responses elicited by COVID-19 vaccines. *New England Journal of Medicine.* https://www.nejm.org/doi/full/10.1056/NEJMc2115596

[10] Differential kinetics of immune responses elicited by COVID-19 vaccines. *New England Journal of Medicine.* https://www.nejm.org/doi/full/10.1056/NEJMc2115596

[11] Low neutralizing antibody titers against the Mu variant of SARS-CoV-2 in BNT162b2 vaccinated individuals. *medRxiv.* https://www.medrxiv.org/content/10.1101/2021.11.19.21266552v1.full

samples was not able to neutralize SARS-CoV-2). The mean geometric mean titre against B.1.621 was **41**- and **20-fold lower** (***P*<0.0001**) compared to B.1.111 and P.1 lineages[12].

Breakthrough Infections and SARS-CoV-2 Transmission

While all WHO EUL authorised vaccines have demonstrated to be effective against severe SARS-CoV-2 infections and hospitalization, the combined effects of low vaccination rates[13], waning vaccine immunity, and the emergence of the Delta variant has led to increased cases of SARS-CoV-2 breakthrough infections, raising concerns among the general population. Breakthrough infections typically have higher viral loads, prolonged PCR positivity, and demonstrate lower levels of vaccine induced NAbs[14,15]. For example, symptomatic hospital staff in Ho Chi Minh City (all vaccinated with the ChAdOx1 nCoV-19) demonstrated higher viral loads (median IQR: **16.5**) relative to asymptomatic cases (median viral load IQR: **30.8**)[16]. Additionally, breakthrough infections were characterised by having lower levels of neutralizing antibodies after vaccination (median % of NAb inhibition: 69.4) and when positive for SARS-CoV-2 (median % of NAb inhibition: 59.4) relative to control participants (median % of NAb inhibition after vaccination: 91.3; median % of NAb inhibition at 7-8 weeks uninfected control: 91.1). The authors highlighted that "the absence of correlation between neutralizing antibody levels and peak viral loads suggested that vaccine might not lower the transmission potential of breakthrough infection cases"[17]. The authors' claim is corroborated by a recently published serological study that confirmed SARS-CoV-2 transmission is correlated to high viral loads, which is uncorrelated to vaccination status and/or the presence of COVID-19 symptoms[18].

[12] Low neutralizing antibody titers against the Mu variant of SARS-CoV-2 in BNT162b2 vaccinated individuals. *medRxiv.* https://www.medrxiv.org/content/10.1101/2021.11.19.21266552v1.full

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

[14] An observational study of breakthrough SARS-CoV-2 Delta variant infections among vaccinated healthcare workers in Vietnam. *The Lancet.* https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(21)00423-5/fulltext

[15] Investigating SARS-CoV-2 breakthrough infections per variant and vaccine type. *medRxiv.* https://www.medrxiv.org/content/10.1101/2021.11.22.21266676v1.full.pdf

[16] An observational study of breakthrough SARS-CoV-2 Delta variant infections among vaccinated healthcare workers in Vietnam. *The Lancet.* https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(21)00423-5/fulltext

[17] An observational study of breakthrough SARS-CoV-2 Delta variant infections among vaccinated healthcare workers in Vietnam. *The Lancet.* https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(21)00423-5/fulltext

[18] Isolation of 4000 SARS-CoV-2 shows that contagiousness is associated with viral load, not vaccine or symptomatic status. *Emerging Microbes & Infections.* https://www.tandfonline.com/doi/full/10.1080/22221751.2021.2008776

Despite the concerns surrounding breakthrough cases, infections are clinically milder[19], are more likely to recover swiftly from illness than unvaccinated persons[20,21], and are still less likely to infect others[22,23]. Studies are recommending continuing the implementation of social distancing and non-pharmaceutical measures in order to mitigate pandemic effects.

Booster Dose

As evidence on the efficacy, safety, effectiveness, and immunogenicity of third (booster) doses becomes available, many countries are continuing to expand their recommendations for booster shots and are slowly beginning to administer third doses to all adults, and sometimes adolescents, who have received their full COVID-19 vaccine jabs at least six months ago. Recently, on 23 November 2021, Switzerland joined other countries in approving the booster to its general population by approving the extension of the Pfizer-BioNTech booster dose to everyone aged 16 years and older[24]. This decision was supported by the published data, made available by Pfizer-BioNTech, on the efficacy and safety of the BNT162b2 booster doses on 10,000 participants 16 years of age and older who completed a two-dose series of the BNT162b2 vaccine[25]. Based on those results, the vaccine efficacy of the booster dose against symptomatic COVID-19 in participants without evidence of prior infection was **95.3%** (95% CI, 89.5-97.9) and **96.5%** (95% CI, 89.3-99.3) for participants aged 16-55 years of age and **93.1%** (95% CI, 78.4-98.6) for participants aged over 55 years[25]. Additionally, the booster dose demonstrated to be safe and well tolerated. On top being efficacious in clinical trials, booster doses have also shown to have a high effectiveness and significantly increase the immune response of recipients. During a test-negative case-control study, the vaccines effectiveness

[19] Vaccination after prior COVID-19 infection: Implications for dose sparing and booster shots. *EBioMedicine.* https://www.thelancet.com/journals/ebiom/article/PIIS2352-3964(21)00379-0/fulltext

[20] 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

[21] Understanding breakthrough infections following mRNA SARS-CoV-2 vaccination. *JAMA.* https://jamanetwork.com/journals/jama/fullarticle/2786040

[22] Virological and serological kinetics of SARS-CoV-2 Delta variant vaccine-breakthrough infections: a multi-center cohort study. *bioRXiv.* https://www.medrxiv.org/content/10.1101/2021.07.28.21261295v1.full?origin=app

[23] Understanding breakthrough infections following mRNA SARS-CoV-2 vaccination. *JAMA Network.* https://jamanetwork.com/journals/jama/fullarticle/2786040

[24] COVID-19 vaccine from Pfizer-BioNTech: Swissmedic approves he extension of the booster dose to everyone aged 16 years and over. *Swissmedic.* https://www.swissmedic.ch/swissmedic/en/home/news/coronavirus-covid-19/covid-19-impfstoff-pfizer-biontech-boosterdosis.html

[25] Efficacy & Safety of BNT162b2 booster – C4591031 2 month interim analysis [press release]. *Pfizer and BioNTech, CDC.* https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-19/02-COVID-Perez-508.pdf.

against symptomatic COVID-19 of the booster dose BNT162b2 in individuals aged 50 years and over who received the ChAdOx1-S or BNT162b2 in the UK was estimated. Based on the results, an effectiveness of **87.4%** (95% CI, 84.9-89.4) for individuals who received the ChAdOx1-S as their full jab and an effectiveness of **84.4%** (95% CI, 82.8-85.8) for individuals who received the BNT162b2 as their full jab was calculated[26]. Additionally, when estimating the vaccine effectiveness against symptomatic COVID-19 of unvaccinated individuals and individuals who received the booster dose from 14 days after vaccination, an absolute effectiveness of **93.1%** (95% CI, 91.7-94.3) after receiving ChAdOx1-S as the primary course and **94.0%** (95% CI 93.4-94.6) after receiving BNT162b2 as the primary course were estimated[26].

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

[26] Effectiveness of BNT162b2 (Comirnaty, Pfizer-BioNTech) COVID-19 booster vaccine against covid-19 related symptoms in England: test negative case-control study. *medRxiv.* https://www.medrxiv.org/content/10.1101/2021.11.15.21266341v1

Synoptic Table

Synoptic table about SARS-CoV-2 vaccines accepted in the WHO's Emergency Use Listing and Novavax Vaccine (as of 26 November 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)**	**BBIBP-CorV, (Sinopharm, China)**	**CoronaVac (Sinovac, China)**	**COVAXIN / BBV152 (Bharat Biotech, India)**	**Novavax/ NVX-CoV2373**
GENERAL VACCINE INFORMATION								
Platform	mRNA-based vaccine	mRNA-based vaccine	Non-replicating vector-based vaccine	Non-replicating vector-based vaccine	Inactivated virus (Vero cell)	Inactivated virus (Vero cell)	Whole-virion inactivated Vero cell	Recombinant protein (nanoparticle) vaccine with Matrix-M adjuvant
Dose and frequency	2 doses, 21 days apart	2 doses, 28 days apart	2 doses, 4-12 weeks apart	1 dose, once [Phase III trials currently testing 2-dose regime, 56 days apart][i]	2 doses, 21 days apart	2 doses, 14 days apart	2 doses, 28 days apart	2 doses, 21 days apart

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

Target population	12 years old and over	12 years old and over	18 years old and over	18 years old and over	18 years old and over	18 years old and over	18 years old and over	18 years old and over
Storage conditions	2°C to 8 °C (for 1 month)	2°C to 8 °C (for 1 month)	2°C until 8 °C	2°C to 8 °C (for 3 months)	2°C until 8 °C	2°C until 8 °C	2°C until 8 °C	2°C to 8 °C
Approving authorities	FDA (11.12.20)[ii]; EMA (21.12.20); WHO EUL (31.12.20); and list of 103 countries (including Switzerland – approved on 20.12.20)	FDA (18.12.20); EMA (06.01.21); WHO EUL (30.04.21); and list of 76 countries (including Switzerland – approved 12.01.21)	FDA (awaiting on approval); EMA (29.01.21); WHO EUL (15.02.21); and list of 124 countries (Switzerland awaiting on approval)	FDA (27.02.21); EMA (11.03.21), WHO EUL (12.03.21), and list of 75 countries (including Switzerland – approved 22.03.21)	WHO EUL (07.05.21); and list of 68 countries (e.g., Argentina, Bahrain, Brazil, China, Indonesia, United Arab Emirates, Zimbabwe)	WHO EUL (01.06.21), and list of 42 countries (e.g., Albania, Chile, Egypt, Hong Kong, Malaysia, Tunisia, Turkey, Ukraine)	WHO EUL (03.11.21) and list of 9 countries (Guyana, Inidia, Iran, Mauritius, Mexico, Nepal, Paraguay, Philippines & Zimbabwe)	Waiting on approval (Not-yet-approved by countries or WHO for emergency use)
Booster shot approving authorities	EMA approved booster for those aged 18 and above, 6 months after the 2nd dose[1] FDA approved booster for those ages 16 and above, 6 months after the 2nd dose[iii]	EMA authorised booster dose for immunocompromised individuals[iv] FDA approved third booster dose for individuals >65 and high-risk individuals, 6 months after the 2nd dose[v]	-	-	-	-	-	-

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

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

[iv] Comirnaty and Spikevax: EMA recommendations on extra doses and boosters. *European Medicines Agency*. https://www.ema.europa.eu/en/news/comirnaty-spikevax-ema-recommendations-extra-doses-boosters

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

EFFECTIVENESS AGAINST ANY SARS-COV-2 INFECTION								
Effectiveness single dose	*Against any SARS-CoV-2 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] **57%** (95% CI, 52-61; Spain) [Apr-Aug][5] **72%** (pooled meta-analysis)[6] **64%** (95% CI, 59%-68%; United States) [May to July 2021][7vi] **19.6%** (95% CI, 17.3-21.9; Norway) [Jan-Sep][8] *Against symptomatic disease*:	*Against SARS-CoV-2 infection:* **60%** (95% CI, 57-64; >2 weeks after dose)[11].[viii] **88.9%** (95% CI, 78.7-94.2)[3] **66%** (95% CI, 56-73; Spain) [Apr-Aug][5] **69%** (pooled meta-analysis)[6] **64%** (95% CI, 59%-68%; United States) [May to July 2021][7ix] **39.6%** (95% CI, 36.3-42.8; Norway) [Jan-Sep][8] *Against symptomatic disease*: **71%** (95% CI, 61-79; Spain) [Apr-Aug][5]	*Against SARS-CoV-2 infection:* **31.4%** (95% CI, 25.7-36.7; Norway) [Jan-Sep][8] *Symptomatic disease:* **67%**[12] **49%** (95% CI, 32.0-62.0; India) [Apr-Jun][13] **41%** (95% CI, 34-48; Spain) [Apr-Aug][5] **51%** (pooled meta-analysis)[6] **46%** (95% CI, 37-54; Spain) [Apr-Aug][5] *Individuals ≥70:* Symptomatic disease: **58%**[9].	*Against SARS-CoV-2 infection:* **50.6%** (95% CI, 14.0-74.0) [<2 weeks after dose]; **76.7%** (95% CI, 30.3-95.3) [>2 weeks after dose][14]; **79%** (95% CI, 77-80) (when corrected for under-recording, VE was estimated to be **69%** (95% CI, 67-71)[15]. **71%** (95% CI, 56-81) [11 March – 15 August][16]. **61%** (95% CI, 29-84) [January-June][17] **50.9%** (95% CI, 35.1-63.0) [June-September; Brazil][18]	Partial protection[22].[xii]	**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[23]. **18.6%** (95% CI, 17.6-19.6) against SARS-CoV-2 infection, **28.1%** (95% CI, 26.3-29.9) against hospitalization, **28.5%** (95% CI, 25.4-31.4) against ICU admission, and **29.4%** (95% CI, 26.7.3-31.9) against death [January-April][24]	*Against symptomatic disease*: **45%** (95% CI,6.0-68.0; India) [Apr-Jun][13] **40%** (95% CI, -21-71; India) less than 7 days after first dose [April-May][25] **1%** (95% CI, -30-25); India) at least 7 days after first dose [April-May][25] **-1%** (95% CI, -51-33; India) at least 21 days after first dose [April-May][25]	Ongoing studies in South Africa[26] and the United Kingdom[27]

