Updated Evidence Base for 2025-2026 Covid-19, RSV and Influenza Immunizations

Supplemental Appendix

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Supplemental methods

Protocol and search strategy

The full study protocol was reviewed by three external vaccine and methodologic experts. Their feedback was incorporated, and the protocol was registered in PROSPERO on July 10, 2025. Minor protocol updates, including extending the dates of the search from June 30, 2025 to July 31, 2025 were subsequently reported to the PROSPERO registry to maintain a complete record.

We searched PubMed, EMBASE, and Web of Science for references published in English from 6/1/24, 8/7/24, or 8/26/23 through 7/31/25 for articles regarding Covid-19, RSV, or influenza, respectively. The Cochrane database primarily contains systematic reviews and meta-analyses, not primary research studies. Since our inclusion criteria specifically excluded systematic reviews and focused only on primary studies, the Cochrane database was not searched. The primary studies that would be synthesized in any Cochrane review were captured through our searches of PubMed/MEDLINE, Embase, and Web of Science. The timeframe of the searches was informed by the dates of the last ACIP Evidence-to-Recommendations (EtR) reviews for each of these three entities. Searches included terms related to each of the three infections, their epidemiology, and vaccine effectiveness, safety and co-administration. The PubMed search strategy is detailed in **Supplemental Tables 1-3**; these search terms were also translated to Embase and Web of Science. All citations from these searches were loaded into EndNote for automatic and manual de-duplication. References were subsequently uploaded into the Covidence screening platform (https://www.covidence.org) where they also underwent a second round of automatic de-duplication.

Given the rapid time frame of the review and the very large number of references identified, we elected to apply “NOT” Boolean operators to narrow our search as outlined in Supplemental Tables 1-3 below. While this approach improved search efficiency by excluding clearly irrelevant study types, this approach carries a theoretical risk of missing relevant studies that reference excluded terms. This trade-off between search efficiency and comprehensiveness is an inherent challenge in rapid systematic reviews.

Immunization products
We focused our analysis on immunization products currently available for clinical use in the United States. For Covid-19 and RSV, we limited all analyses to US-licensed vaccine products and RSV monoclonal antibody prophylaxis. For influenza, we included data for live or inactivated seasonal influenza vaccine products, including both US-licensed vaccines and similar vaccines produced internationally. Studies presenting only aggregated data for multiple vaccine products were included in vaccine effectiveness/efficacy (VE) estimations only if all products were US-licensed.

Study periods of interest
Vaccine safety and coadministration data were systematically extracted irrespective of the study period, provided that the study reported on the above mentioned vaccines. Similarly, studies reporting on vaccine effectiveness for RSV and post-covid conditions (PCC) were included regardless of the study period. For all other Covid-19 VE outcomes, we restricted our analysis to reports with a study period that ended on 1/1/24 or later to reflect more recent and currently circulating Covid-19 variants. For influenza vaccine effectiveness outcomes, we analyzed studies from the 2023-2024 influenza season and later. For epidemiologic studies, we considered data from 1/1/24 or later.

Prespecified adverse events of special interest
For pregnant individuals, these included miscarriage, stillbirth, congenital anomalies, gestational hypertension/pre-eclampsia/eclampsia, small for gestational age, placental abruption, and preterm birth across all vaccines. For non-pregnant populations, these included myocarditis, Guillain-Barré syndrome (GBS), immune thrombocytopenic purpura (ITP), stroke, and central venous sinus thrombosis (CVST) for Covid-19 vaccines; myocardial infarction, stroke, and GBS for RSV vaccines and monoclonal antibodies; and GBS, stroke, and myocardial infarctions for influenza vaccines. We also aimed to collect data on school absenteeism in children across all vaccines; however, no such data were identified in our search. To be eligible for inclusion in the analysis, all safety outcomes had to be reported by vaccine product for Covid-19 and RSV vaccines.

Safety outcomes for influenza vaccines of any type were eligible for analysis, with high-dose or adjuvanted vaccines analyzed separately where those data were available.

Definition of immunocompromised
For the purposes of this review, we defined the immunocompromised status as one or more of the following: history of solid organ or hematopoietic stem cell transplantation; active treatment with chemotherapy, immunosuppressive therapy, or immunomodulators for a chronic underlying disease (such as cancer, autoimmune/autoinflammatory disease, etc.); advanced HIV infection ($CD4^+$ T cell count ≤ 200/μL); primary immunodeficiency. If a study did not list qualifying immunocompromising conditions, it was not included in analyses specific to immunocompromised populations.

Effect estimates
Where possible, we used vaccine effectiveness (VE) as an adjusted percentage as reported in the original study. For studies that reported VE as a relative effect (e.g., hazard ratio, odds ratio, risk ratio, incidence rate ratio, etc.) without providing VE estimates as a percentage, we manually calculated VE using the formula (1 – relative effect) × 100%. For vaccine safety studies, we used adjusted relative effect measures as reported in the original study. For studies that did not report relative effect measures but provided sufficient raw data, we manually calculated unadjusted (crude) estimates. For all calculations involving relative effects, modified Haldane's correction was used when one or more groups included 0 events.[1]

Meta-analytic methods
Studies providing only unadjusted effect estimates were reported in corresponding tables but not included in pooled estimates. For vaccine effectiveness (VE) studies, we meta-analyzed effect estimates using log (relative effect measures) and presented pooled results as VE%. VE estimates were only eligible for meta-analysis if there were 3 or more studies of the study design (e.g., randomized controlled trial [RCT], case-control study [including test-negative design], or cohort study) that contributed data on the same population type for the same vaccine category. If there was overlap in participants included in multiple papers (e.g., multiple analyses of the same RCT), only one was included in pooled analyses. If there was one publication that included estimates from multiple distinct populations (e.g., a study that included a VE estimate from both the VISION and IVY networks), we considered these as separate studies. For safety outcomes, studies were again only eligible for meta-analysis if they were of the same study design. However, whereas for VE estimates, we allowed vaccine product categories (e.g., COVID-19 mRNA vaccines) to be meta-analyzed together given previously published data regarding similar VE of different vaccine categories, for safety outcomes, we only meta-analyzed estimates provided for the same outcome, with the same effect estimates (e.g., odds ratios separate from hazard ratios) and same vaccine product (i.e., BNT162b2 was analyzed separately from mRNA-1273) given previously reported product-specific differences in safety outcomes. For influenza vaccines, when data specific to high-dose or adjuvanted vaccines were reported, data on each of those vaccine types were reported and meta-analyzed separately; otherwise, seasonal influenza vaccines were analyzed in aggregate. When studies provided different estimates by influenza strain with no aggregate estimate they were not included in meta-analyses; similarly, if studies provided multiple estimates by age group within our prespecified populations but no aggregate estimate, they were not included in meta-analyses. All meta-analyses were conducted using DerSimonian-Laird random effects models.

Risk of bias assessment
We conducted a formal risk of bias (RoB) assessment for each study that met the eligibility criteria for full-text review, using standardized RoB checklists. Each publication was assessed by a primary and secondary reviewer following a standardized approach to complete the relevant checklist.

The RoB assessment was undertaken in two stages for all studies. In the first stage, we identified the outcome most relevant to the aims of this systematic review. For studies that reported on multiple types of outcomes (for example, VE and adverse events), we focused the RoB assessment on the outcome type that appears first in the following list: VE, adverse events of special interest, co-administration, adverse events not of special interest, epidemiology. Based on the outcome of interest, each study was assessed via two screening questions that asked whether the study used a comparator group to assess the outcome of interest and whether the study made any attempt to control for confounding in assessing the outcome of interest. Studies

with no comparison group and/or no attempt to control for confounding in assessing the primary outcome were categorized as having a high risk of bias. All other studies moved to the second stage of the RoB assessment.

In the second stage, each study was categorized by study design and the appropriate RoB assessment checklist was used to evaluate the study design, methods, and analysis. All clinical trials, including randomized clinical trials (RCTs), were assessed using the Cochrane Risk of Bias (RoB2) tool that evaluates the domains of randomization, intervention, outcome, outcome measurement, and reported results.[2,3] Observational studies were assessed using the appropriate Newcastle-Ottawa Scale (NOS), reported to be the most widely used tool for assessing RoB in non-randomized studies of healthcare interventions as per a recent review.[4] Cohort studies were assessed using the NOS for Cohort Studies.[5] Case-control studies, including test-negative designs, were assessed using the NOS for Case-Control Studies.[5] Cohort studies and case-control studies were assessed on three broad domains: selection of study groups, comparability of study groups, and the ascertainment of the exposure or outcome for cohort or case-control studies, respectively. Cross-sectional studies were assessed using the NOS for Cross-Sectional Studies-Simplified which evaluates domains of selection, comparability, and exposure.[6] Each checklist presents a series of questions about multiple aspects of the design, methods, and analysis of the study. Based on the responses to these questions, a RoB score was calculated using the standard scoring method for each checklist. Then, using the score mapping standard for each checklist, assigned scores were automatically categorized into one of three bias risk groups: low risk of bias, moderate risk of bias/some concerns, or high risk of bias. For cohort and case-control studies, we categorized risk of bias using domain-specific scoring which notably classifies a study as high risk of bias if any of the individual domains are determined to be at high risk of bias. The RoB categorization is reported in Supplemental Table S4. RoB assessments are one approach to assessing basic factors that can affect study quality and are not designed to evaluate every aspect of the design, methods, and analysis of a given study. The RoB categorization provides a qualitative assessment of the degree of risk of bias based on a limited set of criteria.

Supplemental Results

Summary of epidemiology studies identified in this review

Among 72,939 U.S. veterans presenting to the emergency department with confirmed COVID-19, RSV, or influenza respiratory infections during the 2023-24 season, cumulative hospitalization rates over 30 days were 16.2% for COVID-19, 14.3% for RSV, and 16.3% for influenza (**Table S5**).[7] Among pediatric influenza deaths reported to CDC, the proportion with influenza-associated encephalopathy (IAE) varied by season (2020-21: 0%, 2024-25: 13%), with only 20% of fatal encephalopathy cases having received seasonal influenza vaccination and no underlying medical conditions for 54% (89/166) of fatal cases of influenza associated encephalopathy.[8] In a separate multicenter study of 38 children with acute necrotizing encephalopathy (a severe form of influenza encephalopathy) with documented vaccination status, 32 (84%) were unvaccinated, including 10 of 11 who died. There was no significant medical history reported in 76% (31/41) of the influenza-associated acute necrotizing encephalitis cases.[9] Additional included epidemiology studies are summarized in **Table S5**.

Summary of safety outcomes not specifically identified as being of special interest

In this systematic review and meta-analysis, we identified a number of studies that reported on safety outcomes that we did not initially identify as being of special interest. A detailed list of studies reporting on such outcomes can be found in Supplemental Table S9. Where studies identified a potential serious or life-threatening safety signal associated with vaccine administration outside of highly specialized populations (e.g., individuals living with pre-existing health conditions), we present the data on the outcome identified through our search, relative to what was known about this signal previously.

<u>COVID-19 vaccines</u>

New onset seizures after mRNA-1273 - Ko 2025[10]

Ko et al. conducted a self-controlled case series of adults using a nationwide database in South Korea that linked vaccination registry and healthcare claims data. The study identified 6,066 cases of new-onset seizure in total among 42,155,198 adult participants (0.01% event rate) who received 129,956,027 vaccine doses.

They found that mRNA-1273 was associated with increased risk of new-onset seizure with IRR 1.21 (1.04-1.42) within 28 days of vaccination, while BNT162b2 was not associated with new-onset seizure (IRR 0.95, 95% CI, 0.88 to 1.03). Subgroups stratified by age were consistent with the primary results. We found the risk of bias of the study to be low. A prior systematic review of randomized controlled trials (including three focused on mRNA-1273) found no significant association between COVID vaccination and new-onset seizure, although there was a high degree of uncertainty in the estimate (OR 2.70, 95% CI, 0.76 to 9.57).[11] A prior randomized controlled trial of 30,351 adults found new-onset seizures in 2/15,185 mRNA-1273 recipients, and 0/15,166 placebo recipients (OR 4.99, 95% CI, 0.24 to 104.04).[12] Several studies have found a small association with increased risk of new-onset seizure for mRNA-1273 in children, primarily febrile seizures.[13,14] A systematic review and meta-analysis including 1462 people with seizure disorder from 9 studies found a 5% (95% CI, 3 to 8) increased seizure frequency after mRNA COVID-19 vaccine.[15] In sum, there may be a small association between mRNA-1273 vaccination and risk of new-onset seizure for people without known seizure disorder and a small association with increased risk of seizures in people with baseline seizure disorder, with the absolute risk for both groups very low.

