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Supplementary appendix 1

This appendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

Supplement to: Piechotta V, Siemens W, Thielemann I, et al. Safety and effectiveness of vaccines against COVID-19 in children aged 5–11 years: a systematic review and meta-analysis. *Lancet Child Adolesc Health* 2023; published online April 18. https://doi.org/10.1016/S2352-4642(23)00078-0.

Appendix 1

Supplementary Methods

Search strategies

Starting from January 2022, we searched the COVID-19 L·OVE (Living OVerview of Evidence) platform and World Health Organisation COVID-19 Research Database every 6 weeks. As described in the review protocol (CRD42022306822), we piloted whether a simplified search approach fully identifies the relevant literature. As all eligible studies were included in the COVID-19 L·OVE repository, searches in the World Health Organisation COVID-19 Research Database were terminated after 02 June 2022, as no additional relevant records were identified over the piloting phase.

COVID-19 L·OVE (Living OVerview of Evidence) platform

The L·OVE repository is available from https://iloveevidence.com/. It is regularly updated and includes 41 databases, thereby covering major databases (e.g., PubMed/Medline, EMBASE, CINAHL), trial registries (e.g., ICTRP Search Portal, Clinicaltrials.gov, ISRCTN registry) and preprint servers (e.g., medRxiv, bioRxiv, SSRN Preprints, ChinaXiv).

The search was performed using the following approach:

(1) Filtered by PICO:

> Prevention or treatment

> Public health

> Vaccination

> SARS-CoV-2 vaccines

(2) Combined with the following search string:

infan* OR newborn* OR new-born* OR neo-nat* OR neonat* OR picu* OR nicu* OR baby OR babies OR suckling* OR toddler* OR child* OR adolescen* OR pediatric* OR paediatric* OR pube* OR juvenil* OR preschool* OR youngster* OR kindergart* OR kid OR kids OR boy* OR girl*

World Health Organization COVID-19 Research Database

The WHO COVID-19 research database is available from https://search.bvsalud.org/global-literature-on-novel-coronavirus-2019-ncov/. It covers multiple, multilingual databases, is updated daily, and is based on searches in databases, specific journals (e.g., Eurosurveillance), preprints, and is further complemented by hand searching, and expert-referred scientific articles.

The search was performed using the following search string:

#1	infan$ OR newborn$ OR "new-born" OR "new-borns" OR "neo-natal" OR neonat$ OR picu$ OR nicu$ OR baby OR babies OR suckling$ OR toddler$ OR child$ OR adolescen$ OR pediatric$ OR paediatric$ OR pube$ OR juvenil$ OR preschool$ OR youngster$ OR kindergart$ OR kid OR kids OR boy$ OR girl$ OR youth OR "young people" OR teen*
#2	vaccin$ OR immunis$ OR immuniz* OR innoculat*
#3	mRna OR Comirnaty OR BNT162b2 OR "bnt 162" OR Pfizer-BioNTech OR tozinameran OR Vaxzervria OR Oxford-astrazeneca OR astrazeneca OR "azd 1222" OR azd1222 OR chadox-1 OR covishield OR serum-institute OR ad26.cov2.s OR ad26cov2s OR "jnj 78436735" OR jnj78436735 OR Moderna-biotech OR mRNA-1273 OR elasomeran OR "cx-024414" OR "RNA-1273" OR coronavac OR picovacc OR Sinovac OR Sinopharm OR Bibp OR "bbibp Corv" OR covaxin OR "bbv-152" OR "bbv-152a" OR "bbv-152b" OR "bbv-152c" OR bharat-biotech OR "Sputnik-V" OR "sputnik-light" OR VAC31518 or EpiVacCorona or Convidicea or "Ad5-nCoV" or PakVac OR Novavax OR "NVX-CoV2373" OR "tak-019" OR covovax OR "COVIran Barakat" OR BBV152 OR "WIBP-CorV" OR KoviVac or CoviVac or "ZF-2001" OR ZIFIVAX OR "ZF-UZ-VAC-2001" OR "RBD-Dimer" or QazVac or "QazCovid-in" or "TAK-919" OR "ZyCoV-D" or "CIGB 66" or VLA2001 or CVnCoV OR Zorecimeran OR "CV-07050101" OR curevac OR "INO-4800" OR reluscovtogene-ralaplasmid OR pGX9501 OR "VIR-7831" or "UB-612" or BNT162 or "GRAd-COV2" or "SCB-2019" or "Razi Cov Pars" or Nanocovax or "AdCLD-CoV19" or "KD-414" or "VBI-2902a" or "COVID-eVax" or "S-268019" or "GLS-5310" or Covigenix or "VAX-001" or "Vietnam domestic vaccine" or "EXG-5003" or "AKS-452" or "DS-5670a" or "ABNCoV2" OR EuCorVac OR "IIBR-100" OR ArCov OR "AG0301-COVID19" OR "GX-19N" OR "ARCT-021" OR "LUNAR-COV19" OR "HDT-301" OR HGCO19 OR "AV-COVID-19" OR "PTX-COVID19-B" OR "COVI-VAC" OR CORVax12 OR "MVA-SARS-2-S" OR COH04S1 OR "AdimrSC-2f" OR "bacTRL-Spike" OR "COVAX-19" OR "DelNS1-2019-nCoV-RBD-OPT1" OR "GRAd-COV2" OR "UQ-CSL V451" OR "SCB-2019" OR "VXA-CoV2-1" OR "AdCOVID" OR "AAVCOVID" OR "ChAd-SARS-CoV-2-S" OR HaloVax OR LineaDNA OR MRT5500 OR PittCoVacc OR "T-COVIDTM" OR "LNP-nCoVsaRNA" OR V590 OR V591 OR "ERUCOV-VAC" OR ABNCoV2 OR BUTANVAC OR "Coviran barekat" OR MVC-COV1901 OR Epi-Vac-Corona OR COV2-PreS-dTM-AS03 OR Vidprevtyn OR Corbevax OR GBP510 OR BBV154 OR "Gam-COVID-Vac" OR GAM-KOVID-VAC OR ganulameran OR bnt-162b3 OR abdavomeran OR zorecimeran OR pidacmeran OR "BNT-162c2" OR SCB-2019 OR AG-0302 OR "SpikeVAX" OR covilo OR KCONVAC OR KconecaVac OR "BECOV2A" OR Nuvaxovid OR "MVC-COV1901" OR "aurora cov" OR "epivaccorona n" OR "erucov vac" OR "finlay fr 2" OR "FINLAY-FR-1A" OR "pastu covac" OR "nvsi 06 08" OR fakhravac OR "razi cov pars" OR SpikoGen OR "COVAX-19" OR "zycov d" OR abdavomeran OR "bnt 162b1" OR bnt162b1 OR "bnt-162b1" OR "soberana 02" OR "soberana plus"
#4	#1 AND #2 AND #3

Risk of Bias

ROBINS-I

We used ROBINS-I[1,2] to assess the risk of bias in NRSI. Outcomes rated with ROBINS-I as critical were not included in the data synthesis to avoid misleading conclusions. A study was classified at critical risk of bias if at least one domain was rated as critical according to the following criteria:

- **Bias due to confounding**:
  A study was classified as critical risk of bias due to confounding if confounding was not measured and/or uncontrolled (i.e., baseline characteristics were not reported, analysis was not adjusted for covariates).
- **Bias in selection of participants into the study:**
  A study was considered to be at critical risk for selection bias if a substantial proportion of the follow-up period was likely not included in the analyses and the rate ratio or participants in intervention and control group was not constant over time.
- **Bias in classification of interventions:**
  Critical bias due to misclassification was assigned when there was an extremely high degree of misclassification of intervention status, e.g., due to an unusually strong recall bias. (Considered as unusual.)
- **Bias due to deviations from intended intervention:**
  A study was rated at critical risk of bias due to deviation from the intervention if effects on the outcome may have resulted from the initiation of and adherence to the intervention, such as when the intervention status changed over time and this was not adequately accounted for in the analysis.
- **Bias due to missing data:**
  A study was rated at critical risk for missing data bias if there were critical differences between interventions among participants with missing data, and the missing data could not be identified by appropriate analysis or were not accessible.
- **Bias in measurement of outcomes:**
  Bias in measurement of outcomes was considered critical if the outcome measurement was so different between intervention groups that they could not be reasonably compared (i. e., the methods of outcome assessment (NAAT, antigen test), or testing behavior differed significantly between intervention groups).
- **Bias in selection of the reported results:**
  Bias from selective reporting of results was considered critical when there was evidence or strong suspicion of selective reporting of results (i.e., large deviations from protocol) and the unreported results are likely to differ significantly from the reported results.

QUIPS

The Quality In Prognosis Studies (QUIPS) tool was developed to assess the risk of bias in studies of prognostic factors.[3] The concept is similar to the one of other risk of bias tools and addresses study participation, attrition, outcome measurement, confounding, statistical analysis and reporting, and the measurement of the prognostic factor.

As prognostic factors are defined as any characteristic that is predictive of a person's subsequent outcome,[4] this could also be previous exposures (e.g. history of SARS-CoV-2 infection), but also the vaccination status of individuals when looking at outcomes following SARS-CoV-2 infection. As QUIPS is suitable for risk of bias assessments of single-arm studies, we decided to use this tool. For the domain focusing on the measurement of the prognostic factor, we considered the outlined aspects and applied them to our intervention of interest (i.e., COVID-19 vaccination).

In the respective domain, we assessed the following:

- Whether a clear definition of the vaccination status was provided (i.e. type of vaccine, number of doses, dosage)
- Whether the vaccination status was adequately recorded (e.g. in electronic health records, vaccination registries) or whether it relied on recall of caregivers or participants
- Whether the definition and recording of the vaccination status was the same for all study participants

Data analysis

Primary analyses were performed using a random-effects model. The restricted maximum likelihood (REML) method was used for estimating the between-study variance Tau squared.[5] Study effects for VE were pooled by applying the inverse variance method, while the pooled RR for safety outcomes was calculated by weighting the study effects with the Mantel-Haenszel method. We used the Hartung-Knapp adjustment for random-effects meta-analyses[6,7] with 3 or more studies and, as ad hoc correction, used the 95% CI of the classic random-effects model or the Hartung-Knapp meta-analysis, whichever was wider.[8]

We specified the following subgroup analyses in the protocol anticipating that many of them would not be feasible due to the lack of data: vaccine type; product; incomplete / complete / booster dosing regimen; age group (e.g., 0-4 years vs. 5-11 years); sex (female vs. male); location (geographical region); baseline immunity (seropositive vs. seronegative) through natural infection, or after basic vaccination for booster-vaccination studies; risk groups (e.g., for immunocompromised participants); concomitant treatments (e.g., B-cell depleting therapies). Prespecified sensitivity analyses included risk of bias (e.g., low risk of bias vs. unclear and high risk of bias studies with the same study design); study design (prospective vs. retrospective); type of publication: peer-reviewed vs. other publication formats (e.g. preprint articles, letters); random-effects vs. fixed-effect model meta-analysis; and exclusion of studies with inexplicably high or low effects.

We intended to explore potential publication bias for outcomes with ≥10 included studies through investigation of funnel plot asymmetry and by conducting a linear regression test according to the Cochrane Handbook[9]. However, this was not possible as we included a maximum of 6 studies per outcome in meta-analysis.

Certainty of evidence (GRADE)

The certainty of evidence (CoE) was assessed using the GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach.[10]

GRADE considers five domains (risk of bias, consistency of effect, imprecision, indirectness and publication bias) in addition to the consideration of the underlying study design to rate the certainty of evidence. In accordance with the GRADE guidelines on rating the certainty of evidence for NRSIs, we started with a high CoE for outcomes assessed with ROBINS-I.[11]
For each of the considered domains we downgrade our certainty by 1 level, in case of serious concerns, or by 2 levels in case of very serious concerns, resulting in the overall rating of high, moderate, low or very low for each evaluated outcome.[10]

Study overview

List of included studies

Nr.	Author of main publication	Reference(s)
1.	Amir et al, 2023	Amir O, Goldberg Y, Mandel M, et al. Initial protection against Omicron in children and adolescents by BNT162b2 in Israel: an observational study. Lancet Infect Dis. 2023 Jan;23(1):67-73. doi: 10.1016/S1473-3099(22)00527-8. Epub 2022 Sep 9.
2.	Bartsch et al, 2022 A	Bartsch YC, St Denis KJ, Kaplonek P, et al. SARS-CoV-2 mRNA vaccination elicits robust antibody responses in children. Science translational medicine. 2022, eabn9237. doi: 10.1126/scitranslmed.abn9237
3.	Bartsch et al, 2022 B	Bartsch YC, Chen JW, Kang J, et al. BNT162b2 induces robust cross-variant SARS-CoV-2 immunity in children. npj Vaccines. 2022; 7(1):158. doi: 10.1038/s41541-022-00575-w
4.	Bloise et al, 2022	Bloise S, Marcellino A, Frasacco B, et al. Cross-Sectional Survey on BNT162b2 mRNA COVID-19 Vaccine Serious Adverse Events in Children 5 to 11 Years of Age: A Monocentric Experience. Vaccines. 2022; 10(8):1224. doi: 10.3390/vaccines10081224
5.	Capponi et al, 2022	Capponi M, Pulvirenti F, Cinicola BL, et al. Short-Term Side Effects and SARS-CoV-2 Infection after COVID-19 Pfizer–BioNTech Vaccine in Children Aged 5–11 Years: An Italian Real-World Study. Vaccines. 2022; 10(7):1056. doi: 10.3390/vaccines10071056
6.	Chantasrisawad et al, 2022	Chantasrisawad N, Puthanakit T, Kornsitthikul K, et al. Immunogenicity to SARS-CoV-2 Omicron variant among school-aged children with 2-dose of inactivated SARS-CoV-2 vaccines followed by BNT162b2 booster. Vaccine: X. 2022;12, 100221. doi: 10.1016/j.jvacx.2022.100221
7.	Chemaitelly et al, 2022	Chemaitelly H, AlMukdad S, Ayoub H, et al. Covid-19 Vaccine Protection among Children and Adolescents in Qatar. N Engl J Med. 2022 Nov 17;387(20):1865-1876. doi: 10.1056/NEJMoa2210058. Epub 2022 Nov 2.
8.	Cinicola et al, 2022	Cinicola BL, Mortari, EP, Zicari AM, et al. The BNT162b2 vaccine induces humoral and cellular immune memory to SARS-CoV-2 Wuhan strain and the Omicron variant in children 5 to 11 years of age. Frontiers in Immunology. 2022; 13. doi:10.3389/fimmu.2022.1094727
9.	Cocchio et al, 2022	Cocchio S, Zabeo F, Tremolada G, et al. COVID-19 Vaccine Effectiveness against Omicron Variant among Underage Subjects: The Veneto Region's Experience. *Vaccines*. 2022; 10(8):1362. doi: 10.3390/vaccines10081362
10.	Cohen-Stavi et al, 2022	Cohen-Stavi CJ, Magen O, Barda N, et al. BNT162b2 vaccine effectiveness against Omicron in children 5 to 11 years of age. New England Journal of Medicine. 2022, 387(3), 227-236. doi: 10.1056/NEJMoa2205011
11.	Creech et al, 2022: Phase 2-3 study	Creech CB, Anderson E, Berthaud V, et al. Evaluation of mRNA-1273 Covid-19 Vaccine in Children 6 to 11 Years of Age. N Engl J Med. 2022;386(21):2011-23. doi:10.1056/NEJMoa2203315. European Medicines Agency. Assessment report on extension of marketing authorisation. Procedure No EMEA/H/C/005791/II/00412022. Available from: https://www.ema.europa.eu/en/documents/variation-report/spikevax-previously-covid-19-vaccine-moderna-h-c-5791-ii-41-epar-assessment-report-variation_en.pdf. ModernaTX Inc. A Study to Evaluate Safety and Effectiveness of mRNA-1273 COVID-19 Vaccine in Healthy Children Between 6 Months of Age and Less Than 12 Years of Age. Available from: https://clinicaltrials.gov/ct2/show/NCT04796896.
12.	Creech et al, 2022: Phase 1 study	
13.	Dorabawila et al, 2022	Dorabawila V, Hoefer D, Bauer UE, Bassett MT, Lutterloh E, Rosenberg ES. Effectiveness of the BNT162b2 vaccine among children 5-11 and 12-17 years in New York after the Emergence of the Omicron Variant. medRxiv. 2022. doi:10.1101/2022.02.25.22271454.
14.	Doucette et al, 2022	Doucette EJ, Gray J, Fonseca K, et al. A Longitudinal Seroepidemiology Study to Evaluate Antibody Response to SARS-CoV-2 Virus and Vaccination in Children in Calgary, Canada from July 2020 to April 2022. medRxiv. 2022; 11. doi: 10.1101/2022.11.02.22281665
15.	Elias et al, 2023	Elias MD, Truong DT, Oster ME, et al. Examination of Adverse Reactions After COVID-19 Vaccination Among Patients With a History of Multisystem Inflammatory Syndrome in Children. JAMA Network Open. 2023;6(1):e2248987-e2248987. doi: 10.1001/jamanetworkopen.2022.48987
16.	Fleming-Dutra et al, 2022	Fleming-Dutra KE, Britton A, Shang N, et al. Association of Prior BNT162b2 COVID-19 Vaccination With Symptomatic SARS-CoV-2 Infection in Children and Adolescents During Omicron Predominance. JAMA. 2022;327(22):2210-9. doi:10.1001/jama.2022.7493.

17.	Fowlkes et al, 2022	Fowlkes AL, Yoon SK, Lutrick K, et al. Effectiveness of 2-Dose BNT162b2 (Pfizer BioNTech) mRNA Vaccine in Preventing SARS-CoV-2 Infection Among Children Aged 5-11 Years and Adolescents Aged 12-15 Years - PROTECT Cohort, July 2021-February 2022. MMWR Morb Mortal Wkly Rep. 2022;71(11):422-8. doi:10.15585/mmwr.mm7111e1.
18.	Girard et al, 2022	Girard B, Tomassini JE, Deng W, et al. mRNA-1273 Vaccine-elicited Neutralization of SARS-CoV-2 Omicron in Adolescents and Children. medRxiv. 2022. doi:10.1101/2022.01.24.22269666. Note: Subgroup analysis from Creech et al.
19.	Hartono et al, 2022	Hartono SP, Sharma HP, Bundy V, Thompkins JD, Kochis SR, Brooks JP. Safety outcomes of SARS-CoV-2 vaccination in pediatric patients with a first dose reaction history or allergy to polyethylene glycol or polysorbate. *The Journal of Allergy and Clinical Immunology: In Practice*, *10*(8), 2172-2175. 2022. doi: 10.1016/j.jaip.2022.05.035
20.	Hause et al, 2022 A	Hause AM, Shay DK, Klein NP, et al. Safety of COVID-19 Vaccination in US Children Ages 5-11 Years. Pediatrics. 2022. doi:10.1542/peds.2022-057313. Previous publications: 1) Hause AM, Baggs J, Marquez P, et al. COVID-19 Vaccine Safety in Children Aged 5-11 Years - United States, November 3-December 19, 2021. MMWR Morb Mortal Wkly Rep. 2021;70(5152):1755-60. doi:10.15585/mmwr.mm705152a1. 2) Su JR. Adverse events among children ages 5–11 years after COVID-19 vaccination: updates from v-safe and the Vaccine Adverse Event Reporting System (VAERS). ACIP meeting COVID-19 Vaccines. 2021. URL: https://stacks.cdc.gov/view/cdc/112668 3) Su JR. COVID-19 vaccine safety updates: Primary series in children and adolescents ages 5–11 and 12–15 years, and booster doses in adolescents ages 16–24 years. ACIP meeting COVID-19 Vaccines. 2022. URL: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-01-05/02-covid-su-508.pdf
21.	Hause et al, 2022 B	Hause AM, Baggs J, Marquez P, et al. Safety Monitoring of Pfizer-BioNTech COVID-19 Vaccine Booster Doses Among Children Aged 5–11 Years — United States, May 17–July 31, 2022. MMWR Morb Mortal Wkly Rep 2022;71:1047–1051. doi: 10.15585/mmwr.mm7133a3
22.	Hause et al, 2023 C	Hause AM, Marquez P, Zhang B, et al. Safety Monitoring of Bivalent COVID-19 mRNA Vaccine Booster Doses Among Children Aged 5–11 Years — United States, October 12–January 1, 2023. MMWR Morb Mortal Wkly Rep 2023;72:39–43. doi: 10.15585/mmwr.mm7202a5
23.	Hu et al, 2022	Hu M, Wong HL, Feng Y, et al. Results of safety monitoring of BNT162b2 (Pfizer-BioNTech) COVID-19 vaccine in US children aged 5-17 years. medRxiv. 2022-10. doi: 10.1101/2022.10.28.22281532
24.	Jang et al, 2023	Jang EJ, Choe YJ, Kim RK, Park YJ. BNT162b2 Vaccine Effectiveness Against the SARS-CoV-2 Omicron Variant in Children Aged 5 to 11 Years. JAMA pediatrics. 2023. doi:10.1001/jamapediatrics.2022.5221
25.	Joseph et al, 2022	Joseph G, Klein E, Lustig Y, et al. Real-World Immunogenicity and Reactogenicity of Two Doses of Pfizer-BioNTech COVID-19 Vaccination in Children Aged 5-11 Years. Vaccines (Basel). 2022 Nov 18;10(11):1954. doi: 10.3390/vaccines10111954.
26.	Kastl et al, 2022	Kastl AJ, Weaver KN, Zhang X, et al. Humoral Immune Response and Safety of SARS-CoV-2 Vaccination in Pediatric Inflammatory Bowel Disease. Am J Gastroenterol. 2023 Jan 1;118(1):129-137. doi: 10.14309/ajg.0000000000002016
27.	Khan et al, 2022	Khan FL, Nguyen JL, Singh TG, et al. Estimated BNT162b2 Vaccine Effectiveness Against Infection With Delta and Omicron Variants Among US Children 5 to 11 Years of Age. JAMA Netw Open. 2022;5(12):e2246915. doi:10.1001/jamanetworkopen.2022.46915
28.	Kim et al, 2022	Kim S, Heo Y, Seo SY, Lim DS, Cho E, Lee YK. Adverse events of the Pfizer-BioNTech COVID-19 vaccine in Korean children and adolescents aged 5 to 17 years. Osong Public Health Res Perspect. 2022 Oct;13(5):382-390. doi: 10.24171/j.phrp.2022.0233.
29.	Klein et al, 2022	Klein NP, Stockwell MS, Demarco M, et al. Effectiveness of COVID-19 Pfizer-BioNTech BNT162b2 mRNA Vaccination in Preventing COVID-19-Associated Emergency Department and Urgent Care Encounters and Hospitalizations Among Nonimmunocompromised Children and Adolescents Aged 5-17 Years - VISION Network, 10 States, April 2021-January 2022. MMWR Morb Mortal Wkly Rep. 2022;71(9):352-8. doi:10.15585/mmwr.mm7109e3.
30.	Leung et al, 2022 A	Leung D, Chan EYH, Mu X, et al. Humoral and Cellular Immunogenicity and Safety of 3 Doses of CoronaVac and BNT162b2 in Young Children and Adolescents with Kidney Diseases. medRxiv. 2022-09. doi: 10.1101/2022.09.14.22279916
31.	Leung et al, 2023 B	Leung D, Rosa Duque JS, Yip KM, So HK, Wong W, Lau YL. Effectiveness of BNT162b2 and CoronaVac in children and adolescents against SARS-CoV-2 infection during Omicron BA. 2 wave in Hong Kong. Commun Med 3, 3 (2023). https://doi.org/10.1038/s43856-022-00233-1