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

	66% (95% CI, 60-71; Spain) [Apr-Aug][5] *Individuals ≥70:* Symptomatic disease: **58%**[9]. Hospitalization risk reduced by 35-**45%**[9]. Risk of death reduced by **54%**[9]. *Individuals ≥50:* ≥14 days after first dose: **54%** (95% CI, 47-61) effectiveness against hospitalization [1 January-22 June[10]. [vii]	*Individuals ≥70:* Symptomatic disease: **64%** (95% CI, 46-78; >2 weeks after dose)[11].[x] *Individuals ≥50:* ≥14 days after first dose: **54%** (95% CI, 47-61) effectiveness against hospitalization [1 January-22 June[10].[xi]	Hospitalization risk reduced by **35-45%**[9].	**50.0%** (95% CI, 42.0-57.0; Spain) [Apr-Aug][5] **73.6%** (95% CI, 65.9-79.9; US) [Feb-Jul][19] *Symptomatic disease*: **54%** (95% CI, 45-62; Spain) [Apr-Aug][5] **81%** (95% CI, 79-84) for preventing hospitalization when corrected for under-recording, VE was estimated to be **73%** (95% CI, 69-76)[15]. **75%** (95% CI, 65-82) against severe critical COVID-19[20] **66.1%** against moderate to severe-critical				

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

				COVID-19 cases after 28 days [ENSEMBLE study; Sep 2020-Nov 2021)[21] **85.4%** against severe COVID-19 cases after 28 days [ENSEMBLE study; Sep 2020-Nov 2021)[21] *Individuals ≥50:* 68% (95% CI, 50-79)[10].				
Effectiveness of two doses	*SARS-Cov-2 infection:* **85%**[2]. **94.6%**[28]. **94.5%**[29]. **76%** (95% CI, 69-81) [Jan-Jul][30]. **88.8%** (95% CI, 84.6-91.8) [Dec 2020-May][3] **74%** (95% CI, 72-76) [Jan-Jun][17]	*SARS-Cov-2 infection:* **100%**[28]. **86%** (95% CI, 81-90.6) [January-July][30]. **96.3%** (95% CI, 91.3-98.4) [December-May][3]	*Asymptomatic efficacy:* 61.9%[37] *SARS-CoV-2 infection*: **53%** (95% CI, 12-84) [January-June][17] **27%** (95% CI, 17-37) [4 months	Not Applicable (one dose schedule)	Partial protection[22].[xx]	**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[23].	*Against symptomatic disease*: **71%** (95% CI, 41-85; India) [Apr-Jun][13] *Effectiveness of full vaccination:* **69%** (95% CI; 54-79; India) [May - July 2021][38]	Ongoing studies in South Africa[26] and the United Kingdom[27] **89.7%** protection against SARS-CoV-2 infection (95% CI, 80.2-94.6; United Kingdom)[40]

[xx] Study did not report numerical data on vaccine effectiveness. Further studies are required to validate results. Death reports on fully vaccinated doctors (10 cases during June 2021 in Indonesia). It may be related to new variants [media report]. Indonesian Covid deaths add to questions over Sinovac vaccine. *The Guardian* [press release]. https://www.theguardian.com/world/2021/jun/28/indonesian-covid-deaths-add-to-questions-over-sinovac-vaccine

	77.5% (95% CI, 76.4-78.6) [first month after second dose][4] **47%** (95% CI, 43-51) [5 months after second dose][31] **56%** (95% CI, 53-59) [4 months after second dose][32] **69%** (95% CI, 66-72; Spain) [Apr-Aug][5] **88%** (pooled meta-analysis)[6] **84%** (95% CI, 40-96; Italy) [27 Dec 2020 – 24 Mar 2021] 14-21 days from the first dose and **95%** (95% CI, 62-99; Italy) [27 Dec 2020 – 24 Mar 2021] at least 7 days from the second dose[33] **95%** (95% CI, 93%-96%; United States) [May to July 2021][7xiii]	**85%** (95% CI, 80-90) [January-June][17] **71%** (95% CI, 68-74) [4 months after second dose][32] **63%** (95% CI, 44-76) [June-August][36] **82%** (95% CI, 78-86; Spain) [Apr-Aug][5] **80%** (pooled meta-analysis)[6] **95%** (95% CI, 93%-96%; United States) [May to July 2021][7xvi] **78.2%** (95% CI, 76.7-79.6; Norway) [Jan-Sep][8] *Symptomatic disease*: **91%** after second dose][32] **88%** (95% CI, 79.0-94.0; India) [Apr-Jun][13] **54.0%** (95% CI, 48-60; Spain) [Apr-Aug][5] **43.4%** (95% CI, 4.4-66.5; Norway) [Jan-Sep][8] *Effectiveness of full vaccination:* **80%** (95% CI; 73-86; India) [May - July 2021][38] *Symptomatic disease*: **90%**[12]. **56%** (95% CI, 48-63; Spain) [Apr-Aug][5]				**52.7%** (95% CI, 52.1-53.4) against SARS-CoV-2 infection, **72.8%** (95% CI, 71.8-73.7) against hospitalization, **73.8%** (95% CI, 72.2-75.2) against ICU admission, and **73.7%** (95% CI, 72.3-75.0) against death [January-April][24] *In pregnant women*: **41%** (95% CI, 27.1-52.2%; Brazil) against symptomatic COVID-19, **85%** (95% CI, 59.5-94.8; Brazil) against severe COVID-19, and **75%** (95% CI 27.9-91.2; Brazil)[39]	**50%** (95% CI, 33-62; India) 14 days after second dose [April-May][25] **47%** (95% CI, 29-61; India) 14 days after second dose – excluding participants with previous SARS-CoV-2 infections [April-May][25] **46%** (95% CI, 22-62; India) 28 days after second dose [April-May][25] **57%** (95% CI, 21-76; India) 42 days after second dose [April-May][25]	

[xiii] Results do not disaggregate between mRNA vaccines, BNT162b2 and mRNA-1273.

[xvi] Results do not disaggregate between mRNA vaccines, BNT162b2 and mRNA-1273.

	69.7% (95% CI, 68.6-70.8; Norway) [Jan-Sep][8] *Symptomatic disease*: **72%** (95% CI, 69-75; Spain) [Apr-Aug][5] *Asymptomatic SARS-CoV-2 infection:* **90.6%**[34].[xiv] **73.1** (95% CI, 70.3-75.5)[4] *Hospitalization:* **85%** (95% CI, 73-93) [January-July][30]. **88%** (95% CI, 85-91) [11 March – 15 August][16]. **89%** (95% CI, 87-91) for individuals ≥50 years [1	(95% CI, 89-93; >2 weeks after dose)[11].[xvii] **85%** (95% CI, 80-89; Spain) [Apr-Aug][5] *Asymptomatic SARS-CoV-2 infection:* **90.6%**[34].[xviii] **71%** (95% CI, 61-78) [January-August][36] *Hospitalization:* **91.6%** (95% CI, 81-97) [January-July][30]. **93%** (95% CI, 91-95) [11 March – 15 August)[16]. **89%** (95% CI, 87-91) for individuals ≥50 years [1						

[xiv] Results do not disaggregate between BNT162b2 and mRNA-1273
[xvii] Results do not disaggregate between BNT162b2 and mRNA-1273.
[xviii] Results do not disaggregate between BNT162b2 and mRNA-1273

	January-22 June[10]. [xv] **90%** (95% CI, 89-92) [Dec 2020 – Aug 2021][31] *Individuals ≥65:* **61%** (95% CI, 57-65) against SARS-CoV-2 infection and **86%** (95% CI, 82-88) against hospitalizations[31] *Individuals ≥ 80:* VE of **68.3%** (95% CI, 65.5-70.9) for infections, **73.2%** (95% CI, 65.3-79.3) for hospitalization, **85.1%** (95% CI, 80.0-89.0) for mortality [Germany, 09 Jan – 11 Apr 2021][35]	January-22 June[10]. [xix]							
EFFECTIVENESS AGAINST VARIANTS[xxi]									

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

Alpha (B.1.1.7)	*Single dose:* **48.7%** (95% CI, 45.5 to 51.7)[41] **66%** (95% CI,64-68)[42]. **54.5%** (95 CI, 50.4-58.3)[43] *Two doses:* **93.7%** (95% CI, 91.6 to 95.3)[41] **92%** (95% CI, 90-93)[44]. **89%** (95% CI, 86-91)[42]. **78%** (95% CI, 68-84)[45] **84.4%** (95 CI, 81.8-86.5)[43]	*Single dose:* **88.1%** (95% CI, 83.7 to 91.5)[46] **83%** (95% CI, 80-86)[42]. *Two doses:* **100%** (95% CI, 91.8 to 100)[46] **92%** (95% CI, 86-96)[42]. **98.4%** (95% CI, 96.9-99.1)[47]	*Single dose:* **48.7%** (95% CI 45.5 to 51.7)[41] 6**4%** (95% CI, 60-68)[42]. *Two doses:* **74.5%** (95% CI, 68.4 to 79.4)[41] **73%** (95% CI, 66-78)[44]. 79% (95% CI, 56-90)[45].	-	No published data	*Two doses:* Equally effective **(~76%**) in neutralizing D614G, B.1.1.7 and B.1.429 as the wild-type strain.	No available data	Ongoing studies in South Africa[26] and the United Kingdom[27] Post hoc analysis showed efficacy of **86.3%** (95% CI, 71.3-93.5; United Kingdom) **against B.1.1.7 variants** and **96.4%** (95% CI, 73.8-99.5; United Kingdom) **against non-B.1.1.7 variants.**[40]
Beta (1.351)	*Single dose:* **60%** (95% CI, 52-67)[42]. *Two doses:* **84%** (95% CI, 69-92)[42].	*Single dose:* **61.3%** (95% CI, 56.5 to 65.5)[46] **77%** (95% CI, 69-92)[42]. *Two doses:* **96.4%** (95% CI, 91.9 to 98.7)[46]	*Single dose:* **48%** (95% CI, 28-63)[42].	-	No published data	Neutralization capacity was decreased by factor **5.27**[48].	No available data	No available data

Gamma (P.1)	Neutralization activity reduced by **3.3-fold**[49].	No available data	No available data	No available data	No published data	Demonstrated **42%** vaccine effectiveness in a setting with high P.1 transmission, in individuals aged 70 and above[50]. **50.2%** against P.1 (>14 days after 2nd dose)[51]. Neutralization was decreased by factor **3.92**[48].	No available data	No available data
Delta (1.617.2)	*Single dose:* **30.7%** (95% CI, 25.2 to 35.7)[41]; **57%** (95% CI, 50-63)[45] **22.5%** (95 CI, 17.0-27.4)[43] *Two doses:* **88.0%** (95% CI, 85.3 to 90.1)[41]; **80%** (95% CI, 77-83)[45] **79%** (95% CI,75-82)[44]. **80%** (95% CI, 77-83)[45] **40.5%** (95% CI, 8.7-61.2)[52].	*Single dose:* **72%** effective against symptomatic SARS-Cov-2 infection[56]. *≥14 days after second dose:* **76%** (95% CI, 58-87)[30]. **94.5%** (95% CI, 94.1-95) [2-9 weeks after second dose][53]. **50.6%** (95% CI, 45.0-55.7) [among nursing home residents][54].	*Single dose:* **30.7%** (95% CI 25.2 to 35.7)[41] **73%** (95% CI, 64-80; India) [May – July 2021][38] *Two doses:* **67.0%** (95% CI, 61.3 to 71.8)[41] **67%** (95% CI, 62-71)[45]. **60%** (95% CI, 53-66)[44]. **66.7%** (95% CI, 45-49.6) [2-9 weeks after second dose][53].	**78%** (95% CI, 73-82) against SARS-CoV-2 infection[15]. **3%** (95% CI, -7-12) [August][55] *Individuals ≥50:* **83% (**95% CI, 81-85)[15]	No available data	*Single dose:* **13.8%** (95% CI, -60.2-54.8)[59]. *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[59].	*Single dose*: **44%** (95% CI, 0-71; India) [May – July 2021][38] *Two doses:* **64%** (95% CI, 40-79; India) [May – July 2021][38]	No available data