Transverse myelitis after BNT162b2 or mRNA-1273 - Lim 2025b[16]

Lim et al conducted a self-controlled case series using a nationwide database in South Korea that linked vaccination registry and healthcare claims data in adults. The study identified 159 cases of acute transverse myelitis in total among 128,223,471 vaccine doses (0.0003%). They found that BNT162b2 (IRR 1.99, 95% CI, 1.30 to 3.03) and mRNA-1273 (IRR 2.57, 95% CI, 1.14 to 5.79) were associated with increased risk of acute transverse myelitis within 42 days of vaccination. We found the risk of bias of the study to be low. Other high quality studies have not found an association between transverse myelitis or composite outcomes including transverse myelitis and mRNA platform COVID vaccination. A prior self-controlled case series in Australia found no association between BNT162b2 (IRR 0.58, 95% CI, 0.23 to 1.44) or mRNA-1273 (IRR 7.92, 95% CI, 0.50 to 126.7) and transverse myelitis.[17] A large self-controlled case series from England found no increased risk in the first 28 days after the first BNT162b2 vaccine dose of an acute CNS demyelinating event or the composite outcome of encephalitis, meningitis, and myelitis (IRR 1.02, 95% CI, 0.75 to 1.40, and 1.14, 95% CI, 0.86 to 1.51, respectively).[18] The same study found a trend towards an association between SARS-CoV-2 infection (28 days) and any acute CNS demyelinating event and a significant association with the composite outcome of encephalitis, meningitis, and myelitis (IRR 1.67, 95% CI, 0.93 to 3.00, and IRR 2.70, 95% CI, 1.78 to .411, respectively). Another retrospective study using US data from the TriNetX database also found a significant association between SARS-CoV-2 infection and transverse myelitis (HR 1.46, 95% CI, 1.21 to 1.74).[19] In sum, transverse myelitis is very rare, and there are limited but conflicting data regarding a possible association between BNT162b2 and mRNA-1273 and this outcome.

Pulmonary embolism after BNT162b2 - Zethelius 2024[20]

Zethelius et al conducted a population-based cohort study using national registers in Sweden (N=7,512,450), including individuals aged 18-84 years. Within 28 days of vaccination, they identified 361 cases of pulmonary embolism after 4,708,284 first doses of BNT162b2, finding a significant association after the first dose after adjusting for age, sex, and co-morbidities (HR 1.19, 95% CI, 1.06 to 1.34). They identified 4 cases after 26,689 mRNA-1273 doses given as a second dose after an initial BNT162b2, finding an association with the second dose of mRNA-1273 following a first dose BNT162b2 (HR 3.82, 95% CI, 1.43 to 10.19). They found no significant association after any other dose combinations, including second dose BNT162b2 following first dose BNT162b2 (4,576,712 doses), first dose mRNA-1273 (801,761 doses), or second dose mRNA-1273 following first dose BNT162b2 (729,691 doses). The authors hypothesized that the small association after the early dose of BNT162b2 may reflect the prioritization of the highest risk individuals for early vaccination. The association reported after second dose mRNA-1273 following BNT162b2 had wide confidence intervals and a small total number of cases and may be explained by the same issue. We found the overall risk of bias of the study to be low. Self-controlled case series and cohort studies in the US, France, Germany, Israel, and Japan have consistently found no association between mRNA vaccination and pulmonary embolism when compared to unvaccinated periods or other vaccines.[21–29] On the other hand, studies have consistently shown a marked association between SARS-CoV-2 infection and PE, including in a large population-wide cohort study from England and Wales which found substantially higher rates of PE in the week after confirmed infection (HR 33.2, 95% CI 30.7-35.9).[30] In sum, the collective evidence suggests that BNT162b2 is not associated with risk of pulmonary embolism.

Thyroid disease after BNT162b2 or mRNA-1273 - Bea 2024, Cheng 2025, Shani 2025[31–33]
Bea et al conducted a self-controlled case series over 55 days after vaccination using a nationwide database in South Korea that linked vaccination registry and healthcare claims data in individuals aged 12 or older. For new-onset hypothyroidism (7,685 cases out of 5,407,214 individuals, 0.1%), BNT162b2 (IRR 0.88, 95% CI 0.80-0.96) and mRNA-1273 (IRR 0.74, 95% CI 0.62-0.89) were associated with reduced risk after the first dose, and mRNA-1273 was associated with a reduced risk after the second dose (IRR 0.82, 95% CI 0.70-0.96). For new-onset subacute thyroid disease (363 cases out of 5,407,215 individuals, 0.01%), mRNA-1273 was associated with an increased risk after the second dose (IRR 2.57, 95% CI 1.16-5.72). For new-onset thyroid eye disease, mRNA-1273 was associated with a reduced risk after the first dose (IRR 0.19, 95% CI 0.06-0.64). There were no differences for thyroid outcomes after other doses, and there were no differences in risks for recurrence of hyperthyroidism or exacerbation of hypothyroidism.[31] We assessed the risk of bias for this study to be low.

Cheng et al conducted a retrospective cohort study with propensity score matching of medical records using a global health collaborative clinical research network including 1,166,748 vaccinated (602,882 with BNT162b2 and 249,829 with mRNA-1273) and 1,166,748 unvaccinated individuals. Over 12 months after vaccination, they found that BNT162b2 was associated with an increased risk of new-onset hyperthyroidism (HR 1.16, 95% CI 1.06-1.28) and hypothyroidism (HR 1.85, 95% CI 1.79-1.92) and that mRNA-1273 was associated with increased risk of hyperthyroidism (HR 1.40, 95% CI 1.23-1.59) and hypothyroidism (HR 2.13, 95% CI 2.04-2.23). There were no differences for subacute thyroiditis. Overall rates for hyperthyroidism were 0.2% and for hypothyroidism were 1.4%.[32] The risk of bias assessment found this study to have a low risk of bias.

Shani et al conducted a retrospective cohort study of medical records from a health system covering 52% of the Israeli population, evaluating the risk of autoimmune disease 2-12 months after vaccination with BNT162b2 in people 12 years of age or older in four age groups after controlling for sociodemographics, smoking, and co-morbidities. The study included 3,050,086 individuals of whom 2,455,207 were vaccinated. They found that BNT162b2 was associated with decreased risk of hypothyroid among age 18-44 (HR 0.87, 95% CI 0.81-0.95; overall rate 440/100,000).[33] The risk of bias assessment found this study to have a low risk of bias.

Several prior studies, including a large self-controlled case series and a systematic review of 26 studies, found no association between COVID vaccination and thyroid dysfunction.[34,35]

In sum, we found mixed results on the association between COVID vaccination and thyroid outcomes. Two studies (Bea et al and Shani et al) found a reduction in risk of hypothyroidism after BNT162b2 and mRNA-1273, and an increased risk of hyperthyroidism after some doses (mRNA-1273).[31,33] Another study (Cheng et al) found that both vaccines were associated with increased risk of hypothyroidism and hyperthyroidism.[32] Prior literature has not identified this association. mRNA COVID vaccines may rarely be associated with new-onset thyroid disease, but the overall risk is low and not clinically significant for most individuals.

Autoimmune disease after BNT162b2 (psoriasis, colitis, polymyalgia rheumatica) - Jung 2024, Shani 2024, Woo 2025[33,36,37]
Jung et al conducted a population-based retrospective cohort study using national data in South Korea (all ages included), comparing a vaccination cohort (N=4,629,401) with a historical cohort control (N=4,444,932, all of whom went on to be vaccinated). They found that BNT162b2 was associated with lower risk of primary cicatricial alopecia aHR 0.81 (99% CI 0.68-0.98), psoriasis 0.84 (0.80-0.89), Behcet disease 0.75 (0.62-0.91), rheumatoid arthritis 0.88 (0.85-0.91), and higher risk of systemic lupus erythematosus 1.18 (1.02-1.36). mRNA-1273 was associated with lower risk of primary cicatricial alopecia aHR 0.75 (99% CI 0.58-0.96), psoriasis 0.73 (0.67-0.78), ulcerative colitis 0.83 (0.70-0.99), and rheumatoid arthritis 0.81 (0.78-0.85).[36] We assessed the risk of bias in this study to be low.

Shani et al conducted a retrospective cohort study of medical records from a health system covering 52% of the Israeli population, evaluating the risk of autoimmune disease 2-12 months after vaccination with BNT162b2 in people 12 years of age or older in four age groups after controlling for sociodemographics, smoking, and co-morbidities. The study included 3,050,086 individuals of whom 2,455,207 were vaccinated. They found that

BNT162b2 was associated with increased risk of psoriasis among age 12-17 (HR 1.53, 95% CI 1.18-1.98; overall rate 154/100,000), 18-44 (HR 1.44, 95% CI 1.24-1.60; overall rate 440/100,000), 45-64 (HR 1.69, 95% CI 1.38-2.07; overall rate 307/100,000), and 65+ (HR 1.62, 95% CI 1.25-2.1; overall rate 291/100,000); colitis among age 12-17 (HR 1.93, 95% CI 1.27-2.93; overall rate 63/100,000), 18-44 (HR 1.38, 95% CI 1.13-1.7, overall rate 84/100,000), 45-64 (HR 1.5, 95% CI 1.1-2.04; overall rate 109/100,000); vitiligo among age 45-64 (HR 2.82, 95% CI 1.57-5.08; overall rate 50/100,000); polymyalgia rheumatica age 65+ HR 2.12 (1.3-3.47) (overall rate 100/100,000); no differences for other age groups and diseases (inflammatory bowel disease, uveitis, Grave's disease, rheumatoid arthritis, fibromyalgia, Sjögren's syndrome, giant cell arteritis).[33] We assessed the risk of bias to be low.

Woo et al reported a nationwide self-controlled case series in South Korea that included 376 cases of polymyalgia rheumatica among 44,818,078 vaccine recipients and found that BNT162b2 was not associated with polymyalgia rheumatica (IRR 0.70, 95% CI 0.49-1.02).[37] We assessed the risk of bias to be moderate.

Prior literature has suggested a rare but possible association between BNT162b2 and new-onset and exacerbations of psoriasis,[38–42] although these studies were lower quality than those included in our review. Prior studies of new-onset polymyalgia rheumatica and systemic lupus erythematosus in the context of COVID vaccination are limited to case studies. While several studies suggest that COVID vaccines do not lead to increased risk of colitis flare (including Rossier 2024 included in this review), there is limited prior evidence about the association between COVID vaccines and new-onset colitis.

In sum, we identified one study (Shani et al)[33] that found that BNT162b2 was associated with increased risk of new-onset psoriasis, polymyalgia rheumatica, and colitis in certain age groups, and another study (Jung et al)[36] that found that BNT162b2 and mRNA-1273 were associated with decreased risk of psoriasis, and mRNA-1273 was associated with decreased risk of ulcerative colitis. Jung et al also found that BNT162b2 and mRNA-1273 were associated with decreased risk of a number of other autoimmune conditions. A third study (Woo et al)[37]found that BNT162b2 was not associated with polymyalgia rheumatica, although the risk of bias was moderate. Taken together with the prior literature, there may be a small association between mRNA vaccines and these conditions, although the data are mixed, and some well-designed studies suggest that the risk may be decreased with the vaccines.

Data Visualization

Study characteristics and pooled estimates are publicly available for interactive exploration through a web application found here. The reason that the number of rows is greater than the number of studies is because the data tool includes one row for every unique combination of article/virus/population. Because many articles report on multiple patient populations (and less commonly, multiple viruses), there can be more than one row per study. The data that can be exported from the data tool make this clear as columns for virus and patient population are included in the output.

Additional Discussion of Limitations and Context not in the Main Text

1. **Strain Matching and Vaccine Performance:** Strain matching affects both COVID-19 and influenza vaccine performance. While we focused on variant-specific effectiveness for COVID-19, influenza vaccine effectiveness similarly depends on antigenic match with circulating H1N1, H3N2, and B lineages.
2. **Potential for Publication Bias**: Publication bias may influence which questions were prioritized during brief assessment windows, potentially overrepresenting novel findings while underrepresenting confirmatory studies.
3. **Use and Interpretation of Vaccine Adverse Events Reporting System (VAERS) Data**: To the extent that data from the VAERS database was published in our search horizon, it would have been included in this review. However, much of the data from VAERS that is made available during ACIP meetings is not always published in the same format in peer-reviewed literature, which was the focus of our systematic review. Additionally, many VAERS studies use “reporting odds ratio” (ROR) which, while

useful for early identification of potential AEs, is typically not adjusted for the number of vaccine doses administered during specific time periods and therefore provides no information about relative and absolute risk of various potential AEs.