32.	Malden et al 2022	Malden DE, Gee J, Glenn S, et al. Reactions following Pfizer-BioNTech COVID-19 mRNA vaccination and related healthcare encounters among 7,077 children aged 5-11 years within an integrated healthcare system. Vaccine. 2023 Jan 9;41(2):315-322. doi: 10.1016/j.vaccine.2022.10.079.
33.	Mattiuzzi et al, 2022	Mattiuzzi C, Lippi G. Real-world effectiveness of COVID-19 vaccination among children in Italy. Int J Infect Dis. 2022;122:70-1. doi:10.1016/j.ijid.2022.05.045.
34.	Nygaard et al, 2022	Nygaard U, Holm M, Dungu KHS, et al. Risk of Myopericarditis After COVID-19 Vaccination in Danish Children Aged 5-11 Years. Pediatrics. 2022. doi:10.1542/peds.2022-057508.
35.	Piché-Renaud et al, 2022	Piché-Renaud PP, Swayze S, Buchan S, et al. Vaccine Effectiveness of BNT162b2 Against Omicron in Children Aged 5-11 Years: A Test-Negative Design. 2022. Available from: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4176388.
36.	Price et al, 2022	Price AM, Olson SM, Newhams MM, et al. BNT162b2 Protection against the Omicron Variant in Children and Adolescents. N Engl J Med. 2022;386(20):1899-909. doi:10.1056/NEJMoa2202826.
37.	Ripabelli et al, 2022	Ripabelli G, Sammarco ML, D'Amico A, et al. Safety of mRNA BNT162b2 COVID-19 (Pfizer-BioNTech) vaccine in children aged 5-11 years: Results from an active pharmacovigilance study in central Italy. Hum Vaccin Immunother. 2022 Nov 30;18(6):2126668. doi: 10.1080/21645515.2022.2126668.
38.	Rosa Duque et al, 2022	Rosa Duque JS, Leung D, Yip KM, et al. Effectiveness of BNT162b2 and CoronaVac against paediatric COVID-19-associated hospitalization and moderate-to-severe disease. medRxiv. 2022. doi: 10.1101/2022.09.09.22279426v1
39.	Sacco et al, 2022	Sacco C, Del Manso M, Mateo-Urdiales A, et al. Effectiveness of BNT162b2 vaccine against SARS-CoV-2 infection and severe COVID-19 in children aged 5–11 years in Italy: a retrospective analysis of January–April, 2022. *The Lancet*. 2022; *400*(10346), 97-103. doi: 10.1016/S0140-6736(22)01185-0
40.	Shi et al, 2022	Shi DS, Whitaker M, Marks KJ, et al. Hospitalizations of Children Aged 5-11 Years with Laboratory-Confirmed COVID-19 - COVID-NET, 14 States, March 2020-February 2022. MMWR Morb Mortal Wkly Rep. 2022;71(16):574-81. doi:10.15585/mmwr.mm7116e1.
41.	Simmons et al, 2022	Simmons AE, Amoako A, Grima A, Murison K, Tuite A, Fisman D. Vaccine Effectiveness Against Hospitalization Among Adolescent and Pediatric SARS-CoV-2 Cases in Ontario, Canada. medRxiv. 2022. doi:10.1101/2022.03.24.22272919.
42.	Stich et al, 2022	Stich M, Di Cristanziano V, Tönshoff B, et al. Humoral immune response and live-virus neutralization of the SARS-CoV-2 omicron (BA.1) variant after COVID-19 mRNA vaccination in children and young adults with chronic kidney disease. Pediatr Nephrol. 2022 Nov 21:1–14. doi: 10.1007/s00467-022-05806-9.
43.	Straus et al, 2022	Straus W, Urdaneta V, Esposito DB, et al. Analysis of Myocarditis Among 252 Million mRNA-1273 Recipients Worldwide. Clin Infect Dis. 2022 Jun 6:ciac446. doi: 10.1093/cid/ciac446.
44.	Suntronwong et al 2022	Suntronwong N, Vichaiwattana P, Klinfueng S, et al. SARS-CoV-2 infection-induced seroprevalence among children and associated risk factors during pre-and omicron-dominant wave, from January 2021 through November 2022, Thailand: Longitudinal study. medRxiv, 2022-12. doi: 10.1101/2022.12.01.22283006
45.	Tan et al, 2022	Tan S, Cook AR, Heng D, Ong B, Lye DC, Tan KB. Effectiveness of BNT162b2 Vaccine against Omicron in Children 5 to 11 Years. SSRN. 2022. doi:10.2139/ssrn.4052133.
46.	Walter et al, 2022: Phase 2-3 study	Walter EB, Talaat KR, Sabharwal C, et al. Evaluation of the BNT162b2 Covid-19 Vaccine in Children 5 to 11 Years of Age. N Engl J Med. 2022;386(1):35-46. doi:10.1056/NEJMoa2116298. U.S. Food and Drug Administration. Vaccines and Related Biological Products Advisory Committee Meeting. FDA Briefing Document. EUA amendment request for Pfizer-BioNTech COVID-19 Vaccine for use in children 5 through 11 years of age. 2021. Available from: https://www.fda.gov/media/153447/download. BioNTech SE. A Phase 1/2/3 Study to Evaluate the Safety, Tolerability, and Immunogenicity of an RNA Vaccine Candidate Against COVID-19 in Healthy Children and Young Adults. 2021. Available from: https://clinicaltrials.gov/ct2/show/NCT04816643.
47.	Walter et al, 2022: Phase 1 study	
48.	Wanlapakorn et al, 2022	Wanlapakorn N, Kanokudom S, Phowatthanasathian H, et al. Comparison of the reactogenicity and immunogenicity between two-dose mRNA COVID-19 vaccine and inactivated followed by an mRNA vaccine in children aged 5-11 years. medRxiv, 2022-11. doi: 10.1101/2022.11.07.22282028
49.	Wood et al, 2022	Wood N, Lopez LK, Glover C, et al. Active safety surveillance of COVID-19 mRNA vaccines in children aged 5-15 years in Australia. medRxiv. 2022. doi: 10.1101/2022.07.19.22277827

50.	Yoshida et al 2022	Yoshida M, Kobashi Y, Shimazu Y, et al. Time course of adverse reactions following BNT162b2 vaccination in healthy and allergic disease individuals aged 5–11 years and comparison with individuals aged 12–15 years: an observational and historical cohort study. Eur J Pediatr. 2023; 182:123–133. doi: 10.1007/s00431-022-04643-0
51.	Zambrano et al, 2022	Zambrano LD, Newhams MM, Olson SM, et al. BNT162b2 mRNA Vaccination Against COVID-19 is Associated with Decreased Likelihood of Multisystem Inflammatory Syndrome in U.S. Children Ages 5-18 Years. Clin Infect Dis. 2022 Aug 4:ciac637. doi: 10.1093/cid/ciac637. Epub ahead of print.

List of ongoing studies

Nr.	Author of main publication	Reference(s)
1.	Adeloye et al, 2021	Adeloye D, Katikireddi SV, Woolford L, et al Uptake, effectiveness and safety of COVID-19 vaccines in children and young people in Scotland: Protocol for early pandemic evaluation and enhanced surveillance of COVID-19 (EAVE II). J Glob Health. 2021;11:05026. Available from: https://www.ncbi.nlm.nih.gov/pubmed/35003715.
2.	Assistance Publique - Hôpitaux de Paris	Assistance Publique - Hôpitaux de Paris. Anti-Covid-19 Vaccine in Children With Acute Leukemia and Their Siblings. clinicaltrialsgov. 2021. Available from: https://clinicaltrials.gov/ct2/show/NCT04969601. Assistance Publique – Hôpitaux de Paris / DRCI Anti-Covid-19 vaccine protection in immunocompromised children (1-15 years) with acute leukemia and their siblings (= 12 years). Phase I-II trial evaluating safety and post-vaccination humoral and cellular immunogenicity / PACIFIC STUDY. clinicaltrialsregistereu. 2021. Available from: https://www.clinicaltrialsregister.eu/ctr-search/search?query=eudract_number:2021-002966-41.
3.	Babu et al, 2022	Babu, TM, Feldstein LR, Saydah S, et al CASCADIA: A prospective community-based study protocol for assessing SARS-CoV-2 vaccine effectiveness in children and adults utilizing a remote nasal swab collection and web-based survey design. MedRxiv. 2023. 10.1101/2023.01.05.22283913
4.	BioNTech SE, 2021	BioNTech SE. Study to Evaluate Safety, Tolerability & Immunogenicity of BNT162b2 in Immunocompromised Participants ≥2 Years. clinicaltrialsgov. 2021. Available from: https://clinicaltrials.gov/ct2/show/NCT04895982
5.	BioNTech SE, 2021	BioNTech SE. Study to Evaluate the Safety, Tolerability, and Immunogenicity of an RNA Vaccine Candidate Against COVID-19 in Healthy Children <12 Years of Age. clinicaltrialsgov. 2021. Available from: https://clinicaltrials.gov/ct2/show/NCT04816643. BioNTech SE A phase 1, open-label dose-findings study to evaluate safety, tolerability, and immunogenicity, and phase 2/3 placebo-controlled, observer-blinded, safety, tolerability, and immunogenicity study of a SARS-COV-2 RNA vaccine candidate against COVID-19 in health. EU Clinical Trials Register. 2021. Available from: https://www.clinicaltrialsregister.eu/ctr-search/trial/2020-005442-42/PL. BioNTech SE. A Phase 1/2/3 Study to Evaluate the Safety, Tolerability, and Immunogenicity of an RNA Vaccine Candidate Against COVID-19 in Healthy Children and Young Adults. clinicaltrialsgov. 2021. Available from: https://clinicaltrials.gov/show/NCT04816643.
6.	BioNTech SE, 2022	BioNTech SE. A Study to Learn About Bivalent COVID-19 RNA Vaccine Candidate(s) in Healthy Infants and Children. 2022. Available from: https://clinicaltrials.gov/ct2/show/NCT05630352
7.	Burns et al, 2021	Burns J, Rivers P, LeClair LB, et al Pediatric Research Observing Trends and Exposures in COVID-19 Timelines (PROTECT): Protocol for a Multisite Longitudinal Cohort Study. JMIR Res Protoc. 2022. Available from: https://www.ncbi.nlm.nih.gov/pubmed/35635842.
8.	Chulalongkorn University, 2022	Chulalongkorn University. Comparison of the safety and immunogenicity of two-dose mRNA COVID-19 vaccine and inactivated followed by an mRNA vaccine in children aged 5 - 11 years. thaiclinicaltrialsorg. 2022. Available from: www.thaiclinicaltrials.org/show/TCTR20220212001.
9.	Duke University, 2022	Duke University. Safety of Pediatric COVID-19 Vaccination. clinicaltrialsgov. 2022. Available from: https://clinicaltrials.gov/ct2/show/NCT05157191.
10.	Ferrari et al, 2021	Ferrari L, Caldara F, Teti E, et al Systematic evaluation of the tolerability of two doses of the Pfizer-BioNTech COVID-19 vaccine (BNT162b2) in a diverse cohort of people with HIV (PWH). Hiv Medicine. 2021;22:221-2. Available from: https://pesquisa.bvsalud.org/global-literature-on-novel-coronavirus-2019-ncov/resource/pt/covidwho-1519184.
11.	Hospital Moinhos de Vento, 2022	Hospital Moinhos de Vento. A Real-world Evidence Study of BNT162b2 mRNA Covid-19 Vaccine Among Children in Brazil. 2022. Available from: https://clinicaltrials.gov/ct2/show/NCT05403307
12.	KK Women's and Children's Hospital, 2022	KK Women's and Children's Hospital Determining Reactogenicity and Immunogenicity of Delayed COVID-19 Vaccine Schedule in Children. clinicaltrialsgov. 2022. Available from: https://clinicaltrials.gov/show/NCT05329064. KK Women's and Children's Hospital A Single Arm Phase-IV Study to Determine Reactogenicity and Immunogenicity of Delayed COVID-19 Vaccine Schedule in Children. clinicaltrialsgov. 2022. Available from: https://clinicaltrials.gov/show/NCT05329064.
13.	Merck Sharp & Dohme Corp, 2021	Merck Sharp & Dohme Corp. Safety and Immunogenicity of 9-valent Human Papillomavirus (9vHPV) Vaccine Coadministered With Messenger Ribonucleic Acid (mRNA)-1273 Severe Acute Respiratory

		Syndrome Coronavirus 2 (SARS-CoV-2) Vaccine (V503-076). clinicaltrialsgov. 2021. Available from: https://clinicaltrials.gov/ct2/show/NCT05119855.
14.	ModernaTx Inc, 2021	ModernaTx Inc. A Study to Evaluate Safety and Effectiveness of mRNA-1273 COVID-19 Vaccine in Healthy Children Between 6 Months of Age and Less Than 12 Years of Age. clinicaltrialsgov. 2021. Available from: https://clinicaltrials.gov/show/NCT04796896.
15.	ModernaTx, Inc., 2022	ModernaTx, Inc. A Study to Evaluate Safety and Effectiveness of mRNA-1273 COVID-19 Vaccine in Healthy Children Between 6 Months of Age and Less Than 12 Years of Age. 2022. Available from: https://clinicaltrials.gov/ct2/show/NCT04796896
16.	Murdoch Childrens Research Institute, 2021	Murdoch Childrens Research Institute. Investigating COVID-19 Vaccine Immunity in Children in the Melbourne Infant Study of BCG for Allergy and Infection Reduction. clinicaltrialsgov. 2021. Available from: https://clinicaltrials.gov/show/NCT05168709.
17.	National Vaccine Institute, 2022	National Vaccine Institute. Safety and Immunogenicity of SARS-CoV-2 mRNA vaccine platform in Thai children aged 5-11 years. thaiclinicaltrialsorg. 2022. Available from: www.thaiclinicaltrials.org/show/TCTR20220125002.
18.	National Vaccine Institute, 2022	National Vaccine Institute. Immunogenicity and safety of the booster dose with SARS-CoV-2 mRNA vaccine following fully immunized with inactivated vaccine in Thai children aged 5-11 years for COVID-19 prevention. thaiclinicaltrialsorg. 2022. Available from: www.thaiclinicaltrials.org/show/TCTR20220330001.
19.	Pfizer, 2022	Pfizer. Study of Myo/Pericarditis Associated With COMIRNATY (Vaccine to Prevent COVID-19) in Persons <21 Years of Age. clinicaltrialsgov. 2022. Available from: https://clinicaltrials.gov/show/NCT05295290.
20.	Princess Máxima Center for Pediatric Oncology, 2021	Princess Máxima Center for Pediatric Oncology. Monitoring response on COVID-19 vaccination in children with cancer. clinicaltrialsregistereu. 2021. Available from: https://pesquisa.bvsalud.org/global-literature-on-novel-coronavirus-2019-ncov/resource/en/ictrp-EUCTR2021-003388-90-NL.
21.	Rabin Medical Center, 2021	Rabin Medical Center. SARS-CoV-2 Antibody Response in Children Aged 5-11 Years Following Vaccination. clinicaltrialsgov. 2021. Available from: https://clinicaltrials.gov/ct2/show/NCT05175989.
22.	Program Management Unit for Competitiveness, 2022	Program Management Unit for Competitiveness. Phase 1/2 double-blinded study to Evaluate Adverse Events and Antibody level, Cell-Mediated Immune Response and Immune Response Against SAR-CoV-2 Variants after COVID-19 Vaccination in Thai Children and Adolescents. thaiclinicaltrialsorg. 2022. Available from: www.thaiclinicaltrials.org/show/TCTR20220406002.
23.	Rigshospitalet Denmark, 2022	Rigshospitalet Denmark. Myopericarditis After mRNA COVID-19 Vaccination in Children 5-11 Years Old. clinicaltrialsgov. 2022. Available from: https://clinicaltrials.gov/show/NCT05186571.
24.	The University of Hong Kong, 2022	The University of Hong Kong. Covid-19 Vaccination in Adolescents and Children. clinicaltrialsgov. 2021. Available from: https://clinicaltrials.gov/show/NCT04800133.
25.	University Medical Center Utrecht, 2021	University Medical Center Utrecht. Effectivity of COVID-19 vaccination in people with Down syndrome. clinicaltrialsregistereu. 2021. Available from: https://www.clinicaltrialsregister.eu/ctr-search/trial/2021-002613-34/NL.
26.	University of Bologna, 2021	University of Bologna. Monitoring COVID-19 Vaccination Response in Fragile Populations. clinicaltrialsgov. 2021. Available from: https://clinicaltrials.gov/ct2/show/NCT05222139.

List of studies awaiting classification

Studies awaiting classification were those that nearly met inclusion criteria, but relevant information was missing to fully determine eligibility (e.g. with missing subgroup data for our age-group of interest), or those that may become eligible for future versions of this review (e.g. studies using COVID-19 vaccines in the relevant age-group, however without approval in the EU).