	42% (95% CI, 13-62)[30]. **89.8%** (95% CI, 89.6-90.0) [2-9 weeks after second dose][53]. **69.7%** (95% CI, 68.7-70.5) [≥20 weeks after second dose][53]. **64.6%** (95 CI, 60.6-68.2)[43] **52.4%** (95% CI, 48.0-56.4) [among nursing home residents][54]. **53%** (95% CI, 39-65) [4 months after second dose][31] **50%** (95% CI, 47-52) [August; elderly Veteran population][55] *Against severe COVID-19:* **91.4%** (95% CI, 82.5-95.7)[52].	**86.7%** (95% CI, 84.3-88.7)[47] **56.6%** (95% CI, 42.0-67.5) *against infection*[57] **84.2%** (95% CI, 56.4-94.3) *against symptomatic infection*[57] **64%** (95% CI, 62-66) [August; elderly Veteran population][55] *10-14 weeks after second dose:* **90.3%** (95% CI, 67.2-97.1)[53].	**47.3%** (95% CI, 66.3-67.0) [≥20 weeks after second dose][53]. **81%** (95% CI, 71-88; India) [May – July 2021][38] Odds ratio of **5.45** (95% CI, 1.39-21.4) to become infected with B.1.167.2 compared to non-B.1.167.2 [58].					
Mu (B.1.621)	Mu variant is 9.1 times more resistant than the	*Two doses:* **90.4%** (95% CI, 73.9-96.5)[47]	No available data	No available data	No available data	No available data		No available data

	wild type strain when vaccinated with BNT162b2[60]	(demonstrated similar protective measures as against the Alpha variant)					No available data	
EFFECTIVENESS AGAINST HOSPITALIZATION								
Any SARS-CoV-2 infection	*Single dose:* **85%** (pooled meta-analysis)[6] *Two doses:* **91%** (pooled meta-analysis)[6] **91%** (95% CI, 93%-96%; United States) [May to July 2021][7xxii]	*Single dose:* **73%** (pooled meta-analysis)[6] *Two doses:* **88%** (pooled meta-analysis)[6] **91%** (95% CI, 93%-96%; United States) [May to July 2021][7xxiii]	*Single dose:* **56%** (pooled meta-analysis)[6] *Two doses:* **91%** (pooled meta-analysis)[6]	No available data	No available data	No available data	No available data	No available data
Alpha	Single dose: **83%** (95% CI, 62-93) **53%** (95% CI, 7-83; England) [Feb-Sep 2021][61] Two doses: **95%** (95% CI, 78-99)[62]. **71%** (95% CI, 12-95; England) [Feb-Sep 2021][61] *Against death:*	No available data	Single dose: **76%** (95% CI, 61-85) **3%** (95% CI, -38 – 39; England) [Feb-Sep 2021][61] Two doses: **86%** (95% CI, 53-96)[62]. **26%** (95% CI, -39 – 73; England) [Feb-Sep 2021][61] *Against death:*	***Beta*** **67%** effective at preventing hospitalizations[63]. *Against death:* 96% effective at preventing death[63].	No available data	No available data	No available data	No available data

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

	98.2% (95% CI, 95.9-99.2) [2-9 weeks][53]. **90.4%** (95% CI, 85.1-93.8) [≥20 weeks][53].		**94.1%** (95% CI, 91.8-95.8) [2-9 weeks][53]. **78.7%** (95% CI, 52.1-90.4) [≥20 weeks][53].					
Gamma	No available data	No available data	No available data	**72.9%** (95% CI, 35.1-91.1)[18] *Against ICU admission:* **92.5%** (95% CI, 54.9-99.6)[18] *Against death:* **90.5%** (95% CI, 31.5-99.6)[18]	No available data	No available data	No available data	No available data
Delta	*Single dose:* **94%** (95% CI, 46-99)[62]. **91%** (95% CI, 90-93)[64] **4%** (95% CI, -21 – 44; England) [Feb-Sep 2021][61] *Two doses:* **96%** (95% CI, 86-99)[62].	*Single dose:* **81%** (95% CI, 81-90.6)[30]. *Two doses:* **84%** (95% CI, 80-87)[64] **95%** (95% CI, 92-97) [June-August][66] **96.7%** (95% CI, 93.9-98.2)[8]	*Single dose:* **71%** (95% CI, 51-83)[62] **88%** (95% CI, 83-91)[64] **2%** (95% CI, -19 – 31; England) [Feb-Sep 2021][61] *Two doses:* **92%** (95% CI, 75-97)[62].	**71%** [63] **85%** (95% CI, 73-91)[15]. **91%** (95% CI, 88-94)[64] **85%** effective at preventing severe disease and hospitalization[69].	*Single dose:* Does not offer clinically meaningful protection against severe illness [70,xxiv] *Two doses:* **88%** (95% CI, 55-98) adjusted risk reduction in	*Single dose:* Does not offer clinically meaningful protection against severe illness [70,xxvi] *Two doses:* **88%** (95% CI, 55-98) adjusted risk reduction in	No available data	No available data

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

	88% (95% CI, 78.9-93.2)[52]. **75%** (95% CI, 24-93.9)[30]. **84%** (95% CI, 79-89)[65]. **98.4%** (95% CI, 97.9-98.8) [2-9 weeks][53]. **92.7%** (95% CI, 90.3-94.6) [≥20 weeks][53]. **96%** (95% CI, 95-96)[64] **80%** (95% CI, 73-85) [June-August][66] **93%** (95% CI, 84-96)[67] **96.8%** (95% CI, 93.9-98.3)[2 months after the second dose][4] **93%** (95% CI, 84-96)[31] **91.5%** (95% CI, 89.5-93.2)[8] **24%** (95% CI, -2 – 64; England) [Feb-Sep 2021][61] *Against death:*	*Against ICU admission:* **86%** (95% CI, 79-90)[64] **96%** against severe COVID-19 infection[56].	**95.2%** (95% CI, 94.6-95.6) [2-9 weeks][53]. **77.0%** (95% CI, 70.3-82.3) [≥20 weeks][53]. **94%** (95% CI, 92-95)[64] **14%** (95% CI, -5 – 46; England) [Feb-Sep 2021][61] *Against ICU admission:* *Single dose:* **92%** (95% CI, 84-96)[64] *Two doses*: **96%** (95% CI, 94-98)[64] *Against death:* **91%** (95% CI, 86-94) [≥2 weeks after second dose][68]	*Individuals ≥50:* **84% (**95% CI, 81-85)[15] *Against ICU admission:* **94%** (95% CI, 88-98)[64]	developing severe illness.[70,xxv]	developing severe illness.[70,xxvii]		

[xxv] Study does not differentiate between the two inactivated vaccines, BBIBP-CorV and CoronaVac.
[xxvii] Study does not differentiate between the two inactivated vaccines, BBIBP-CorV and CoronaVac.

	90% (95% CI, 83-94) [≥2 weeks after second dose][68]							
DURATION OF PROTECTION, TRANSMISSION & BREAKTHROUGH INFECTIONS								
Duration of protection (antibodies)	Median time between second dose and infection: **146 days (IQR, 121-167)**[71] *Anti-SARS-CoV-2 Antibodies:* 1 month after 2nd dose: **1762 KU/L (IQR: 933-3761)** 3 months after 2nd dose: **1086 KU/L (IQR: 629-2155)** 6 months after 2nd dose: **802 KU/L (IQR, 447-1487)**[72] No health worker had antibodies BELOW method-dependent cut-off (0.8 KU/L) *Neutralizing antibodies:*	*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[76] *Neutralizing antibodies:* At peak immunity, NAb titre was **5,848**, after 8 months titre was **133**[73] *Pseudovirus neutralizing antibodies:* At peak immunity, pseudovirus NAb titre was **1,569**, after 8 months titre was **273**[73]	*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**: 0.30 GMR (CI, 0.24-0.39)[77] *Cellular Immune Response:* **Day 182** after first dose: median of **237 SFUx10^6 PBMC (IQR, 109-520)**[77] **6 months** after second dose: **(median 1240,**	*Neutralizing antibodies:* Remained largely stable for **8-9 months**[78] Remained **stable for 8 months**; At 4 weeks after immunization NAb titre was **146**, after 8 months titre was **629**[73] *Pseudovirus neutralizing antibodies:* Remained **stable for 8 months**; At 4 weeks after immunization pseudovirus NAb titre was **391**, after 8 months titre was **185**[73] *Binding antibodies:*	*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)[80] **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**	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[82]. **80-90%** of anti-S IgG and Nab titers against wild type waned **6 months** after second vaccination[83] *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%	No available data	No available data

	At peak immunity, NAb titre was **1,789**, after 8 months titre was **53**[73] *Pseudovirus neutralizing antibodies:* At peak immunity, pseudovirus NAb titre was **700**, after 8 months titre was **160**[73] *Anti-spike Protein RBD IgG Antibodies:* At peak immunity, RBD titre was **21,564**, after 8 months titre was **755**[73] **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)[74]	*Anti-spike Protein RBD IgG Antibodies:* At peak immunity, RBD titre was **25,677**, after 8 months titre was **1,546**[73] *Humoral & Cellular Immune Response:* CD8+ T cell response was **0.017%** 8 months after full vaccination[73]	**IQR 432-2002**) in groups with 15-25 week interval between doses[77] *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)[74] **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)[74]	Remained stable **6 months** irrespective of age group[78] *Humoral & Cellular Immune Response:* Antibody responses were detected in all vaccine recipients on **day 239** (stable response for at least 8 months)[79] CD8+ T cell response was **0.12%** 8 months after vaccination[73] *Anti-spike Protein RBD IgG Antibodies:* Remained **stable for 8 months**; At 4 weeks after immunization titre was **1,361**, after 8 months titre was **843**[73]	(95% CI: 147.3-1593)[80] *Anti-RBD IgG*: Decreased up to **41.8%** 2 months after second dose and dropped to **42.9%** decrease after 7 months[81] *Binding Antibodies:* Decreased **82.1%** 7 months after second dose[81]	seropositivity, **2.4** (IQR, 1.0-5.0)[74] **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)[74]		

	Older age groups (≥60): 1 month after 2nd dose: 100% seropositivity, **29.4** (IQR, 22.5-33.3) 3 months after 2nd dose: 100% seropositivity, **14.8** (IQR, 7.4-18.7)[74] <u>*Sub-populations:*</u> **Older age (≥65): 38%** to **42%** decrease of humoral antibodies compared to 18- to 45-year-old[75] **Older age (≥65) AND men: 37%** to **46%** decrease compared to 18- to 45-year-old women[75] **Immunosuppression: 65% to 70%** decrease compared to non-immunosuppressed[75]									

	Obesity (BMI ≥30): **31%** increase in neutralizing antibody compared with nonobese[75] *Humoral & Cellular Immune Response:* CD8+ T cell response was **0.016%** 8 months after full vaccination[73]							
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[84] VE reduced from **87%** (95% CI, 85-89) to **56%** (95%	**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.[90] **46.0** (95% CI, -52.4-83.2) reduction of	VE reduced by 7% (95% CI, -18 - 2) for every 30 days from the second dose for those aged 18 to 64 years[45]. VE reduced from **58%** (95% CI, 51-65) to **27%** (95% CI, 17-37) after 4 months.[32] VE reduced from **88%** (95% CI, 87-	A study observed sustained and stable vaccine effectiveness starting 14 days post vaccination to a maximum of **152** days after vaccination[15]. VE decreased from **89.4%** in May to **51.7%** in July[36]	No available data	No available data	No available data	No available data

	CI, 53-59) after 4 months.[32] VE reduced from **91%** (95% CI, 91-92) in March to **50%** (95% CI, 47-52) in August[55] VE reduced from **89.0%** (95% CI, 84.6-92.1; United States) [May to August] to **62.7%** (95% CI, 62.4-63.1; United States) [May to August][85xxviii] VE decreased by **18.5% points** (95% CI 8.4-33.4) among all ages and **19.9% points** among older individuals (95% CI; 9.2-36.7) [Overall average from Systematic	observed incidence rate (**severe** SARS-CoV-2 infection) if vaccinated from Dec 2020 – Apr 2021 than Jul 2021 – Dec 2020.[90] VE against the Delta variant declined from **94.1%** (95% CI, 90.5-96.3) 14-60 days after vaccination to **80.0%** (95% CI, 70.2-86.6) 151-180 days after vaccination.[47] **91%** [January-March] **71%** (95% CI, 53-83) [April-May] **63%** (95% CI, 44-76)[36]	89) in March to **3%** (95% CI, -7-12) in August[55] VE decreased by **18.5% points** (95% CI 8.4-33.4) among all ages and **19.9% points** among older individuals (95% CI; 9.2-36.7) [Overall average from Systematic Review and Meta-Regression][86xlii] *Effectiveness for symptomatic COVID-19 disease:* VE decreased by **25.4%** (95% CI, 13.7-42.5) among all ages and **32.0%** (95% CI, 11.0-69.0) among older individuals [Overall average	VE decreased from **86.4%** (95% CI, 85.2-87.6) in March 2021 to **13.1%** (95% CI, 9.2-16.8) in September 2021[88] *Fully vaccinated HCWs*: Adjusted **VE was 82.3%** (95% CI, 75.1-87.4%; United States) [16 Dec 2020 to 30 Sept 2021][89xlv] *Fully vaccinated HCWs during the period of Delta variant predominance*: Adjusted **VE was 76.5%** (95% CI, 40.9-90.6; United States) [01 July 2021 to 30 Sept 2021][89xlvi]				

[xxviii] Study does not differentiate between the two mRNA vaccines, Pfizer and Moderna.
[xlii] Study does not differentiate between Pfizer/BioNTech-Comirnaty, Moderna-mRNA-1273, Janssen-Ad26.COV2.S and AstraZeneca-Vaxrevria.
[xlv] Study does not differentiate between Pfizer, Moderna, and Janssen.
[xlvi] Study does not differentiate between Pfizer, Moderna, and Janssen.