4. **Heterogeneity and Meta-analytic Scope:** We limit quantitative pooling to studies with comparable designs, populations, vaccine products, and outcomes, using prespecified inclusion criteria. We also used random-effects models, acknowledging the possibility for residual heterogeneity. However, meta-analysis across diverse observational studies should be interpreted with caution and given the breadth of included studies and the brief time horizon for this review we were unable to conduct detailed subgroup analyses to explore all potential sources of heterogeneity in each pooled estimate. Additionally, some of our pooled estimates were obtained from smaller numbers of studies. Heterogeneity estimates may be biased towards 0 for pooled estimates from a relatively small number of studies. Therefore, low heterogeneity estimates associated with pooled estimates from a small number of studies should be interpreted with caution. All study characteristics and pooled estimates are provided in an interactive format on the web, allowing readers and professional societies to examine heterogeneity across studies within specific domains of interest in greater detail.
5. **Absence of Formal GRADE Assessments**: Because this work was designed to provide an updated evidence base rather than to formulate recommendations, we did not perform a formal GRADE assessment. Given the rapid timeline and the focus on summarizing newly published studies rather than comprehensively evaluating all available evidence, incorporating GRADE was beyond scope. We anticipate professional societies and other guidance bodies to apply such frameworks when developing recommendations based on these findings.
6. **Absence of Systematically Reported Baseline Incidence Data**: The absence of systematically reported baseline incidence data across studies limits the ability to contextualize relative effectiveness estimates as absolute risk reductions. Because incidence varies substantially by population, geography, and time period, readers and guideline developers should interpret these findings in light of local epidemiology and current surveillance data.
7. **Risk of Bias Assessment:** The RoB assessment utilized standard checklists mapped to standard categorizations which are designed to provide a qualitative assessment of the degree of risk of bias based on a limited set of criteria. RoB assessments checklists are one approach to assessing basic factors that can affect study quality and are not designed to evaluate every aspect of the design, methods, and analysis of a given study, but do not capture all potential sources of bias that may impact the interpretation of study results.

Supplemental Table 1. PubMed Covid-19-related search terms

#	Descriptor	String
1	Disease - COVID-19	("COVID-19"[majr] OR "SARS-CoV-2"[majr]) OR “SARS-CoV-2”[tiab] OR “COVID-19”[tiab] NOT (“COVID-19 pandemic”[ti] OR “COVID-19 era”[ti])
2	COVID-19 vaccine specific terms (inc. brand names)	"COVID-19 Vaccines"[majr] OR Comirnaty[tiab] OR SPIKEVAX[tiab] OR MNEXSPIKE[tiab] OR Vaxzevria[tiab] OR Nuvaxovid[tiab] OR Covovax[tiab] OR NVX-CoV2373[tiab]
3	Date filter	2024/06/01:2025/7/31[pdat]
4	Language filter	english[lang]
5	Epidemiologic search terms	(Inciden*[tiab] OR prevalen*[tiab] OR hospitalization[tiab] OR hospitalisation[tiab] OR hospitalized[tiab] OR hospitalised[tiab] OR death[tiab] OR mortality[tiab] OR survival[tiab] OR severity[tiab] OR "long-term"[tiab] OR ICU[tiab] OR “critical care”[tiab] OR “medically-attended”[tiab]) AND ("United States"[Mesh] OR "United States"[tiab])
6	Immune landscape search terms	(seroprevalence[tiab] OR serolog*[tiab] OR immunity[tiab] OR "Immunity, Humoral"[majr]) AND ("United States"[Mesh] OR "United States"[tiab])
7	Variant search terms	variant[tiab] OR subvariant[tiab] OR subtype[tiab]
8	General vaccine search terms	"COVID-19 Vaccines"[majr] OR vaccin*[ti] OR immuni*[ti] OR booster[ti] OR "Vaccines"[majr] OR "Vaccination"[majr]
9	Vaccine effectiveness and immunogenicity search terms	"Immunogenicity, Vaccine"[majr] OR ((vaccin*[tiab] AND (efficacy[tiab] OR effectiveness[tiab])) OR "Vaccine Efficacy"[majr]
10	Safety and adverse event search terms	"Vaccine Safety"[tiab] OR "adverse event*"[tiab] OR "side effect*"[tiab] OR thrombosis[tiab] OR clot[tiab] OR stroke[tiab] OR myocarditis[tiab] OR pericarditis OR "Guillain-Barré"[tiab] OR demyelin*[tiab] OR ADEM[tiab] OR "acute disseminated encephalomyelitis"[tiab] OR anaphylaxis[tiab] OR "multisystem inflammatory syndrome"[tiab] OR "MIS-A"[tiab] OR "MIS-C"[tiab] OR "injection site reaction*"[tiab] OR "Myocardial infarction”[tiab] OR “heart attack”[tiab] OR STEMI[tiab] OR “acute coronary syndrome”[tiab] OR “birth outcome”[tiab] OR stillbirth[tiab] OR preterm[tiab] OR “congenital anomal*”[tiab] OR miscarriage[tiab] OR "congenital abnormalities"[MeSH] OR "birth defect*"[tiab] OR "fetal abnormalit*"[tiab] OR "neural tube defect*"[tiab] OR "malformation*"[tiab] OR "fetal development"[tiab] OR "hypertension, pregnancy-induced"[MeSH] OR "preeclampsia"[MeSH] OR “preeclampsia”[tiab] OR “pre-eclampsia”[tiab] OR "eclampsia"[tiab] OR "gestational hypertension"[tiab] OR "hypertensive disorders of pregnancy"[tiab] OR “pregnancy-induced hypertension”[tiab]
11	Co-administration and adjuvant search terms	Coadministration*[tiab] OR "co-administration*"[tiab] OR "simultaneous administration"[tiab] OR adjuvant[tiab]
12	Exclude if not human	(animals[mh] NOT humans[mh])
13	Exclusion by publication type	“case reports”[pt] OR “clinical trial protocol”[pt] OR “Clinical Trial, Veterinary”[pt] OR “Comment”[pt] OR “Editorial”[pt] OR “Guideline”[pt] OR “letter”[pt] OR “practice guideline”[pt] OR “Published Erratum”[pt]
14	Additional terms for exclusion	modeling[ti] OR modelling[ti] OR "mathematical model"[tiab] OR "simulation model"[tiab] OR simulation[ti] OR "cost-effectiveness"[ti] OR costing[ti] OR "cost analysis"[tiab] OR "economic evaluation"[tiab] OR "cost utility"[tiab] OR microsimulation[tiab] OR "markov model"[tiab] OR "agent-based model"[tiab] OR macaque[ti] OR primate[ti] OR "case report"[ti] OR "mouse model"[tiab] OR murine[tiab] OR "in vitro"[ti] OR "cell line"[tiab] OR "protein structure"[tiab] OR "molecular docking"[tiab] OR "molecular dynamics"[tiab] OR "animal model"[tiab]

		OR rodent[tiab] OR bioinformatics[tiab] OR "receptor binding"[tiab] OR "viral genome"[tiab]
15	OR terms 1	1 OR 2
16	OR terms 2	5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11
17	NOT terms	12 OR 13 OR 14
18	Combined	15 AND 3 AND 4 AND 16 NOT 17

Supplemental Table 2. PubMed RSV-related search terms

#	Descriptor	String
1	Disease - RSV	"Respiratory Syncytial Virus Infections"[majr] OR "Respiratory Syncytial Virus, Human"[majr] OR "Respiratory Syncytial Virus Vaccines"[majr] OR "Respiratory Syncytial Virus Vaccines"[majr] OR RSV[tiab] OR “Respiratory syncytial virus”[tiab]
2	RSV vaccine specific terms (inc. brand names)	"Respiratory Syncytial Virus Vaccines"[majr] OR Abrysvo[tiab] OR Arexvy[tiab] OR MRESVIA[tiab] OR Beyfortus[tiab] OR nirsevimab[tiab] OR ENFLONSIA[tiab] OR clesrovimab[tiab] OR Synagis[tiab] OR palivizumab[tiab]
3	Date filter	2024/8/7:2025/7/31[pdat]
4	Language filter	english[lang]
5	Epidemiologic search terms	(Inciden*[tiab] OR prevalen*[tiab] OR hospitalization[tiab] OR hospitalisation[tiab] OR hospitalized[tiab] OR hospitalised[tiab] OR death[tiab] OR mortality[tiab] OR survival[tiab] OR severity[tiab] OR "long-term"[tiab] OR “medically-attended”[tiab] OR (“lower respiratory tract”[tiab] AND (disease[tiab] OR infection[tiab]))) AND ("United States"[Mesh] OR "United States"[tiab])
6	Immune landscape search terms	((seroprevalence[tiab] OR serolog*[tiab] OR immunity[tiab] OR "Immunity, Humoral"[majr]) AND ("United States"[Mesh] OR "United States"[tiab])) OR "Immunity, Maternally-Acquired"[majr] OR “maternal antibod*"[tiab] OR ((transplacental[tiab] OR placental[tiab]) AND antibod*[tiab])
7	Variant search terms	“RSV A”[tiab] OR “RSV B”[tiab] OR subtype[tiab]
8	General vaccine search terms	"Respiratory Syncytial Virus Vaccines"[majr] OR vaccin*[ti] OR immuni*[ti] OR booster[ti] OR "Vaccines"[majr] OR "Vaccination"[majr] OR immunoprophylaxis[ti] OR "monoclonal antibody"[ti] OR mAb[ti]
9	Vaccine effectiveness and immunogenicity search terms	"Immunogenicity, Vaccine"[majr] OR ((vaccin*[tiab] AND (efficacy[tiab] OR effectiveness[tiab])) OR "Vaccine Efficacy"[majr]
10	Safety and adverse event search terms	"Vaccine Safety"[tiab] OR "adverse event*"[tiab] OR "side effect*"[tiab] OR thrombosis[tiab] OR stroke[tiab] OR "Guillain-Barré"[tiab] OR demyelin*[tiab] OR ADEM[tiab] OR "acute disseminated encephalomyelitis"[tiab] OR "injection site reaction*"[tiab] OR ((preterm[tiab] OR premature[tiab]) AND (delivery[tiab] OR birth[tiab])) OR "Myocardial infarction”[tiab] OR “heart attack”[tiab] OR STEMI[tiab] OR “acute coronary syndrome”[tiab] OR “birth outcome”[tiab] OR stillbirth[tiab] OR preterm[tiab] OR “congenital anomal*”[tiab] OR miscarriage[tiab] OR "congenital abnormalities"[MeSH] OR "birth defect*"[tiab] OR "fetal abnormalit*"[tiab] OR "neural tube defect*"[tiab] OR "malformation*"[tiab] OR "fetal development"[tiab] OR "hypertension, pregnancy-induced"[MeSH] OR "preeclampsia"[MeSH] OR “preeclampsia”[tiab] OR “pre-eclampsia”[tiab] OR "eclampsia"[tiab] OR "gestational hypertension"[tiab] OR "hypertensive disorders of pregnancy"[tiab] OR “pregnancy-induced hypertension”[tiab]
11	Co-administration and adjuvant search terms	Coadministration*[tiab] OR "co-administration*"[tiab] OR "simultaneous administration"[tiab] OR adjuvant[tiab]
12	Exclude if not human	(animals[mh] NOT humans[mh])
13	Exclusion by publication type	“case reports”[pt] OR “clinical trial protocol”[pt] OR “Clinical Trial, Veterinary”[pt] OR “Comment”[pt] OR “Editorial”[pt] OR “Guideline”[pt] OR “letter”[pt] OR “practice guideline”[pt] OR “Published Erratum”[pt]
14	Additional terms for exclusion	modeling[ti] OR modelling[ti] OR "mathematical model"[tiab] OR "simulation model"[tiab] OR simulation[ti] OR "cost-effectiveness"[ti] OR costing[ti] OR "cost analysis"[tiab] OR "economic evaluation"[tiab] OR "cost utility"[tiab] OR microsimulation[tiab] OR "markov model"[tiab] OR "agent-based model"[tiab] OR

		macaque[ti] OR primate[ti] OR "case report"[ti] OR "mouse model"[tiab] OR murine[tiab] OR "in vitro"[ti] OR "cell line"[tiab] OR "protein structure"[tiab] OR "molecular docking"[tiab] OR "molecular dynamics"[tiab] OR "animal model"[tiab] OR rodent[tiab] OR bioinformatics[tiab] OR "receptor binding"[tiab] OR "viral genome"[tiab]
15	OR terms 2	1 OR 2
16	OR terms 2	5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11
17	NOT terms	12 OR 13 OR 14
18	Combined	15 AND 3 AND 4 AND 16 NOT 17