Nr.	Author of main publication	Reference(s)	Reason
1.	Bharat Biotech International L, 2021	Bharat Biotech International L. COVAXIN in a Pediatric Cohort. clinicaltrialsgov. 2021. Available from: https://www.clinicaltrials.gov/ct2/show/NCT04918797.	Vaccine not approved in EU
2.	Biological E Limited, 2021	Biological E Limited. Biological E´s CORBEVAX vaccine clinical study for protection against Covid-19 disease in children. Clinical Trials Registry - India. 2021. Available from: http://www.ctri.nic.in/Clinicaltrials/pmaindet2.php?trialid=60393.	Vaccine not approved in EU
3.	Brumels K, 2022	Brumels K, Jensen-Bender W. Pharmacology Focus: Pfizer-BioNTech's COVID-19 Vaccine for Children 5 to 11 Years of Age. S D Med. 2022;75(1):36-7. Available from: https://www.ncbi.nlm.nih.gov/pubmed/35015942.	No full text available
4.	CanSino Biologics I, Ab, 2021	CanSino Biologics I, Ab - This is an international multicenter s-a, open-label study to evaluate the i, responses, safety profiles of children aged y, adolescents aged y, et al A Study to Evaluate the Safety and Immunogenicity of a 2-dose Regimen With Ad5-nCoV and Ad5-nCoV-IH in Children and Adolescents Aged 6-17 Years. clinicaltrialsgov. 2021. Available from: https://clinicaltrials.gov/ct2/show/NCT05169008.	Vaccine not approved in EU
5.	Center for Genetic E, Biotechnology, 2021	Center for Genetic E, Biotechnology. Evaluation of the safety and immunogenicity of the vaccine candidate "ABDALA" in children and adolescents. RPCEC. 2021. Available from: https://rpcec.sld.cu/en/trials/RPCEC00000381-En.	Vaccine not approved in EU
6.	Chantasrisawad et al, 2022	Chantasrisawad N, Puthanakit T, Kornsitthikul K, et al Immunogenicity to SARS-CoV-2 Omicron variant among school-aged children with 2-dose of inactivated SARS-CoV-2 vaccines followed by BNT162b2 booster. Vaccine: X. 2022. 12, 100221. Available from: https://www.sciencedirect.com/science/article/pii/S259013622200081X	Vaccine not approved in EU
7.	Children's Oncology Group, 2022	Children's Oncology Group. Evaluation of Immunologic Response Following COVID-19 Vaccination in Children, Adolescents and Young Adults With Cancer. clinicaltrialsgov. 2022. Available from: https://clinicaltrials.gov/ct2/show/NCT05228275.	Type of assessed vaccine(s) unclear
8.	Cinnagen, 2022	Cinnagen. Immunogenicity and Safety of the SpikoGen COVID-19 Vaccine in Children Aged 5 to <12 Years and 12 to <18 Years Compared With Adults Aged 18 to 40 Years. clinicaltrialsgov. 2022. Available from: https://clinicaltrials.gov/ct2/show/NCT05231590. CinnaGen Company. Comparison of immunogenicity and safety of SpikoGen vaccine in children aged 5 to 12 years, adolescents aged 12 to 18 years and adults aged 18 to 40 years. Iranian Registry of Clinical Trials. 2021. Available from: http://en.irct.ir/trial/60331.	Vaccine not approved in EU
9.	Cinza-Estévez et al, 2022	Cinza-Estévez Z, Resik-Aguirre S, Figueroa-Baile NL, et al Immunogenicity and Safety Assessment of a SARS-CoV-2 Recombinant Spike RBD Protein Vaccine (Abdala) in Paediatric Ages 3 to 18 Years Old: A Double-Blinded, Multicentre, Randomised, Phase 1/2 Clinical Trial (ISMAELILLO Study). 2022. Available from: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4304730	Vaccine not approved in EU
10.		Clover Biopharmaceuticals AUSPL. Safety and Immunogenicity of SCB-2019 in Children <18 Years of Age. clinicaltrialsgov. 2022. Available from: https://www.clinicaltrials.gov/ct2/show/NCT05193279.	Vaccine not approved in EU

11.	Dailey et al, 2022	Dailey J, Kozhaya L, Dogan M, et al Antibody Responses to SARS-CoV-2 After Infection or Vaccination in Children and Young Adults With Inflammatory Bowel Disease. Inflamm Bowel Dis. 2022;28(7):1019-26. Available from: https://www.medrxiv.org/content/10.1101/2021.06.12.21258810v1.	Results of age groups mixed in preprint
12.	Erasmus Medical Center, 2021	Erasmus Medical Center. COVID-19 Antibody Responses In Cystic Fibrosis. clinicaltrialsgov. 2021. Available from: https://clinicaltrials.gov/ct2/show/NCT05217784. Rabin Medical Center. COVID-19 Antibody Responses in Cystic Fibrosis (CAR-CF). clinicaltrialsgov. 2022. Available from: https://clinicaltrials.gov/ct2/show/NCT04992234. Universitätsklinikum Köln. Covid-19 Antibody Responses in Cystic Fibrosis. clinicaltrialsgov. 2021. Available from: https://clinicaltrials.gov/ct2/show/NCT05012306. University Hospital Motol. COVID-19 Antibody Responses in Cystic Fibrosis. clinicaltrialsgov. 2021. Available from: https://clinicaltrials.gov/ct2/show/NCT05052294. Vastra Gotaland Region. COVID-19 Antibody Responses in Cystic Fibrosis. clinicaltrialsgov. 2021. Available from: https://clinicaltrials.gov/ct2/show/NCT04992234.	Type of assessed vaccine(s) unclear
13.	Federal University of Espirito Santo, 2022	Federal University of Espirito Santo. Efficacy, Immunogenicity and Safety of Inactivated Vaccine (Coronavac) Against SARS-COV2 in Children and Adolescents. clinicaltrialsgov. 2022. Available from: https://clinicaltrials.gov/ct2/show/NCT04992260.	Vaccine not approved in EU
14.	Fernandes et al, 2022	Fernandes EG, Lopez-Lopes GIS, Silva VO, et al Safety and immunogenicity of an inactivated SARS-CoV-2 vaccine (CoronaVac) in inadvertently vaccinated healthy children. Rev Inst Med Trop Sao Paulo. 2021;63:e83. Available from: https://www.scielo.br/j/rimtsp/a/m8pRZSBYWvLzz9LpWn7wmDR/?lang=en.	Vaccine not approved in EU
15.	Finlay Vaccine I, 2021	Finlay Vaccine I. SOBERANA PLUS PEDIATRIA. Cuban Registry of Clinical Trials. 2021. Available from: https://rpcec.sld.cu/en/trials/RPCEC00000391-En.	Vaccine not approved in EU
16.	Finlay Vaccine I, 2021	Finlay Vaccine I. SOBERANA PEDIATRIA. Cuban Registry of Clinical Trials. 2021. Available from: https://rpcec.sld.cu/en/trials/RPCEC00000374-En.	Vaccine not approved in EU
17.	Florentino et al, 2022	Florentino PTV, Alves FJO, Cerqueira-Silva T, et al Vaccine effectiveness of CoronaVac against COVID-19 among children in Brazil during the Omicron period. Nat Commun 13, 4756 (2022). https://doi.org/10.1038/s41467-022-32524-5. Florentino PTV, Alves FJO, Cerqueira-Silva T, et al Vaccine effectiveness of CoronaVac against symptomatic and severe COVID-19 among children in Brazil during the Omicron period (preprint). Research Square. 2022. Available from: https://www.researchsquare.com/article/rs-1604882/v1.	Vaccine not approved in EU
18.	Gomez et al, 2022	Gomez RP, Delgado YR, Iriarte CR, et al Open label phase I/II clinical trial and predicted efficacy of SARS-CoV-2 RBD protein vaccines SOBERANA 02 and SOBERANA Plus in children. medRxiv. 2022. Available from: https://medrxiv.org/cgi/content/short/2022.03.03.22271313.	Vaccine not approved in EU
19.	Gonzalez et al, 2022	González S, Olszevicki S, Gaiano A, et al Effectiveness of BBIBP-CorV, BNT162b2 and mRNA-1273 vaccines against hospitalisations among children and adolescents during the Omicron outbreak in Argentina: A retrospective cohort study. Lancet Reg Health Am. 2022 Sep;13:100316. doi: 10.1016/j.lana.2022.100316. Epub 2022 Jul 16. Gonzalez S, Olszevicki S, Gaiano A, et al Effectiveness of BBIBP-CorV, BNT162b2 and mRNA-1273 Vaccines Against Hospitalisations Among Children and Adolescents During the Omicron Outbreak in Argentina. SSRN. 2022. Available from: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4087375.	Vaccine not approved in EU
20.	Greish et al, 2022	Greish K, Alawadhi A, Jaradat A, et al Safety and Immunogenicity of COVID-19 BBIBP-CorV Vaccine in Children 3-12 Years Old. Vaccines (Basel). 2022;10(4). Available from: https://www.mdpi.com/2076-393X/10/4/586/htm.	Vaccine not approved in EU

21.	Gunale et al 2023	Gunale B, Kapse D, Kar S, et al A Phase 2/3 observer-blind, randomized, controlled study to determine the safety and immunogenicity of SARS-CoV-2 recombinant spike protein vaccine in Indian children and adolescents aged 2 to 17 years. *medRxiv*, 2023-01. Available from: https://www.medrxiv.org/content/10.1101/2023.01.03.23284130v2	Vaccine not approved in EU
22.	Han et al, 2021	Han B, Song Y, Li C, et al Safety, tolerability, and immunogenicity of an inactivated SARS-CoV-2 vaccine (CoronaVac) in healthy children and adolescents: a double-blind, randomised, controlled, phase 1/2 clinical trial Lancet Infect Dis. 2021;21(12):1645-53. Available from: https://www.ncbi.nlm.nih.gov/pubmed/34197764. Han B, Song Y, Li C, et al Safety, Tolerability and Immunogenicity of an Inactivated SARS-CoV-2 Vaccine (CoronaVac) in Healthy Children and Adolescents: A Randomised, Double-Blind, and Placebo-Controlled, Phase 1/2 Clinical Trial SSRN Electronic Journal 2021. Available from: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3820545.	Vaccine not approved in EU
23.	Hause et al, 2022	Hause AM, Baggs J, Marquez P, et al Safety Monitoring of Pfizer-BioNTech COVID-19 Vaccine Booster Doses Among Children Aged 5–11 Years — United States, May 17–July 31, 2022. MMWR Morb Mortal Wkly Rep 2022;71:1047–1051. doiI: http://dx.doi.org/10.15585/mmwr.mm7133a3.	Vaccine not approved in EU
24.	Instituto Finlay de Vacunas, 2021	Instituto Finlay de Vacunas. SOBERANA PEDIATRIA CLINICA 1. Cuban Registry of Clinical Trials. 2021. Available from: https://rpcec.sld.cu/en/trials/RPCEC00000384-En.	Vaccine not approved in EU
25.	Janssen Vaccines Prevention B. V., 2021	Janssen Vaccines Prevention B. V. A Randomized, Double-blind, Placebo-controlled, Phase 2/3 Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of Different Dose Levels of Ad26.COV2.S Administered as a Two-dose Regimen Followed by a Booster in Healthy Children From Birth to 1. EU Clinical Trials Register. 2021. Available from: https://www.clinicaltrialsregister.eu/ctr-search/trial/2020-005720-11/3rd.	Vaccine not approved in EU
26.	Jara et al, 2022	Jara A, Undurraga EA, Flores JC, et al Effectiveness of an Inactivated SARS-CoV-2 Vaccine in Children and Adolescents: A Large-Scale Observational Study. SSRN. 2022. Available from: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4035405.	Vaccine not approved in EU
27.	Jara et al, 2022	Jara A, Undurraga EA, Zubizarreta JR, et al Effectiveness of CoronaVac in children 3-5 years of age during the SARS-CoV-2 Omicron outbreak in Chile. Nat Med. 2022. Available from: https://www.nature.com/articles/s41591-022-01874-4.	Vaccine not approved in EU
28.	Li et al, 2022a	Li M, Liu Q, Wu D, et al Association of COVID-19 Vaccination and Clinical Severity of Patients Infected with Delta or Omicron Variants - China, May 21, 2021-February 28, 2022. China CDC Wkly. 2022;4(14):293-7. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9008265/.	Vaccine not approved in EU
29.	Li et al, 2022b	Li G, Cappuccini F, Marchevsky NG, et al Safety and immunogenicity of the ChAdOx1 nCoV-19 (AZD1222) vaccine in children aged 6-17 years: a preliminary report of COV006, a phase 2 single-blind, randomised, controlled trial Lancet. 2022 Jun 11;399(10342):2212-2225. doi: 10.1016/S0140-6736(22)00770-X. Erratum in: Lancet.	Vaccine not approved in EU
30.	Li et al, 2022c	Li M, Weng S, Wang Q, et al Reduced binding activity of vaccine serum to omicron receptor-binding domain. Front Immunol. 2022 Jul 28;13:960195. doi: 10.3389/fimmu.2022.960195.	Vaccine not approved in EU
31.	Lu et al, 2022	Lu Q, Wang YY, Wang QH, et al Safety of inactivated COVID-19 vaccine in tuberous sclerosis complex patients with epilepsy treated with rapamycin. Seizure. 2022;99:71-4. Available from: https://www.seizure-journalcom/article/S1059-1311(22)00114-5/fulltext.	Vaccine not approved in EU
32.	ModernaTx, Inc, 2022	ModernaTx, Inc. A Study to Evaluate the Safety and Immunogenicity of the mRNA-1273.214 COVID-19 Vaccine in Healthy Children Between 6 Months to Less Than 6 Years of Age. 2022. Available from: https://clinicaltrials.gov/ct2/show/NCT05436834	Vaccine not approved in EU
33.	Novavax, 2022	Novavax. Safety and Immunogenicity of NVX-CoV2373 in Children 6 Months to < 12 Years. 2022. Available from: https://clinicaltrials.gov/ct2/show/NCT05468736	Vaccine not approved in EU

34.	Puspitarani et al, 2022	Puspitarani F, Sitaresmi MN, Ahmad RA. Adverse events following immunization of COVID-19 vaccine among children aged 6–11 years. Frontiers in public health. 2022. 10. Available from: https://www.scienceopen.com/document_file/a4b73628-77d2-42fd-a3f1-ffad9469e426/PubMedCentral/a4b73628-77d2-42fd-a3f1-ffad9469e426.pdf	Vaccine not approved in EU
35.	Rigshospitalet Denmark, 2021	Rigshospitalet Denmark. Incidence of MIS-C Following SARS-CoV-2 Infection. clinicaltrialsgov. 2021. Available from: https://clinicaltrials.gov/ct2/show/NCT05186597.	Vaccine not approved in EU
36.	Serum Institute of India Private Limited Pune, 2021	Serum Institute of India Private Limited Pune. The study to check the safety and immune response of (Covid-19 vaccine) COVOVAX in adults (more than 18 years of age) and pediatric population (more than 2 years and less than 17 years of age) in India. Clinical Trials Registry - India. 2021. Available from: http://www.ctri.nic.in/Clinicaltrials/pmaindet2.php?trialid=49327.	Vaccine not approved in EU
37.	Seventh Medical Center of P. L. A. General Hospital, 2022	Seventh Medical Center of P. L. A. General Hospital Evaluate the Safety and Immunogenicity of Ad5 COVID-19 Vaccines for Booster Use in Children Aged 6-17 Years. clinicaltrialsgov. 2022. Available from: https://clinicaltrials.gov/ct2/show/NCT05330871.	Vaccine not approved in EU
38.	Sinovac Biotech Co Ltd	Sinovac Biotech Co Ltd. Lot-to-lot Consistency of an Inactivated SARS-CoV-2 Vaccine Between Different Workshops in Healthy Children Aged 3-17 Years. clinicaltrialsgov. 2021. Available from: https://clinicaltrials.gov/ct2/show/NCT05112913 .	Vaccine not approved in EU
39.	Sinovac Research Development Co Ltd, 2020	Sinovac Research Development Co Ltd. Safety and Immunogenicity Study of Inactivated Vaccine for Prevention of COVID-19. clinicaltrialsgov. 2020. Available from: https://clinicaltrials.gov/ct2/show/NCT04551547.	Vaccine not approved in EU
40.	Sinovac Research Development Co Ltd, 2021	Sinovac Research Development Co Ltd. Efficacy, Immunogenicity and Safety of COVID-19 Vaccine , Inactivated in Children and Adolescents. clinicaltrialsgov. 2021. Available from: https://clinicaltrials.gov/ct2/show/NCT04992260.	Vaccine not approved in EU
41.	Sinovac Research Development Co Ltd, 2021	Sinovac Research Development Co Ltd. Safety of an Inactivated SARS-CoV-2 Vaccine for Prevention of COVID-19 in Children and Adolescents. clinicaltrialsgov. 2021. Available from: https://clinicaltrials.gov/ct2/show/NCT04992208.	Vaccine not approved in EU
42.	Sinovac Research Development Co Ltd, 2021	Sinovac Research Development Co Ltd. Safety of an Inactivated SARS-CoV-2 Vaccine (CoronaVac) in Children and Adolescents. clinicaltrialsgov. 2021. Available from: https://clinicaltrials.gov/ct2/show/NCT04992208.	Vaccine not approved in EU
43.	Sinovac Research Development Co Ltd, 2022	Sinovac Research Development Co Ltd. Immunogenicity of an Inactivated COVID-19 Vaccine. clinicaltrialsgov. 2022. Available from: https://clinicaltrials.gov/ct2/show/NCT05198336.	Vaccine not approved in EU
44.	Smith et al, 2021	Smith D, Pollard A. A phase II study of a candidate COVID-19 vaccine in children (COV006). ISRCTN registry. 2021. Available from: https://www.isrctn.com/ISRCTN15638344.	Vaccine not approved in EU
45.	Soto et al, 2022	Soto JA, Melo-González F, Gutierrez-Vera C, et al An inactivated SARS-CoV-2 vaccine is safe and induces humoral and cellular immunity against virus variants in healthy children and adolescents in Chile. medRxiv. 2022. Available from: https://medrxiv.org/cgi/content/short/2022.02.15.22270973.	Vaccine not approved in EU
46.	Soto et al, 2022	Soto JA, Melo-González F, Gutierrez-Vera C, et al Inactivated Vaccine-Induced SARS-CoV-2 Variant-Specific Immunity in Children. Mbio.2022. 13(6), e01311-22. Available from: https://journals.asm.org/doi/full/10.1128/mbio.01311-22	Vaccine not approved in EU
47.	St. Jude Children's Research Hospital, 2021	St. Jude Children's Research Hospital Evaluating Immune Response to COVID-19 Vaccines in Patients With Cancer, Transplant or Cellular Therapy Recipients. clinicaltrialsgov. 2021. Available from: https://clinicaltrials.gov/ct2/show/NCT05164016.	Type of assessed vaccine(s) unclear

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50.	Subhash et al, 2022	Subhash T, Vikram P, SubbaReddy G, et al Safety, tolerability and immunogenicity of Biological E's CORBEVAX™ vaccine in children and adolescents: A Prospective, Randomised, Double-blind, Placebo controlled, Phase-2/3 Study (preprint). medRxiv. 2022. Available from: https://doi.org/10.1101/2022.04.20.22274076.	Vaccine not approved in EU
51.	Suntronwong et al, 2022	Suntronwong N, Vichaiwattana P, Klinfueng S, et al SARS-CoV-2 infection-induced seroprevalence among children and associated risk factors during pre- and omicron-dominant wave, from January 2021 through November 2022, Thailand: Longitudinal study. medRxiv, 2022-12. Available from: https://www.medrxiv.org/content/10.1101/2022.12.01.22283006v1	Vaccine not approved in EU
52.	Thuluva et al, 2022	Thuluva S, Paradkar V, Gunneri S, et al Safety, tolerability and immunogenicity of Biological E's CORBEVAX™ vaccine in children and adolescents: A prospective, randomised, double-blind, placebo controlled, phase-2/3 study. *Vaccine. 2022.40*(49), 7130-7140. Available from: https://www.sciencedirect.com/science/article/pii/S0264410X22013081	Vaccine not approved in EU
53.	Toepfner et al, 2022	Toepfner N, von Meissner W, Strumann C, et al Safety of the BNT162b2 mRNA COVID-19 Vaccine in Children below 5 Years in Germany (CoVacU5): An Investigator-initiated Retrospective Cohort Study (preprint). medRxiv. 2022. Available from: https://www.medrxiv.org/content/10.1101/2022.05.17.22275005v1.	Vaccine not approved in EU for this age group
54.	Trang et al, 2023	Trang H, Tsoi J. Impacts of COVID-19 vaccination on the ocular surface microbiota, cornea, uvea, macular vasculature and vision in children. 2023. Available from: https://www.chictr.org.cn/showprojen.aspx?proj=187584	
55.	US Food and Drug Administration (FDA), 2022	US Food and Drug Administration (FDA). FDA Briefing Document; EUA amendment request for Pfizer-BioNTech COVID-19 Vaccine for use in children 6 months through 4 years of age, 2022. Available from: https://www.fda.gov/media/159195/download.	Vaccine not approved in EU
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57.	Vadrevu et al, 2022	Vadrevu KM, Reddy S, Jogdand H, et al Immunogenicity and reactogenicity of an inactivated SARS-CoV-2 vaccine (BBV152) in children aged 2-18 years: interim data from an open-label, non-randomised, age de-escalation phase 2/3 study. Lancet Infect Dis. 2022 Sep;22(9):1303-1312. doi: 10.1016/S1473-3099(22)00307-3. Epub 2022 Jun 16. Vadrevu KM, Reddy S, Jogdand H, et al Immunogenicity and safety of an inactivated SARS-CoV-2 vaccine (BBV152) in children from 2 to 18 years of age: an open-label, age-de-escalation phase 2/3 study. medRxiv. 2021. Available from: https://www.medrxiv.org/content/10.1101/2021.12.28.21268468v1.	Vaccine not approved in EU
58.	Valneva Austria GmbH, 2022	Valneva Austria GmbH. Paediatric VLA2001-321 Study. clinicaltrialsgov. 2022. Available from: https://clinicaltrials.gov/ct2/show/NCT05298644.	Vaccine not approved in EU
60.	Wang et al, 2022a	Wang X, Chang H, Tian H, et al Epidemiological and clinical features of SARS-CoV-2 infection in children during the outbreak of Omicron variant in Shanghai, March 7-31, 2022. Influenza Other Respir Viruses. 2022 Nov;16(6):1059-1065. doi: 10.1111/irv.13044. Epub 2022 Aug 31. Wang X, Chang H, Tian H, et al Epidemiological and clinical features of SARS-CoV-2 Infection in children during the outbreak of Omicron Variant in Shanghai, March 7-March 31, 2022. medRxiv. 2022. Available from: https://www.medrxiv.org/content/10.1101/2022.04.28.22274421v1.	Vaccine not approved in EU
61.	Wang et al, 2022 A	Wang XL, Zhai J, Zou YX. [Clinical characteristics and vaccination status of SARS-CoV-2 Omicron variant infected children]. Zhonghua Er Ke Za Zhi. 2022 Jun 15;60(7):671-675. Chinese. doi: 10.3760/cma.j.cn112140-20220506-00417. Epub ahead of print.	Vaccine not approved in EU