	Review and Meta-Regression][86xxix] *Effectiveness for symptomatic COVID-19 disease:* VE decreased by **25.4%** (95% CI, 13.7-42.5) among all ages and **32.0%** (95% CI, 11.0-69.0) among older individuals [Overall average from Systematic Review and Meta-Regression[86xxx] *Effectiveness for severe COVID_19 disease:* VE decreased by **8.0%** (95% CI, 3.6-15.20) among all ages and **9.7%** (95% CI; 5.9-14.7) among older	VE reduced from **90%** (95% CI, 88-91) to **71%** (95% CI, 68-74) after 4 months[32] 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[36] VE reduced from **92%** (95% CI, 92-93) in March to **64%** (95% CI, 62-66) in August[55] VE against infection was **82%** (95% CI, 79-85) 14-90 days after the second dose and appeared to	from Systematic Review and Meta-Regression][86xliii] *Effectiveness for severe COVID_19 disease:* VE decreased by **8.0%** (95% CI, 3.6-15.20) among all ages and **9.7%** (95% CI; 5.9-14.7) among older individuals [Overall average from Systematic Review and Meta-Regression][86xliv]	VE decreased by **18.5% points** (95% CI 8.4-33.4) among all ages and **19.9% points** among older individuals (95% CI; 9.2-36.7) [Overall average from Systematic Review and Meta-Regression][86xlvii] *Effectiveness for symptomatic COVID-19 disease:* VE decreased by **25.4%** (95% CI, 13.7-42.5) among all ages and **32.0%** (95% CI, 11.0-69.0) among older individuals [Overall average from Systematic				

[xxix] Study does not differentiate between Pfizer/BioNTech-Comirnaty, Moderna-mRNA-1273, Janssen-Ad26.COV2.S and AstraZeneca-Vaxrevria.
[xxx] Study does not differentiate between Pfizer/BioNTech-Comirnaty, Moderna-mRNA-1273, Janssen-Ad26.COV2.S and AstraZeneca-Vaxrevria.
[xliii] Study does not differentiate between Pfizer/BioNTech-Comirnaty, Moderna-mRNA-1273, Janssen-Ad26.COV2.S and AstraZeneca-Vaxrevria.
[xliv] Study does not differentiate between Pfizer/BioNTech-Comirnaty, Moderna-mRNA-1273, Janssen-Ad26.COV2.S and AstraZeneca-Vaxrevria.
[xlvii] Study does not differentiate between Pfizer/BioNTech-Comirnaty, Moderna-mRNA-1273, Janssen-Ad26.COV2.S and AstraZeneca-Vaxrevria.

	individuals [Overall average from Systematic Review and Meta-Regression][86xxxi] *Effectiveness against Hospitalization and Death:* After reaching peak VE (96.8%) 2 months after 2nd dose, **VE did not decline over time**, except for 7th months (VE 55.6%) with very few cases[84] VE reduced by 22% (95% CI, 6-41) for every 30 days from the second dose for those aged 18 to 64 years[45].	**wane over time** and was **63%** (95% CI, 55-68) 91-180 days after the second dose [27 Dec 2020 – 26 Oct 2021; Finland][87xxxv] VE decreased from **89.2%** (95% CI, 88.8-89.6) in March 2021 to **58.0%** (95% CI, 56.9-59.1) in September 2021[88] *Fully vaccinated HCWs*: Adjusted **VE was 82.3%** (95% CI, 75.1-87.4%; United States) [16 Dec 2020 to 30 Sept 2021][89xxxvi] *Fully vaccinated HCWs during the*		Review and Meta-Regression][86xlviii] *Effectiveness for severe COVID_19 disease:* VE decreased by **8.0%** (95% CI, 3.6-15.20) among all ages and **9.7%** (95% CI; 5.9-14.7) among older individuals [Overall average from Systematic Review and Meta-Regression][86xlix]				

[xxxi] Study does not differentiate between Pfizer/BioNTech-Comirnaty, Moderna-mRNA-1273, Janssen-Ad26.COV2.S and AstraZeneca-Vaxrevria.
[xxxv] Study does not differentiate between COMIRNATY/BNT162b2 and SPIKEVAX/ mRNA-1273.
[xxxvi] Study does not differentiate between Pfizer, Moderna, and Janssen.
[xlviii] Study does not differentiate between Pfizer/BioNTech-Comirnaty, Moderna-mRNA-1273, Janssen-Ad26.COV2.S and AstraZeneca-Vaxrevria.
[xlix] Study does not differentiate between Pfizer/BioNTech-Comirnaty, Moderna-mRNA-1273, Janssen-Ad26.COV2.S and AstraZeneca-Vaxrevria.

	VE against infection was **82%** (95% CI, 79-85) 14-90 days after the second dose and appeared to **wane over time** and was **63%** (95% CI, 55-68) 91-180 days after the second dose [27 Dec 2020 – 26 Oct 2021; Finland][87xxxii] VE decreased from **86.9%** (95% CI, 86.5-87.3) in March 2021 to **43.3%** (95% CI, 41.9-44.6) in September 2021[88] *Fully vaccinated HCWs*: Adjusted **VE was 82.3%** (95% CI, 75.1-87.4%; United States) [16	*period of Delta variant predominance*: Adjusted **VE was 76.5%** (95% CI, 40.9-90.6; United States) [01 July 2021 to 30 Sept 2021][89xxxvii] VE reduced from **89.0%** (95% CI, 84.6-92.1; United States) [May to August] to **62.7%** (95% CI, 62.4-63.1; United States) [May to August][85xxxviii] VE decreased by **18.5% points** (95% CI 8.4-33.4) among all ages and **19.9% points** among older individuals (95% CI; 9.2-36.7) [Overall average from Systematic							

[xxxii] Study does not differentiate between COMIRNATY/BNT162b2 and SPIKEVAX/ mRNA-1273.
[xxxvii] Study does not differentiate between Pfizer, Moderna, and Janssen.
[xxxviii] Study does not differentiate between the two mRNA vaccines, Pfizer and Moderna.

	Dec 2020 to 30 Sept 2021][89xxxiii] *Fully vaccinated HCWs during the period of Delta variant predominance*: Adjusted **VE was 76.5%** (95% CI, 40.9-90.6; United States) [01 July 2021 to 30 Sept 2021][89xxxiv]	Review and Meta-Regression][86xxxix] *Effectiveness for symptomatic COVID-19 disease:* VE decreased by **25.4%** (95% CI, 13.7-42.5) among all ages and **32.0%** (95% CI, 11.0-69.0) among older individuals [Overall average from Systematic Review and Meta-Regression)[86xl] *Effectiveness for severe COVID_19 disease:* VE decreased by **8.0%** (95% CI, 3.6-15.20) among all ages and **9.7%** (95% CI; 5.9-14.7) among older individuals							

[xxxiii] Study does not differentiate between Pfizer, Moderna, and Janssen.
[xxxiv] Study does not differentiate between Pfizer, Moderna, and Janssen.
[xxxix] Study does not differentiate between Pfizer/BioNTech-Comirnaty, Moderna-mRNA-1273, Janssen-Ad26.COV2.S and AstraZeneca-Vaxrevria.
[xl] Study does not differentiate between Pfizer/BioNTech-Comirnaty, Moderna-mRNA-1273, Janssen-Ad26.COV2.S and AstraZeneca-Vaxrevria.

		[Overall average from Systematic Review and Meta-Regression][86xli]						
Transmission prevention	*Prior Delta Variant:* Vaccine effectiveness against infectiousness given infections **41.3%**[91] VE against transmission **88.5%**[91] VE against onwards transmission of Alpha **57% (95% CI, 5-85)**[61] *During Delta Variant:* Similar Ct values (<25) were found in both vaccinated and unvaccinated groups[92]	VE against onwards transmission: **52%** (95% CI, 33-69)[17] VE against transmission from vaccinated index case to unvaccinated contact is **63%** (95% CI, 46-75) and **40%** (95% CI, 20-54) to a vaccinated contact. [95li]	**48%** (limited data) May not be able to block the transmission of the alpha variant as efficiently as the wild type[96]. VE against transmission from vaccinated index case to unvaccinated contact is **63%** (95% CI, 46-75) and **40%** (95% CI, 20-54) to a vaccinated contact. [95lii] Evidence of fully vaccinated individuals infecting other	Limited data	Unknown	Unknown	No available data	No available data

[xli] Study does not differentiate between Pfizer/BioNTech-Comirnaty, Moderna-mRNA-1273, Janssen-Ad26.COV2.S and AstraZeneca-Vaxrevria.

[li] Study does not differentiate between Comirnaty/BNT162b2, Spikevax/ mRNA-1273, and Vaxzevria/ ChAdOz1 nCOV-19.

[lii] Study does not differentiate between Comirnaty/BNT162b2, Spikevax/ mRNA-1273, and Vaxzevria/ ChAdOz1 nCOV-19.

	Studies from Scotland and England demonstrated reductions in secondary infections among families of vaccinated individuals compared to families of unvaccinated individuals[93,94]. VE against onwards transmission: **62%** (95% CI, 57-67)[17] VE against transmission from vaccinated index case to unvaccinated contact is **63%** (95% CI, 46-75) and **40%** (95% CI, 20-54) to a vaccinated contact. [95l]		fully vaccinated individuals[97] 81 breakthrough infections among 1100 HCWs; 32 breakthrough infections among 4000 HCWs[97] VE against onwards transmission of Alpha **35% (95% CI, -26 – 74)**[61] VE against onwards transmission of Delta **42% (95% CI, 14-69)**[61]						

[l] Study does not differentiate between Comirnaty/BNT162b2, Spikevax/ mRNA-1273, and Vaxzevria/ ChAdOz1 nCOV-19.

	VE against onwards transmission of Delta **31% (95% CI, -3 – 61**)[61]							
Breakthrough infections	From 6,161 patients with a positive nasopharyngeal SARS-CoV-2 PCR, 1,120 (18%) were breakthrough infections – 97% of these occurred after 2 May (emergence of Delta variant). Of the 1,120 cases, 126 (12%) were hospitalized. Of the 126 breakthrough admissions, 59 were vaccinated with BNT162b2[98]. Individuals vaccinated in January and February had a **51%** (95% CI, 40-68) increased risk for breakthrough infections	From 6,161 patients with a positive nasopharyngeal SARS-CoV-2 PCR, 1,120 (18%) were breakthrough infections – 97% of these occurred after 2 May (emergence of Delta variant). Of the 1,120 cases, 126 (12%) were hospitalized. Of the 126 breakthrough admissions, 36 were vaccinated with mRNA-1273. Breakthrough infections remained under 1% for fully vaccinated individuals (no difference	As of 10 June, 1.5 million individuals have been fully vaccinated with Covishield in Odisha Province, India. Between 1 March to 10 June, 239 breakthrough infections (SARS-CoV-2 positive after having received two doses of Covishield) were identified. Of these, 199 (83.3%) were symptomatic, 24 (10.0%) were hospitalized - 59 individuals had comorbidities[100] Median antibody titer: 647.5 AU/ml[100] Vietnamese study:	From 6,161 patients with a positive nasopharyngeal SARS-CoV-2 PCR, 1,120 (18%) were breakthrough infections – 97% of these occurred after 2 May (emergence of Delta variant). Of the 1,120 cases, 126 (12%) were hospitalized. Of the 126 breakthrough admissions, 10 were vaccinated with Ad26.COV2.S[98]. **4.2%** of fully vaccinated HCWs developed breakthrough infections – all cases were	No available data	No available data	As of 10 June, 380,000 individuals have been fully vaccinated with Covaxin in Odisha Province, India. Between 1 March to 10 June, 35 breakthrough infections (SARS-CoV-2 positive after having received two doses of Covishield) were identified. Of these, 29 (82.9%) were symptomatic, 3 (8.6%) were hospitalized. 5 individuals had comorbidities[100] Median antibody titer: 213.5 AU/ml[100]	No available data

	compared to individuals vaccinated in March and April[99] Breakthrough infections remained under 1% for fully vaccinated individuals (no difference between Pfizer or Moderna recipients between May and August 2021.[85]	between Pfizer or Moderna recipients between May and August 2021.[85]	High viral loads were observed 2-3 days before symptom onset among 49 symptomatic breakthrough cases (out of 62). Their peak viral loads measured at any point in time were higher than that of asymptomatic cases (IQR: 16.5 log10/mL vs 30.8 log10/mL, respectively). NAbs were measured for 10 breakthrough cases, all 10 cases had lower NAbs at day 14 and 90 post second vaccination compared to controls[101]	symptomatic but mild, only one case required hospitalization[liii] 102 Rate of breakthrough infections was comparable to Pfizer and Moderna recipients during the initial stages of the study, but increased to 1.96% (2 times the breakthrough rate of mRNA vaccines).[85]			**4.2%** of fully vaccinated HCWs developed breakthrough infections – all cases were symptomatic but mild, only one case required hospitalization [liv] 102	

[liii] Study does not differentiate between Covishield (*n*=62.4%) and Covaxin (*n*=37%).
[liv] Study does not differentiate between Covishield (*n*=62.4%) and Covaxin (*n*=37%).