Supplemental Table 3. PubMed Influenza related search terms

#	Descriptor	String
1	Disease - Influenza	"Influenza, Human"[majr] OR "Influenza A virus"[Mesh] OR "Influenza B virus"[majr] OR influenza[tiab] OR flu[ti]
2	Influenza vaccine specific terms (inc. brand names)	"Influenza Vaccines"[majr] OR Fluzone[tiab] OR Afluria[tiab] OR Fluad[tiab] OR Flucelvax[tiab] OR FluMist[tiab] OR Flublok[tiab] OR Fluarix[tiab] OR Flulaval[tiab] OR Fluvirin[tiab] OR Agriflu[tiab] OR Arepanrix[tiab] OR Audenz[tiab] OR Afluria[tiab]
3	Date filter	2023/8/26:2025/7/31[pdat]
4	Language filter	english[lang]
5	Epidemiologic search terms	(Inciden*[tiab] OR prevalen*[tiab] OR hospitalization[tiab] OR hospitalisation[tiab] OR hospitalized[tiab] OR hospitalised[tiab] OR death[tiab] OR mortality[tiab] OR survival[tiab] OR severity[tiab] OR "long-term"[tiab] OR "medically-attended"[tiab]) AND ("United States"[Mesh] OR "United States"[tiab])
6	Immune landscape search terms	(seroprevalence[tiab] OR serolog*[tiab] OR immunity[tiab] OR "Immunity, Humoral"[majr]) AND ("United States"[Mesh] OR "United States"[tiab])
7	Variant search terms	variant[tiab] OR subvariant[tiab] OR subtype[tiab] OR H1N1[tiab] OR H3N2[tiab] OR "B/Victoria"[tiab]
8	General vaccine search terms	"Influenza Vaccines"[majr] OR vaccin*[ti] OR immuni*[ti] OR booster[ti] OR "Vaccines"[majr] OR "Vaccination"[majr]
9	Vaccine effectiveness and immunogenicity search terms	"Immunogenicity, Vaccine"[majr] OR ((vaccin*[tiab] AND (efficacy[tiab] OR effectiveness[tiab])) OR "Vaccine Efficacy"[majr]
10	Safety and adverse event search terms	"Vaccine Safety"[tiab] OR "adverse event*"[tiab] OR "side effect*"[tiab] OR thrombosis[tiab] OR stroke[tiab] OR "Guillain-Barré"[tiab] OR demyelin*[tiab] OR ADEM[tiab] OR "acute disseminated encephalomyelitis"[tiab] OR anaphylaxis[tiab] OR "injection site reaction*"[tiab] OR myocarditis[tiab] OR pericarditis[tiab] OR "Myocardial infarction"[tiab] OR "heart attack"[tiab] OR STEMI[tiab] OR "acute coronary syndrome"[tiab] OR "birth outcome"[tiab] OR stillbirth[tiab] OR preterm[tiab] OR "congenital anomal*"[tiab] OR miscarriage[tiab] OR "congenital abnormalities"[MeSH] OR "birth defect*"[tiab] OR "fetal abnormalit*"[tiab] OR "neural tube defect*"[tiab] OR "malformation*"[tiab] OR "fetal development"[tiab] OR "hypertension, pregnancy-induced"[MeSH] OR "preeclampsia"[MeSH] OR "preeclampsia"[tiab] OR "pre-eclampsia"[tiab] OR "eclampsia"[tiab] OR "gestational hypertension"[tiab] OR "hypertensive disorders of pregnancy"[tiab] OR "pregnancy-induced hypertension"[tiab]
11	Co-administration and adjuvant search terms	Coadministration*[tiab] OR "co-administration*"[tiab] OR "simultaneous administration"[tiab] OR adjuvant[tiab]
12	Exclude if not human	(animals[mh] NOT humans[mh])
13	Exclusion by publication type	"case reports"[pt] OR "clinical trial protocol"[pt] OR "Clinical Trial, Veterinary"[pt] OR "Comment"[pt] OR "Editorial"[pt] OR "Guideline"[pt] OR "letter"[pt] OR "practice guideline"[pt] OR "Published Erratum"[pt]

14	Additional terms for exclusion	modeling[ti] OR modelling[ti] OR "mathematical model"[tiab] OR "simulation model"[tiab] OR simulation[ti] OR "cost-effectiveness"[ti] OR costing[ti] OR "cost analysis"[tiab] OR "economic evaluation"[tiab] OR "cost utility"[tiab] OR microsimulation[tiab] OR "markov model"[tiab] OR "agent-based model"[tiab] OR macaque[ti] OR primate[ti] OR "case report"[ti] OR "mouse model"[tiab] OR murine[tiab] OR "in vitro"[ti] OR "cell line"[tiab] OR "protein structure"[tiab] OR "molecular docking"[tiab] OR "molecular dynamics"[tiab] OR "animal model"[tiab] OR rodent[tiab] OR bioinformatics[tiab] OR "receptor binding"[tiab] OR "viral genome"[tiab]
15	OR terms 2	1 OR 2
16	OR terms 2	5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11
17	NOT terms	12 OR 13 OR 14
18	Combined	15 AND 3 AND 4 AND 16 NOT 17

Supplemental Table S4. Study characteristics.

Study	Population[1]	Study design[2]	Country/region	Setting details	Risk of bias
Abdul Rahim 2025	A, E	Case-control	Malaysia	Multi-center	Low
Abdurakhmanov 2024	A, E	Observational - other	Turkey	Single-center	Moderate
Abou Chakra 2025	C, A, E	Case-control	France	Multi-center	Low
Ab Rahman 2024	A, E	Observational - other	Malaysia	Multi-center	Low
Abukhalil 2024	C, A, E	Observational - other	Palestine		High
Acuti Martellucci 2025	A, E	Cohort	Italy	Population-based	Low
Adelglass 2025	A	Observational - other	US	Multi-center	High
Adin 2024	A, E	Observational - other	US, Turkey		High
Aftab 2024	C, A, E	Observational - other	US	VAERS database	High
Ahmed Al Qahtani 2025	A, E	Observational - other	Saudi Arabia	Single-center	High
Ahn 2024	C	Cohort	South Korea		Moderate
Al-Haddad 2024	A	Observational - other	Iraq	Single-center	High
Al-Rousan 2024	C, A, E	Observational - other	Worldwide	WHO database	High
Alami 2025	P	Observational - other	US	VAERS database	High
Alawfi 2024	A	Observational - other	Saudi Arabia	Survey-based	High
Albahari 2025	A, E	Observational - other	Qatar	Single-center	High
Alejandre 2024	I, C	Cohort	Spain	Single-center	High
Ali 2024	C, A	Observational - other	Qatar	Single-center	High
Almeida 2025	A, E, IC	Observational - other	US	Multi-center	High
Almodóvar-Fernández 2024	A, E	Observational - other	Spain	Single-center	High

Study	Population[1]	Study design[2]	Country/region	Setting details	Risk of bias
Alves 2025	A, E	Observational - other			High
Amaralde Avila Machado 2025	C, A, E	Observational - other	Germany, Finland		High
Amicizia 2023	E	Observational - other	Italy		HiAndersengh
Amstutz 2024	C, A, E, IC	Observational - other	Switzerland	Multi-center	High
Andersen 2025a	A, E	Cohort	US	Multi-center	Low
Andersen 2025b	I, C	Cohort	US	Multi-center	Moderate
Andersson 2024	E	Cohort	Denmark, Finland, Sweden		Low
Ann Costa Clemens 2024	A, E	RCT	Brazil	Multi-center	Low
Appaneal 2025	A, E	Case-control	US	Nationwide (VAMC)	Low
Arbetter 2024	I, C	RCT	31 countries		Moderate
Arcolaci 2025	A, E	Observational - other	Italy	Multi-center	High
Arepalli 2025	A, E	Observational - other	US	Multi-center	High
Ares-Gómez 2024	I, C	Cohort	Spain	Multi-center	Low
Asiri 2025	A, E	Observational - other	Saudi Arabia	Single-center	High
AşkınTuran 2024	A	Observational - other	Turkey	Single-center	High
Athan 2024	E	RCT	Australia	Multi-center	Low
Awasthi 2025	C, A, E	Observational - other	US	Nationwide (CDC surveillance)	Moderate
Aydillo 2024	A, E	Cohort		Multi-center	Moderate
Aydin 2024	A	Observational - other	Turkey	Single-center	High
Baba 2024	C, A, E	Observational - other	Japan	Single-center	High
Babalola 2025	A, E	Cohort	US	Single-center	High
Baden 2024	A, E	RCT	US		Low
Bahakel 2025	C, IC	Observational - other	US	Multi-center	High
Bajema 2025a	A, E	Cohort	US	Multi-center (VAMC)	Low

Study	Population[1]	Study design[2]	Country/region	Setting details	Risk of bias
Bajema 2025b	E, IC	Cohort	US	VAMC	Low
Barbas Del Buey 2024	I	Cohort	Spain	Multi-center	Low
Barnay 2025	A, E	Cohort	France	Multi-center	High
Barouch 2024	A, E	Cohort	US		High
Battis 2024	A, E	Observational - other	US	Single-center	High
Baum 2024	A, E	RCT	England	Multi-center	Low
Bea 2024	C, A, E	Observational - other	South Korea	Nationwide	Low
Beller 2025	A, E	Observational - other	Germany	Single-center	High
Bellitto 2024	IC	Cohort	11 countries in Europe		High
Ben Kridis 2024	A, E, IC	Observational - other	Tunisia	Single-center	High
Bennett 2024a	A	RCT	Australia	Multi-center	Low
Bennett 2024b	A, IC	RCT	South Africa	Multi-center	Low
Bennett 2025	C	RCT	US	Multi-center	Low
Berthaud 2024	C	Observational - other	US, Canada		High
Beurrier 2025	C, A, E	Observational - other	France	Nationwide	High
Biegus 2024	A, E	Observational - other	Poland	Single-center	High
Blanquart 2025	E	Case-control	France	Nationwide	Low
Blauvelt 2025	P	Case-control	US	Single-center	Low
Bolu 2025	A, E	Observational - other	Nigeria	Multi-center	High
Bosch 2024	A	Cohort	US	Multi-center	Low
Boulefaa 2025	A, E	Observational - other	France	Nationwide	High
Briggs 2025	A, E	Observational - other	Worldwide		High
Buynak 2024	E	RCT	US	Multi-center	Moderate
Byoun 2024	A, E	Cohort	South Korea	Nationwide	Low
Caffrey 2024	A, E, IC	Case-control	US	Nationwide (VAMC)	Low

Study	Population[1]	Study design[2]	Country/region	Setting details	Risk of bias
Carazo 2025	E	Case-control	Canada	Multi-center	High
Carbajal 2024	I, C	Case-control	France	Single-center	Low
Carcione 2025	I, C	Observational - other	Australia		High
Chalkias 2024	A	RCT	US	Multi-center	High
Chandler 2024	E	RCT	Panama		Moderate
Chemaitelly 2024a	C, A, E	Cohort	Qatar		Low
Chemaitelly 2024b	I, C, A, E	Case-control	Qatar	Multi-center	Low
Chen 2024a	A, E	Observational - other	Taiwan	Single-center	High
Chen 2024b	C, A, E, IC	Observational - other	England		Low
Chen 2025	A, E	Observational - other	Taiwan	Nationwide	Low
Cheng 2024	A, E, IC	Observational - other	Taiwan	Nationwide	Low
Cheng 2025	C, A, E	Cohort		TriNetX	Low
Chewaskulyong 2024	IC	Observational - other	Thailand	Multi-center	High
Chime 2025	A	RCT	US, Canada, Finland, Spain, South Korea		Moderate
Cho 2024	E	Observational - other	South Korea	Nationwide	Low
Cho 2025	I, C, A, E	Observational - other	Worldwide	VigiBase	High
Choi 2024a	A, E	Case-control	South Korea	Multi-center	High
Choi 2024b	A, E	RCT	South Korea	Single-center	High
Choi 2024c	C, A, E	Observational - other	South Korea	Nationwide	Low
Choi 2024d	A	Observational - other	South Korea	Nationwide	Moderate
Choi 2025a	P	Observational - other	South Korea	Nationwide	High
Choi 2025b	A, E	Cohort	US	Nationwide (VAMC)	Low
Choi 2025c	A, E	Case-control	South Korea	Multi-center	Moderate
Chong 2024	A, E	Cohort	Singapore	Nationwide	Low