62.	Wang et al, 2022 B	Wang L, Wu Z, Ying Z, et al Safety and immunogenicity following a homologous booster dose of CoronaVac in children and adolescents. Nature communications. 2022;13(1), 6952. Available from: https://www.nature.com/articles/s41467-022-34280-y	Vaccine not approved in EU
63.	Wang et al, 2022 C	Wang Z, Fang X, Han T, et al Safety and tolerability of COVID-19 vaccine in children with epilepsy: a prospective, multicenter study. Pediatric Neurology. 2023;140, 3-8. Available from: https://www.sciencedirect.com/science/article/pii/S0887899422002570	
64.	WestVac Biopharma Co Ltd, 2021	WestVac Biopharma Co Ltd. Phase I/II Clinical Trial of Recombinant COVID-19 Vaccine (Sf9 Cells) in Children and Adolescents. clinicaltrialsgov. 2021. Available from: https://clinicaltrials.gov/ct2/show/NCT05013983.	Vaccine not approved in EU
65.	Xia et al, 2021	Xia S, Zhang Y, Wang Y, et al Safety and immunogenicity of an inactivated COVID-19 vaccine, BBIBP-CorV, in people younger than 18 years: a randomised, double-blind, controlled, phase 1/2 trial The Lancet Infectious Diseases. 2022;22(2):196-208. Available from: https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00462-X/fulltext.	Vaccine not approved in EU
66.	Xia et al, 2022	Xia S, Duan K, Zhang Y, et al Safety and Immunogenicity of an Inactivated COVID-19 Vaccine, WIBP-CorV, in Healthy Children: Interim Analysis of a Randomized, Double-Blind, Controlled, Phase 1/2 Trial Front Immunol. 2022 Jun 24;13:898151. doi: 10.3389/fimmu.2022.898151.	Vaccine not approved in EU
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68.	Yi et al, 2022	Yi C, Zheng X, Lin K, Xiao J. Safety of inactivated COVID-19 vaccine in pediatric patients with rheumatic diseases. 2022. Available from: https://assets.researchsquare.com/files/rs-1658641/v1/39c9590a-a01e-4c7d-ac15-20168f8089d0.pdf?c=1664795941	Vaccine not approved in EU
69.	Yin et al, 2022	Yin R, Lu Q, Jiao JL, et al Characteristics and related factors of viral nucleic acid negative conversion in children infected with Omicron variant strain of SARS-CoV-2. Zhonghua Er Ke Za Zhi. 2022. 1307-1311. Available from: https://pesquisa.bvsalud.org/global-literature-on-novel-coronavirus-2019-ncov/resource/fr/covidwho-2143847	Vaccine not approved in EU
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71.	Zhu et al, 2021	Zhu F, Jin P, Zhu T, et al Safety and immunogenicity of a recombinant adenovirus type-5-vectored COVID-19 vaccine with a homologous prime-boost regimen in healthy participants aged 6 years and above: a randomised, double-blind, placebo-controlled, phase 2b trial Clin Infect Dis. 2021. Available from: https://academic.oup.com/cid/article/75/1/e783/6374123.	Vaccine not approved in EU

EU: European Union

List of excluded studies after full-text screening

Nr.	Reference	Exclusion reason
1.	Abbate A, Gavin J, Madanchi N, et al Fulminant myocarditis and systemic hyperinflammation temporally associated with BNT162b2 mRNA COVID-19 vaccination in two patients. Int J Cardiol. 2021;340:119-21. doi:10.1016/j.ijcard.2021.08.018.	Wrong patient population
2.	Abdel-Qader DH, Hazza Alkhatatbeh I, Hayajneh W, Annab H, Al Meslamani AZ, Elmusa RA. IgA nephropathy in a pediatric patient after receiving the first dose of Pfizer-BioNTech COVID-19 vaccine. Vaccine. 2022;40(18):2528-30. doi:10.1016/j.vaccine.2022.03.003.	Wrong patient population
3.	Acuti Martellucci C, Flacco ME, Soldato G, et al Effectiveness of COVID-19 Vaccines in the General Population of an Italian Region before and during the Omicron Wave. Vaccines (Basel). 2022;10(5). doi:10.3390/vaccines10050662.	Wrong patient population
4.	Akgün Ö, Cakmak F, Guliyeva V, et al Humoral Response and Safety of BNT162b2 mRNA Vaccine in Children with Rheumatic Diseases under Immunomodulatory Treatment: A Preliminary Study. Rheumatology (Oxford). 2022. doi:10.1093/rheumatology/keac140.	Wrong patient population
5.	Aldè M, Di Berardino F, Ambrosetti U, et al Audiological and vestibular symptoms following SARS-CoV-2 infection and COVID-19 vaccination in children aged 5–11 years. American Journal of Otolaryngology. 2023. 44(1), 103669. doi: 10.1016/j.amjoto.2022.103669	Wrong outcomes
6.	Althaus T, Landier J, Zhu F, et al The Impact of SARS-CoV-2 Vaccination and Infection on Neutralising Antibodies: A Nation-Wide Cross-Sectional Analysis. 2022. https://dx.doi.org/10.2139/ssrn.4233128	Wrong patient population
7.	Alwafi H, Naser AY, Aldhahir AM, et al COVID-19 vaccination side effects among the child age group: a large cross-sectional online based survey in Saudi Arabia. BMC Infectious Diseases. 2022. 22(1), 1-9. doi: 10.1186/s12879-022-07905-2	Wrong patient population
8.	Araujo da Silva AR, de Carvalho BRR, Esteves MM, Teixeira CH, Souza CV. Role of COVID-19 vaccinal status in admitted children during OMICRON variant circulation in Rio de Janeiro, city-Preliminary report. medRxiv. 2022. doi:10.1101/2022.02.10.22270817.	Wrong intervention
9.	Araujo da Silva AR, de Carvalho BRR, Esteves MM, Teixeira CH, Souza CV. Role of COVID-19 vaccinal status in admitted children during OMICRON variant circulation in Rio de Janeiro, city-Preliminary report (preprint). medRxiv. 2022. doi:10.1101/2022.02.10.22270817.	Wrong intervention
10.	Bartsch YC, Chen J, Kang J, et al BNT162b2 induces robust cross-variant SARS-CoV-2 immunity in children (preprint). medRxiv. 2022. Available from: https://www.medrxiv.org/content/10.1101/2022.05.18.22275283v1.	Wrong comparator
11.	Bartsch YC, St Denis KJ, Kaplonek P, et al Comprehensive antibody profiling of mRNA vaccination in children. medRxiv. 2021. Available from: https://biorxiv.org/cgi/content/short/2021.10.07.463592.	Wrong intervention
12.	Belsky JA, Carroll WR, Feliciano A, Jacob SA. Side effects following COVID-19 vaccination in pediatric patients with sickle cell disease. Pediatric Blood & Cancer. 2022. e30193. doi: 10.1002/pbc.30193	Wrong patient population
13.	Bianchi S, Angi A, Passucci M, Palumbo G, Baldacci E, Testi AM. Severe Immune Thrombocytopenia (ITP) Following SARS-CoV-2 mRNA Vaccine in a Girl on Immunosuppressive Treatment and in Prolonged Stable Phase of ITP. Mediterr J Hematol Infect Dis. 2022;14(1):e2022011. doi:10.4084/MJHID.2022.011.	Wrong patient population
14.	Bizjak M, Emeršič N, Barbone F, et al High incidence of multisystem inflammatory syndrome and other autoimmune diseases after SARS-CoV-2 infection compared to COVID-19 vaccination in children and adolescents in south central Europe. Clinical and Experimental Rheumatology. 2022. doi: 10.55563/clinexprheumatol/i1l2xn	Wrong patient population
15.	Body A, Ahern E, Lal L, et al Protocol for SARS-CoV-2 post-vaccine surveillance study in Australian adults and children with cancer: an observational study of safety and serological and immunological response to SARS-CoV-2 vaccination (SerOzNET). BMC Infect Dis. 2022;22(1):70. doi:10.1186/s12879-021-07019-1.	Wrong patient population
16.	Bonzano L, Djuric O, Mancuso P, et al Incidence and Characteristics of Adverse Events after COVID-19 Vaccination in a Population-Based Programme. Vaccines. 2022; 10(7):1111. https://doi.org/10.3390/vaccines10071111	Wrong patient population
17.	Bots SH, Riera Arnau J, Belitser SV, et al Myocarditis and pericarditis associated with SARS-CoV-2 vaccines: A population-based descriptive cohort and a nested self-controlled risk interval study using electronic health care data from four European countries. 2022. doi: 10.3389/fphar.2022.1038043	Wrong patient population
18.	Boylan M, Roddy J, Lim N, Morgan R, McAdam B, Kiernan F. Recovery of a critically ill patient with COVID-19 myocarditis. Ir J Med Sci. 2022;191(3):1445-9. doi:10.1007/s11845-021-02681-5.	Wrong patient population
19.	Burns MD, Muir C, Atyeo C, et al Relationship between anti-spike antibodies and risk of SARS-CoV-2 infection in infants born to COVID-19 vaccinated mothers. Vaccines. 2022. 10(10), 1696. https://dx.doi.org/10.3390/vaccines10101696	Wrong outcomes
20.	Cahen-Peretz A, Tsaitlin-Mor L, Kam HA, et al Boosting maternal and neonatal anti–SARS-CoV-2 humoral immunity using a third mRNA vaccine dose. JCI insight. 2023. *8*(1). https://dx.doi.org/10.1172/jci.insight.158646	Wrong outcomes
21.	Cari L, Fiore P, Naghavi Alhosseini M, Sava G, Nocentini G. Blood clots and bleeding events following BNT162b2 and ChAdOx1 nCoV-19 vaccine: An analysis of European data. J Autoimmun. 2021;122:102685. doi:10.1016/j.jaut.2021.102685.	Wrong patient population
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24.	Chen LL, Chua GT, Lu L, et al Omicron variant susceptibility to neutralizing antibodies induced in children by natural SARS-CoV-2 infection or COVID-19 vaccine. Emerg Microbes Infect. 2022;11(1):543-7. doi:10.1080/22221751.2022.2035195.	Wrong patient population
25.	Chen WC, Lin YP, Cheng CM, et al Detection of SARS-CoV-2 Neutralizing Antibodies in Vaccinated Pregnant Women and Neonates by Using a Lateral Flow Immunoassay Coupled with a Spectrum-Based Reader. Biosensors. 2022. 12(10), 891. https://dx.doi.org/10.3390/bios12100891	Wrong patient population
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27.	Cieslewicz A, Dudek M, Krela-Kazmierczak I, Jablecka A, Lesiak M, Korzeniowska K. Pancreatic Injury after COVID-19 Vaccine-A Case Report. Vaccines (Basel). 2021;9(6). doi:10.3390/vaccines9060576.	Wrong patient population
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29.	Collignon C, Frachette C, Callot D, et al Two pediatric cases of multisystem inflammatory-like syndrome following COVID-19 vaccination. Archives de Pédiatrie. 2022. 29(8), 620-623. https://dx.doi.org/10.1016/j.arcped.2022.08.018	Wrong patient population
30.	Committee on Infectious D. COVID-19 Vaccines in Children and Adolescents. Pediatrics. 2022;149(1). doi:10.1542/peds.2021-054332.	Wrong study design
31.	Cotugno N, Franzese E, Angelino G, et al Evaluation of Safety and Immunogenicity of BNT162B2 mRNA COVID-19 Vaccine in IBD Pediatric Population with Distinct Immune Suppressive Regimens. Vaccines. 2022; 10(7):1109. https://doi.org/10.3390/vaccines10071109	Wrong patient population
32.	Crommelynck S, Thill P. Pharmacovigilance for COVID-19 vaccines: A 1-year experience in France. Infectious Diseases Now. 2022. 52(8), S16-S18. https://dx.doi.org/10.1016/j.idnow.2022.09.018	Wrong study design
33.	Dailey J, Kozhaya L, Dogan M, et al Antibody Responses to SARS-CoV-2 after Infection or Vaccination in Children and Young Adults with Inflammatory Bowel Disease. medRxiv. 2021. doi:10.1101/2021.06.12.21258810.	Wrong patient population
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41.	Gao F, Mallajoysula V, Arunachalam P, et al Robust T Cell Responses to the Pfizer/Biontech Vaccine Compared to Infection and Evidence of Attenuated Cd8+ T Cell Responses Due to Covid-19. 2022. https://dx.doi.org/10.2139/ssrn.4173451	Wrong patient population
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44.	Gouda N, Dimitriadou M, Sotiriou G, et al The impact of COVID-19 vaccination on glycaemic control in children and adolescents with type 1 diabetes mellitus on continuous glucose monitoring. Acta Diabetol 59, 1609–1614 (2022). https://doi.org/10.1007/s00592-022-01968-y	Wrong outcomes
45.	Gulmez R, Ozbey D, Agbas A, et al Humoral and cellular immune response to SARS-CoV-2 mRNA BNT162b2 vaccine in pediatric kidney transplant recipients compared with dialysis patients and healthy children. Pediatric Nephrology. 2022. 1-10. https://dx.doi.org/10.1007/s00467-022-05813-w	Wrong patient population
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53.	Kaicker S, Martinko K, Bussel JB. Effects of COVID-19 vaccination on platelet counts and bleeding in children, adolescents, and young adults with immune thrombocytopenia. Pediatric Blood & Cancer. 2023. 70(1), e30051. https://dx.doi.org/10.1002/pbc.30051	Wrong outcomes
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58.	Koirala A, Winkler NE, Quinn H, et al Understanding SARS-CoV-2 Delta and Omicron Variant Transmission and Vaccine Impact in Schools and Child-Care Settings in Australia. Available at SSRN 4301765. 2023. doi: 10.2139/ssrn.4301765	Wrong patient population
59.	Lai FTT, Huang L, Peng K, et al Post-Covid-19-vaccination adverse events and healthcare utilization among individuals with or without previous SARS-CoV-2 infection. J Intern Med. 2022;291(6):864-9. doi:10.1111/joim.13453.	Wrong patient population
60.	Larkin K, Sharma A, Drachtman R, Salaru G. Supraclavicular lymphadenopathy after COVID-19 vaccination. Pediatr Blood Cancer. 2022;69(5):e29516. doi:10.1002/pbc.29516.	Wrong patient population
61.	Layan M, Gilboa M, Gonen T, et al Impact of BNT162b2 vaccination and isolation on SARS-CoV-2 transmission in Israeli households: an observational study. medRxiv. 2021. doi:10.1101/2021.07.12.21260377.	Wrong intervention
62.	Lee E, Kim K, Kim M, et al Adverse reactions to coronavirus disease 2019 vaccines in children and adolescents. Allergy Asthma & Respiratory Disease. 2022;10(1):9-14. doi:10.4168/aard.2022.10.1.9.	Wrong study design
63.	Leung D, Mu X, Rosa Duque J, et al Safety and immunogenicity of 3 doses of BNT162b2 and CoronaVac in children and adults with inborn errors of immunity. Authorea Preprints. 2022. https://dx.doi.org/10.3389/fimmu.2022.982155	Wrong patient population
64.	Li H, Lin H, Chen X, et al A need of COVID19 vaccination for children aged <12 years: Comparative evidence from the clinical characteristics in patients during a recent Delta surge (B.1.617.2). medRxiv. 2021. doi:10.1101/2021.11.05.21265712.	Wrong intervention
65.	Li M, Hao J, Jiang T, et al Maternal and neonatal safety of COVID-19 vaccination during the peri-pregnancy period: A prospective study. Journal of Medical Virology. 2023. 95(1), e28378. https://dx.doi.org/10.1002/jmv.28378	Wrong outcomes
66.	Li X, Gao L, Tong X, et al Autoimmune conditions following mRNA (BNT162b2) and inactivated (CoronaVac) COVID-19 vaccination: A descriptive cohort study among 1.1 million vaccinated people in Hong Kong. J Autoimmun. 2022;130:102830. doi:10.1016/j.jaut.2022.102830.	Wrong patient population
67.	Liu Y, Liunuobei Z, Wang L, et al Clinical and Humoral Immune Response Characterization of SARS-CoV-2 Omicron BA. 2.38 Infection in Pediatric Patients. 2022. Available at SSRN 4307105.	Wrong patient population
68.	Liu Z, Le K, Zhou X, et al Neutralising antibody potency against SARS-CoV-2 wild-type and omicron BA. 1 and BA. 4/5 variants in patients with inflammatory bowel disease treated with infliximab and vedolizumab after three doses of COVID-19 vaccine (CLARITY IBD): an analysis of a prospective multicentre cohort study. The Lancet Gastroenterology & Hepatology. 2022. https://dx.doi.org/10.1016/S2468-1253(22)00389-2	Wrong patient population
69.	Ma AL, Leung D, Chan EY, et al Antibody responses to 2 doses of mRNA COVID-19 vaccine in pediatric patients with kidney diseases. Kidney Int. 2022;101(5):1069-72. doi:10.1016/j.kint.2022.01.035.	Wrong patient population
70.	Madhi SA, Kwatra G, Myers JE, et al South African Population Immunity and Severe Covid-19 with Omicron Variant. medRxiv. 2022. doi:10.1101/2021.12.20.21268096.	Wrong intervention
71.	Manno EC, Amodio D, Cotugno N, et al Higher Troponin Levels on Admission are associated With Persistent Cardiac Magnetic Resonance Lesions in Children Developing Myocarditis After mRNA-Based COVID-19 Vaccination. The Pediatric Infectious Disease Journal 2022. 42(2), 166-171. https://dx.doi.org/10.1097/INF.0000000000003762	Wrong patient population
72.	Marks KJ, Whitaker M, Anglin O, et al Hospitalizations of Children and Adolescents with Laboratory-Confirmed COVID-19 - COVID-NET, 14 States, July 2021-January 2022. MMWR Morb Mortal Wkly Rep. 2022;71(7):271-8. doi:10.15585/mmwr.mm7107e4.	Wrong intervention
73.	Marshall NE, Blanton MB, Doratt BM, et al SARS-CoV-2 Vaccine Booster Elicits Robust Prolonged Maternal Antibody Responses and Passive Transfer Via The Placenta And Breastmilk. bioRxiv, 2022-11. https://dx.doi.org/10.1101/2022.11.29.518385	Wrong outcomes
74.	Miller AD, Yousaf AR, Bornstein E, et al Multisystem Inflammatory Syndrome in Children During Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Delta and Omicron Variant Circulation—United States, July 2021–January 2022, Clinical Infectious Diseases, Volume 75, Issue Supplement_2, 1 October 2022, Pages S303–S307, https://doi.org/10.1093/cid/ciac471	Wrong patient population
75.	Mizrahi B, Sudry T, Flaks-Manov N, et al Long covid outcomes at one year after mild SARS-CoV-2 infection: nationwide cohort study. Bmj. 2023. 380. https://dx.doi.org/10.1136/bmj-2022-072529	Wrong patient population

76.	Morgan MC, Atri L, Harrell S, Al-Jaroudi W, Berman A. COVID-19 vaccine-associated myocarditis. World Journal of Cardiology. 2022. 14(7), 382. https://dx.doi.org/10.4330/wjc.v14.i7.382	Wrong study design
77.	Morgans HA, Bradley T, Flebbe-Rehwaldt L, et al Humoral and cellular response to the COVID-19 vaccine in immunocompromised children. Pediatric Research. 2022. 1-6. https://dx.doi.org/10.1038/s41390-022-02374-4	Wrong patient population
78.	NN. Research of Safety and Immune Response of COVID-19 Vaccination in Healthy Children and Children With Chronic HBV infection. Chinese Clinical Trial Registry. 2021. http://www.epistemonikos.org/documents/bdecb55cf5ef303e1cef29c521537f18dbef1ded.	Wrong study design
79.	NN. In brief: Myocarditis with the Pfizer/BioNTech and Moderna COVID-19 vaccines. Med Lett Drugs Ther. 2021;63(1629):e9. https://www.ncbi.nlm.nih.gov/pubmed/34544112.	Wrong patient population
80.	NN. Covid-19-vaccine-pfizer-biontech: Multisystem inflammatory syndrome in children like symptoms: case report. Reactions Weekly 2022;1891(1):109-. https://search.bvsalud.org/global-literature-on-novel-coronavirus-2019-ncov/resource/en/covidwho-1660881.	Wrong patient population
81.	Novavax Inc. Novavax Announces Positive Results of COVID-19 Vaccine in Pediatric Population of PREVENT-19 Phase 3 Clinical Trial Press release - PR Newswire - Feb 10, 2022, 16:02 ET. 2022. http://www.epistemonikos.org/documents/9abc620055771277a5debe06b04c31a2bc1dc6db.	Wrong publication type
82.	Nyberg T, Ferguson NM, Nash SG, et al Comparative Analysis of the Risks of Hospitalisation and Death Associated with SARS-CoV-2 Omicron (B.1.1.529) and Delta (B.1.617.2) Variants in England. SSRN. 2022. http://www.epistemonikos.org/documents/37f955c813703d443b9882ab7c928d4c8d292847.	Wrong outcomes
83.	Nygaard U, Holm M, Hartling UB, et al Multisystem Inflammatory Syndrome in Children Following the SARS-CoV-2 Delta Variant in Denmark: Clinical Phenotype and Risk by Vaccination Status and Compared to the Pre-Delta COVID-19 Era. SSRN. 2022. http://www.epistemonikos.org/documents/29fdcafbfb4e0ea54de47a73cf427fefc24a1ffb.	Wrong intervention
84.	Oliver SE, Wallace M, Link-Gelles R. COVID-19 Vaccines: Safe and Effective in Children Ages 5-11 Years. Pediatrics. 2022. doi:10.1542/peds.2022-057314.	Wrong study design
85.	Pandit T, Pandit R, Goyal L. Uncommon Side Effects of COVID-19 Vaccination in the Pediatric Population. Cureus. 2022. 14(10). https://dx.doi.org/10.7759/cureus.30276	Wrong study design
86.	Patel T, Kelleman M, West Z, et al Comparison of MIS-C Related Myocarditis, Classic Viral Myocarditis, and COVID-19 Vaccine related Myocarditis in Children. medRxiv. 2021. doi:10.1101/2021.10.05.21264581.	Wrong intervention
87.	Perez MA, Hsiao HM, Chen X, et al Serologic Responses to COVID-19 Vaccination in Children with History of Multisystem Inflammatory Syndrome (MIS-C). medRxiv, 2022-11. https://dx.doi.org/10.1101/2022.11.19.22282551	Wrong patient population
88.	Pescarini JM, Cardoso AM, Santos RV, et al Vaccine Coverage and Effectiveness Against Laboratory-Confirmed Symptomatic and Severe COVID-19 in Indigenous People in Brazil: A Cohort Study. 2022. https://regroup-production.s3.amazonaws.com/documents/ReviewReference/594853273/SSRN-id4224510.pdf?response-content-type=application%2Fpdf&X-Amz-Algorithm=AWS4-HMAC-SHA256&X-Amz-Credential=AKIAYSFKCAWYQ4D5IUHG%2F20230131%2Fus-east-1%2Fs3%2Faws4_request&X-Amz-Date=20230131T154354Z&X-Amz-Expires=604800&X-Amz-SignedHeaders=host&X-Amz-Signature=e8ba0b190cc45abd2cfa08f4ddfd2cc6777d738e972ce59aa04fb6c202abf812	Wrong patient population
89.	Pillay A, Yeola A, Tea F, et al Infection and vaccine induced Spike antibody responses against SARS-CoV-2 Variants of concern in immune naïve children and adults. 2022. https://dx.doi.org/10.21203/rs.3.rs-2262275/v1	Wrong patient population
90.	Pinto Pereira SM, Nugawela MD, Rojas NK, et al Post-COVID-19 condition at 6 months and COVID-19 vaccination in non-hospitalised children and young people. Archives of Disease in Childhood. 2023. https://dx.doi.org/10.1136/archdischild-2022-324656	Wrong patient population
91.	Plexision. Immunity After COVID-19 Vaccination. clinicaltrialsgov. 2021. http://www.epistemonikos.org/documents/ebfe929bb8894b479b6a673da0c2ce87669f82ce.	Wrong patient population
92.	Pontificia Universidad Catolica de Chile. Immune Response to Anti COVID-19 Vaccine in Immunocompromised Patients: a Cohort Study. clinicaltrialsgov. 2021. https://clinicaltrials.gov/show/NCT04888793.	Wrong patient population
93.	Porwal T, Agarwal A. Covid-19 vaccine-induced skin rash: A case study. Indian Academy of Clinical Medicine. 2021;22(3-4):154-5. https://search.bvsalud.org/global-literature-on-novel-coronavirus-2019-ncov/resource/en/covidwho-1576291.	Wrong patient population
94.	Princess Máxima Center for Pediatric Oncology. Prospective monitoring of immune response following COVID-19 vaccination in children with cancer. Netherlands Trial Register. 2021. http://www.epistemonikos.org/documents/3bc3eb50037491f07c6d27cb88dd2fcd6b5293b1.	Wrong patient population
95.	Qassim SH, Hasan MR, Tang P, et al Effects of SARS-CoV-2 Alpha, Beta, and Delta variants, age, vaccination, and prior infection on infectiousness of SARS-CoV-2 infections. medRxiv, 2022-07. https://dx.doi.org/10.3389/fimmu.2022.984784	Wrong outcomes
96.	Qin CX, Auerbach SR, Charnaya O, et al Antibody response to 2-dose SARS-CoV-2 mRNA vaccination in pediatric solid organ transplant recipients. Am J Transplant. 2022;22(2):669-72. doi:10.1111/ajt.16841.	Wrong patient population
97.	Rose J, McCullough PA. WITHDRAWN: A Report on Myocarditis Adverse Events in the U.S. Vaccine Adverse Events Reporting System (VAERS) in Association with COVID-19 Injectable Biological Products. Curr Probl Cardiol. 2021:101011. doi:10.1016/j.cpcardiol.2021.101011.	Paper withdrawn
98.	Rostad CA, Chen X, Sun HY, et al Functional antibody responses to SARS-CoV-2 variants in children with COVID-19, MIS-C, and after two doses of BNT162b2 vaccination. J Infect Dis. 2022. doi:10.1093/infdis/jiac215.	Wrong patient population
99.	Sahn B, Lu Y, Hui-Yuen JS, et al The safety of COVID-19 vaccination in immunocompromised children and young adults with immune-mediated inflammatory disease. Acta Paediatrica. 2022. https://dx.doi.org/10.1111/apa.16652	Wrong patient population