SAFETY AND ADVERSE EVENTS								
Common side effects	Pain at the injection site, fatigue, headache, myalgia, chills and fever[103], arthralgia[104] Optimal safety for asthma patients[105]. The vaccine is considered safe for cancer patients undergoing treatments[106].	Pain at injection site, headache, fatigue, myalgia, arthralgia[107], Covid arm (cutaneous hypersensitivity)[108]. The vaccine is considered safe for cancer patients undergoing treatments[106].	Fatigue, myalgia, arthralgia, headache[109], lethargy, fever, & nausea[110].	Headache, fever, chills, fatigue, myalgia, and nausea[111].	Pain at the injection site, dizziness, fever, headache, fatigue, nausea, vomiting, & allergic dermatitis[110,112].	Pain at injection site, headache, fatigue, tremors, & flushing[113], inflammatory reaction, urticaria[114], myalgia[115]	Pain at injection site, headache, pyrexia, fatigue, myalgia[116]	Pain at injection-site, headache, muscle pain, fatigue[40]
Rare adverse events	Myocarditis & myopericarditis[117-119], anaphylaxis and swelling of the lips, face, and tongue related to anaphylaxis[120] (11 anaphylaxis cases per million doses administered)[121], axillary lymphadenopathy, paroxysmal ventricular arrhythmia, leg paresthesia[122],	Myocarditis & myopericarditis [117-119], orofacial swelling & anaphylaxis[120]. Potential risk factor for Bell's palsy[140] (most improve upon follow-up)[163], herpes zoster reactivation[127], varicella zoster reactivation[127], herpes zoster ophtalmicus[164],	Transverse myelitis, high fever[109,174], cutaneous hypersensitivity[174], vasculitis[175], thromboembolism[176], vaccine induced immune thrombotic thrombocytopenia[177, 178-180], intracerebral haemorrhage[181], small vessel vasculitis[178-180],	Thrombosis, thrombocytopenia, increased risk of developing Guillain-Barré syndrome post vaccination[200], herpes zoster ophtalmicus[164], pseudothrombocytopenia[201], vaccine induced thrombocytopic thrombosis[202], cutaneous reactions[159]	Cutaneous reactions[159] Rare adverse events were similar among the vaccine groups and control group within 7 days[203]. Pityriasis rosea[204], uveitis[205]	Myalgia, fever[113], pityriasis rosea (lesions improved completely after ~8 weeks)[124], reactivation of herpes zoster and herpes simplex[114]. Most reactions improved without treatment within a few weeks[114], Guillain-Barré syndrome[206], subacute thyroiditis[207],	No available data	Cutaneous reactions[159] Myocarditis was reported in one vaccine recipient, occurring 3 days after second dose[40]

	pityriasis rosea[123] (lesions improved completely after ~8 weeks)[124], lymphocytic vasculitis[125], varicella-zoster reactivation [126-128], Kikuchi-Fujimoto disease[129], thrombotic thrombocytopenic purpura[130,131], IgA nephropathy flare-up[132], Guillain-Barré syndrome [133,134], pustural psoriasis[135], immunoglobulin A vasculitis[136], immune complex vasculitis[137], Rhabdomyolysis[138], subacute thyroiditis[139], Bell's Palsy[140], erythema multiforme[141], vaccine induced interstitial lung disease[142], macular neuroretinopathy[143], brachial	eczema & urticaria[165], transverse myelitis[166], Guillain-Barré syndrome[167,168], acute generalized exanthematous pustulosis[169], rhabdomyolysis[170, 171], herpes zoster ophtalmicus[164], eczema & urticaria[165], transverse myelitis[166], Guillain-Barré syndrome[167,168], acute generalized exanthematous pustulosis[169], rhabdomyolysis[170, 171], cervical lymphadenopathy[172], glomerulonephritis[151], Behçet's disease[173], neurological autoimmune disease[154], axillary adenopathy[155], multiple	psoriasis[182], rosacea, raynaud's phenomenon[165], Ischaemic stroke[183], anaphylaxis[184], recurrent herpes zoster[185,lv], generalized bullous fixed drug eruption[186], Guillain-Barré syndrome[134,187], pityriasis rosea[188,189]. Vaccination in individuals with adrenal insufficiency can lead to adrenal crises[134,187], Dariers disease[188,189], vaccine induced acute localized exanthematous pustulosis[190], Henoch-Schönlein Purpura[191], rhabdomyolysis[192], Grave's disease[193], acute	97% of reported reactions after vaccine administration were non-serious[111].		erythema multiforme[208], uveitis[205], vaccine induced thrombotic thrombocytopenia[209], serum sickness-like reaction[210], cutaneous reactions[159]		

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

	neuritis[144], thyroid eye disease[145], exacerbation of subclinical hyperthyroidism[146], rhabdomyolysis[147], internal jugular vein thrombosis[148], herpes simplex virus keratitis[149], cervical lymphadenopathy[150],glomerulonephritis[151], Ramsay-Hunt syndrome[152], Sweet's syndrome[153], neurological autoimmune disease[154], axillary adenopathy[155], multiple sclerosis[156], meningoencephalitis[157], intracerebral haemorrhage due to vasculitis[158], cutaneous reactions[159], pigmented purpuric dermatosis[160]	sclerosis[156], cutaneous reactions[159]	demyelinating polyradiculoneuropathy[194], erythema nodosum [195], polyarthralgia[196], recurrence of cutaneous T-cell lymphoma[197], neurological autoimmune disease[154], multiple sclerosis[156], sudden sensorineural hearing loss[198], acute-onset polyradiculoneuropathy[199], cutaneous reactions[159]						

	Systemic allergic symptoms were more common in BNT162b2 than mRNA-1273, however, anaphylaxis rates were similar for both mRNA vaccines[161] Having adverse reactions is associated with enhanced SARS-CoV-2 IgG antibody response[162]							
Potential associated adverse events (causal links not yet proven)	Cerebral venous sinus thrombosis and intracranial haemorrhage[211], aseptic meningitis[212], autoimmune hepatitis[213,214], multiple sclerosis relapse[215], myeloperoxidase anti-neutrophil cytoplasmic antibody-positive optic perineuritis[216],	Cerebral venous sinus[231], Autoimmune hepatitis[213], myocardial infarction[232], autoimmune haemolytic anaemia[233], hypophysitis & panhypopituitarism[234], erythema nodosum-like rash[234], pulmonary embolism[235], minimal change disease[236],	Autoimmune hepatitis[213,240,241], Acute hyperglycaemic crisis[242], Facial nerve palsy, cervical myelitis[183], alopecia areata[243], takotsubo (stress) cardiomyopathy[244], acute disseminated encephalomyelitis[245], cerebral venous sinus thrombosis[246,231]	Facial Diplegia[248], acute macular neurotinopathy[249], cerebral venous sinus thrombosis[231,250], oral lichen planus[251]	No available data	Likely vaccine associated disease enhancement (VADE)[252]	No available data	No available data

	central retinal vein occlusion[217], paracentral acute middle maculopathy & acute macular neurotinopathy[218], Stevens-Johnson syndrome/ toxic epidermal necrolysis[219,220], lichenoid cutaneous skin eruption[221], acute mania and psychotic features[222], acute psychosis due to anti-N-methyl-D-aspartate receptor (anti-NMDAR) encephalitis[223], alopecia areata[224], rhombencephalitis[225], multisystem inflammation and organ dysfunction[226], aplastic anaemia[227], bullous pemphigoid[228], minimal change disease[229], miller fisher syndrome[230]	encephalomyelitis[237], lupus nephritis[238] One case developed IgA Nephropathy after receiving the second dose of mRNA-1273[239].	(higher risk for women)[177], ophthalmic vein thrombosis[247]						

Myocarditis data	Mainly reported in young adults and adolescents [253] Israeli study: Estimated incidence within 42 days after receipt of first dose per 100,000 vaccinated persons was **2.13** cases (95% CI, 1.56-2.7)[254] Male patients Incidence of **4.12** (95% CI, 2.99-5.26) per 100,000 vaccinated[254] **3.19** cases (95% CI, 2.37-4.02) per 100,000 vaccinated[255] Female patients	Mainly reported in young adults and adolescents [253] 5.8 cases per 1 million second dose administrations[256]	No available data	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[40]

	Incidence of **0.23** (95% CI, 0-0.49) per 100,000 vaccinated[254] **0.39** cases (95% CI, 0.10-0.68) per 100,000 vaccinated[255] <u>≥30 years</u> Incidence of **1.13** (95% CI, 0.66-1.60) per 100,00 vaccinated[254] 5.8 cases per 1 million second dose administrations[256] 5.07 cases per 100,000[257] <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)[254]								

	Risk per 100,000 persons 1st dose (male): **0.64** 2nd dose (male); **3.83** 1st dose (female): **0.07** 2nd dose (female): **0.46** 1st dose (male 16-19): **1.34** 2nd dose (male 16-19): **15.07**[255]							
	CHILDREN VACCINATION							
Efficacy	*Adolescents (12-15):* After one dose had efficacy of **75% (CI, 7.6-95.5)** After second dose efficacy of **100% (CI, 78.1-100)**[258]. *Children (5-11):* After second dose efficacy of **90.7% (CI, 67.7-98.3)**[259]	*Adolescents (12-17):* After one dose had efficacy of **92.7% (CI, 67.8-99.2)** After second dose efficacy of **93.3% (CI, 47.9-99.9)**[261]. *Children (6month-11):* Ongoing trials[262]	No available data Paused ongoing trials in children aged 6-17 due to concerns over rare blood clots reported in adult population[263].	No available data Announced at begging of April ongoing study in adolescents but paused to investigate blood clots in adult population[263].	*Children (3-17):* Unknown. Ongoing clinical trial only looked at safety, tolerability, and immunogenicity[lvi] * * The study design administered **three doses** of 2 µg, 4 µg, or 8 µg of vaccine	*Children (3-17):* Unknown. Clinical trial only looked at safety, tolerability and immunogenicity[264].	No available data	*Adolescents (16-17):* PREVENT-19 clinical trial[lvii] expanded to assess efficacy, safety, and immunogenicity in 12–17-year-old adolescents[265]

[lvi] 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

[lvii] 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

	Children (Under 5 years): Ongoing trials[260]							
Immunogenicity	*Adolescents (12-15) serum-neutralizing titer:* 1 month after 2nd dose had **1283.0 GMN_{50} (CI, 1095.5-1402.5)**[258]. *Adolescents/young adult (16-25) serum-neutralizing titer:* 1 month after 2nd dose had **705.1 GMN_{50} (CI, 621.4-800.2)**[258]. *Children (5-11):* 1 month after 2nd dose had **1,197.6 GMT (95% CI, 1106.1-1296.6)** SARS-CoV-2-neutralizing antibody[259] *Children (Under 5):* Ongoing trials[260]	*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%**[266] *Children (6month-11):* Ongoing trials[262]	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 **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[267]	*Children (3-17):* Neutralizing antibody response after 2nd dose **(100%)** with GMT ranging from **45.9-212.6**[264]	Ongoing clinical trial[268]	Ongoing clinical trial[269]

Effectiveness	*Against SARS-CoV-2 infection:* **91.5%** (95% CI, 88.2-93.9)[270] **91%** (95% CI, 88-93)[271] *Against hospitalization:* **81%** (95% CI, -55-98)[271] **93%** (95% CI,83-97)[272]	No available data	No available data	No available data	No available data	No available data	No available data	No available data
Safety and Adverse events	*Adolescents (12-15):* Local and systemic events were generally mild to moderate Severe injection-site pain **(1.5%)** Fever **(20%)** High Fever **(0.1%)** Adverse events **(6%)** Severe adverse events **(0.6%)**[258]. *Adolescent/young adults (16-25):* Local and systemic events were generally mild to moderate	*Adolescents (12-17):* Solicited local reactions after 2nd dose **(93.4%)** Most common solicited adverse reactions were Injection-site pain **(92.7%)** Headache **(70.2%)** Fatigue **(67.8%)** Grade 3 adverse events **(6.8%)** Few reported cases of acute myocarditis and pericarditis	No available data	No available data	*Children (3-17):* Most common adverse reaction was pain at injection site in 3–5-year group **(4%)**, 6-12-year group **(1.2%)**, and 13-17-year group **(7.9%)** Most common systemic reactions in all three age cohorts were mild to moderate **fever** and **cough** Adverse events were mostly mild	*Children (3-17):* Adverse reactions in 12–17 year group **(35%)**, 3-5 year group **(26%)**, and 6-11 year group **(18%)** Reported at least one adverse event **(27%)** Most reported events were mild and moderate and only **(<1%)** grade 3 events Injection-site pain **(13%)** Fever **(25%)**[264]	Ongoing clinical trial[268]	Ongoing clinical trial[269]