Study	Population[1]	Study design[2]	Country/region	Setting details	Risk of bias
Chung 2025	C, A, E	Case-control	US	Flu VE Network	Low
Churilla 2024	C	Observational - other	US	Multi-center	High
Clark 2024	E	RCT	Belgium, Finland, France, Spain, England		Moderate
Clothier 2024	C, A, E	Observational - other	Australia		High
Coma 2024	I	Cohort	Spain		Low
Copland 2024	C	Observational - other	England	English National Immunisation Management Service (NIMS)	Low
Costantino 2024	C, A, E	Case-control	Italy	RespiVirNet network	Low
Couvillion 2024	A	Observational - other	US	Single-center	High
Dammann 2025	I, C	Cohort	Germany	Multi-center	Low
Darko 2024	C, A, E	Cohort	Ghana	Multi-center	High
daSilva 2025	A, E, IC	Observational - other	Brazil	Single-center	High
Davis 2025	A	RCT	US	Multi-center	Low
de-la-Plaza-San-Frutos 2024	A	Observational - other	Spain		High
de la Cueva 2024	C, A, E	Observational - other	Germany, Belgium, Spain		High
Denoble 2024	P	Case-control	US	VSD database	Low
Deshmukh 2024	E	Cohort	US	Nationwide	Low
Dixit 2024	C	Observational - other	US	Multi-center	High
Diya 2025a	A	Observational - other	US	Multi-center	High
Diya 2025b	A, E	Observational - other	US	Multi-center	High
Domachowske 2024	I, C, IC	Observational - other	US, Japan, Belgium, Poland, South Africa, Spain, England, Ukraine		High
Domnich 2024	A, E	Case-control	Italy	Single-center	Low
Domnich 2025	A, E	Observational - other	Italy		High
DosSantos 2024	C, A, E	Observational - other	South Korea		High

Study	Population[1]	Study design[2]	Country/region	Setting details	Risk of bias
Dudukina 2025	C, A, E	Cohort	Denmark	Nationwide	Moderate
Dulfer 2023	A, E	RCT	Netherlands	Single-center	Low
Duskin-Bitan 2024	A, E	Case-control	Israel	Multi-center	Low
Elbaz 2024	A, E	Case-control	Israel	Multi-center	Low
Elemuwa 2024	C, A, E	Observational - other	Nigeria	Nationwide	High
El Hilali 2024	C, A, E	Observational - other	Morocco		High
Emborg 2025	E	Case-control	Denmark	Nationwide	Low
Erdwiens 2025	C, A, E	Case-control	Germany	Nationwide	Low
Esteban-Cledera 2024	C, A	Cohort	Spain	Multi-center	Low
Estrella-Porter 2025	I, C	Observational - other	Spain	Nationwide (pharmacovigilance database)	High
Fabbri 2025	A, E	Cohort	Italy	Nationwide	Low
Farisogullari 2024	A, E	Cohort	Europe	EULAR COVAX registry	High
Fatima 2025	A	Observational - other	Dubai	Population-based	High
Fazal 2025	I, C	Observational - other	US		Moderate
Fell 2024	I	Case-control	Canada		Low
Ferguson 2024	A, E	RCT	US, Argentina, Canada, Germany, Japan, Netherlands, Poland, Spain		Moderate
Ferraioli 2025	A, E	Observational - other	Italy	Single-center	High
Ferrari 2024	C, A, E	Observational - other	Italy	Multi-center	High
Fierro 2025	A, E	RCT	US	Multi-center	Low
Figueroa 2024a	A, E	Observational - other	US	Multi-center	High
Figueroa 2024b	C	Observational - other	US		High
Figueroa 2025a	C	Observational - other	US	Multi-center	High
Figueroa 2025b	C	Observational - other	US, Dominican Republic		High

Study	Population[1]	Study design[2]	Country/region	Setting details	Risk of bias
Fitzpatrick 2024	C	Observational - other	Canada		High
Fitzpatrick 2025	C, A, E	Observational - other	Canada	Multi-center	High
Folegatti 2025	C, A	Observational - other	US, Poland, Czech Republic, Spain		High
Fonseca 2024	A, E	RCT	Brazil	Multi-center	Low
Fontana 2024	A, E	Observational - other	US	DILIN registry	High
Fotakis 2024	A, E	Cohort	Italy	Nationwide	Low
Fraenza 2025	I, C, A, E, IC	Observational - other	Europe	Data submitted to the European Union	High
Frankenthal 2025	A, E	Observational - other	Israel	Survey-based	High
Frutos 2024	C, E	Case-control	US	Multi-center	Low
Frutos 2025	C, A, E	Case-control	US	Multi-center	Low
Fry 2025	A, E, IC	Case-control	US		Low
Gaddh 2023	A, E	Cohort	US	Multi-center	Low
Gallagher 2024	C, A, E	Cohort	US	TriNetX	Low
Ganelin-Cohen 2024	C, A, E	Cohort	Israel	Multi-center	Low
Gao 2024	C, A	RCT	China	Single-center	Low
Gào 2024	C, A, E	Case-control	China	Multi-center	Low
Garrett 2025	A, E, IC	Cohort	7 countries in Africa		High
Gentile 2025	I	Case-control	Argentina	Multi-center	Low
Getahun 2024	P	Cohort	US	VSD database	Low
Gharpure 2025	C, A, E, IC	Case-control	Argentina, Brazil, Chile, Paraguay, Uruguay, Australia, New Zealand, Thailand		High
Giang 2024	A, E	Observational - other	Canada		High
Giovanetti 2025	I, C, A, E	Observational - other	US		Low
Gligorov 2025	C	Observational - other			High
Göbel 2025	C, A, E	Cohort	Germany	Multi-center	High
Gonen 2023	A, E	Cohort	Israel	Single-center	Low

Study	Population[1]	Study design[2]	Country/region	Setting details	Risk of bias
Goodyear 2024	A, E, IC	RCT	England	Multi-center	High
Gordon 2024	C, A, E	Observational - other	US	VAERS database, institutional database	High
Goswami 2025	A, E	RCT	US	Multi-center	Moderate
Granja López 2024	A, E	Observational - other	Spain	Single-center	High
Grieshaber 2025	I, C	Observational - other	Germany		Moderate
Grima 2024	A, E, IC	Observational - other	Canada	Single-center	Low
Grimaldi 2023	C, A, E, IC	Cohort	France	Nationwide	Low
Grisanti 2025	C, A, E	Cohort	Italy	Single-center	Low
Guerrero-Del-Cueto 2025	I, C	Case-control	Spain	Single-center	Low
Hall 2025	P	Cohort	US	Nationwide	Low
Hammam 2024	A, E	Observational - other	Egypt	Survey-based	High
Hashimoto 2024	E	Observational - other	Japan		Low
Havers 2024	I	Observational - other	US	COVID-NET	Low
Havlin 2025	IC	Observational - other			High
Hikichi 2024	A, E	Observational - other	Japan	Single-center	High
Holzwarth 2025	C	Observational - other	Germany	Multi-center	High
Hsiao 2024	P	Cohort	US	Kaiser Permanente Northern California	Low
Huang 2025a	A, E	Observational - other	Taiwan	Single-center	High
Huang 2025b	I, C	RCT	China	Multi-center	Low
Hwang 2025a	C, A, E	Observational - other	Worldwide	VigiBase	High
Hwang 2025b	C, A, E	Observational - other	South Korea	Nationwide	Low
Ioannou 2025	A, E	Cohort	US	Multi-center (VAMC)	Low
Ip 2024	A, E	Cohort	England	Multi-center	Low

Study	Population[1]	Study design[2]	Country/region	Setting details	Risk of bias
Ip 2025	A, E	Cohort	China	Population-based	Low
Ison 2025	A, E	RCT	17 countries in Africa, Asia, Oceania, Europe, North America		Moderate
Itamochi 2024	A, E	Observational - other	Japan	Multi-center	High
Ito 2025	A, E	Cohort	Japan	Multi-center	Moderate
Jaffry 2023	C, A, E	Observational - other	US	VAERS database	High
Jain 2024	C, A	Cohort	US	Multi-center	Low
Jajou 2024	C, A	Cohort	Netherlands	Netherlands (population-based)	Low
Jajou 2025	A, E	Cohort	Netherlands	Netherlands (population-based)	Low
Jarrot 2024	A, E	Observational - other	France		High
Jeong 2024a	C, A, E	Observational - other	Worldwide	VigiBase	High
Jeong 2024b	C, A, E	Observational - other	Worldwide	WHO Pharmacovigilance Database	High
Jeong 2025a	C, A, E	Observational - other	Worldwide	WHO Pharmacovigilance Database	High
Jeong 2025b	I, C, A, E	Observational - other	Worldwide	WHO database	High
Jeong 2025c	I, C, A, E	Observational - other	Worldwide		High
Jęśkowiak-Kossakowska 2024	A, E	Observational - other	Poland	Population-based	High
Jiang 2025	C	Case-control	China		High
Jimeno Ruiz 2024	I	Cohort	Spain		High
Jin Hsieh 2025	P	Cohort		TriNetX	Low
Jirawattanadon 2024	A, E	Observational - other	Thailand	Single-center	High
Jobe 2025	C, A, E	Observational - other	US	NREVSS database	Low
Jorda 2025	A, E	RCT	Austria	Single-center	Low
Jorgensen 2024	P	Cohort	Canada		Low
Jung 2024	C, A, E	Cohort	South Korea		Low
Kälin 2024	A, E	Cohort	Switzerland	Nationwide	High

Study	Population[1]	Study design[2]	Country/region	Setting details	Risk of bias
Kandinov 2025	A, E	RCT	Multiple countries		Moderate
Kang 2024	A, E	Observational - other	Worldwide	VigiBase	High
Karam 2024	A, E	Observational - other	Lebanon	Lebanese National Pharmacovigilance Program (LNPVP)	High
Katatbeh 2024	A, E	Observational - other	Jordan	Survey-based	High
Kawai 2025	A, E	Cohort	Japan	Multi-center	High
Kern 2025	A, E, IC	Observational - other	Denmark		Moderate
Khalid 2024	A, E	RCT	US	Single-center	Low
Kikuchi 2024	A, E	Cohort	Japan		High
Kim 2024	C, A, E	Cohort	South Korea	Nationwide	Low
Kim 2025a	A, E	Cohort	South Korea	Nationwide	Low
Kim 2025b	C	Observational - other	South Korea	Nationwide	Low
Kim 2025c	P, I	Cohort	South Korea	Nationwide	Low
Kirwan 2024	A	Cohort	England	Nationwide	Low
Kissling 2025	C, A, E	Case-control	Europe	Multi-center	High
Ko 2024	C	Observational - other	South Korea		High
Ko 2025	A, E	Observational - other	South Korea	Nationwide	Low
Konishi 2025	A, E	Observational - other	Japan	Single-center	High
Kothari 2024	C	RCT	India	Multi-center	Low
Kumar 2024	C, A, E	Observational - other	US	Optum Labs database	Moderate
Kurucu 2024	C, A, IC	Observational - other	Turkey	Multi-center	High
Kwaah 2025	C, A	Case-control	US	Nationwide (military healthcare)	High
Kyung 2025	I, C, A, E	Observational - other	Worldwide	WHO Pharmacovigilance Database	High
Lacroix 2025	P	Observational - other	France	Multi-center	High

Study	Population[1]	Study design[2]	Country/region	Setting details	Risk of bias
Lafleur 2024	E	Observational - other	Canada	Multi-center	High
Lambo 2025	C, A, E	Cohort	Caribbean	Multi-center	High
Laniece Delaunay 2025	P, C, A, E, IC	Case-control	Europe	Multi-center	Low
Lauring 2025	A, E	Observational - other	US	IVY network, VAMC	Moderate
LaVerriere 2025	I, C, A, E	Observational - other	US	Single-center	Moderate
Lee 2023	I, C, A, E	Observational - other	Worldwide	VigiBase	High
Lee 2024a	I, C, A, E	Observational - other	Worldwide	VigiBase	High
Lee 2024b	P, I, C, A, E	Observational - other	Worldwide	VigiBase	High
Lee 2024c	C	Case-control	China	Multi-center	Low
Lee 2024d	C, A, E	Cohort	South Korea	Multi-center	Low
Lee 2025a	I, C, A, E	Observational - other	Worldwide	VigiBase	High
Lee 2025b	A, E	Case-control	Canada		Low
Lee 2025c	C	Cohort	Canada		Low
Lee 2025d	P	Cohort	South Korea	Nationwide	Low
Lefferts 2024	I, C	Case-control	US	Multi-center	Low
Lei 2025	C, A, E	Case-control	China	Multi-center	Low
Leung 2024	A, E	Cohort	China	Single-center	High
LeVu 2023	C, A, E	Observational - other	France	Nationwide	Low
LeVu 2024	C, A, E	Case-control	France	Nationwide	Low
Levy 2024	I, C, A, E	Observational - other	US	Multi-center	Low
Levy 2025a	A, E	Case-control	US	Multi-center	High
Levy 2025b	IC	Observational - other	Israel	Single-center	High
Lewis 2025	A, E, IC	Case-control	US	Multi-center	Low
Lewnard 2024	C, A, E	Cohort	US	Kaiser Permanente Southern California	Low