100.	Sakaida K, Iwashima S, Katuki J, et al Multisystem inflammatory syndrome in Children After BNT162b2 Messenger RNA SARS-CoV-2 Vaccination. Pediatrics International 2022. https://dx.doi.org/10.1111/ped.15441	Wrong patient population
101.	Seery V, Raiden S, Russo C, et al Antibody response against SARS-CoV-2 variants of concern in children infected with pre-Omicron variants: An observational cohort study. EBioMedicine. 2022 83, 104230. doi: 10.1016/j.ebiom.2022.104230.	Wrong intervention
102.	Shahid R, Tang W, Klein AL, Kwon D, Amdani S. Is the mRNA COVID-19 Vaccine Safe in Patients With a Prior History of Myocarditis?	Wrong patient population
103.	Shire ZJ, Reicherz F, Lawrence S, et al Antibody response to the BNT162b2 SARS-CoV-2 vaccine in paediatric patients with inflammatory bowel disease treated with anti-TNF therapy. Gut 2022;71:1922-1924. J Card Fail. 2022 Jul 13;S1071-9164(22)00575-9. doi: 10.1016/j.cardfail.2022.06.011. Online ahead of print.	Wrong patient population
104.	Shurrab FM, Al-Sadeq DW, Abou-Saleh H, et al Assessment of the Neutralizing Antibody Response of BNT162b2 and mRNA-1273 SARS-CoV-2 Vaccines in Naive and Previously Infected Individuals: A Comparative Study. Vaccines (Basel). 2022;10(2). doi:10.3390/vaccines10020191.	Wrong patient population
105.	Slomski A. Moderna COVID-19 Vaccine Safe and Effective for Children 6 Months to 5 Years. JAMA. 2022. 328(24), 2388-2388. https://dx.doi.org/10.1001/jama.2022.20056	Wrong study design
106.	Smirnov VS, Lyalina LV, Milichkina AM, et al Longitudinal Randomized Cohort Study of SARS-CoV-2 Antibody Seroprevalence in the St. Petersburg Population (preprint). Viruses. 2022;14(5):913. doi:10.3390/v14050913.	Wrong intervention
107.	Sorg AL, Schönfeld V, Siedler A, et al SARS-CoV-2 variants and the risk of pediatric inflammatory multisystem syndrome temporally associated with SARS-CoV-2 among children in Germany. Infection (2022). https://doi.org/10.1007/s15010-022-01908-6	Wrong intervention
108.	Spencer EA, Klang E, Dolinger M, Pittman N, Dubinsky MC. Seroconversion following SARS-CoV-2 Infection or Vaccination in Pediatric IBD Patients. medRxiv. 2021. doi:10.1101/2021.05.18.21257400.	Wrong patient population
109.	Stringhini S, Zaballa M-E, Pullen N, et al Seroprevalence of anti-SARS-CoV-2 antibodies six months into the vaccination campaign in Geneva, Switzerland. medRxiv. 2021. doi:10.1101/2021.08.12.21261929.	Wrong intervention
110.	Suehiro M, Okubo S, Nakajima K, et al Adverse events following COVID-19 vaccination in young Japanese people: A case-control study of the risk of systemic adverse events by a questionnaire survey. medRxiv. 2021. doi:10.1101/2021.10.01.21264393.	Wrong patient population
111.	Sulemankhil I, Abdelrahman M, Negi SI. Temporal Association Between the COVID-19 Ad26.COV2.S Vaccine and Acute Myocarditis: A Case Report and Literature Review. Cardiovasc Revasc Med. 2022;38:117-23. doi:10.1016/j.carrev.2021.08.012.	Wrong patient population
112.	Sunder A, Alqatari HM, Taha OE, et al COVID-19 vaccinations in pregnancy: Save mother and baby from COVID-19 pandemic. International Journal of Gynecology & Obstetrics. 2022. https://dx.doi.org/10.1002/ijgo.14532	Wrong outcomes
113.	Sutardi AQAI, Ramatillah DL. Evaluation Comparison between Sinovac and Pfizer Vaccine among Indonesian Children and Teenager under 18 Years Old. International Journal of Applied Pharmaceutics. 2022;14(Special issue 2):22-30. doi:10.22159/ijap.2022.v14s2.44745.	Wrong patient population
114.	Suthar MS, Arunachalam PS, Hu M, et al Durability of immune responses to the BNT162b2 mRNA vaccine. Med (N Y). 2022;3(1):25-7. doi:10.1016/j.medj.2021.12.005.	Wrong patient population
115.	Toh ZQ, Mazarakis N, Nguyen J, et al Comparison of antibody responses to SARS-CoV-2 variants in Australian children. Nature Communications, 13(1), 7185. https://dx.doi.org/10.1038/s41467-022-34983-2	Wrong patient population
116.	Tomasoni D, Tavelli A, Rodano A, et al Reactogenicity of mRNA-1273 vaccine in people living with HIV (PLWH): a prospective study. Hiv Medicine. 2021;22:23-4. <Go to ISI>://WOS:000711388200023.	Wrong patient population
117.	Topf KG, Sheppard M, Marx GE, et al Impact of the COVID-19 Vaccination Program on case incidence, emergency department visits, and hospital admissions among children aged 5–17 Years during the Delta and Omicron Periods—United States, December 2020 to April 2022. Plos one. 2022. 17(12), e0276409. https://regroup-production.s3.amazonaws.com/documents/ReviewReference/594853153/SSRN-id4229903.pdf?response-content-type=application%2Fpdf&X-Amz-Algorithm=AWS4-HMAC-SHA256&X-Amz-Credential=AKIAYSFKCAWYQ4D5IUHG%2F20230131%2Fus-east-1%2Fs3%2Faws4_request&X-Amz-Date=20230131T154354Z&X-Amz-Expires=604800&X-Amz-SignedHeaders=host&X-Amz-Signature=a073a8156efec32eff792d587c7f9c477db4e9ccb4ec2e8cd1b28f2c029f165c	Wrong outcomes
118.	Topf KG, Sheppard M, Marx GE, et al Impact of the COVID-19 Vaccination Program on case incidence, emergency department visits, and hospital admissions among children aged 5–17 Years during the Delta and Omicron Periods—United States, December 2020 to April 2022. medRxiv. 2022. https://dx.doi.org/10.1101/2022.10.07.22280822	Wrong outcomes
119.	Toussia-Cohen S, Nir O, Peretz-Machluf R, et al Maternal and neonatal immune responses following COVID-19 infection and vaccinations in pregnancy. Vaccines. 2022. 10(12), 2019. https://dx.doi.org/10.3390/vaccines10122019	Wrong outcomes
120.	Tri A, Mills K, Nilsen K. Pediatric COVID-19 Vaccination: A Description of Adverse Events or Reactions Reported in Kansans Aged 6 to 17. Kansas Journal of Medicine. 2022. 15(3), 390-393. https://dx.doi.org/10.17161/kjm.vol15.18431	Wrong patient population
121.	Umbrello M, Brena N, Vercelli R, et al Successful treatment of acute spleno-porto-mesenteric vein thrombosis after ChAdOx1 nCoV-19 vaccine. A case report. J Crit Care. 2021;65:72-5. doi:10.1016/j.jcrc.2021.05.021.	Wrong patient population
122.	Villagrasa-Boli P, Monte-Serrano J, Martinez-Cisneros S, et al Papular acrodermatitis of childhood-like eruption triggered by SARS-CoV-2 vaccination: Report of two cases. Dermatol Ther. 2022;35(2):e15252. doi:10.1111/dth.15252.	Wrong patient population

123.	Wisniewski M, Chun A, Volpi S, et al Outcomes After SARS-CoV-2 Vaccination Among Children With a History of Multisystem Inflammatory Syndrome. JAMA Netw Open. 2022;5(3):e224750. doi:10.1001/jamanetworkopen.2022.4750.	Wrong patient population
124.	Wong J, Sharma S, Yao JV, Aggarwal A, Grigg L. COVID-19 mRNA vaccine (Comirnaty)-induced myocarditis. Med J Aust. 2022;216(3):122-3. doi:10.5694/mja2.51394.	Wrong patient population
125.	Wu K, Werner AP, Koch M, et al Serum Neutralizing Activity Elicited by mRNA-1273 Vaccine. N Engl J Med. 2021;384(15):1468-70. doi:10.1056/NEJMc2102179.	Wrong patient population
126.	Yadav V, Kumar P, Kushal A, Yadav R, Anjali P. Covid-19 Morbidity amongst Covishield Vaccinated Vs Non-Vaccinated: A Comparative Study. National Journal of Community Medicine. 2022;13(2):60-3. doi:10.5455/njcm.20211014065554.	Wrong patient population
127.	Yang H, Li Z, Zhang R, et al Safety of primary immunization using inactivated SARS-CoV-2 vaccine (CoronaVac®) among population aged 3 years and older in a large-scale use: A multi-center open-label study in China. Vaccine. 2023. https://dx.doi.org/10.1016/j.vaccine.2023.01.020	Wrong patient population
128.	Yang Y, Xing H, Zhao Y. Transplacental transmission of SARS-CoV-2 immunoglobulin G antibody to infants from maternal COVID-19 vaccine immunization before pregnancy. Journal of Medical Virology. 2023. 95(1), e28296. https://dx.doi.org/10.1002/jmv.28296	Wrong intervention
129.	Zerbo O, Ray GT, Fireman B, et al Maternal SARS-CoV-2 Vaccination and Infant Protection Against SARS-CoV-2 During the First 6 Months of Life. Research Square. 2022. rs-3. https://dx.doi.org/10.21203/rs.3.rs-2143552/v1	Wrong patient population
130.	Zhang K, Jiang SY, Yan K, et al Clinical characteristics of 16 neonates infected with SARS-CoV-2 during Omicron variant outbreak. Zhonghua er ke za zhi= Chinese Journal of Pediatrics. 2022. 60(11), 1158-1162. https://dx.doi.org/10.3760/cma.j.cn112140-20220617-00561	Wrong patient population
131.	Zhang YF, Liang SS, Wu PL, et al Clinical features of severe acute respiratory syndrome coronavirus 2 Omicron variant infection in children: an analysis of 201 cases. Zhongguo dang dai er ke za zhi= Chinese journal of contemporary paediatrics. 2023. 25(1), 5-10. https://dx.doi.org/10.7499/j.issn.1008-8830.2207052	Wrong study design

Exclusion reason	**Frequency**
Wrong patient population	85
Wrong intervention	15
Wrong outcomes	15
Wrong study design	11
Wrong comparator	2
Paper withdrawn	1
Wrong publication type	1
Wrong setting	1
Total	131

Supplementary results

Risk of Bias

Judgements per study and outcome are provided for each domain of the respective assessment tool in the provided RoB spreadsheet (Appendix 2) and summarised below.

Risk of bias in RCTs

Overall, we had some concerns of bias for most outcomes assessed (13/17). Efficacy outcomes (VE against SARS-CoV-2 infection, symptomatic COVID-19, hospitalisation, mortality, and MIS-C) were all judged with some concerns, due to performing a per-protocol rather than an intention-to-treat analysis, leading to missing outcome data in both trials[12,13] and the probability of selective reporting in one trial as interim analysis was not performed according to pre-specified rule.[12]
All safety outcomes (AESIs, local and systemic reactions, and unsolicited AEs), except for SAEs, were also judged with some concerns of bias. Our concerns originated from the measurement of the outcomes as parts of the study personnel were not blinded (e.g., persons administering vaccinations). Outcomes were self-reported events (electronic study diary), and possible knowledge of group assignment (communicated knowingly or unknowingly by study personnel) could have influenced the reporting or assessment of events by individual study participants or caregivers. We judged SAEs with a low risk of bias, because a possible knowledge of the intervention status would probably not affect ascertainment of SAEs given the objectiveness of the outcome due to their underlying severity.

Risk of bias in NRSIs

The overall risk of bias in NRSIs was rated at least with a serious risk in about half of the outcomes (serious risk: 13/40; critical risk: 8/40). All but two assessed outcomes referred to effectiveness data. Key concerns mainly originated from incomplete or missing adjustment for relevant confounders (e.g. comorbidities, (time since) previous SARS-CoV-2 infection, socioeconomic status or risk of exposure, etc.). Outcomes that were not judged as “serious” or “critical” were rated with a moderate risk of bias (19/40), mainly due to potential residual confounding and the probability of selective reporting due to the retrospective study designs. Those were: SARS-CoV-2 infections reported in 6 studies,[14-19] symptomatic COVID-19 reported in 5 studies,[17,18,20-22] and COVID-19 related hospitalisation reported in 4 studies.[16,21-23]
As recommended in the ROBINS-I guidance, outcomes rated with a critical risk of bias were not further included in data synthesis.[2] Those were: SARS-CoV-2 infections in 1 study,[24] COVID-19 related hospitalisation reported in 3 studies,[25-27] ICU-admissions reported in 2 studies,[26,27] deaths reported in 1 study,[27] and myocarditis in 1 study.[28]

Risk of bias in single-arm studies

As only the approved dosing schedule was included in our review, data from dose-finding phase 1 trials were assessed along with other single-arm studies with the QUIPS-tool. All assessed outcomes were safety outcomes (SAEs, AESIs, local and systemic reactions, and unsolicited AEs), and 43/52 were rated as “high” for the overall risk of bias. Local and systemic reactions, and unsolicited AEs were mostly rated with a high risk of bias, mainly due to the subjectivity in the outcome assessment, and the potential of confounding due to missing assessment of relevant confounders (e.g. sex, comorbidities, etc.). Serious AEs and AESIs reported by the phase 1 trials[12,13] were judged with a moderate risk of bias, as confounding was also not considered. We had no concerns in outcome measurement as participants were closely monitored and objective definitions used. Serious AEs and AESIs reported by the observational studies were rated with a serious risk of bias, as in addition to concerns of potential confounding, there were concerns of attrition or in the measurement of the outcomes (e.g. because data was derived from a nationwide voluntary reporting system and several events probably not reported).

Study characteristics

Study, participant and intervention characteristics

Study	Study design	Type of publication	Geographical region	Study period	Variant of Concern	COI disclosures	Financial support	Follow-up
Amir et al[14]	Three arm retrospective cohort study†	Peer-reviewed	Israel	12.2021-01.2022	Omicron	Nothing to disclose	No funding received	≥ 14 days
Bartsch et al A[29]	Cohort study	Peer-reviewed	NR	NR	Wildtype, Beta, Delta, Omicron	Potentially irrelevant‡	Industry sponsored	28 days after each dose
Bartsch et al B[30]	Cohort study	Peer-reviewed	NR	NR	Wildtype,Alpha, Beta, Gamma, Delta, Omicron	Potentially relevant§	Non-industrial	14 and/or 28 days after each dose
Bloise et al[31]	Cross-sectional study¶	Peer-reviewed	Italy	15.12.-21.12.2021	NA‖	Nothing to disclose	No funding received	24–48 h, 7 and 20 days after each dose
Capponi et al[32]	Cross-sectional study†	Peer-reviewed	Italy	01.02.-28.02.2022	Omicron	Nothing to disclose	No funding received	14 days after each dose
Chantasrisawad et al[33]	single-arm phase 2 clinical trial	Peer-reviewed	Thailand	04.2022-05.2022	Omicron	Nothing to disclose	Non-industrial	14 days after second dose
Chemaitelly et al[16]	Matched cohort study†	Peer-reviewed	Qatar	01.-07.2022	Omicron	Nothing to disclose	No funding received	Median 69 days (IQR, 31-97 days)
Cinicola et al[34]	Cross-sectional study	Peer-reviewed	Italy	02.-03.2022	Wildtype, Omicron	Nothing to disclose	Non-industrial**	7 to 15 days after second dose
Cocchio et al[35]	Retrospective cohort study†	Peer-reviewed	Italy	02.-04.2022	Omicron	Nothing to disclose	No funding received	≥ 70 days after last dose
Cohen-Stavi et al[17]	Retrospective cohort study emulating a target trial†	Peer-reviewed	Israel	11.2021-01.2022	Omicron	Potentially relevant§	Non-industrial	14 to 27 days after first dose, 7 to 21 days after the second dose Median 17 days after first dose
Creech et al- Phase 2/3[13]	RCT, phase 2-3	Peer-reviewed	USA, Canada	NR	Pre-Omicron††	NR	Industry sponsored	Median 51 days after 2nd dose
Creech et al- Phase 1[13]	RCT, phase 1	Peer-reviewed	USA, Canada	NR	Pre-Omicron††	NR	Industry sponsored	NR
Dorabawila et al[25]	Retrospective cohort study†	Preprint	USA	11.2021-01.2022	Omicron	Nothing to disclose	No funding received	Up to 48 days
Doucette et al[36]	Longitudinal cohort study	Preprint	Canada	07.2020-04.2022	Omicron	NR	Non-industrial**	NR

Study	Study design	Type of publication	Geographical region	Study period	Variant of Concern	COI disclosures	Financial support	Follow-up
Elias et al[37]	Cross-sectional study[¶]	Peer-reviewed	USA	12.2021-02.2022	NA[‖]	Potentially relevant[§]	Non-industrial	1 to 304 days after vaccination (median 81 days [IQR, 48-193 days] after dose 1; 63 days [IQR, 36-173 days] after dose 2)
Flemming-Dutra et al[20]	Case-control, test-negative[†]	Peer-reviewed	USA	12.2021-02.2022	Omicron	Nothing to disclose	Non-industrial	2 months since 2nd dose
Fowlkes et al[15]	Prospective cohort study[¶]	Other	USA	12.2021-02.2022	Omicron	Potentially irrelevant[‡]	NR	14-82 days
Girard et al [38*]	Single-arm, observational	Preprint	USA, Canada	NR	Omicron	Potentially relevant[§]	Industry sponsored	Day 57 (28 Days post 2nd dose)
Hartono et al [39]	Case series[¶]	Peer-reviewed	USA	05.2021-02.2022	NA[‖]	Potentially relevant[§]	Non-industrial	NR
Hause et al A[40]	Passive surveillance, single-arm	Other	USA	11.2021-02.2022	NA[‖]	Potentially irrelevant[‡]	Non-industrial[**]	NR
Hause et al B[41]	Passive Surveillance, single-arm	Other	USA	05.-07.2022	NA[‖]	Nothing to disclose	Non-industrial[**]	NR
Hause et al C[42]	Passive Surveillance, single-arm	Other	USA	10.2022-01.2023	NA[‖]	Nothing to disclose	Non-industrial[**]	NR
Hu et al[43]	Active Surveillance, single-arm	Preprint	USA	11.2021- 06.2022	NA[‖]	Potentially irrelevant[‡]	Non-industrial[**]	From first day of vaccination to receipt of next dose, death, disenrollment, end of risk window or end of study period
Jang et al[19]	Retrospective cohort study	Peer-reviewed	South Korea	03.-08.2022	Omicron	Nothing to disclose	No funding received	Reported intervals: 15-30, 31-60, 61-90; used in meta-analysis: 15-30
Joseph et al[44]	Prospective cohort study	Peer-reviewed	Israel	11.2021-05.2022	Delta, Omicron	Nothing to disclose	No funding received	data collections on day 21 (visit 2), day 90 (visit 3), and day 180 (visit 4)
Kastl et al[45]	Prospective cohort study[¶]	Peer-reviewed	USA	03.2021 (onging)	NA[‖]	Potentially relevant[§]	Non-industrial	up to 18 months
Khan et al[18]	Case-control, test-negative[†]	Peer-reviewed	USA, Puerto Rico	11.2021-12.2021; 01.2022-09.2022	Delta, Omicron	Potentially relevant[§]	Industry sponsored	up to ≥90 days after vaccination
Kim et al[46]	Passive Surveillance, single-arm	Peer-reviewed	Korea	03.-07.2022	NA[‖]	Nothing to disclose	Non-industrial[**]	NR
Klein et al[47]	Case-control, test-negative	Other	USA	04.2021-01.2022	Omicron	Potentially relevant[§]	Non-industrial	14-67 days