	Severe injection-site pain **(3.4%)** Fever **(17%)** Adverse events **(6%)** Severe adverse events **(1.7%)**[258]. *Children (5-11):* Pain at injection site, fatigue, headache, chills were reported. Overall, the vaccine is safe and tolerable[259] *Children (Under 5):* Ongoing trials[260] Multisystem inflammatory syndrome (causal link not yet proven)[273] *Adverse events cases:* 15-year old boy developed nephrotic syndrome[274]	(mainly in males)[275] *Children (6-11):* Vaccine was generally well tolerated[266] *Children (6month-11):* Ongoing trials[262]			to moderate in severity[267]				

Myocarditis Data	Few reported cases of acute myocarditis and pericarditis in 16-25 year olds (mainly in males)[275] <u>16-29 years</u> Incidence of **5.49** (95% CI, 3.59-7.39) per 100,00 vaccinated[254] <u>Male patients (16-29 years)</u> Incidence of **10.69** (95% CI, 6.93-14.46) per 100,000 vaccinated[254] Incidence of **13.6 cases** (95% CI, 9.30-19.20) per 100,000 vaccinated[255]	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	No available data
HETEROLOGOUS VACCINATION								

Vaccine Schedule	**BNT162b2/ChAdOx1** Administration of ChAdOx1 as second/booster dose	**ChAdOx1/mRNA-1273** Administration of mRNA-1273 as second/booster dose	**ChAdOx1/BNT162b2** Administration of BNT162b2 as second/booster dose	Not Applicable (one dose schedule) For more information refer to booster section	**BBIBP/BNT162b2**	**CoronaVac/ChAdOx1** Press releases have confirmed that Thailand will use the AstraZeneca vaccine as the second dose for individuals whose first dose was Sinovac[lviii] **CoronaVac/Convidecia**	**ChAdOx1/BBV152** Administration of Covaxin as second/booster dose	Ongoing trial[276] (Com-Cov2)[lix]
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)**[277]. *SFC frequency (T0cell ELISpot):*	**Spike-specific IgG antibodies:* Heterologous **(3602 BAU/mL)** vs. Homologous **(4189 BAU/mL)**[48] **Neutralizing antibodies:* Heterologous **(100%)** vs. Homologous **(100%)**[278].	*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[279]. *IgG antibody titres:*	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. Homolougous ChAdOx1 **(818**	*RBD antibody titres:* Heterologous **(1866 GMT; 95% CI, 1003-3472)** vs. Homologous Covishield **(2260 GMT; 95% CI, 1881-2716)** vs. Homologous Covaxin **(710**	No available data Ongoing trial[276]

[lviii] 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/

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

	Heterologous **(99 SFC/10^6 PBMCs)** vs. Homologous **(80 SFC/10^6 PBMCs)**[277]**.** ***Heterologous mRNA:*** **84.7%** effectiveness (95% CI, 83.1-86.1)[8]	***Heterologous mRNA:*** **84.7%** effectiveness (95% CI, 83.1-86.1)[8] *Results based on immunosuppressed population	Heterologous **(3684 BAU/mL)** vs. Homologous **(101.2 BAU/mL)** at day 14[279]. *Neutralizing antibodies:* Heterologous **(100%)** at day 14 vs. Homologous **(30%)** at day 14[279]. Heterologous (**median 99%)** vs. Homologous (BNT162b2/BNT162b2) **(median 62%)**[280]			**U/mL; 95% CI: 662.5-1010)**[281] **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)[282]	**GMT, 95% CI, 461-1092)**[283] *N-protein IgG:* Heterologous **(1145 GMT; 95% CI, 520.7-2520)** vs. Homologous Covishield **(353.7 GMT; 95% CI, 219.9-568.9)** vs. Homologous Covaxin **(742.4 GMT; 95% CI, 485.8-1134)**[283] *Neutralizing antibody titres :* Heterologous **(171.4 GMT; 95% CI, 121.3-242.3)** vs. Homologous Covishield **(111 GMT; 95% CI, 98.59-124.9)** vs. Homologous Covaxin **(86 GMT; 95% CI, 138.2-252.0)**[283]	

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[280]	No available data	No available data	No available data	*Neutralizing antibody titres **B.1**:* **539.4 GMT (95% CI, 263.9-1103)[283]** *Neutralizing antibody titres **Alpha**:* **396.1 GMT (95% CI, 199.1-788)[283]** *Neutralizing antibody titres **Beta**:* **151 GMT (95% CI, 80.21-284.3)[283]** *Neutralizing antibody titres **Delta**:* **241.2 GMT (95% CI, 74.99-775.9)[283]**	No available data
Reactogenicity	Observed increase in systemic reactogenicity after boost in heterologous schedules in comparison with homologous schedules[277]	*Adverse events in heterologous and homologous vaccination groups were very similar[278]. *Majority of adverse events self-reported were Pain at injection	*Adverse events in heterologous:* Headache **(44%)**, Myalgia **(43%)**, Malaise **(42%)**, Fever **(2%)**, Injection site pain **(88%)**, Induration **(35%)**, Erythema **(31%)**[279].	Not Applicable (one dose schedule) For more information refer to booster section	Unknown (on-going clinical trial)[284]	**CoronaVac/ChAdOx1:** Unknown **CoronaVac/Convidecia:** Convidecia recipients reported more adverse reactions and reported higher	*Most common local adverse events:* Pain at injection site **(11.1%)[283]** *Most common systemic adverse events:*	No available data Ongoing trial[276]

	Adverse events in heterologous: Adverse events **(90)** Grade 1 **(54.4%)** Grade 2 **(37.8%)** Grade 3 **(7.8%)** Grade 4 **(0%)** Arthralgia, Migraine, Back Pain[277]. *Adverse events in homologous:* Adverse events **(81)** Grade 1 **(59.3%)** Grade 2 **(39.5%)** Grade 3 **(1.2%)** Grade 4 **(0%)**[277].	site, Swelling at injection site, Fever, Headaches, Fatigue, Chills, GI effects, Myalgia, Arthralgia[278]. *Results based on immunosuppressed population	*Severity of adverse events in heterologous:* Mild **(68%)**, Moderate **(30%)**, Severe **(2%)**[279].			occurrence of solicited injection-site pain)[282]	Pyrexia **(27.77%, 11.1%)** after 1st and 2nd dose Malaise **(33.3%, 5.5%)** after 1st and 2nd dose[283]	
BOOSTER DOSES								
Vaccine Schedule	**BNT162b2/BNT162b2**	**mRNA-1273/mRNA-1273**	**ChAdOx1/ChAdOX1**	**Ad26.CoV.2.S/ Ad26.CoV.2.S**	**SinoPharm/SinoPharm**	**CoronaVac/CoronaVac**	**Covaxin/Covaxin**	**NVX-CoV2373/NVX-CoV2373**
Approved Administration	*Israel:* 12-year-old and over can received homologous booster shot 5	Phase II booster trial of three booster doses are ongoing[285]	Preliminary results on tolerability and immunogenicity of third dose of ChAdOx1	Johnson & Johnson has said it will submit all of their new data to the FDA for	*UAE:* Offering booster doses of Pfizer and Sinopharm to people who	**Turkey** and the **United Arab Emirates** began	Ongoing clinical trials[lxv]	Ongoing phase II trials[287]

[lxv] Bharat Biotech to initiate trials of booster dose of Covid-19 vaccine. *Clinical Trials Arena.* https://www.clinicaltrialsarena.com/news/bharat-biotech-booster-dose/

	months after full jab[lx] *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 with some countries administering to overall population[lxi]	Moderna sought FDA approval of its COVID-19 vaccine booster[lxii] *United States:* Starting September, adults who received mRNA vaccine 8 months ago are eligible for booster.	vaccines showed strong boost to the immune response[286]	potential consideration for adding a booster dose and consideration to authorize two-dose regimen[lxiii]	received full Sinopharm jab ≥6 months ago	homologous booster shots **Indonesia** and **Thailand** are considering giving homologous booster shot to HCW[lxiv]		Results below are based on ongoing phase II trial

[lx] 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/

[lxi] 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/

[lxii] 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/

[lxiii] 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

[lxiv] 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/

Time-to-booster dose	**6 months to 8 months** after initial two-dose regimen Israel offers up to **5 months** after initial two-dose regimen	**6 months to 8 months** after initial two-dose regimen	**6-9 months** after initial two-dose regimen	**6 months** after one dose regimen[78]	**6 months** after initial two-dose regimen	**6 months to 12 months** After primary vaccination **8 months** after the primary vaccination to healthy adults ≥60 years	Ongoing clinical trials[xxxvii]	**6 months** after initial two-dose regimen (**189 days**)[287]
Efficacy	*Symptomatic COVID-19:* **95.6%** during Delta prevalent period[288] **95.3% (**95% CI, 89.5-98.3)[289] **96.5%** (95% CI, 89.3-99.3) in *16-55 year old*[289] **93.1%** (95% CI, 78.4-98.6) in *≥55 year old*[289]	No available data	No available data	No available data	No available data	No available data	Ongoing clinical trials[xxxvii]	No available data
Immunogenicity	*Neutralizing titers:* Elicits **>5-8 more** for wild type after 6 months after 2nd dose[290] *IgG Antibodies in ≥ 60 years:*	Booster doses (mRNA1273 or mRNA1273.351) increased neutralizing antibody titers against wild-type[292]	*Antibody Levels:* Higher levels after third dose (tIgG EU **3746**; IQR: 2047-6420) [286]	5X10[10] vp booster dose elicited **9-fold** increase at day 7 compared to first dose after 29 days in 18-55-year-olds[78]	Ongoing trial[284] *IgG Seroconversion:* **175/176** vaccinees were seropositive for IgG 14 days after	Neutralizing Antibodies: **60%** higher NAbs activity against wild-type compared to 2-doses[83]	Ongoing clinical trials[xxxvii]	*Anti-spike IgG:* Increase of **4.6-fold** compared to peak response after 2nd dose (**Day 217 GMEU = 200408**; 95% CI:

	97% seroconversion with increase in IgG antibody titers[291]		*Spike Cellular Immune Response:* Increased from **200 SFUx10^6 PBMC (IQR, 127-389)** after the second dose to **399 SFUx10^6 PBMC (IQR, 314-662)** after the third one[286]	1.25X10^{10} vp booster dose elicited **6-7.7-fold** increase at day 28 compared to first dose after 29 days in 18-55 and ≥65-year-old[78]	receiving third dose[81] Mean IgG value increased **8.00-fold** compared to before third vaccination[81] *Anti-RBD IgG:* Increased by **8.14-fold** higher than before third vaccine[81] *Memory B cells:* Third dose increased the percentage of RBD-specific memory B cells **(0.96%)[81]**	Anti-S IgG and NAbs: **20-fold** increase 4 weeks post booster vaccination NAbs were maintained **60** to **180 days** post booster[83]		159796-251342)[287] *Wild-type Neutralizing Response:* Increase of **4.3-fold** compared to peak response after 2nd dose **(IC50 = 6231; 95% CI: 4738-8195)** [287] *Older Participants (60-84):* **5.4-fold** increase in antibody response[287] *Younger Participants (18-59):* **3.7-fold** increase in antibody response[287]
Immunogenicity against variants	*Beta (B.1.351):* Elicits **15-21** more neutralizing titers for Beta variant after 6 months after 2nd dose[290]	Preliminary results of booster doses of mRNA-1273 vaccine show robust antibody	Third dose provided higher antibody titters against Alpha, Beta, and Delta variants[286]	No available data	Ongoing trial[284] **Beta (B.1.351):** **71.6%** plasma inhibitions against Beta variant[81]	**Beta (B.1.351):** **3.0-fold** decrease in neutralizing antibodies	Ongoing clinical trials[xxxvii]	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[290]	response against Delta variant[285]			**Delta (B.1.671.2):** **83.4%%** plasma inhibitions against Delta variant[81] **Lambda:** **89.0%** plasma inhibitions against Lambda variant[81]	compared to wild type[83] **Gamma (P.1):** **3.1-fold** decrease in neutralizing antibodies compared to wild type[83] **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[83]		Delta (B.1.671.2)[287] *Delta (B.1.671.2):* Increase of **6.6-fold** in antibody response compared to Delta response observed with primary vaccination[287]
Reactogenicity	Preliminary results show consistent tolerability[290] **25%** reported at least one adverse event[289] *Common solicited AE:* Injection site pain, injection site redness, injection site swelling,	Similar safety and tolerability compared to second dose[285] *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[77]	No available data	Ongoing trial[284]	The third shot is considered to be safe[82]. *Common side effects:* Pain at the injection site. *Adverse events:* Unrelated to the vaccination	Ongoing clinical trials[xxxvii]	Booster dose was **well tolerated** Local and systemic **reactogenicity increased** between Dose 1, Dose 2, and Dose 3 **90%** of symptoms were

	fatigure, muscle pain, fever[289] *≥Grade 3 AE:* **6.6%** reported grade 3 or higher reactogenicity with **0.7%** being local reactions and **5.9%** systemic events[289]	**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)**[292]						rated as mild or moderate[287]
Protection against COVID-19	***Confirmed Infection:*** Youngest age group (16-29): **17.6 (95% CI, 15.6-19.9) lower rate** in booster group[293] 30-39 age group: **8.8 (95% CI, 8.2-9.5) lower rate** in booster group[293] 40-49 age group: **9.7 (95% CI, 9.2-10.4) lower rate** in booster group[293]	No available information	No available information	No available information	No available information	No available information	Ongoing clinical trials[xxxvii]	No available information