Study	Population[1]	Study design[2]	Country/region	Setting details	Risk of bias
Li 2024a	C	Observational - other	China	Multi-center	High
Li 2024b	C, A, E	Observational - other	US	VAERS database	High
Li 2025a	E	Observational - other	US	VAERS database	High
Li 2025b	P	Observational - other	US	VAERS database	High
Lim 2025a	C	Observational - other	China	Multi-center	High
Lim 2025b	A, E	Observational - other	South Korea	Nationwide	Low
Lin 2024	A	Observational - other	Malaysia	Single-center	High
Link-Gelles 2024	A, IC	Case-control	US	VISION network	Low
Link-Gelles 2025a	A, E, IC	Case-control	US	Multi-center	Low
Link-Gelles 2025b	IC	Case-control	US	Multi-center	Low
Liu 2025	C	Observational - other	US	VAERS database	High
Lloyd 2025a	C, A, E	Observational - other	US	Nationwide (CVS Health, Carelon Research, Optum, medicare databases)	High
Lloyd 2025b	E	Observational - other	US	Nationwide (Medicare database)	High
López de Las Huertas 2025	C, A, E	Observational - other	Europe	Eudravigilance	High
López-Contreras 2023	A	Observational - other	Mexico	Single-center	High
Lophatananon 2023	E	Cohort	England		Low
Lu 2024a	E	Observational - other	US	Nationwide (Medicare database)	Low
Lu 2024b	E	Observational - other	US	Nationwide (Medicare database)	Low
Lu 2024c	A, E	Observational - other	Taiwan	Nationwide (Vaccine Injury Compensation Program)	High
Ma 2024a	A, E	Case-control	US	IVY network	Low
Ma 2024b	C, A, E	Observational - other	US	Nationwide (CDC surveillance)	Low

Study	Population[1]	Study design[2]	Country/region	Setting details	Risk of bias
Maan 2024	A, E	Observational - other	Europe	Multi-center	High
Machado 2024	C, A, E	Observational - other	Germany, Finland		High
Mackenzie 2025	I, C, A, E	Observational - other	Europe	Eudravigilance	High
Madhi 2025	P	RCT	Worldwide		Low
Madni 2024	C	Observational - other	US		High
Magnus 2024a	A	Cohort	Norway	Nationwide	Low
Magnus 2024b	P	Cohort	Sweden, Denmark, Norway		Low
Malange 2025	P	Case-control	US	Multi-center	Low
Manniche 2024	C, A, E	Observational - other	Denmark, Sweden		High
Mansou 2024	C, A, E	Observational - other	Canada		High
Mantovani 2024	A	Observational - other	Italy	Single-center	High
Mao 2025	A	RCT	China	Single-center	High
Marchese 2025	A, E	RCT	England	Multi-center	Low
Marouk 2025	I	Cohort	France	Multi-center	High
Marron 2024	P, C, A, E, IC	Case-control	Ireland	Multi-center	Low
Martínez-Baz 2025	C, A, E	Case-control	Spain	Multi-center	Low
Matsuzono 2024	A, E	Observational - other	Japan	Single-center	High
Maurel 2024	I, C, A, E	Case-control	Europe	Multi-center	High
Mayer 2025	A	RCT	US, Canada, England		Low
Mazarakis 2025	A, E	RCT	Australia		Low
McLeod 2024	A, E	RCT	Australia	Multi-center	Low
Meidani 2024	A, E, IC	RCT	Iran	Single-center	High
Memon 2024	C	Observational - other	Ireland	Single-center	High
Mensah 2024	P	Case-control	England	Multi-center	Low
Metz 2024	P	Cohort	US	Multi-center	Low

Study	Population[1]	Study design[2]	Country/region	Setting details	Risk of bias
Mi 2024	C, A, E	Case-control	China	Multi-center	Moderate
Minendez 2024	A	Observational - other	Mexico		Moderate
Mohamed 2024	A, E	Observational - other	Saudi Arabia	Single-center	High
Moisset 2024	IC	Observational - other	France	Nationwide	Low
Mok 2025	A, E	Cohort	China	Multi-center	Low
Moline 2025	I, C	Case-control	US	Multi-center	Moderate
Mombelli 2024	A, E, IC	RCT	Spain, Switzerland		Moderate
Moon 2024	C, A, E	Observational - other	South Korea	Multi-center	High
Moor 2024	C	Observational - other	Germany	Multi-center	High
Morciano 2024	C, A, E	Observational - other	Italy	Multi-center	Low
Moreira Puga 2025	A	RCT	Brazil, Pakistan		Low
Moro 2024	C, A, E	Observational - other	US	VAERS database	High
Moscara 2023	A, E	Cohort	Italy	Single-center	High
Moss 2023	A, E	Cohort	Israel	Single-center	Low
Mukherjee 2025	A, E	Cohort	US	Multi-center	Low
Munro 2025	I, C	RCT	England, France, Germany		Low
Murdoch 2023	A	RCT	Australia, New Zealand		Low
Mutter 2025	E	Cohort	Israel		Low
Naficy 2024	A, E	RCT	US	Multi-center	Moderate
Nakafero 2024	A, E, IC	Observational - other	England	Nationwide	Low
Nakashima 2023	A, E, IC	Observational - other	Japan	Single-center	High
Nakayama 2025	C	RCT	Japan	Multi-center	Low
Namiki 2024	A	Observational - other	Japan	Single-center	High
Naqid 2024	A	Observational - other	Iraq	Multi-center	High

Study	Population[1]	Study design[2]	Country/region	Setting details	Risk of bias
Nasreen 2025	C, A, E	Observational - other	Ethiopia, Ghana, Kenya, Malawi, Mali, Mozambique, Nigeria, Argentina, Australia, Canada, Denmark, Finland, Indonesia, South Korea, South Africa, Spain, England		Low
Nazar 2024	C, A, E	Observational - other	Europe	Eudravigilance	High
Nazar 2025	C, A, E	Observational - other	Europe	Eudravigilance	High
Nelli 2025	A, E, IC	Observational - other	Italy	Single-center	High
Neutel 2025	E	RCT	US	Multi-center	Low
Ng 2024	A, E	Observational - other	Singapore	Nationwide	High
Nguyen 2025a	E	Observational - other	Australia	Nationwide	High
Nguyen 2025b	C, A	Case-control	US	Multi-center	Low
Nguyen 2025c	P, A, E, IC	Case-control	Belgium, Germany, Italy, Spain		Low
Nham 2025	A, E	Case-control	South Korea	Multi-center	Low
Nong 2025	A, E	Observational - other	US		High
Nunes 2024	E	Cohort	Belgium, Denmark, Italy, Spain, Norway, Portugal, Sweden		Low
Núñez 2025	I, C	Case-control	Spain	Multi-center	Low
Nv 2024	C	Cohort	US	Single-center	High
Obeng 2025	A, E	Observational - other	US	Multi-center	High
Ocanade Sentuary 2025	I	Observational - other	France	Single-center	High
Öcek 2024	A, E	Observational - other	Turkey	Single-center	High
Ogawa 2025	E	Observational - other	Japan		Low
Oh 2024	I, C, A, E	Observational - other	Worldwide	Vigilbase	High
Okada 2025	A, E	RCT	Japan	Multi-center	Low
Okoye 2024	A, E	Observational - other	Italy	Multi-center	High

Study	Population[1]	Study design[2]	Country/region	Setting details	Risk of bias
Omole 2025a	A, E	RCT	US	Multi-center	Low
Omole 2025b	A, E	RCT	US (including Puerto Rico)	Multi-center	Low
Otsuki 2024	P, I	RCT	Japan		Low
Özdemir 2024	C, A	Observational - other	Turkey	Single-center	High
Padilla-Pantoja 2024	A	Observational - other		Multi-center	High
Pakanen 2025	A, E	Observational - other	Finland	Nationwide	High
Pan 2025	A, E	Observational - other	US	N3C database	Low
Park 2024a	C, A, E	Observational - other	South Korea	Nationwide	High
Park 2024b	C, A, E	Observational - other	South Korea	Nationwide	Moderate
Parveen 2024	A	Cohort	Pakistan		High
Pasquale 2025	A, E	Cohort	Italy		Low
Pathak 2025	C, A, E	Observational - other	US	VAERS database	High
Pattinson 2024	C, A, E	Cohort	US		Low
Patton 2025	I, C	Observational - other	US	RSV-NET, NVSN	Low
Payne 2024	IC	Case-control	US	Multi-center	Low
Payne 2025	A, E, IC	Cohort	US	Nationwide (Medicare database)	Low
Peck 2024	C, A, E	Observational - other	Singapore	Nationwide	High
Pekdiker 2024	A, E	Observational - other	Turkey	Single-center	High
Pérez-Gimeno 2024	C	Case-control	Spain	SiVIRA database	Low
Pérez Marc 2025	I	Case-control	Argentina	Multi-center	Low
Perramon-Malavez 2025a	I	Cohort	Spain	Population-based	Low
Perramon-Malavez 2025b	I, C	Observational - other	Spain, Italy, England		Low
Petr 2024	A, E, IC	Observational - other	Czech Republic	Single-center	High

Study	Population[1]	Study design[2]	Country/region	Setting details	Risk of bias
Pham-Huy 2024	C	Observational - other	Canada	Single-center	High
Pinto 2024	A, E	Observational - other	Brazil		High
Pira 2024	A, E	Observational - other	Italy	Single-center	High
Płatkowska-Adamska 2024	A, E	Observational - other	Poland	Single-center	High
Poder 2023	A	RCT	US, Germany, Estonia		Low
Popham 2025	E	Cohort	US	RSV-NET	High
Prabhu 2025	A	Cohort	Malaysia		High
Prasert 2024	A	RCT	Thailand	Multi-center	Low
Prasertsakul 2025	C	Case-control	Thailand	Multi-center	High
Pratt 2025	I, C, A, E	Observational - other	US		Low
Primicerio 2025	A, E	Observational - other	Denmark	Single-center	High
Prins 2025	A, E, IC	Case-control	Netherlands		Low
Pudasaini 2024	A, E	Cohort	Germany		High
Ramsay 2023	A, E	RCT	Australia	Multi-center	Low
Reeves 2025	P, A	Case-control	US	Multi-center	Low
Regan 2023	P	Cohort	US, Canada	PRESTO (Pregnancy Study Online)	Moderate
Regan 2024	P	Cohort	US	Optum Labs database	Low
Reynolds 2024	C, A, E	Observational - other	Australia	Multi-center	High
Riccomi 2024	A, E	Observational - other	Italy	Multi-center	High
Rigamonti 2024	C	Cohort	Italy		Low
Rigamonti 2025	C	Cohort	Italy	Multi-center	Low
Rius-Peris 2025	I, C	Observational - other	Spain	Multi-center	Moderate
Rogers 2024	C, A, E	Observational - other	US	VAERS database	High
Rose 2025	C, A, E	Case-control	England, Northern Ireland,		High

Study	Population[1]	Study design[2]	Country/region	Setting details	Risk of bias
			Scotland, Denmark		
Rossier 2024	A, IC	Cohort	Switzerland	Single-center	High
Rouleau 2025	C, A, E	Observational - other	Canada	Population-based	High
Rousculp 2024	A	Cohort	US, Canada		Moderate
Ruzafa Martinez 2024	E	Cohort	Spain	Single-center	Low
Ryu 2024	E, IC	Observational - other	South Korea	Nationwide	Low
Saavedra 2025	A, E	Cohort	Brazil	Population-based	High
Safrai 2024	A	Cohort	Israel	Single-center	Moderate
Salmaggi 2025	C, A, E	Observational - other	Italy		Moderate
Sankar 2025	C, A, E	Observational - other	South Africa	Nationwide (AEFI database)	High
Schmader 2024	E	RCT	US	Multi-center	Low
Semenzato 2024	C, A	Cohort	France	Nationwide	Low
Separovic 2025	E	Case-control	Canada		Low
Shah 2024	C, A, E	Observational - other	US		High
Shaharir 2025	A, E	Observational - other	Malaysia	Survey-based	High
Shani 2024	C, A, E	Cohort	Israel	Multi-center	Low
Shapiro 2023	E	Observational - other	US	Single-center	High
Sharff 2024	A, E	Observational - other	US	Kaiser Permanente Northwest	High
Shaw 2024a	A	RCT	US	Multi-center	Low
Shaw 2024b	E	RCT	US	Multi-center	Low
Shemer 2025	A, E	Case-control	Israel	Single-center	Low
Sher 2024	C	Observational - other	US	Multi-center	High
Sheth 2025	P	Case-control	US	Multi-center	Low
Shi 2023	C	RCT	China		Moderate