Study	Study design	Type of publication	Geographical region	Study period	Variant of Concern	COI disclosures	Financial support	Follow-up
Leung et al A[48]	Retrospective ecological surveillance study†	Peer-reviewed	China	01.-04.2022	Omicron	Potentially irrelevant‡	Non-industrial	Mean 24 days (SD 9 days)
Leung et al B[49]	Non-randomized phase 2 trial	Preprint	China	05.2021-NR	Wildtype, Omicron	Nothing to disclose	Non-industrial	post-dose: 14-42 days, adverse reactions: 7 days unsolicited adverse events: 28 days
Malden et al[50]	Cross-sectional study¶	Peer-reviewed	USA	11.2021-02.2022	NA‖	Nothing to disclose	Non-industrial**	0 to 14 days after each dose
Mattiuzzi et al[26]	Retrospective cohort study	Short communication	Italy	Data until 27.04.2022	Omicron††	Nothing to disclose	No funding received	< 120 days since completion of primary vaccination schedule
Nygaard et al[51]	Prospective cohort study†	Peer-reviewed	Denmark	11.2021-03.2022	NA‖	Nothing to disclose	Non-industrial	At least 4 weeks; max. 97 days
Piché-Renaud et al[22]	Case-control, test-negative†	Preprint	Canada	01.-05.2022	Omicron (BA.1, BA.2)	Potentially relevant§	Non-industrial	≥90 days after vaccination
Price et al[52]	Case-control, test-negative¶	Peer-reviewed	USA	12.2021-02.2022	Omicron	Potentially irrelevant‡	Non-industrial	≥ 14 days
Ripabelli et al[53]	Active surveillance study	Peer-reviewed	Italy	12.2021-01.2022	NA‖	Nothing to disclose	No funding received	up to 10 days after vaccination
Rosa Duque et al[54]	Retrospective ecological study†	Preprint	China	01.-04.2022	Omicron (BA.2)	Potentially relevant§	Non-industrial	Mean 27·4 days
Sacco et al[21]	Retrospective cohort study†	Peer-reviewed	Italy	01.-04.2022	Omicron	Nothing to disclose	No funding received	SARS-CoV-2: Jan 17 to April 10 Severe disease: Jan 17 to March 13
Shi et al[27]	Retrospective cohort study†	Other	USA	12.2021-02.2022	Delta, Omicron	Potentially irrelevant‡	Non-industrial	≥14 days since last dose
Simmons et al[55]	Case-control study†	Preprint	Canada	02.2021-01.2022	Delta, Omicron	Potentially irrelevant‡	Non-industrial	NR
Stich et al[56]	Retrospective cohort study	Peer-reviewed	Germany	04.2021-04.2022	Omicron (BA.1)	Potentially relevant§	Non-industrial**	Median 34 days (IQR 22 to 63)
Straus et al[28]	Passive Surveillance, single-arm	Peer-reviewed	Global	12.2020-02.2022	NA‖	Potentially relevant§	Industry sponsored	From implementation of vaccine programmes to 15.02.2022
Suntronwong et al[24]	longitudinal serological cohort study¶	Preprint	Thailand	01.2021-11.2022	Omicron	Nothing to disclose	Non-industrial**	until 09.11.2022
Tan et al[23]	Cohort study†	Preprint	Singapore	01.-02.2022	Omicron	Nothing to disclose	No funding received	≥ 7 days after 2nd dose
Walter et al- Phase 2/3[12]	RCT, phase 2-3	Peer-reviewed	USA, Spain, Finland, and Poland	06.-10.2021	Pre-Omicron††	Potentially relevant§	Industry sponsored	Median 2·3 months (range, 0 to 2·5)

Study	Study design	Type of publication	Geographical region	Study period	Variant of Concern	COI disclosures	Financial support	Follow-up
Walter et al- Phase 1[12]	RCT, phase 1	Peer-reviewed	USA, Spain, Finland, and Poland	03.-09.2021	Pre-O micron[††]	Potentially relevant[§]	Industry sponsored	From dose 1 to 1 month after dose 2
Wanlapakorn et al[57]	prospective cohort study[¶]	Preprint	Thailand	03.-06.2022	Omicron	Nothing to disclose	Non-industrial	Safety: 7 days after each dose; Blood samples: before 1st dose and 2nd dose, and 1 month after 2nd dose
Wood et al[58]	Active surveillance study	Preprint	Australia	07.2021-05.2022	NA[‖]	Nothing to disclose	Non-industrial	Up to 3 days after each dose
Yoshida et al[59]	observational and historical cohort study	Peer-reviewed	Japan	up to 06.2022	NA[‖]	Potentially relevant[§]	Non-industrial[**]	7 days after each dose
Zambrano et al[60]	Case-control, test-negative[¶]	Peer-reviewed	USA	07.2021-04.2022	Omicron	Potentially irrelevant[‡]	Non-industrial	≥121 days

Study, participant and intervention characteristics (continued)

Study	Age in years	Sex (% female)	% seropositive or with known previous infection	Comorbidities (% of eg diabetes, cancer, etc)	Intervention	Number of doses	Number assigned to intervention group	Comparator	Number assigned to control group
Amir et al[14]	Range 5-10	% person days at risk: IG: 48·3% CG: 48·5%	0%	NR	BNT162b2	2	NR; person-days at risk 2nd dose = 366,364	BNT162b2 (3-7 days after 1st dose)	NR; person-days at risk internal control (3-7 days from 1st dose) = 367,168
Bartsch et al A[29]	Median 8 (range 6-11)	50·0%	0%	NR	mRNA-1273	2	12	NR	NR
Bartsch et al B[30]	Median 9 (range 5-11)	34%	0%	NR	BNT162b2	1-2	32	NA	NA
Bloise et al[31]	Mean: 114 months (SD: 4·24)‡‡	55·9%	6·4%	19·3%	BNT162b2	2	569	NA	NA
Capponi et al[32]	Mean 8·2 (SD 3)	47·0%	10·5%	5% (non-allergic) 12·3% (allergy)	BNT162b2	2	579	NA	NA
Chantasrisawad et al[33]	BNT162b2 (3 weeks): mean 8·4 (SD 1·8) BNT162b2 (8 weeks): 8·9 (SD 1·8)	BNT162b2 (3 weeks): 41·1% BNT162b2 (8 weeks): 59·3%	NR	NR	BNT162b2 (8 weeks)	2	56	BNT162b2 (3 weeks)	54
Chemaitelly et al[16]	Median 8 (IQR 8-12)	49·9%	0%	14·4%	BNT162b2	2	18,728	No vaccination	(IQR, 31-97 days)
Cinicola et al[34]	Mean 8·1 (SD 2·3)	37%	11·1%	NR	BNT162b2	2	27	NA	NA
Cocchio et al[35]	NR	NR	NR	NR	BNT162b2	2	40,318	No vaccination	81,895
Cohen-Stavi et al[17]	Median 8 (IQR 7-11)	49·0%	0%	8·0%	BNT162b2	2	94,728	No vaccination	94,728
Creech et al- Phase 2/3[13]	Mean 8·5 (SD 1·65)	49·2%	8·6%	NR	mRNA-1273	2	3007	Placebo	995
Creech et al- Phase 1[13]	Median 9 (range 6-11)	48·7%	7·4%	NR	mRNA-1273	2	380	NA	NA
Dorabawila et al[25]	IG: mean 8·3 (SD/range NR) CG: mean 7·8 (SD/range NR)	NR	NR	NR	BNT162b2	2	365,502	No vaccination	NR
Doucette et al[36]	Range 5-11	NR	NR	NR	BNT162b2, mRNA-1273	≥1	464	NA	NA

Study	Age in years	Sex (% female)	% seropositive or with known previous infection	Comorbidities (% of eg diabetes, cancer, etc)	Intervention	Number of doses	Number assigned to intervention group	Comparator	Number assigned to control group
Elias et al[37]	Median 8·0 (IQR 6·1-9·1)	IG: 32·2%	NR	NR	BNT162b2, mRNA-1273	1-2	87	NA	NA
Flemming-Dutra et al[20]	Median 8 (range 5-11)	49%	25·45%	NR	BNT162b2	2	15,778	No vaccination	58,430
Fowlkes et al[15]	Range 5-11	NR	NR	10·20%	BNT162b2	2	640	No vaccination	336
Girard et al[38*]	Mean 8·8 (range 6-11)	40·0%	0%	NR	mRNA-1273	2	20	NA	NA
Hartono et al[39]	Average 13 (range 8-17)[§§]	22·2%	NR	NR	BNT162b2	2	9	NA	NA
Hause et al A[40]	Mean 8 (range 5-11)	49·7%	NR	NR	BNT162b2	2	NR; approx. 16 million doses administered	NA	NA
Hause et al B[41]	NR	NR	NR	NR	BNT162b2	3rd dose	657,302	NA	NA
Hause et al C[42]	Median 9 (range 5-11)	49·0%	NR	NR	bivalent BNT162b2 or bivalent mRNA-1273	3rd-5th dose[¶¶]	953,359	NA	NA
Hu et al[43]	Range: 5-11	NR for age group	NR	NR	BNT162b2	1-3	NR, >1·8 million	NA	NA
Jang et al[19]	Range: 5-11	IG: 49·5% CG: 48·7%	IG: 20·5% CG: 47·7%	NR	BNT162b2	2	29,473	No vaccination	3,016,913
Joseph et al[44]	Mean 9·18 (SD 1·97, range 5-11)	37·3%	0%	NR	BNT162b2	2	110	NA	NA
Kastl et al[45]	Range 5-11	44%	10%	100% (inflammatory bowel disease)	BNT162b2	2-3	118	NA	NA
Khan et al[18]	Mean 9 (SD 2)	51%	Cases: 9% Controls: 18%	3-4%	BNT162b2	1-3	69,383	No vaccination	101,420
Kim et al[46]	Range 5-11	NR	NR	NR	BNT162b2	1-2	NR, approx. 58,636 (number of administered 1st doses)	NA	NA
Klein et al[47]	NR	51·7%	NR	8·1% chronic respiratory conditions, 4·6% chronic non-respiratory condition	BNT162b2	2	582	No vaccination	8599
Leung et al A[48]	NR	NR	NR	NR	BNT162b2	1	71,207	No vaccination	181,973

Study	Age in years	Sex (% female)	% seropositive or with known previous infection	Comorbidities (% of eg diabetes, cancer, etc)	Intervention	Number of doses	Number assigned to intervention group	Comparator	Number assigned to control group
Leung et al B[49]	9·1 (IQR 8·6-12·1)	52%	NR	Advanced chronic kidney disease (stage 3 or above)	BNT162b2	1-3	25	NA	NA
Malden et al[50]	Median 8 (range 5-11)	49%	10%	NR	BNT162b2	1-2	7,077	NA	NA
Mattiuzzi et al[26]	Range 5-11	NR	NR	NR	BNT162b2 or mRNA-1273	2	1,204,468	No vaccination	2,291,598
Nygaard et al[51]	Range 5-11	NR	NR	NR	BNT162b2	1-2	208,088	NA	433,484
Piché-Renaud et al[22]	IG: mean 7·82 (SD 2·05) CG: mean 7·4 (SD 2·1)	IG: 46·1% CG: 48·3%	IG: 2·2% CG: 3·6%	IG: 23·1% CG: 22·8%	BNT162b2	1-2	8606	No vaccination	4314
Price et al[52]	Median 8 (IQR 6-10)	44·0%	NR	82% of cases, and 73% of controls with at least 1 underlying condition	BNT162b2	2	70	No vaccination	467
Ripabelli et al[53]	Mean 8·9 (SD 1·8)	50·7%	0·06%	6·6%	BNT162b2	1-2	229	NA	NA
Rosa Duque et al[54]	Range: 5-11	42·8%	NR	NR	BNT162b2	1	12	No vaccination	956
Sacco et al[21]	Range: 5-11	48·6%	0%	NR	BNT162b2	2	1,063,035	No vaccination	176,8497
Shi et al[27]	IG: median 9 (IQR 8-11) CG: median 7 (IQR 8-9)	45·6%	NR	NR	BNT162b2	2	48	No vaccination	301
Simmons et al[55]	NR	NR	NR	Immunocompromised: 0·9% asthma: 1·9%	BNT162b2 or mRNA-1273	1	NR	No vaccination	NR
Stich et al[56]	Range 5-11	NR	NR	100% (chronic kidney disease including kidney transplant recipients)	BNT162b2	2	43	NA	NA
Straus et al[28]	NR; <12[llll]	52·4%	NR	NR	mRNA-1273	1-3	36,782 Person-Years	No vaccination[***]	NR
Suntronwong et al[24]	Range 5-7	51·4%	27·4%	NR	BNT162b2	1-3	89	No vaccination	108
Tan et al[23]	Median 8 (IQR 6-10)	48·7%	NR	NR	BNT162b2	2	110,339	No vaccination	65,411
Walter et al- Phase 2/3[12]	Mean 8·2 (SD 1·94)	47·9%	8·7%	20·5%	BNT162b2	2	1528	Placebo	757

Study	Age in years	Sex (% female)	% seropositive or with known previous infection	Comorbidities (% of eg diabetes, cancer, etc)	Intervention	Number of doses	Number assigned to intervention group	Comparator	Number assigned to control group
Walter et al- Phase 1[12]	Mean 7·9 (SD 1·89)	68·7%	NR	NR	BNT162b2	2	16	NA	NA
Wanlapakorn et al[57]	Mean 6·2 (SD 1·1)	53·3%	10%	10% (asthma, autism)	BNT162b2	2	30	NA	NA
Wood et al[58]	Range: 5-11	Dose 1: 28·0% Dose 2: 30·0%	NR	Dose 1: 36·0%, Dose 2: 39·0%	BNT162b2	1-3	Dose 1: 132,313 Dose 2: 79,542	NA	NA
Yoshida et al[59]	Mean 8·8 (SD 1·9)	48·7%	NR	51·3% (allergic disease)	BNT162b2	1-2	421	NA	NA
Zambrano et al[60]	Cases: median 8·5 (IQR 6·9-10·3) Controls: median 7·9 (IQR 6·7-9·7)	NR	NR	NR	BNT162b2	2	53	No vaccination	321

NR: not reported, CG: control group, COI: conflicts of interest, IG: intervention group, IQR: inter quartile range, NA: not applicable, not reported, RCT: randomised controlled trial, SD standard deviation

[*]Subsample of Creech et al. [†]Passive surveillance (registries used). [‡]Less than 33% of authors and neither first-or last author declare relevant financial COIs (see column COI disclosures). [§]More than 33% of authors or first-or last author declare relevant financial COIs (see column COI disclosures). [¶]Active surveillance. [‖]Variant of concern not relevant in safety-only studies. [**]Academia or governmental. [††]If variants were not reported by the study, cases were differentiated by calendar time. [‡‡]Average age indicated as it was reported. Age given in months. [§§]Average age indicated as it was reported. The data were extracted exclusively from cases between 5 and 11 years of age. [¶¶]Bivalent booster, children had already received 2-4 doses before further booster. [‖‖]This could also include children <5 years of age, but mRNA-1273 was not approved in younger children before the end of the observation period. [***]Compared with expected rate from a population-based data estimate derived from individuals without a diagnosis of COVID-19 between March 2020 and January 2021 from the US Premier Healthcare Database.

Overview of reported outcomes per study

Study	Efficacy/Effectiveness							Immunogenicity			Safety				
	COVID-19 related mortality	ICU admission due to COVID-19	Hospital admission due to COVID-19	Symptomatic COVID-19	SARS-CoV-2 infection	Multisystem inflammatory syndrome in children (MIS-C)	Long-term effects of COVID-19 ('Long COVID' or Post-COVID)	Neutralizing antibody response	IgG response	T-cell response	Adverse events	Serious adverse events	Reactogenicity -local events	Reactogenicity - systemic reactions	Adverse events of special interest
Amir et al[14]	..	..	..	..	Yes	..	..	..	..	..	..	..	..	..	..
Bartsch et al A[29]	..	..	..	..	..	..	..	Yes	..	..	..	..	..	..	..
Bartsch et al B[30]	..	..	..	..	..	..	..	Yes[†]	Yes[†]	Yes[†]	..	..	..	..	..
Bloise et al[31]	..	..	..	..	..	..	..	..	..	..	Yes[‡]	Yes[‡]	..	..	Yes[‡]
Capponi et al[32]	..	..	..	..	..	..	..	..	..	..	Yes[‡]	Yes[‡]	Yes[‡]	Yes[‡]	Yes[‡]
Chantasrisawad et al[33]	..	..	..	..	..	..	..	Yes	Yes	..	..	..	..	..	..
Chemaitelly et al[16]	Yes	Yes	Yes	..	Yes	..	..	..	..	..	..	..	..	..	..
Cinicola et al[34]	..	..	..	..	..	..	..	Yes	Yes	Yes	..	..	..	..	..
Cocchio et al[61]	..	..	..	..	Yes	..	..	..	..	..	..	..	..	..	..
Cohen-Stavi et al[17]	..	..	..	Yes	Yes	..	..	..	..	..	..	..	..	..	..
Creech et al-Phase 2/3[13]	..	..	..	Yes	Yes	Yes	..	..	..	..	..	..	..	..	..
Creech et al-Phase 1[13]	..	..	..	..	..	..	..	..	..	..	Yes	Yes	Yes	Yes	Yes
Dorabawila et al[25]	..	..	Yes	..	Yes[§]	..	..	..	..	..	..	..	..	..	..
Doucette et al[36]	..	..	..	..	..	..	..	..	Yes	..	..	..	..	..	..
Elias et al[37]	..	..	..	..	..	..	..	..	..	..	Yes[‡]	..	..	..	..
Fleming-Dutra et al[20]	..	..	..	Yes	..	..	..	..	..	..	..	..	..	..	..
Fowlkes et al[15]	..	..	..	..	Yes	..	..	..	..	..	..	..	..	..	..
Hartono et al[39]	..	..	..	..	..	..	..	..	..	..	..	..	..	..	Yes[‡]

Study	Efficacy/Effectiveness							Immunogenicity			Safety				
	COVID-19 related mortality	**ICU admission due to COVID-19**	**Hospital admission due to COVID-19**	**Symptomatic COVID-19**	**SARS-CoV-2 infection**	**Multisystem inflammatory syndrome in children (MIS-C)**	**Long-term effects of COVID-19 ('Long COVID' or Post-COVID)**	**Neutralizing antibody response**	**IgG response**	**T-cell response**	**Adverse events**	**Serious adverse events**	**Reactogenicity -local events**	**Reactogenicity - systemic reactions**	**Adverse events of special interest**
Hause et al A[40]	..	..	..	..	..	..	..	..	..	..	Yes‡	Yes‡	Yes‡	Yes‡	Yes‡
Hause et al B[41]	..	..	..	..	..	..	..	..	..	..	Yes‡	Yes‡	Yes‡	Yes‡	Yes‡
Hause et al C[42]	..	..	..	..	..	..	..	..	..	..	Yes‡	Yes‡	Yes‡	Yes‡	Yes‡
Hu et al[43]	..	..	..	..	..	..	..	..	..	..	..	..	..	..	Yes‡
Jang et al[19]	..	..	..	Yes	Yes	..	..	..	..	..	..	..	..	..	..
Joseph et al[44]	..	..	..	..	..	..	..	Yes	Yes	..	..	Yes	Yes	Yes	..
Kastl et al[45]	..	..	..	..	..	..	..	..	Yes	..	..	..	..	..	..
Khan et al[18]	..	..	..	Yes	Yes	..	..	..	..	..	..	..	..	..	..
Kim et al[46]	..	..	..	..	..	..	..	..	..	..	Yes‡	Yes‡	Yes‡	Yes‡	Yes‡
Klein et al[47]	..	..	Yes	..	..	..	..	..	..	..	..	..	..	..	..
Leung et al A[48]	..	..	..	..	Yes¶	..	..	..	..	..	..	..	..	..	..
Leung et al B[49]	..	..	..	..	..	..	..	Yes	Yes	Yes	Yes	Yes	Yes	Yes	..
Malden et al[50]	..	..	..	..	..	..	..	..	..	..	Yes‡	..	Yes‡	Yes‡	..
Mattiuzzi et al[26]	..	Yes§	Yes§	..	..	..	..	..	..	..	..	..	..	..	..
Nygaard et al[62]	..	..	..	..	..	..	..	..	..	..	..	..	..	..	Yes‡
Girard et al [38]*	..	..	..	..	..	..	..	Yes	..	..	..	..	..	..	..
Piché-Renaud et al[22]	..	..	Yes	Yes	..	..	..	..	..	..	..	..	..	..	..
Price et al[52]	Yes	Yes	Yes	..	..	..	..	..	..	..	..	..	..	..	..
Ripabelli et al[53]	..	..	..	..	..	..	..	..	..	..	Yes‡	Yes‡	..	..	..
Rosa Duque et al[54]	..	..	Yes¶	..	..	..	..	..	..	..	..	..	..	..	..
Sacco et al[21]	Yes	Yes	Yes	Yes	Yes	..	..	..	..	..	..	..	..	..	..
Shi et al[27]	Yes§	Yes§	Yes§	..	..	..	..	..	..	..	..	..	..	..	..
Simmons et al[55]	..	..	Yes¶	..	..	..	..	..	..	..	..	..	..	..	..