	50-59 age group: **12.2 (95% CI, 11.4-13.1) lower rate** in booster group[293] Oldest age group (≥60): **11.3 (95% CI, 10.4-12.3) lower rate** in booster group [294] **12.4 (95% CI, 11.9-12.9) lower rate** in booster group[293] ***Severe Illness:*** 40-59 age group: **22.0 (95% CI, 10.3-47.0) lower rate** in booster group[293] Older population (≥60): **19.5 (95% CI, 12.9-29.5) lower rate** in booster group[294] **18.7 (95% CI, 15.7-22.4) lower**								

	rate in booster group[293]								
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%**[295] *Effectiveness in ≥50:* **84.4%** (95% CI, 82.8-85.8) against symptomatic COVID-19[296] **94.0%** (93.4-94.6) against symptomatic COVID-19 compared with unvaccinated[296]					For more detailed information regarding immunogenicity of third dose refer to study[lxvi]			

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

	HETEROLOGOUS BOOSTER DOSES							
Vaccine Schedule	*Heterologous 1:* **mRNA1273/BNT162b2** *Heterologous 2:* **Ad26.CoV.2.S/BNT162b2** ***Received BNT162b2 as booster dose	*Heterologous 1:* **BNT162b2/mRNA1273** *Heterologous 2:* **Ad26.CoV.2.S/mRNA1272** ***Received mRNA1273 as booster dose	No available data	*Heterologous 1:* **BNT162b2/Ad26.CoV.2.S** *Heterologous 2:* **mRNA1273/Ad26.CoV.2.S** ***Received Ad26.CoV.2 as booster dose	*Heterologous:* **SinoPharm/BNT162b2**	*Heterologous 1:* **CoronaVac/ChAdOx1** *Heterologous 2 :* **CoronaVac/BNT162b2**	No available data	*Heterologous:* Ongoing trial of heterologous booster shot using NVX-CoV2373[lxvii]
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[297] 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	No available data	No available data
Immunogenicity	*Binding Antibody Responses:* **2-fold or greater rise** in bAb noted in **98-100%** of BNT162b2 recipients[298]	*Binding Antibody Responses:* **2-fold or greater rise** in bAb noted in **96-100%** of mRNA1273 recipients[298]	No available data	*Heterologous 1:* **14.8 to 32.4-fold** increase in neutralization titers against wild-type virus[297]	No available data	*Heterologous 1:* Heterologous vaccination had a **9-fold greater GMT** (7,947 U/mL) than fully patients fully vaccinated with	No available data	No available data

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

	Neutralizing Antibody Responses: **341.3-677.9 IU50/mL** 15 days after booster with BNT162b2[298] Participants who received mRNA-based booster vaccination had four-fold increase compared to Ad26.COV2.S. [298]	*Neutralizing Antibody Responses:* **676.1-901.8 IU50/mL** 15 days after booster with mRNA1273[298] Participants who received mRNA-based booster vaccination had four-fold increase compared to Ad26.COV2.S. [298]		*Binding Antibody Responses (bAb):* **2-fold or greater rise** in bAb noted in **98-100%** of Ad26.COV2.S. recipients[298] *Neutralizing Antibody Responses:* **31.2-382.2 IU50/mL** 15 days after booster with Ad26.COV2.S. [298]		AZD1222 and the highest antibody response, IgA, and neutralizing antibodies than other groups[299] *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**[300] Single booster dose of BNT162b2 induced higher anti-spike RBD IgG antibody levels, compared to single booster dose of CoronaVac[74]		

Immunogenicity against variants	*Binding Antibody Responses:* Baseline bAb levels for **Delta** were **34-45% lower** compared to Wa-1 strain[298] Following boost, bAB levels for **Delta** were **15-36% lowe**r compared to Wa-1 strain[298]	*Binding Antibody Responses:* Baseline bAb levels for **Delta were 34-45% lower** compared to Wa-1 strain[298] Following boost, bAB levels for **Delta** were **15-36% lower** compared to Wa-1 strain[298] *Neutralizing Antibody Responses:* **Delta and Beta** variants were only available in those boosted with mRNA-1273[298]	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) [297] *Binding Antibody Responses:* Baseline bAb levels for **Delta** were **34-45% lower** compared to Wa-1 strain[298] Following boost, bAB levels for **Delta** were **15-36% lower** compared to Wa-1 strain[298]	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**[299]	No available data	No available data
Reactogenicity	*Adverse Events:* **72-92%** participants reported local pain or tenderness[298]	*Adverse Events:* **75-86%** participants reported local pain or tenderness[298]	No available data	*Adverse Events:* **71-84%** participants reported local pain or tenderness[298]	No available data	Similar results to homologous booster administration	No available data	No available data

	Malaise, myalgias, and headaches were commonly reported[298] **14.4%** of the participants reported unsolicited adverse events[298]	Malaise, myalgias, and headaches were commonly reported[298] **15.6%** of participants reported unsolicited adverse events[298]		Malaise, myalgias, and headaches were commonly reported[298] **12%** of participants reported unsolicited adverse events[298]				
Other	*Heterologous 2 – Effectiveness in ≥50:* **87.4%** (95% CI, 84.9-89.4) against symptomatic COVID-19[296] **93.1%** (95% CI, 91.7-94.3) against symptomatic COVID-19 compared to unvaccinated[296]					Ongoing clinical trial examining immunogenicity and safety of third dose vaccination with ChAdOx1 or BNT162b2 vaccine among adults who received full jab of CoronaVac[lxviii]		

[lxviii] 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	COVAXIN/ BBV152 (Bharat Biotech, India)	Novavax/ NVX-CoV2373
	FURTHER INFORMATION							
Storage conditions	2°C to 8 °C (for 1 month)	2°C to 8 °C (for 1 month)	2°C until 8 °C	2°C to 8 °C (for 3 months)	2°C until 8 °C	2°C until 8 °C	2°C until 8 °C	2°C to 8 °C
Approving authorities	FDA (11.12.20)[lxix]; EMA (21.12.20); WHO EUL (31.12.20); and list of countries (including Switzerland – approved on 20.12.20)	FDA (18.12.20); EMA (06.01.21); WHO EUL (30.04.21); and list of 51 countries (including Switzerland – approved 12.01.21)	FDA (awaiting on approval); EMA (29.01.21); WHO EUL (15.02.21); and list of 121 countries (Switzerland awaiting on approval)	FDA (27.02.21); EMA (11.03.21), WHO EUL (12.03.21), and list of 59 countries (including Switzerland – approved 22.03.21)	WHO EUL (07.05.21); and list of 55 countries (e.g., Argentina, Bahrain, Brazil, China, Indonesia, United Arab Emirates, Zimbabwe)	WHO EUL (01.06.21), and list of 33 countries (e.g., Albania, Chile, Egypt, Hong Kong, Malaysia, Tunisia, Turkey, Ukraine)	WHO EUL (03.11.21) and list of 9 countries (Guyana, Inidia, Iran, Mauritius, Mexico, Nepal, Paraguay, Philippines & Zimbabwe)	Waiting on approval (Not-yet-approved by countries or WHO for emergency use)

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

IMMUNOGENICITY								
Immunogenicity	*7-14 days after second dose:* *18-55 years*: GMT ranged from **1.7 to 4.6** times the GMT of the convalescent serum[301]. *65-85 years*: GMT ranged from **1.1 to 2.2** times the GMT of the convalescent serum[301].	*14 days after second dose:* *18-55 years*: $PRNT_{80}$ GMT **654.3 (95% CI, 460.1-930.5**)[302]. *56-70 years:* $PRNT_{80}$ GMT **878 (95% CI, 516-1494**)[303]. *≥71 years*: $PRNT_{80}$ GMT **317 (95% CI, 181-557**)[303].	*28 days after second dose median antibody titres:* *18–55 years*: **20,713 AU/mL [IQR 13,898 - 33,550**][304] *56–69 years*: 1**6,170 AU/mL [IQR 10,233 - 40,353]**[304]. *≥70 years*: **17,561 AU/mL [IQR 9,705 - 37,796]**[304].	*29 days after vaccination:* *18-55 years:* GMC **586 (95% CI, 445-771**); GMT **224 (95% CI, 168-298**)[305]. *≥65 years*: GMC **312 (95% CI, 246-396); GMT 212 (95% CI, 163-266**)[305]. *57 days after vaccination:* *18-55 years*: **754 (95% CI, 592-961**); GMT **288 (95% CI, 221-376**)[305].	*14 days after second dose:* *18-55 years:* GMT ***211.2* (95% CI, 158.9-280.6**)[306]. *≥60 years: GMT **131.5** (95% CI, 108.2-159.7**)[306].	*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)[307]. *2 weeks after second dose:* 164.4 BAU/ mL[308] *4 weeks after second dose:* 94.8 BAU/ mL[308] *8-12 weeks after second dose:*	*Single dose (≥4 weeks:* **43.8%** seropositive for anti-spike antibody > 15 AU/mL[309] GMT **16.8 (95% CI, 15.80-17.88)** for SARS-CoV-2 spike antibody titre[309] *Two doses (≥4 weeks)*: **80.0%** seropositive for anti-spike antibody > 15 AU/mL[309] GMT **48.3 (95% CI, 47.46-48.92)** for SARS-CoV-2 spike antibody titre[309]	

						34.7 BAU/ mL[308]		
Immunogenicity against the Mu variant	6.8-fold decrease in neutralizing titres when compared to convalescent sera[310]	Neutralizing titre similar to that of BNT162b2 sera[310]	Neutralizing titre similar to that of BNT162b2 sera[310]	No available data	No available data	No available data	No available data	No available data
				EFFICACY				
Single dose[lxx]	**52%** (95% CI, 29.5 to 68.4; starting at 12 days) or 82.2% (75.1 to 87.3; starting at ≥14 days)[311]. **91%** (95% CI, 85-94)[312]. ≥80 years : **71.4%** (95% CI, 46.5-90.6) vaccine efficacy for symptomatic disease 14 days after one dose	**95.2%** (95% CI, 91.2.8 to 97.4; starting at >14 days)[107].	**72.8%** (starting at 22 days up to 60 days)[314]. **88%** (95% CI, 75-94)[312].[lxxii] ≥80 years : **80.4%** (95% CI, 36.4-94.5) vaccine efficacy for symptomatic disease 14 days after one dose [United Kingdom, 18 Dec 2020 – 26 Feb 2021[313] ≥65 years :	Single dose vaccine	Unknown	**35.1%** (95% CI, -6.6 to -60.5) [conducted in a setting with high P.1 transmission][315].	No available data	**83.4%** (95% CI, 73.6-89.5) starting at ≥14 days[40]

[lxx] Against SARS-COV-2 infection

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

	[United Kingdom, 18 Dec 2020 – 26 Feb 2021][313] ≥65 years : **56%** (95% CI 19-76) at 28-34 days and **62%** (95% CI 23-81) at 35-48 days post-vaccination [United Kingdom, 8 Dec 2020 – 15 Mar 2021][313] [lxxi]		**56%** (95% CI 19-76) at 28-34 days and **62%** (95% CI 23-81) at 35-48 days post-vaccination [United Kingdom, 8 Dec 2020 – 15 Mar 2021][313] [lxxiii]					
Two doses[lxxiv]	**95.0%** (95% CI, 90.3-97.6) starting at ≥7 days in population without prior SARS-CoV-2 infection[122] **94.6%** (95% CI, 89.9-97.3) starting at ≥7 days in population with or without prior infection[122]	**94.1%** (95% CI, 89.3-96.8) after median follow-up of less than 63 days[107] **93.2%** (95% CI, 91.0-94.8)[316] Against severe disease: **98.2%** (95% CI, 92.8-99.6)[316]	**63.1% (**95% CI, 51.8-71.7) starting at ≥14 days for two standard doses[314] **80.7%** (95% CI, 62.1-90.2) starting at ≥14 days for first low dose and standard second dose[314] **66.7%** (95% CI, 57.4-74.0) starting at ≥14 days for	**66.9%** (95% CI 59.0-73.4) after 14 days and **66.1%** (95% CI 55.0-89.1) after 28 days for VE against moderate-severe-critical COVID-19[318] **76.7%** (95% CI 54.6 to 89.1) after 14 days and **85.4%** (95% CI 54.2 to 96.9) after 28 days for VE	After 14 days, efficacy against symptomatic cases was **72.8%** (95% CI 58.1-82.4; in WIV04 vaccine) or **78.1%** (95% CI 64.8 to 86.3; in HBO2 vaccine).[203]	After 14 days, efficacy against symptomatic cases was **50.7%** (95% CI 35.9 to 0-62.0).[113] 99.17% of NAb titres were above or equal to the Nab positivity cut-off (20 units) against wild-type[319].	*Symptomatic SARS-CoV-2 infection:* **77.8%** (95% CI, 65.2-86.4)[320] *Severe symptomatic SARS-CoV-2 infection:* **93.4** (95% CI, 57.1-99.8)[320] *Symptomatic COVID-19 in ≥60 years old:*	**89.7%** (95% CI, 80.2-94.6) starting at ≥7 days[40] **90.4%** (95% CI, 82.9-94.6)[321] **100%** (95% CI, 87-100) against moderate-to-severe COVID-19[321] **100%** (95% CI, 34.6-100)

[lxxi] Does not differentiate between BNT162b2 and ChAdOx1 nCoV-19.
[lxxiii] Does not differentiate between BNT162b2 and ChAdOx1 nCoV-19.
[lxxiv] Against SARS-CoV-2 infection.