Study	Population[1]	Study design[2]	Country/region	Setting details	Risk of bias
Shi 2024	E	Observational - other	US	Nationwide (Medicare database)	Low
Shinjoh 2024	C	Case-control	Japan	Multi-center	Low
Shinjoh 2025	C	Case-control	Japan	Multi-center	Low
Shoji 2024	A, E	Observational - other	Japan	Multi-center	High
Shrestha 2024	A	Cohort	US	Multi-center	Moderate
Silva-Afonso 2025	I, E	Case-control	Spain	Single-center	Low
Silverman 2025	I, C	Observational - other	US	Multi-center	High
Simões 2025	P	RCT		Multi-center	Low
Skowronski 2024	C, A, E	Case-control	Canada	Sentinel Practitioner Surveillance Network	Low
Slingerland 2023	A, E	Observational - other	Netherlands	Nationwide	High
Smith 2025	C, A, E	Observational - other	Canada	Multi-center	High
Smolarchuk 2024	C, A, E, IC	Case-control	Canada		Low
Sodagari 2025	P, A, E, IC	Observational - other	US	VAERS database	High
Soe 2024a	C	Cohort	Canada		High
Soe 2024b	E	Cohort	Canada	Multi-center	High
Strid 2024	A, E	Observational - other	US	VAERS database	High
Subaiea 2025	A, E	Observational - other	Saudi Arabia	Multi-center	High
Sumer 2025	A	Observational - other		Not reported	High
Sun 2025a	C, A, E, IC	Cohort	US	Nationwide	High
Sun 2025b	I, C, A, E	Case-control	China		Moderate
Surie 2024	A, E	Case-control	US	Multi-center	Low
Suseeladevi 2024	P	Cohort	England	Nationwide	Low
Swift 2024	C, A, E	Cohort	US		Low

Study	Population[1]	Study design[2]	Country/region	Setting details	Risk of bias
Takada 2025	C, A, E	Observational - other	Japan	Nationwide (Japanese Adverse Drug Event Report (JADER) database)	High
Talib 2024	A, E	Observational - other	Canada	Single-center	High
Tamir-Hostovsky 2024	I	Case-control	Israel	Single-center	Low
Tanaka 2024	A, E	Cohort	Canada		Low
Tani 2024	A	Cohort	Japan	Single-center	High
Tartof 2024a	A	Case-control	US	Multi-center	Low
Tartof 2024b	C	Case-control	US	Kaiser Permanente Southern California	Low
Tartof 2024c	E	Case-control	US		Low
Taylor 2024	A, E	Observational - other	US	Multi-center	Low
Tenforde 2024	C, A, E	Case-control	US	Multi-center	Low
Testi 2024a	C	Observational - other	Colombia, Mexico, India, Turkey, Slovenia, Palestine, Spain		High
Testi 2024b	C, A, E	Observational - other	England	Nationwide	High
Tetsuka 2024	A	Cohort	Japan	Single-center	Moderate
Thanborisutkul 2025	C, A, E	Observational - other	Thailand	Single-center	High
Thepveera 2025	C	Observational - other	Thailand	Single-center	High
Thomas 2023	A, E, IC	RCT	US	Multi-center	Low
Tian 2024	A	Cohort	China	Single-center	High
Top 2024	P, C, A, E, IC	Cohort	Canada		High
Top 2025	I, C	Observational - other	Canada	Immunization Monitoring Program Active (IMPACT) centers	Low
Torres 2025	I, C	Cohort	Chile	Multi-center	Low
Tursinov 2025	C, A, E	Observational - other	Uzbekistan	Population-based	High
Umezawa 2025	A, E	Observational - other	Japan	Single-center	High

Study	Population[1]	Study design[2]	Country/region	Setting details	Risk of bias
van Ewijk 2025	C, A	Observational - other	Netherlands		High
Villanueva 2024	A, E	Cohort	Australia, Brazil		Low
Vita 2025	A, E, IC	Observational - other			High
Walsh 2024	A, E	RCT	US	Multi-center	Low
Walsh 2025	E	RCT	US, Canada, Japan, Finland, Netherlands, Argentina, South Africa		High
Walter 2024	C, A, E	RCT	US	Multi-center	Low
Wan 2024	C, A, E	Cohort	China		Low
Wang 2024a	C, A, E	Observational - other	US	VAERS database	High
Wang 2024b	C	RCT	China	Single-center	Moderate
Ward 2025	E	Cohort	England, Scotland		Low
Wee 2025	A, E	Cohort	Singapore	Nationwide	Low
Wen 2025	C	Observational - other	China	Single-center	High
Werner 2023	A, E	Cohort	Germany	Survey-based	High
Whitaker 2024	C, A, E	Case-control	England, Scotland, Wales		Moderate
Williams 2025	I	Case-control	England	Multi-center	Low
Wilson 2025	E, IC	Cohort	US	Multi-center	Low
Woestenberg 2025	P	Cohort	Netherlands	Nationwide	High
Won 2024	E	Cohort	South Korea	Nationwide	Low
Woo 2024	C, A	Observational - other			High
Woo 2025	A, E	Observational - other	South Korea	Nationwide	Moderate
Wu 2025a	A, E	Observational - other	US	VAERS database	High
Wu 2025b	C, A	Cohort	US	Multi-center	Low

Study	Population[1]	Study design[2]	Country/region	Setting details	Risk of bias
Xiang 2024	A, E	Cohort	England	UK Biobank	Low
Xie 2024	A, E	Cohort	US	Multi-center (VAMC)	Low
Xu 2024	A, E	Observational - other	US	Kaiser Permanente	Low
Xu 2025a	A, E	Cohort	Sweden		Low
Xu 2025b	C, A, E	Observational - other	US	Kaiser Permanente Southern California	Low
Yamamoto 2024	A, E	Observational - other	Japan		High
Yaron 2025	E, IC	Cohort	Israel		Low
Yechezkel 2024	C, A, E, IC	Cohort	Israel		Moderate
Yih 2024	C, A, E	Observational - other	US	VAERS/VSD databases	Low
Yildirim 2025	A, IC	Observational - other	Turkey	Multi-center	High
Yin 2024	A	Observational - other	US	Single-center	High
Yoon 2024	A, E	Observational - other	South Korea	Nationwide	Low
Yoon 2025	C, A	Observational - other	South Korea		High
Youngster 2024	A	Cohort	Israel	Single-center	High
Yousaf 2025	C	Case-control	US	Multi-center	Low
Yumru Çeliksoy 2024	A	Observational - other	Turkey	Survey-based	High
Yunker 2024	Unspecified	Observational - other	US	Multi-center	Moderate
Zahrani 2024	C, A	Cohort	Saudi Arabia	Multi-center	Low
Zaidi 2025	A, E	Observational - other	Pakistan		High
Zawiasa-Bryszewska 2025	A, E, IC	Cohort	Poland	Multi-center	Low
Zeno 2024	C, A, E	Case-control	South America	Multi-center	Low
Zethelius 2024	A, E	Cohort	Sweden	Nationwide	Low
Zhang 2025	I, C, A, E	Case-control	China	Multi-center	Moderate
Zhu 2024a	E	RCT	China	Single-center	Low

Study	Population[1]	Study design[2]	Country/region	Setting details	Risk of bias
Zhu 2024b	C, A, E	Case-control	US	Multi-center	Moderate
Zhu 2025a	C	Case-control	China	Single-center	Low
Zhu 2025b	C, A, E	Case-control	US		Low
Zornoza Moreno 2024	C	Observational - other	Spain	Survey-based	High

[1] Populations: A - Adult; C - Children; E - Elder; I - Infants; IC - Immunocompromised Adults; P - Pregnant.

[2] "Observational - other" is defined as all observational studies except for case-control studies and (prospective or retrospective) cohort studies.

Supplemental Table S5. Key findings of epidemiologic studies.

Population	Outcome	Study Label	Findings
a. Covid-19			
Pregnancy	Complication of disease	Metz 2024	In 1,502 pregnant US patients with first SARS-CoV-2 infection December 2021 to September 2023, prevalence of Post-Acute Sequelae of Covid-19 was 9.3% measured at a median of 10.3 months after infection.
Infant	Maternal immunization	Havers 2024	In COVID-19-NET sites (~10% of US population), percentage of hospitalized infants whose mothers had been vaccinated during pregnancy: ● Oct 2022-Sept 2023: 18% ● Oct 2023-April 2024: < 5%
Infant/Child/ Adult/Older adult	Hospitalization and medically-attended infection by variant	Lewnard 2024	In the 2023-2024 respiratory virus season, among 7694 cases, ED presentation and hospital admission were 54% (95% CI, 32 to 69) and 51% (95% CI, -15 to 79) lower, respectively, among BA.2.86 lineages (eg JN.1) than non-BA.2.86 lineage. ARI- associated ED presentations and hospital admissions were 62% (95% CI, -2 to 86) and 85% (95% CI, -12 to 98) lower, respectively, among BA.2.86 lineages (JN.1) than among non-BA.2.86 lineages.
Infant/Child/ Adult/Older Adult	Variant predominance	Ma 2024b	Between May 2023 to September 2024, the JN.1 variant emerged and rapidly attained predominance, JN.1 and descendants were dominant in 2024. Increases in COVID-19 cases occurred during bothJN.1 predominance and co-circulation periods.
Child/Adult/ Older Adult	Hospitalization by variant	Levy 2024	In the 2023-2024 respiratory virus season, a multistate viral genomic surveillance program demonstrated that both JN.1 and HV.1 were less likely than EG.5 to account for infections among inpatients versus outpatients (aOR 0.60 [95% CI, 0.43-0.84] and 0.35 [95% CI, 0.21-0.58], respectively).

Population	Outcome	Study Label	Findings
Adult/Older Adult	Hospitalization or death	Taylor 2024	Between Oct 2023-Apr 2024: ● Two-thirds of all Covid-19-associated hospitalizations were among individuals age ≥65 years ● Half of in-hospital deaths were among patients age ≥75 years ● Only 12% of hospitalized patients had received 2023-2024 Covid-19 vaccine.
		Choi 2025b	Among 130,263 US veterans ≥18 years with Covid-19 (Sept 2023-Oct 2024), odds of hospitalization (compared to XBB era): ● JN.1 predominance: OR 0.81 (95% CI, 0.74 to 0.89) ● KP predominance: OR 0.80 (95% CI, 0.72 to 0.88) ● In-hospital mortality: 2.7-3.5% across all eras
Adult/Older Adult	Complication of disease	Mukherjee 2025	No association between vaccination and presentation of neurologic symptoms among a cohort of 1,300 individuals with neurologic post-acute sequelae of Covid-19
Adult/Older Adult	Complication of disease	Babalola 2025	Among 2,511 essential workers with confirmed SARS-COV-2 infection, 475 (18.9%, 95% CI 17.4 to 20.5) developed post-acute sequelae of COVID-19 (PASC). In multivariable models, development of PASC was associated with multiple SARS-COV-2 infections and being unvaccinated at first infection.
Adult/Older Adult	Mortality	Xie 2024	Among 8625 individuals hospitalized for Covid-19 (median age 73.9), the unadjusted death rate at 30 days was 5.70%. Patients hospitalized for Covid-19 had a higher risk of death compared with those hospitalized for seasonal influenza (adjusted death rate, 5.70% vs. 4.24% at 30 days; adjusted HR, 1.35 [95% CI, 1.10-1.66]).
b. RSV			
Infant	Incidence of hospitalization	Jimeno Ruiz 2024	Following introduction of nirsevimab in Spain (comparing a pre-nirsevimab period of October 1, 2022 - March 31, 2023 versus October 1, 2023 - March 31, 2024), incidence rates of RSV-related lower respiratory tract infection hospitalizations declined by 79% (95% CI, 66-88%) among infants <3 months old and by 67% (95% CI, 36-85%) among infants 3-6 months old.

Population	Outcome	Study Label	Findings
Infant	Complication of disease	Patton 2025	RSV hospitalization rates in infants 0-7 months declined 43% in 2024-2025 vs 2018-2020 baseline; greatest relative hospitalization rate reduction (52%) in 0-2 month age group
Infant/Child/ Adult/Older Adult	Patterns of genetic diversity and signals of transmission using amplicon-based whole genome sequencing of both RSV-A and RSV-B	LaVerriere 2025	In a single-site analysis of RSV-positive nasopharyngeal swabs from Boston Medical Center in 2024, ● >80% of the samples were RSV-B, and ● 45/48 RSV-B samples mapped into a single clade (B.D.E.1).
Adult/Older Adult	Incidence of disease	Bosch 2024 Lauring 2025	Over the 2023-24 RSV season: ● Adults 18-64 years: RSV-ARI incidence 26.4/1,000 person-years (1.5% attack rate) ● Adults 60-64 years: 40.2/1,000 person-years (2.3% attack rate) Analysis of 482 specimens (September 2023-April 2024) showed no association between vaccination and specific RSV variants, indicating absence of antigenic drift in the context of vaccination
Older Adult	Incidence of disease, hospitalization, and death	Popham 2025	Adults ≥65 years in NY (2023-2024 season), per 100,000: ● RSV incidence: skilled nursing facility (SNF) 4,347; assisted living facility (ALF) 1,985; community dwelling (CD) 582 ● Hospitalization: SNF 966; ALF 945; CD 138 ● Death: SNF 60; ALF 95; CD 5
c. Influenza			
Infant/Child	Complication of disease	Fazal 2025, Silverman 2025	Among pediatric influenza-associated encephalopathy cases (including acute necrotizing encephalopathy), 80-84% occurred in unvaccinated children
Child/Adult/ Older Adult	Genetic characterization of influenza viruses	Frutos 2025	● Among 286 influenza A(H3N2) isolates, all belonged to the hemagglutinin (HA) clade 2a.3a.1, which includes the A(H3N2) strain selected for the 2024-2025 cell-culture grown influenza vaccine. ● Among 158 sequenced A(H1N1)pdm09 isolates, 104 belonged to HA clade 5a.2a, and 54 belonged to HA clade.