Study	Efficacy/Effectiveness							Immunogenicity			Safety				
	COVID-19 related mortality	**ICU admission due to COVID-19**	**Hospital admission due to COVID-19**	**Symptomatic COVID-19**	**SARS-CoV-2 infection**	**Multisystem inflammatory syndrome in children (MIS-C)**	**Long-term effects of COVID-19 ('Long COVID' or Post-COVID)**	**Neutralizing antibody response**	**IgG response**	**T-cell response**	**Adverse events**	**Serious adverse events**	**Reactogenicity -local events**	**Reactogenicity - systemic reactions**	**Adverse events of special interest**
Stich et al[56]	..	..	..	..	..	..	..	Yes	..	..	..	..	..	..	..
Straus et al[28]	..	..	..	..	..	..	..	..	..	..	..	..	..	..	Yes‡
Suntronwong et al[24]	..	..	..	..	Yes§	..	..	..	..	..	..	..	..	..	..
Tan et al[23]	..	..	Yes	Yes	..	..	..	..	..	..	..	..	..	..	..
Walter et al-Phase 2/3[12]	Yes	Yes	Yes	Yes	..	Yes	..	Yes	..	..	Yes	Yes	Yes	Yes	Yes
Walter et al-Phase 1[12]	..	..	..	..	..	..	..	Yes	..	..	Yes‡	Yes‡	Yes‡	Yes‡	Yes‡
Wanlapakorn et al[57]	..	..	..	..	..	..	..	Yes	Yes	..	..	..	Yes	Yes	..
Wood et al[58]	..	..	..	..	..	..	..	..	..	..	Yes‡	..	Yes‡	Yes‡	Yes‡
Yoshida et al[59]	..	..	..	..	..	..	..	..	..	..	..	..	..	Yes‡	..
Zambrano et al[60]	..	..	..	..	..	Yes	..	..	..	..	..	..	..	..	..

*Subsample of Creech et al. †Outcome data presented graphically only. ‡Safety data from single-arm studies were not included in meta-analysis. §Estimates excluded from meta-analysis due to critical risk of bias (see Appendix 2). ¶Estimates were excluded from the meta-analysis since a single-dose scheme was examine.

Vaccine effectiveness

Vaccine effectiveness against pre-Omicron SARS-CoV-2 variants

SARS-CoV-2 infection

One NRSI assessed VE after the first dose against Delta-infections (VE 56%, 95% CI 50 to 61, N=61,350).[18] VE after two doses against SARS-CoV-2 infections with pre-Omicron virus variants (not specified) was 73% (95% CI 41% to 87%, N=3497, CoE: moderate) in the identified RCT, and 85% (95% CI 80 to 89, N=59,786, CoE: moderate) in a NRSI against Delta-infections. Booster vaccinations were not recommended for children 5-11 years before the Omicron era.

Symptomatic COVID-19

Single-dose VE against symptomatic COVID-19 was 49% (95% CI 37 to 59, 1 NRSI, N=61,350) in the Delta-era.[18] VE against symptomatic COVID-19 caused by pre-Omicron variants after complete basic immunization (i.e. 2 doses) was 86·7% (95% CI 58·1% to 95·8%, 2 RCTs, N=5465, CoE: moderate) in RCTs and 84% (95% CI 75 to 91, 1 NRSI, N=59,786, CoE: moderate) in an observational study.

Hospitalisation due to COVID-19

Hospitalisations due to COVID-19 were reported in one RCT (pre-Omicron era), with no cases in either group.[12]

COVID-19 related mortality

COVID-19 related mortality was reported in one RCT (pre-Omicron era). No deaths were reported for either group.[12]

Multisystem inflammatory syndrome in children (MIS-C)

There were zero cases of MIS-C reported in the RCTs.

Long-term effects of COVID-19 ('Long COVID' or Post-COVID)

We identified no data on the effect of COVID-19 vaccination on long COVID, neither from RCTs nor from observational studies.

The summary of our vaccine effectiveness findings against pre-Omicron SARS-CoV-2 variants comprising relative and absolute effects and GRADE assessments are presented per outcome in the table below.

Summary of vaccine effectiveness findings against pre-Omicron SARS-CoV-2 variants

Population: Children, aged 5-11 years
Intervention: EMA-approved COVID-19 mRNA vaccines (BNT162b2, 2 doses à 10 μg, 21 days apart OR mRNA-1273, 2 doses à 50 μg, 28 days apart)
Comparison: Placebo or no intervention
Outcomes: Vaccine efficacy/effectiveness
Setting: Pre-Omicron SARS-CoV-2 variants

Outcomes	Design	Absolute effect* with placebo/no vaccination	Absolute effect* with vaccination	Relative effect† (95% CI)	Timing of outcome measurement	No. of participants (studies)	Certainty of the evidence (GRADE)
SARS-CoV-2 infection (PCR- or antigen-test confirmed)	RCT	1641 per 100,000	**443 per 100,000** (213 to 968)	VE 73% (41-87); IRR 0·27 (0·13-0·59)	Median 51 days after 2nd dose	3497[13]	⊕⊕⊕◯ MODERATE[a]
	NRSI	17,491 per 100,000	**2624 per 100,00** (1574 to 3498)	VE 85% (80-89); VE-ratio 0·15 (0·11-0·20)	Up to 3 months after 2nd dose	59,786[18]	⊕⊕⊕◯ MODERATE[b]
Symptomatic COVID-19	RCT	1,319 per 100,000	**175 per 100,000** (55 to 553)	VE 86·7% (58·1-95·8); IRR 0·13 (0·042-0·42)	Median 50-70 days after 2nd dose	5465[12,13]	⊕⊕⊕◯ MODERATE[c]
	NRSI	NR‡	**N.E.**	VE 84% (75-91); VE-ratio 0·16 (0·09-0·25)	Up to 3 months after 2nd dose	59,786[18]	⊕⊕⊕◯ MODERATE[b]
Hospitalisation due to COVID-19	RCT	N.E., 0 cases observed	**N.E.,** 0 cases observed	VE N.E., 0 cases observed	Median 2·3 months after 2nd dose	2285[12]	⊕⊕◯◯ LOW[d]
	NRSI	NA	NA	VE NA	NA	0	NA
COVID-19 related mortality	RCT	N.E., 0 cases observed	**N.E.,** 0 cases observed	VE N.E., 0 cases observed	Median 2·3 months after 2nd dose	2285 ([12])	⊕⊕◯◯ LOW[d]
	NRSI	NA	NA	VE NA	NA	0	NA
Multisystem inflammatory syndrome in children (MIS-C)	RCT	N.E., 0 cases observed	**N.E.,** 0 cases observed	VE N.E., 0 cases observed	Median 50-70 days after 2nd dose	5465[12,13]	⊕⊕◯◯ LOW[d]
	NRSI	NA	NA	VE NA	NA	0	NA
Long-term effects of COVID-19 ('Long COVID' or Post-COVID)	RCT	NA	NA	VE NA	NA	0	NA
	NRSI	NA	NA	VE NA	NA	0	NA

Abbreviations: **CI:** confidence interval, **EMA:** European Medicines Agency, **GRADE:** Grading of Recommendations, Assessment, Development and Evaluation, **NA:** not applicable, **N.E.:** not estimable, **NR:** not reported, **NRSI:** non-randomized study of intervention, **PCR:** polymerase chain reaction, **RCT:** randomized controlled trial, **SARS-CoV-2**: Severe acute respiratory syndrome coronavirus type 2, **VE:** vaccine efficacy/effectiveness
Footnotes: *Note: The estimated absolute effect refers to the difference between the observed baseline risk reported for the unvaccinated control group and the risk for experiencing an outcome after vaccination. The absolute effect estimated for the intervention group is based on the relative effect magnitude of an effect and the baseline risk; i.e. (observed risk /100,000 unvaccinated children) * relative effect. † Note: Relative effects (vaccine effectiveness [VE] or risk ratios [RR] were derived from meta-analysis, or of one study if no pooled estimate was available. ‡Note: Crude number of symptomatic COVID-19 cases in unvaccinated children not reported.
GRADE Working Group grades of evidence: **High certainty:** we are very confident that the true effect lies close to that of the estimate of the effect. **Moderate certainty:** we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is the possibility that it is substantially different. **Low certainty:** our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect. **Very low certainty:** we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.
Support for Judgements: [a]One level for serious imprecision (one study with few events). [b]One level for serious imprecision (data of only one study). [c]One level for serious imprecision (artificial precision induced by analysis method). [d]Two levels for very serious imprecision (zero or few events).

Vaccine effectiveness against Omicron SARS-CoV-2 variant

Vaccine effectiveness against SARS-CoV-2 infections and symptomatic COVID-19 over time

Study	Timepoint of first measurement after full vaccination (T_1)	VE (95% CI) at T_1	Timepoint of last measurement after full vaccination (T_2)	VE (95% CI) at T_2
SARS-CoV-2 Infections				
Chemaitelly 2022[16]	1 month	49·6% (28·5 to 64·5)	4+ months	-9·5% (-76·8 to 32·2)
Cocchio 2022[61]	14 to 34 days	53% (51 to 55)	70+ days	23% (20 to 26)
Dorabawila 2022[25]	14 to 20 days	52% (49 to 53)	42 to 48 days	-41% (-65 to -29)
Khan 2022[18]	1 month after dose 2	45% (41 to 49)	9+ months after dose 2	-2% (-32 to 20)
Khan 2022[18]	1 month after dose 3	58% (50 to 46)	4 months after dose 3	53% (-5 to 79)
Jang 2023[19]	15 to 30 days	57·6% (51·6 to 62·8)	61 to 90 days	41·2% (34·3 to 47·4)
Symptomatic COVID-19				
Piché-Renaud 2022[22]	7 to 29 days	67% (60 to 72)	90+ days	35% (21 to 46)
Sacco 2022[21]	15 to 28 days	29·3% (28·1 to 30·4)	43 to 84 days	21·2% (19·7 to 22·7)
Khan 2022 (BA.4/5 subline)[18]	3 months after dose 2	7% (-3 to 16)	9+ months after dose 2	-4% (-37 to 21)
Khan 2022 (BA.4/5 subline)[18]	3 months after dose 3	56% (47 to 63)	3 to 5 months after dose 3	48% (24 to 65)

Single-dose vaccine effectiveness

Two studies each assessed VE after the first dose against Omicron-infections (VE 18·9%, 95% CI 0·2 to 34·2),[18,49] against symptomatic COVID-19 (VE 9·9%, 95% CI 3·6 to 15·7),[18,22] and against hospitalizations due to COVID-19 (VE 55·2%, 95% CI 16·1 to 76·1).[54,55]

Vaccine safety

Overview of reported safety outcomes

Study	Outcome definition	Follow-up	Participants in intervention group with event	Participants in control group with event	Relative effect (95% CI)
Serious adverse events					
Bloise et al[31]	Any SAEs as per standard definition[*]	Any Dose - ≤20 days	0/569	/	/
Capponi et al[32]	Any SAEs as per standard definition[*], including myocaridits and anaphylaxis	Dose 2 - ≤2 weeks	0/579	/	/
Creech et al - Phase 1[13]	Any SAEs as per standard definition[*]	Any Dose - ≤28 days	2/380	/	/
		Any Dose - >28 days	3/380	/	/
Creech et al - Phase 2/3[13]	Any SAEs as per standard definition[*]	Any Dose - median of 82 days (IQR 14-94)	6/3007	2/995	RR 0·99 (0·20 to 4·91)
haHause et al A[40]	Any SAEs as per standard definition[*,†]	Any Dose - ≤21 days	194/ approx. 16 Million	/	/
	Deaths[†]	Any Dose - ≤21 days	4/ approx. 16 Million	/	/
Hause et al B[41]	Any SAEs as per standard definition[*,†]	Dose 3 - ≤10 weeks	3/657,302	/	/
	Deaths[†]	Dose 3 - ≤10 weeks	0/657,302	/	/
Hause et al C[42]	Any SAEs as per standard definition[*,†]	3rd-5th Dose - January 1st, 2023	2/861,251	/	/
	Deaths[†]	3rd-5th Dose - January 1st, 2023	0/861,251	/	/
Joseph et al[44]	Any SAE	Any Dose	0/110	/	/
Kim et al[46]	Any SAEs as per standard definition[*]	Any Dose - July 2nd, 2022	2/94,518	/	/
Leung et al B[49]	Any SAE	Any Dose	0/25	/	/
Ripabelli et al[53]	SAEs (fever ≥39°C, paresthesia, clustered rash)	Dose 1 - up to 7 to 10 days after vaccination	3/229	/	/
		Dose 2 - up to 7 to 10 days after vaccination	1/199	/	/
Walter et al – Phase 1[12]	Any SAEs as per standard definition[*]	Any Dose - median of 2· 3 months (range 0-2· 5)	0/16	/	/
Walter et al – Phase 2/3[12]	Any SAEs as per standard definition[*]	Any Dose - median of 2· 3 months (range 0-2· 5)	1/1518	1/750	RR 0·49 (0·03 to 7·89)
Adverse events of special interest					
Bloise et al[31]	Myocarditis or pericarditis	Any Dose - ≤20 days	0/569	/	/
Capponi et al[32]	Myocarditis or pericarditis	Dose 2 - ≤2 weeks	0/579	/	/
Creech et al - Phase 1[13]	Any AE (serious or nonserious) of scientific and medical concern specific to the Sponsor's product or program[‡]	Any Dose - ≤28 days	0/380	/	/
		Any Dose - >28 days	5/380	/	/
Creech et al - Phase 2/3[13]	Any AE (serious or nonserious) of scientific and medical concern specific to the Sponsor's product or program[‡]	Any Dose - median of 82 days (IQR 14-94)	4/3007	2/995	RR 0·66 (0·12 to 3·61)
Hause et al A[40]	Verified myocarditis reports[†]	Any Dose - ≤21 days	17/ approx. 16 Million	/	/
	MIS-C, CDC case definition[†]	Any Dose - ≤21 days	21/ approx. 16 Million	/	/
	Confirmed MIS-C[§]	Any Dose - ≤21 days	4/384,905	/	/
Hause et al B[41]	Myocarditis	Dose 3 - ≤10 weeks	0/657,302	/	/

Study	Outcome definition	Follow-up	Participants in intervention group with event	Participants in control group with event	Relative effect (95% CI)
Hause et al C[42]	Myocarditis	3rd-5th Dose - January 1st, 2023	0/861,251	/	/
Hu et al[43]	Myocarditis/Pericarditis[¶]	Any Dose - ≤21 days	<11/603,585	/	/
	Myocarditis/Pericarditis[‖]	Any Dose - ≤21 days	<11/572,742	/	/
	Myocarditis/Pericarditis[**]	Any Dose - ≤21 days	<11/ 605,143	/	/
Kim et al[46]	Myocarditis/pericarditis	Any Dose - July 2nd, 2022	1/94,518	/	/
Hartono et al[39]	Allergic reactions	Dose 2[††]	1/9	/	/
Nygaard et al[51]	Myopericarditis	Any Dose - ≤97 days	1/ 208,088	9/433,484[‡‡]	RR 4·6 (0·1 to 156·1)
Straus et al[28]	Myocarditis and myopericarditis (Brighton collaboration case definition) [§§]	Any Dose - February 15th, 2022	0/49,043 Person-Years	expected: 4/100,000 Person- Years[¶¶]	NA
Walter et al – Phase 1[12]	Myocarditis, pericarditis, hypersensitivity, or anaphylaxis	Any Dose - median of 2· 3 months (range 0-2· 5)	0/16	/	/
Walter et al – Phase 2/3[12]	Myocarditis, pericarditis, hypersensitivity, or anaphylaxis	Any Dose - median of 2.3 months (range 0-2.5)	0/1501	0/741	NA
Wood et al[58]	Myocarditis or pericarditis	Dose 1 - ≤3 days	0/132,313	/	/
		Dose 2 - ≤3 days	0/79,542	/	/
		Dose 3 - ≤3 days	0/59	/	/
Local reactions					
Capponi et al[32]	Any local reaction (pain, tenderness, itch, redness)	Dose 1 - NR	314/579	/	/
		Dose 2 - ≤2 weeks	309/579	/	/
Creech et al - Phase 1[13]	Solicited local adverse reactions (injection site pain/tenderness, erythema (redness swelling/induration (hardness), groin or underarm swelling or tenderness ipsilateral to the side of injection)	Dose 1 - ≤7 days	339/378	/	/
		Dose 2 - ≤7 days	355/379	/	/
Creech et al - Phase 2/3[13]	Solicited local adverse reactions (injection site pain/tenderness, erythema (redness swelling/induration (hardness), groin or underarm swelling or tenderness ipsilateral to the side of injection)	Dose 1 - ≤7 days	2818/3005	481/994	RR 1·94 (1·82 to 2·07)
		Dose 2 - ≤7 days	2847/2986	491/968	RR 1·88 (1·77 to 2·00)
Hause et al A[40]	Local reactions (Injection site reactions were: itching, injection site pain, redness, or swelling)	Dose 1 - ≤7 days	27,716/48,795	/	/
		Dose 2 - ≤7 days	22,396/39,416	/	/
Hause et al B[41]	Local reactions (Injection site reactions were: itching, injection site pain, redness, or swelling)	Dose 3 - ≤7 days	2226/3249	/	/
Hause et al C[42]	Local reactions (Injection site reactions were: itching, injection site pain, redness, or swelling)	3rd-5th Dose - ≤7 days	1740/2647	/	/
Joseph et al[44]	Any local reaction (pain at injection site, erythema, edema, itching)	Dose 1 ≤7 days	37/110	/	/

Study	Outcome definition	Follow-up	Participants in intervention group with event	Participants in control group with event	Relative effect (95% CI)
	Any local reaction (pain at injection site, erythema, edema, itching)	Dose 2 ≤7 days	20/110	/	/
Kim et al[46]	Local reactions (pain, redness, swelling, itching, urticaria, and others (not further defined) ‖ ‖	Dose 1 - ≤7 days	336/1025	/	/
		Dose 2 - ≤7 days	148/541	/	/
Leung et al B[49]	Local reactions (headache, fatigue, myalgia, nausea, diarrhea, and others (not further defined)	Dose 1-3	Number of events not reported, but frequencies presented graphically (see figure 5 of the referenced manuscript)	/	/
Malden et al[50]	Local reactions (fatigue, headache, myalgia, fever, nausea, rash, chills)	Dose 1 - ≤14 days	3140/6247	/	/
		Dose 2 - ≤14 days	1113/3401	/	/
Walter et al – Phase 1[12]	Local reactions (injection site pain, tenderness, redness, or swelling)	Dose 1 - ≤7 days	14***/16	/	/
		Dose 2 - ≤7 days	14***/16	/	/
Walter et al – Phase 2/3[12]	Local reactions (injection site pain, tenderness, redness, or swelling)	Dose 1 - ≤7 days	1150/1511	254/749	RR 2·24 (2·02 to 2·49)
		Dose 2 - ≤7 days	1096/1501	237/741	RR 2·28 (2·05 to 2·55)
Wanlapakorn et al.[57]	Local reactions (mostly pain at injection site, redness, swelling)	Dose 1 - ≤7 days, Dose 2 - ≤7 days	Overall number of participants with events not reported, but for each observed reaction (see figure 2 of the referenced manuscript)	/	/
Wood et al[58]	Any local reaction (pain, itching, redness, swelling)	Dose 1 - ≤3 days	28,997/132,313	/	/
		Dose 2 - ≤3 days	18,560/79,542	/	/
		Dose 3 - ≤3 days	16/59	/	/
Systemic reactions					
Capponi et al[32]	Any systemic reaction (asthenia, headache, fever >37,5C, joint pain, abdominal pain, chills, rash)	Dose 1 - NR	166/579	/	/
		Dose 2 - ≤2 weeks	198/579	/	/
Creech et al - Phase 1[13]	Solicited systemic adverse reactions (Solicited systemic reactions were: fever, irritability/crying, sleepiness, loss of appetite)	Dose 1 - ≤7 days	207/378	/	/
		Dose 2 - ≤7 days	284/379	/	/
Creech et al - Phase 2/3[13]	Solicited systemic adverse reactions (Solicited systemic reactions were: fever, irritability/crying, sleepiness, loss of appetite)	Dose 1 - ≤7 days	1743/3005	519/994	RR 1·11 (1·04 to 1·19)
		Dose 2 - ≤7 days	2332/2986	485/968	RR 1·56 (1·46 to 1·66)