		Prevention against COVID-19 illness: **93.2%** (95% CI, 91.0-94.8; United States) [316] *Prevention against severe disease:* **98.2%** (95% CI, 92.8-99.6; United States) [316] *Prevention against asymptomatic infection starting 14 days after second infection:* **63.0%** (95% CI, 56.6-68.5; United States) [316]	pooled analysis efficacy[314] *Against mild-to-moderate symptomatic COVID-19 >14 days after second injection*: **21.9%** (95% CI, -49.9 to 59.8; South Africa) [24 June – 09 November 2020][317]	against severe-critical COVID-19[318]			**67.8%** (95% CI, 65.2-86.4) against symptomatic COVID-19[320] *Symptomatic COVID-19 in 18-59 years old:* **79.4%** (95% CI, 66.0-88.2) against symptomatic COVID-19[320]	against severe COVID-19[321] **90%** (95% CI, 80-95) (≥7 days after second dose)[322]
Against asymptomatic infection	**90%** (starting at 14 days) regardless of symptom status[323]	**63.0%** (95% CI, 56.6-68.5)[316]	Statistically non-significant **reduction of 22.2%** (95% CI -9.9 to 45.0) for asymptomatic cases **61.9%** efficacy[37]	At day 71, vaccine efficacy against asymptomatic infections was **65.5%** (95% CI 39.9 to 81.1)[318].	Efficacy against symptomatic and asymptomatic cases was **64%** (95% CI 48.8 to 74.7; in WIV04 vaccine) or 73.5% (95% CI 60.6 to 82.2; in HBO2 vaccine)[203].	Unknown	**63.6** (95% CI, 29.0-82.4) efficacy against asymptomatic cases[320]	Unknown

EFFICACY AGAINST VARIANTS								
Alpha (B.1.1.7)	Two doses of the vaccine **effectively neutralize** the B.1.1.7 variant and the D614G substitution[324].	**NAbs remained high** and consistent with titres of the wildtype for the B.1.1.7 variant[325].	**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[96].	**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[326].	**10.4-fold** reduction in neutralization capacity when compared to natural infection sera[319]. **85.83%** of NAb titres were above or equal to the Nab positivity cut-off (20 units) against wild-type[319]. Neutralization decreased by **4.1-fold** when compared to wild-type[327].	$PRNT_{50}$ **0.8** when compared with wild type against Alpha (no significant difference in neutralization capacity)[328]	Two dose efficacy against the B.1.1.7 variant **86.3%** (95% CI, 71.3-93.5)[40] **93.6%** (95% CI, 81.7-97.8) against the Alpha variant[321] *Against non-B.1.1.7 variant* **96%** (95% CI, 74-99.5) (≥7 days after second dose)[322] *Against B.1.1.7 variant* **86%** (95% CI, 71-94) (≥7 days after second dose)[322]
Beta (B.1.351)	Neutralization was **diminished by a factor of 5**. Despite this, the BNT162b2 mRNA vaccine still provides some	NAbs were **6-fold** lower. Nevertheless, NAbs were still found to be protective[325].	Two doses of the vaccine had no efficacy against the B.1.351 (VE = **21.9%;** 95% CI, -49.9 to 59.8)[317].	Efficacy against moderate-severe-critical Covid-19 due to the variant was **52.0%** (>14 days) and **64.0%** (>28 days). Efficacy against	No published data	NT_{GM} **35.03 (95% CI, 27.46-44.68**); **8.75-fold** reduction in neutralization capacity when compared to	GMT **61.57 (95% CI, 36.34-104.3)** against Beta variant with significant reduction in neutralization titre[333]	**51.0%** (95% CI, -0.6-76.2) efficacy against B.1.351 variant[334]

	protection against B.1.351[329] **100%** (95% CI, 53.5-100)[330].		*Against mild-to-moderate symptomatic COVID-19 associated with B.1.351 variant >14 days after second injection*: **10.4%** (95% -76.8 to 54.8; South Africa) [24 June – 09 November 2020][317]	severe-critical COVID-19 was **73.1%** (>14 days) and **81.7%** (>28 days)[318]. Demonstrated **3.6-fold** reduction in neutralization sensitivity[331]. Neutralization titres were decreased by **6.7-fold**[332].		natural infection sera[319]. **82.5%** of NAb titres were above or equal to the Nab positivity cut-off (20 units) against wild-type[319].		
Gamma (P.1)	*Single dose:* *≥21 days*: **83%** against hospitalization and death[335]. *Two doses*: *≥14 days*: **98%** against hospitalization and death[335].	**3.2-fold** reduction in neutralization capacity when compared to wild-type[336].	*Single dose:* *≥21 days*: **94%** against hospitalization and death[335]. *Two doses:* **64%** (95% CI, -2-87) [n=18][337] Efficacy against Zeta (P.2) [2 doses]: **69%** (95% CI, 55-78)[337]	Demonstrated **3.4-fold** reduction in neutralization sensitivity[331].	No published data	**49.6%** against P.1 (>14 days after 1st dose)[315]. Neutralization decreased by **7.5-fold** when compared to wild-type[327].	No available data	No available data
Delta (1.671.2)	**Reduced NAb activity** relative to B.1.1.7 strain[338].	**2.1-fold** reduction in neutralization capacity when compared to wild-type[336].	*Single dose:* *≥21 days*: **90%** against hospitalization and death[335].	Demonstrated **1.6-fold** reduction in neutralization sensitivity[331].	Demonstrated **reduced neutralizing capacity**. However, there were no	NT_{GM} **24.48** (95% CI,19.2-31.2)[319]. **69.17%** of NAb titres were above or equal to the	**65.2** (95% CI, 33.1-83.0) estimated efficacy[116]	No available data

				Neutralization titres were decreased by **5.4-fold**[332].	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[326].	Nab positivity cut-off (20 units) against wild-type[319].	GMT **68.97** (95% CI, 24.72-192.4) against Delta variant with significant reduction in neutralization titre[333]	
PHASE III TRIALS RESULTS[lxxv]								
Number of participants (vaccine/ placebo)	43,448 (21,720/ 21,728)[122]	30,420 (15,210/15,210)[107]	17,178 (8597/8581)[314]	39,321 (19,630/19,691)[318]	26,917 (13,459/13458); or 26,914 (13,465/13,458)[203]	9,823 (4,953/4,870)[113]	25,798 (12,899/12899)[116]	14,039 (7,020/7,019)[40]
Total COVID-19 cases (vaccine/ control)	170(8/162)[122]	196 (11/185)[107]	332 (84/248)[314]	464 (116/348)[318]	121(26/95) or 116(21/95)[203]	253(85/168)[113]	130 (24/106)[116]	106(10/96)[40]

[lxxv] Phase III trials were conducted between 27 July and 14 November 2020 for BNT162b2/ COMIRNATY, 27 July and 23 October 2020 for Spikevax/ Moderna, 23 April and 6 December 2020 for Vaxzevria/ ChAdOx1 nCoV-19/ AZD1222/ Covishield, 21 September 2020 and 22 January 2021 for Janssen Covid-19 vaccine/ Johnson & Johnson, 16 July and 20 December 2020 for Sinopharm/ BBIB-CorV, 21 July and 16 December 2020 for the Sinovac/ CoronaVac vaccine, 16 November 2020 and 7 January 2021 for the COVAXIN vaccine, and 28 September 2020 and 28 November 2020 for the Novavax vaccine. All trials were conducted prior to the transmission of the more contagious variant strains, particularly the delta variant (B.1.617.2). Studies are currently ongoing to determine the effectiveness of the vaccines against the delta variant.

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)[122].	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)[107].	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)[314].	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[318].	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)[203].	After 14 days, efficacy against symptomatic cases was **50.7%** (95% CI 35.9 to 0-62.0).[113]	**77.8%** (95% CI, 65.2-86.4) against symptomatic COVID-19 starting at ≥14 days after second dose[116]	**83.4%** (95% CI, 73.6-89.5) starting at ≥14 days after first dose[40] **89.7%** (95% CI, 80.2-94.6) starting at ≥7 days after second dose[40]
Efficacy against hospitalization and death	**100%** (after 7 days)[122]	**100%** (≥14 days)[107]	**100%** (after 21 days)[314]	**76.7%** (≥14 days) or **85.4%** (≥28 days)[318]	**100%** (>14 days)[203]	**100%** (>14 days)[113]	**93.4%** (>14 days) against severe COVID-19[116]	**100%** (after 7 days)[40].
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 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	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	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	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[112].	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[113].	Rates of local and systemic AEs reported in the BBV152 group as mild (11·2%), moderate (0·8%), or severe (0·3%) were comparable	<u>Phase II:</u> Nine serious adverse events were reported, only one of which was assessed as related to the vaccine: acute colitis[340].

	the general population[103,339].	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[107].	experimental or control vaccine (out of 11 636 vaccine recipients): transverse myelitis, haemolytic anaemia and a case of fever higher than 40°C [109].	the vaccine: Guillain-Barré syndrome (1), pericarditis (1), brachial radiculitis (1), hypersensitivity (1), Bell's Palsy (2), & severe generalized weakness, fever & headache (1)[318].			to the placebo group [116] 15 deaths, none considered related to the vaccine or placebo[116]	
	PHASE III TRIAL OTHER							
Comments	Specific populations were excluded (HIV and immunocompromised patients, and pregnant women).	Calculation of efficacy were not based on the total number of confirmed Covid-19 cases.		**<u>2-DOSE EFFICACY</u>** *<u>Efficacy against symptomatic (moderate to severe/ critical) SARS-CoV-2 infection</u>* **94%** (95% CI, 58-100) in the US. **75%** (95% CI, 55-87) globally.[20] *<u>Efficacy against severe/ critical SARS-CoV-2 infection</u>*	Only 2 severe cases occurred in the control group and none in the vaccine group (very few cases to get a reliable estimate).	-	-	Novavax is currently awaiting FDA, EMA, and WHO EUL approval. Upcoming information regarding results of clinical trials or approval will be updated in upcoming reports

				100% (95% CI, 33-100)[20]					

	VACCINE PRODUCTION SITES							
	BNT162b2/ COMIRNATY (Pfizer-BioNTech, USA)[lxxvi]	**Spikevax/ Moderna COVID-19 Vaccine/ mRNA-1273 (Moderna, USA)**[lxxvii]	**Vaxzevria/ ChAdOx1 nCoV-19/ AZD1222/ Covishield (AstraZeneca/Oxford, UK, India)**[lxxviii]	**Janssen COVID-19 vaccine/Johnson & Johnson (Janssen, USA)**[lxxix]	**Sinopharm/BBIBP-CorV, China**[lxxx]	**Sinovac CoronaVac, China**[lxxxi]	**COVAXIN / BBV152 (Bharat Biotech, India)**	**Novavax/ NVX-CoV2373**
EUL holder	BioNTech Manufacturing GmbH (Germany)	ModernaTX, Inc. (USA)[1] Moderna Biotech (Spain)[2]	AstraZeneca AB (Sweden)	Janssen-Cilag International NV (Belgium)	Beijing Institute of Biological Products Co., Ltd. (BIBP) (China)	Sinovac Life Sciences Co., Ltd. (China)	Bharat Biotech International Limited (India)	Novavax (USA)

[lxxvi] 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

[lxxvii] 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

[lxxviii] 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

[lxxix] 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

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

[lxxxi] 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

Production sites (Drug substance)	BioNTech Manufacturing GmbH (Mainz, Germany) BioNTech Manufacturing Marburg (Marburg, Germany) Rentschler Biopharma SE (Laupheim, Germany) Wyeth BioPharma Division of Wyeth Pharmaceuticals (USA)	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) SK Bioscience (Republic of Korea) Halix B.V (Netherlands) WuXi Biologics (China)	Janssen Vaccines & Prevention B.V. (The Netherlands) Janssen Biologics B.V. (The Netherlands) Emergent Manufacturing Operations Baltimore LLC (USA)	Beijing Institute of Biological Products Co., Ltd. (China)	Sinovac Life Sciences Co., Ltd. (China)	-	Novavax (Bohumil, Czech Republic)
Production sites (Drug product)	Baxter Oncology GmbH (Halle/ Westfallen, Germany) BioNTech Manufacturing GmbH (Mainz, Germany) Pfizer Manufacturing Belgium NV (Belgium)	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)	Janssen Biologics B.V. (The Netherlands) Janssen Pharmaceutica NV (Belgium) Aspen SVP. (South Africa) Catalent Indiana LLC. (USA)	Beijing Institute of Biological Products Co., Ltd. (China)	Sinovac Life Sciences Co., Ltd. (China)	-	Novavax (Bohumil, Czech Republic)

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

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