Study	Outcome definition	Follow-up	Participants in intervention group with event	Participants in control group with event	Relative effect (95% CI)
Hause et al A[40]	Systemic reactions (abdominal pain, myalgia, chills, diarrhea, fatigue, fever, headache, joint pain, nausea, rash, or vomiting)[†††]	Dose 1 - ≤7 days	20,006/48,795	/	/
		Dose 2 - ≤7 days	16,161/39,416	/	/
Hause et al B[41]	Systemic reactions (abdominal pain, myalgia, chills, diarrhea, fatigue, fever, headache, joint pain, nausea, rash, or vomiting)[†††]	Dose 3 - ≤7 days	1482/3249	/	/
Hause et al C[42]	Systemic reactions (abdominal pain, myalgia, chills, diarrhea, fatigue, fever, headache, joint pain, nausea, rash, or vomiting)[†††]	3rd-5th Dose - ≤7 days	1215/2647	/	/
Joseph et al[44]	Any systemic reaction (fatigue, fever, myalgia, headache, lymphadenopathy)	Dose 1 ≤7 days	12/110	/	/
		Dose 2 ≤7 days	7/110	/	/
Kim et al[46]	Systemic reactions (fever, chills, headache, joint pain, myalgia, fatigue or tiredness, nausea, vomiting, diarrhea, abdominal pain, rash, armpit tenderness, chest pain, heart palpitations, and others (not further defined)[‡‡‡]	Dose 1 - ≤7 days	275/1025	/	/
		Dose 2 - ≤7 days	121/541	/	/
Leung et al B[49]	Systemic reactions (headache, fatigue, myalgia, nausea, diarrhea, and others (not further defined)	Dose 1-3	Number of events not reported, but frequencies presented graphically (see figure 5 of the referenced manuscript)	/	/
Malden et al[50]	Systemic reactions (fatigue, headache, myalgia, fever, nausea, rash, chills[ɔ]	Dose 1 - ≤14 days	2 176/6 247	/	/
		Dose 2 - ≤14 days	1 076/3 401	/	/
Walter et al – Phase 1[12]	Systemic reactions (fever, vomiting, diarrhea, headache, fatigue/tiredness, chills, new or worsened muscle or joint pain)	Dose 1 - ≤7 days	8[§§§]/16	/	/
		Dose 2 - ≤7 days	8[§§§]/16	/	/
Walter et al – Phase 2/3[12]	Systemic reactions (fever, vomiting, diarrhea, headache, fatigue/tiredness, chills, new or worsened muscle or joint pain)	Dose 1 - ≤7 days	715/1511	334/749	RR 1·06 (0·96 to 1·17)
		Dose 2 - ≤7 days	771/1501	272/741	RR 1·40 (1·26 to 1·56)
Wanlapakorn et al.[57]	Systemic reactions (fever, headache, myalgia, nausea, vomiting, diarrhea)	Dose 1 - ≤7 days, Dose 2 - ≤7 days	Overall number of participants with events not reported, but for each observed reaction (see figure 2 of the referenced manuscript)	/	/
Wood et al[58]	Any systemic reactions	Dose 1 - ≤3 days	13,066/132,313	/	/

Study	Outcome definition	Follow-up	Participants in intervention group with event	Participants in control group with event	Relative effect (95% CI)
	(myalgia/arthralgia, headache, fever >38C, chills, fatigue, gastrointestinal symptoms)				
		Dose 2 - ≤3 days	10,234/79,542	/	/
		Dose 3 - ≤3 days	7/59	/	/
Yoshida et al[59]	Systemic adverse reactions (Headache, diarrhea, dizziness, fatigue, muscle pain, nausea, fever, and medication use)	Any dose - ≤ 7 days	190/421	/	/
UNSOLICITED ADVERSE EVENTS					
Bloise et al[31]	Any AE	Any Dose	NR/569[¶¶¶]	/	/
Capponi et al[32]	Any AE	Dose 1 - NR	332/579	/	/
		Dose 2 - ≤2 weeks	309/579		
Creech et al - Phase 1[13]	Unsolicited AEs irrespective of causality	Any Dose - ≤28 days	119/380	/	/
Creech et al - Phase 2/3[13]	Unsolicited AEs irrespective of causality	Any Dose - ≤28 days	716/3007	194/995	RR 1·56 (1·46to 1·66)
Elias et al[37]	Any adverse reactions	Dose 1	30/87	/	/
		Dose 2	32/73	/	/
Hause et al A[40]	Any reported adverse events (incl. Serious)[‡]	Up to 19.12.2021	7379/ approx. 16 Million	/	/
	Any health impact (child was unable to complete normal daily activities, missed school, or received care from a medical professional because of new symptoms or conditions) [†††]	Dose 1 - ≤7 days	7515/48,795	/	/
		Dose 2 - ≤7 days	4515/29,899	/	/
Hause et al B[41]	Any reported adverse events (incl. Serious)[‡]	Dose 3 - ≤10 weeks	581/657,302	/	/
	Any health impact (child was unable to complete normal daily activities, missed school, or received care from a medical professional because of new symptoms or conditions) [†††]	Dose 3 - ≤7 days	546/3249		
Hause et al C[42]	Any reported adverse events (incl. Serious)[‡]	3rd-5th Dose - January 1st, 2023	847/861,251	/	/
	Any health impact (child was unable to complete normal daily activities, missed school, or received care from a medical professional because of new symptoms or conditions) [†††]	3rd-5th Dose - January 1st, 2023	506/2647	/	/
Kim et al[46]	Non-serious AE (redness at the injection site, pain, swelling, myalgia, fever, headache, chills, and others)[‖‖‖]	Any Dose - July 2nd, 2022	61/94,518	/	/
Leung et al B[49]	Any AE	Any Dose	2/25	/	/
Malden et al[50]	Any AE	Dose 1 - ≤14 days	3934/6247	/	/
		Dose 2 - ≤14 days	1601/3401	/	/
Ripabelli et al[53]	Any AE – mild (Injection site pain, redness, or swelling, tiredness/ asthenia, headache,	Dose 1 - up to 7 to 10 days after vaccination	187/229	/	/

Study	Outcome definition	Follow-up	Participants in intervention group with event	Participants in control group with event	Relative effect (95% CI)
	chills, nausea, insomnia, restlessness, decreased appetite, abdominal pain, and fever <38°C)				
		Dose 2 - up to 7 to 10 days after vaccination	139/199	/	/
	Any AE – moderate (Lymphadenopathy, muscle/joint pain, localized rash, vomiting, diarrhea, pain in a limb other than that injected, and fever ≥38 and <39°C)	Dose 1 - up to 7 to 10 days after vaccination	9/229	/	/
	Any health impact	Dose 2 - up to 7 to 10 days after vaccination	21/199	/	/
Walter et al – Phase 1[12]	Any AE	Dose 1 - ≤1 month	7/16	/	/
Walter et al – Phase 2/3[12]	Any AE	Dose 2 - ≤1 month	166/1518	69/750	RR 1·40 (1·26to 1·56)
Wood et al[58]	Any AE	Dose 1 - ≤3 days	33,597/132,313	/	/
		Dose 2 - ≤3 days	22,115/79,542	/	/
		Dose 3 - ≤3 days	17/59	/	/

AE: adverse event; CDC: Centers for Disease Control; CI: confidence interval; IQR: inter quartile range; MIS-C: Multisystem Inflammatory Syndrome in Children associated with COVID-19; NA: not applicable; NR: not reported**.**

*Any AE that leads to death, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, leads to persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, congenital anomaly or birth defects, or medically important events. †Obtained from Vaccine Adverse Events Reporting System (VAERS). ‡A comprehensive list of investigated AESIs is provided in table 39 of the EMA Assessment report. §Obtained from US Centers for disease control Vaccine Safety Datalink (VSD). ¶CVS Health database. ‖ Optum Pre-adjudicated claims database. **HealthCore database.†† All participants experienced an allergic reaction after dose 1. ‡‡Background incidences (2014-2018). §§Level 1, definitive case; level 2, probable case; level 3, possible case; level 4, reported events with insufficient evidence; level 5, not a case of myocarditis/pericarditis. ¶¶Expected cases based on background incidence rates from the US Premier Healthcare Database. ‖‖Text Message-Based Vaccine Safety Surveillance System. ***14/16 reported injection site pain; unclear whether remaining 2 participants had experienced other/additional local reactions. †††Obtained from Vaccine Safety Datalink (v-safe). ‡‡‡Text Message-Based Vaccine Safety Surveillance System. §§§8/16 reported fatigue; unclear whether the other 8 participants had experienced other/additional systemic reactions. ¶¶¶Events were recorded on days 2, 7, and 20 after each dose, however not over the whole period. ‖‖‖COVID-19 vaccination management system (CVMS, a web-based passive vaccine safety surveillance system).

Additional outcomes

ICU admission due to COVID-19

Data on ICU admissions were reported in five NRSIs. Two of these are not further described due to the critical risk of bias. [26,27] Evidence from a hospital-based, case–control, test-negative study resulted in 5/70 ICU admission for fully vaccinated and 55/467 for unvaccinated patients.[52] A cohort study from Italy observed zero ICU admissions in n=1,063,035 vaccinated and 15 ICU admissions in 1,768,497 unvaccinated children.[21] Another cohort study from Qatar observed no cases, in either vaccinated or unvaccinated children (n=18728 per group).[16] Adjusted effect estimates were not available.

Immunogenicity

Overview of reported immunogenicity outcomes

Study	Serological test	Definition of seroresponse	Variant	Participants with seroresponse	GMT (95% CI)
Neutralising antibody response					
Bartsch et al A[29]	Pseudovirus Neutralising Assay [pNT50]	NR	Wildtype	NR/9	934·7 (198·4 to 1671·1)
			Beta	NR/7	43·4 (25·2 to 61·5)
			Delta	NR/9	262·0 (88·2 to 435·8)
			Omicron	NR/7	47·6 (19·2 to 76·1)
Chantasrisawad et al[33]	sVNT: surrogate virus neutralization test	% inhibition	Omicron (BA.1)	NR	BNT162b2 (8 weeks): 54·0 (47·6 to 61·0) BNT162b2 (3 weeks): 16·7 (11·7 to 23·8)
	pVNT: pseudovirus neutralization test (BA)	ID50	Omicron (BA.2)	NR	BNT162b2 (8 weeks): 254 (205 to 313) BNT162b2 (3 weeks): 41 (25 to 68)
Cinicola et al[34]	NR	NR	Wildtype	NR/27	1024 (1024 to 1024)
Creech et al Phase 2/3[13]	Pseudovirus Neutralising Assay [PsVNA ID50]	Increase in titers by a factor of at least 4 from baseline*	Wildtype	313/316	1610·2 (1456·6 to 1780·0)
Creech et al Phase 1[13]			Wildtype	67/67	1204·6 (986·7 to 1470·8)
			Delta	133/134	756·4 (651·0 to 878·8)
Girard et al[38†]	Pseudovirus Neutralising Assay [PsVNA ID50]	NR‡	Omicron	20/20	95 (NR§)
			Wildtype	20/20	2102 (NR§)
Leung et al B[49]	Surrogate virus neutralization test (sVNT)	NR	Wildtype	73·9% and 93·8% were seropositive after doses 2 and 3	Responses rose with every dose: 29·7%, 51·7% and 78·6%
	Surrogate virus neutralization test (sVNT)	NR	Omicron	lower sVNT% compared to wildtype	Responses rose slightly from dose 2 to 3 but remained <30%: 18·5% and 27·2%
Stich et al[56]	live virus neutralization assay	clear cytopathic effect of ≥10% of that of the virus control well (cells plus virus)	Omicron	all children: 32/43 kidney transplant recipients: 14/23	NR
Walter et al Phase 2/3[12]	SARS-CoV-2 mNeonGreen virus	Increase in titers by a factor of at least	Delta	262/264	1197·6 (1106·1 to 1296·6)

Study	Serological test	Definition of seroresponse	Variant	Participants with seroresponse	GMT (95% CI)
Walter et al Phase 1[12]	microneutralization assay-NT50	4 from baseline*	Delta	NR/15	4163 (2584·7 to 6704)
IgG antibody response					
Cinicola et al[34]	DiaSorin Liaison SARS-CoV-2 TrimericS IgG assay, BAU/ml	NR	NR	NR/27	8380 (5120 to 11800)
	Anti-SARS-CoV-2 NCP ELISA assay	NR	NR	NR/27	0·45 (0·22 to 1·3)
Chantasrisawad et al[33]	Anti-S-RBD IgG against the ancestral strain, BAU/mL	NR	Omicron	NR	BNT162b2 (8 weeks): 2119 (1900 to 2364) BNT162b2 (3 weeks): 2242 (2041 to 2463)
Doucette et al[36]	Abbott ARCHITECT SARS-CoV-2 nucleocapsid IgG assay	Sample calibration (S/C) value of ≥1·4	Omicron	Visit 3¶: 0/21 Visit 4: 98/290	NR
	Abott ARCHITECT SARS-CoV-2 spike IgG II RUO assay	≥50·0 arbitrary units (AU)/mL	Omicron	Visit 3: 21/21 Visit 4: 290/290	NR
Joseph et al[44]	SARS-CoV-2 IgG II Quant (Abbott, IL, USA); day 180; BAU/IU	NR	Omicron	NR	all children: 1076 (712·3 to 1624·0) Infected children: 1479·0 (878·2 to 2490·0) Uninfected children: 535·3 (288·4 to 933·6)
Kastl et al[45]	LabCorp Cov2Quant IgG Assay, mg/mL, (median, IQR)	Results of 1·0 mg/mL or greater	NR	25/25	28·0 (18·0 to 47·0)
Leung et al B[49]	S-RBD IgG	NR	Wildtype	NR	RBD IgG responses rose with every dose: 0·63, 1·35 and 2·23
Wanlapakorn et al[57]	Receptor-binding domain (RBD) (Total RBD Ig) (U/mL)	NR	NR	NR	pre dose 1: 0·4 (0·4 to 0·4) pre dose 2: 74·7 (55·3 to 101·0) post dose 2: 10654·0 (8477·0 to 13390·0)
	Anti-RBD IgG (BAU/mL)	NR	NR	NR	pre dose 1: 0·5 (0·4 to 0·7) pre dose 2: 94·8 (74·7 to 120·0) post dose 2: 2872·0 (2193·0 to 3763·0)
T-cell response					
Cinicola et al [34]	Standard IFN gamma ELISpo, SFC/ 10^6 PBMCs	NR	Wildtype	NR/27	563 SFC/10^6 (154 to 1985)
			Omicron	NR/27	27 SFC/10^6 (5 to 140)
Leung et al B[49]	Based on PBMC	NR	Wildtype	NR	CD4+ 0·010%, 0·010%, 0·028% CD8+ 0·010%, 0·005%, 0·012%
		NR	Omicron	NR	T cells not diminished compared to wildtype

BAU: binding antibody units; CI: confidence interval; GMT: geometric mean titer; IU: international unit; IQR: inter quartile range; NR: not reported; PBMC: Peripheral blood mononuclear cells, SFC: spot-forming cells.

*If the baseline measurement was less than the lower limit of quantitation, seroresponse by titers that were at least 4 times the lower limit of quantitation.

[†]Subgroup analysis of Creech et al. [‡]Possible that same definition was used as for Creech et al. as data of a random sub-sample were analysed. [§]Plotted in graph (figure 1 of the original paper); significantly lower for omicron than against wildtype. [¶] Longitudinal study; first visit after implementation of vaccination for children 5-11 years of age.

Subgroup analyses

Subgroup category	Subgroup defined in study	Results	Comments / interpretation
Vaccine type	mRNA	NA	-Only mRNA vaccines approved in European Union.
Product	-BNT162b2 (Comirnaty) -mRNA-1273 (Spikevax)	-See VE against pre-Omicron SARS-CoV-2 variants: -Walter et al[12] vs. Creech et al[13]: Symptomatic COVID-19 -See Figure 3: -Walter et al[12] vs. Creech et al[13]: SAEs, Local and systemic reactions, AEs	-No relevant differences and overlapping 95% CIs for all outcomes except local reactions. -BNT162b2[12]may have a higher risk than mRNA-1273[13] for local reactions after the first and second dose (Figure 3).
Incomplete/ complete/ booster dosing regimen	1 dose (incomplete) vs. 2 doses (complete) vs. 3 doses (booster)	Omicron period: -SARS-CoV-2 Infections: VE (95% CI) 1 dose: Leung et al A[48]: 33 (3·0 to 53·3) Khan et al[18]: 14 (6 to 21) RE meta-analysis: 18·9 (0·2 to 34·2) 2 doses: RE meta-analysis (Figure 2): 41·6 (28·1 to 52·6) 3 doses: Khan et al[18]: 55 (50 to 60)Symptomatic COVID-19: 1 dose: Piché-Renaud et al[22]: 13 (4 to 21) Khan et al.: 7 (-4 to 16) RE meta-analysis: 9·9 (3·6 to 15·7) 2 doses: RE Model (Figure 2): 36·2 (21·5 to 48·2) 3 doses: Khan et al[18]: 61 (55 to 67) Hospitalisation: 1 dose: Piché-Renaud et al[22]: 53 (NA, NA) Simmons et al[55]: 34·0 (-45·0 to 73·0) Rosa Duque et al[54]: 65·6 (38·2 to 82·5) RE meta-analysis: 55·2 (16·1 to 76·1) 2 doses RE Model (Figure 2): 75·3 (68·0 to 81·0)	-Complete vaccination and booster vaccination may be associated with higher VE against SARS-CoV-2 infections, symptomatic COVID-19, and hospitalisation than incomplete vaccination (1 dose). -Results are imprecise and should be interpreted with caution.
Age group (e.g., 0-4 years vs. 5-11 years)	NA	NA	-Only children 5-11 years were included in the analysis. -See Table 1.
Sex (female vs. male)	Female vs. male (2 doses and Omicron 3 doses)	Khan et al[18]: 2 doses; Delta period: VE (95% CI) Female: 80 (70 to 87) Male: 80 (72 to 87) 2 doses; Omicron period:	- Evidence limited but indicated no sex differences.

Subgroup category	Subgroup defined in study	Results	Comments / interpretation
		Female: 16 (12 to 19) Male: 17 (13 to 21) 3 doses; Omicron period: Female: 49 (41 to 56) Male: 49 (41 to 56)	
Location (geographical region)	USA vs. Israel USA vs. Singapore	-See Figure 2: -SARS-CoV-2 infections: USA[15,18,25] vs. Israel[14,17] vs. Italy[61] vs. Qatar[16] vs. South Korea[19] -Symptomatic COVID-19: USA[18,20] vs. Singapore[23] vs. Israel[17] vs. Italy[21] -Hospitalisation: USA[47,52] vs. Singapore[23]vs. Italy[21] vs. Qatar[16] vs. Canada[22]	-No relevant or consistent differences observed except for SARS-CoV-2 infections where VE was higher for studies conducted in Israel[14,17]compared to the other studies.
Baseline immunity (seropositive vs. seronegative) through natural infection, or after basic vaccination for booster-vaccination studies	Prior SARS-CoV-2 infection: no vs. yes	Omicron period: Prior SARS-CoV-2 infection ≥90 days ago:[18] VE (95% CI) With prior infection: 58 (49 to 66) at <3 months 27 (17 to 35) at 3 months or more Without prior infection: 37 (34 to 41) at <3 months -7 (-12 to -1) at 3 months or more	-Baseline immunity reported rarely which limits this subgroup analysis. -See Table 1.
Risk groups (e.g., for immunocompromised participants)	NA	NA	-VE according to risk groups not reported.
Concomitant treatments (e.g., B-cell depleting therapies)	NA	NA	-No subgroup analyses were available for concomitant treatments.

AE: adverse event; CI: confidence interval EPAR: European public assessment report; mRNA: messenger ribonucleic acid; NA: not applicable; NRSI: non-randomized studies of interventions; SAE: serious adverse event

Sensitivity analyses

Sensitivity analysis	Sensitivity analysis conducted	Results	Comments / interpretation
Risk of bias, e.g., low risk of bias vs. unclear and high risk of bias studies with the same study design	NA	NA	-No outlier results identified. -Sensitivity analysis not meaningful due to lack of studies and lack of low risk of bias results.
Study design (e.g. controlled vs. uncontrolled; prospective vs. retrospective)	NA	NA	-No outlier results identified. -Sensitivity analysis not meaningful due to lack of studies and variation of study designs.
Type of publication: peer-reviewed vs. other publication formats (e.g. preprint articles, letters)	Symptomatic COVID-19: Preprint vs. peer reviewed article	SARS-CoV-2 infections: VE (95% CI) Random-effects metaanalysis Preprint:[25] 44·2% (27·5 to 57·0) vs. Peer-reviewed articles:[14,16-19,61] 42·6% (28·2 to 54·2) Symptomatic COVID-19: VE (95% CI), random-effects meta-analysis: Preprint:[22,23] 44·9% (95% CI 21·6 to 61·4) vs. peer-reviewed articles:[17,18,20,21] 28·1% (95% CI 24·5 to 31·6) Hospitalisation: VE (95% CI) Random-effects metaanalysis Preprint:[22,23,54] 77·4% (61·9 to 86·6) vs. Peer-reviewed articles:[21,52] 73·5% (66·2 to 79·3)	-Sensitivity analyses did not reveal any signals regarding type of publication
Random-effects vs. fixed-effect model meta-analysis	-All outcomes included in meta-analysis: see Figure 2 and Figure 3.	-Differences between random-effects and fixed-effects estimates from meta-analyses were marginal for all outcomes for point estimates. -The 95% CI was considerably wider for the random-effects model for the outcomes: SARS-CoV-2 infections, COVID-19, hospitalisation, local reactions dose 1 and dose 2. See Figure 2 and Figure 3.	-Comparing all random-effects and fixed-effects estimates from meta-analyses did not indicate clinically relevant differences between the point estimates but relevant differences for precision of the following outcomes: SARS-CoV-2 infections, COVID-19, hospitalisation, local reactions dose 1 and dose 2.
Exclusion of studies with inexplicably high or low effects	NA	NA	-No outlier results identified.

NA: not applicable

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