Population	Outcome	Study Label	Findings
Infant/Child/ Adult/Older Adult	Trends in incidence, vaccination rates, and mortality from the 2018-19 - 2023-24 influenza seasons	Giovanetti 2025	During the pre-pandemic period (2018-2019 to 2019-2020), influenza cases typically rose in late autumn, peaked in mid-winter, and tapered off by early spring. Influenza cases were lower in the 2020-2021 influenza season. During influenza season 2022-2023 and influenza season 2023-2024, influenza activity exhibited a robust rebound, with higher peaks compared to the pre-pandemic era.
Infant/Child/ Adult/Older Adult	Test positivity, Genetic characterization of influenza viruses	Yunker 2024	In the 2023-2024 season, among 52,343 people tested for influenza or RSV in the Johns Hopkins Hospital System, 6.5% (3245/52343) tested positive for influenza A or B: 77.9% Influenza A, 22.1% Influenza B. Among 424 (72.2%) samples used for clade and subclade classifications, 71.7% belonged to the H1N1pdm lineage, 16.7% to the H3N2 lineage, and 11.3% to the B Victoria lineage.
Adult/Older Adult	Mortality	Xie 2024	Among 2647 individuals hospitalized for influenza (median age 70.2), the unadjusted death rate at 30 days was 3.04% (adjusted death rate, 4.24%). Patients hospitalized for influenza had a lower risk of death compared to those hospitalized for Covid-19.
d. Multiple			
Infant/Child	Complication of disease	Andersen 2025b	Among 56,634 hospitalized children: ● RSV patients youngest (mean 0.7 vs. 1.7 years for flu) ● RSV highest ICU admission (28% vs. 22%) ● RSV highest oxygen requirement (46% vs. 20-26%) ● RSV highest mechanical ventilation (12% vs. 8%) ● Covid-19 and influenza had higher in-hospital mortality than RSV
Infant/Child/ Adult/Older Adult	Prevalence and incidence of co-detection of RSV, Influenza A, Influenza B, and SARS-CoV-2	Pratt 2025	In a retrospective analysis from September 2022 to April 2024 the prevalence and incidence of co-detection of RSV, influenza A, influenza B, and SARS-CoV-2 in the northeastern United States was as follows: ● Positivity Rates: 16.68% for SARS-CoV-2, 11.66% for influenza A, 0.83% for influenza B, and 9.11% for RSV during the study period. ● Co-detections were observed in 0.49% of samples, with SARS-CoV-2/influenza A co-detection being the most common.

Population	Outcome	Study Label	Findings
Adult/Older Adult	Hospitalization, ICU admission, death	Bajema 2025a	Among 72,939 US veterans (2023-2024 season): ● Covid-19: 16.2%, 3.0%, and 0.9% for hospitalization, ICU admission, and death, respectively ● RSV: 14.5%, 1.8%, and 0.7% ● Influenza: 16.3%, 1.5%, and 0.7%

ALF: assisted living facility, ARI: acute respiratory illness, CD: community dwelling, ICU: intensive care unit, SNF: skilled nursing facility

Supplement Table S6. Summary results of studies reporting vaccine effectiveness against medically-attended infection, symptomatic infection, ICU admission, hospitalization >6 months after vaccine administration, long-term symptoms, death, or composite endpoints.[a]

Population	Vaccine	Outcome	Study design(s)	# Studies	Study label	VE % (95% CI)
a. Covid-19						
Infant, Child, Adult, Older Adult	Combined mRNA vaccines	Long COVID, onset 30 days to 6 months post-infection	Cohort	1	Swift 2024, 2 doses Swift 2024, ≥2 doses	2 (-9 to 13) -10 (-24 to 3)
Child	BNT162b2_XBB	Composite outcome of hospital admission, emergency department visit, or urgent care visit	Case-control	1	Tartof 2024b, 5-17 y	65 (36 to 81)
Child	BNT162b2 or mRNA-1273 (not disaggregated)[b]	PCC Symptoms *PCC: Post– COVID-19 Condition	Case-control	1	Yousaf 2025, 1+ PCC symptom Yousaf 2025, 2+ PCC symptoms	57 (2 to 81) 73 (31 to 90)
Child	BNT162b2	Long COVID (population-level, 28-179d post-infection)[c]	Cohort	1	Wu 2025b, 5-11 y, Omicron period	60 (40 to 74)
Child, Adult	BNT162b2	Long COVID (population-level, 28-179d post-infection)[c]	Cohort	1	Wu 2025b, 12-20y, Delta period	95 (91 to 98)
Child, Adult	BNT162b2	Long COVID (population-level, 28-179d post-infection)[c]	Cohort	1	Wu 2025b, 12-20y, Omicron period	75 (50 to 88)
Child, Adult	BNT162b2	Symptomatic Infection (Defined as “COVID-19 infection”)	Cohort	1	Wan 2024, 2-dose Wan 2024, 3-dose	16 (14 to 17) 25 (24 to 27)
Child, Adult	BNT162b2	Severe Infection (Defined as “ICU admission or use of ventilatory support within 7 days after COVID-19 infection”)	Cohort	1	Wan 2024, 2-dose Wan 2024, 3-dose	43 (23 to 58) 41 (24 to 54)
Child, Adult	BNT162b2	Mortality	Cohort	1	Wan 2024, 2-dose Wan 2024, 3-dose	44 (30 to 54) 54 (44 to 63)

Population	Vaccine	Outcome	Study design(s)	# Studies	Study label	VE % (95% CI)
Child, Adult, Older Adult	2024-2025 mRNA vaccines[d]	Hospitalization, up to 83 days post-dose	Case-control	1	Laniece Delaunay 2025	66 (34 to 85)
Adult	Combined XBB1.5 vaccines (mRNA or protein)	Hospitalization, 7-209 days post-vaccination	Cohort	1	Payne 2025[e]	41 (23 to 55)
	mRNA XBB1.5	Hospitalization or death, 0-3 months post-dose	Case-control	1	Lee 2025b	58 (14 to 80)
	Combined XBB1.5 vaccines (mRNA or protein)	ICU admission, 7-209 days post-vaccination	Cohort	1	Payne 2025	39 (-3 to 64)
	Combined XBB1.5 vaccines (mRNA or protein)	Death, 7-209 days post-dose	Cohort	1	Payne 2025	58 (1 to 82)
	mRNA XBB1.5 or bivalent BA.4/5	Symptomatic infection, moderate (ILI/ARI 5+ days or sick leave)	Cohort	1	Kirwan 2024	40 (20 to 55)
	mRNA XBB1.5	Infection; up to ~17 weeks post-dose	Cohort	1	Shrestha 2024, pre-JN.1 predominance Shrestha 2024, JN.1 predominance	42 (32 to 51) 19 (-1 to 35)
	BNT162b2_XBB.1.5	Medically-attended infection, 15-133 days post-dose	Case-control	1	Caffrey 2024, ED/UC visit Caffrey 2024, outpatient visit	48 (37 to 57) 34 (14 to 50)
	2024-2025 U.S. Licensed vaccines (KP.2 mRNA vaccine	Medically-attended infection (ED/UC encounter), 7-119 days post-dose	Case-control	1	Link-Gelles 2025a	30 (20 to 39)

Population	Vaccine	Outcome	Study design(s)	# Studies	Study label	VE % (95% CI)
	or JN.1 Novavax)					
	Combined XBB1.5 vaccines (mRNA or protein)	Medically-attended infection, 7-209 days post-dose	Cohort	1	Payne 2025	40 (27 to 51)
	2023-2024 booster dose, mRNA or protein-based	Medically-attended infection (ED/UC encounter), 7-299 post-dose	Case-control	1	Link-Gelles 2025b	22 (18 to 26)
	mRNA bivalent booster	Long COVID: compatible symptoms with onset 31-365 days from infection	Cohort	1	Wee 2025[f]	49 (38 to 59)
Adult/Older Adult	2024-2025 mRNA vaccines	Hospitalization, up to 83 days post-dose	Case-control	1	Laniece Delaunay 2025[g]	67 (33 to 86)
	mRNA bivalent BA.4/5 (comparison: last booster >1 year ago)	Hospitalization within 121-365 days after vaccination	Cohort	1	Chong 2024[h]	13 (0 to 25)
	Combined XBB1.5 vaccines (mRNA or protein)	Hospitalization with JN.1 lineage, 90-179 days after vaccine[i]	Case-control	1	Ma 2024a[i]	23 (-12 to 48)
	Combined XBB1.5 vaccines	Hospitalization, at ~10-211 days	Cohort	1	Ioannou 2025	17 (6 to 26)
	Combined XBB1.5 vaccines	Hospitalization, at 120-179 days post-dose, in JN.1-predominant period	Case-control	1	Link-Gelles 2025b	14 (2 to 24)
	mRNA XBB1.5	Hospitalization, 7 days - 9 months	Case-control	1	Nham 2025	37 (24 to 48)

Population	Vaccine	Outcome	Study design(s)	# Studies	Study label	VE % (95% CI)
	XBB1.5 mRNA	Hospitalization, up to 10 months	Case-control	1	Carazo 2025[j]	30 (25 to 34)
	BNT162b2_ XBB1.5 or Novavax XBB1.5	Hospitalization or death, 6 month follow-up	Cohort	1	Fotakis 2024[k]	% severe cases averted: 2.1 (1.8 to 2.3)
	Combined XBB1.5 vaccines (mRNA or protein)	Death, ~10-211 days	Cohort	1	Ioannou 2025	27 (6 to 42)
	Combined XBB1.5 vaccines (mRNA or protein)	Death, 7-209 days post-dose	Cohort	1	Payne 2025	59 (41 to 72)
	mRNA XBB1.5	Infection, at 8-120 days post-dose	Cohort	1	Chong 2024	41 (34 to 48)
	mRNA XBB1.5	Infection, 7days - ~8 months	Case-control	1	Nham 2025	21 (9 to 31)
	BNT162b2_XBB .1.5	Symptomatic infection, at 15-156 days post-dose	Case-control	1	Tartof 2024a	40 (34 to 45)
	Combined XBB1.5 vaccines (mRNA or protein)	Symptomatic infection, ~10-211 days	Cohort	1	Ioannou 2025	-3 (-7 to 0)
	BNT162b2_XBB .1.5	Medically-attended infection (ED visit), 0-6 months post-dose	Cohort	1	Andersen 2025a	45 (34 to 54)
	mRNA XBB1.5	Medically-attended infection (ED visit), 0-4 months post-dose	Cohort	1	Chong 2024	50 (27 to 66)

Population	Vaccine	Outcome	Study design(s)	# Studies	Study label	VE % (95% CI)
	BNT162b2 KP.2 vaccine	Medically-attended infection, 0-3 months post-dose	Case-control	1	Appaneal 2025, ED/UC visits Appaneal 2025, outpatient visits	57 (46 to 65) 56 (36 to 69)
	mRNA bivalent booster	Long COVID: compatible symptoms with onset 31-365 days from infection	Cohort	1	Wee 2025	38 (27 to 47)
Older Adult	Combined XBB1.5 vaccines (mRNA or protein)	Hospitalization, 7-209 days post-vaccination	Cohort	1	Payne 2025	53 (44 to 62)
	Combined 2023-2024 booster dose, mRNA or protein-based	Hospitalization, 7-299 days following vaccination	Case-control	1	Link-Gelles 2025b	31 (27 to 35)
	mRNA XBB1.5	Hospitalization or ED visit, median 57 days post-dose	Case-control	1	Levy 2025a	61 (48 to 71)
	mRNA XBB1.5	Hospitalization or death, 0-3 months post-dose	Case-control	1	Lee 2025b	60 (52 to 67)
	Combined XBB1.5 vaccines (mRNA or protein)	ICU admission, 7-209 days post-vaccination	Cohort	1	Payne 2025	51 (34 to 64)
	Combined XBB1.5 vaccines (mRNA or protein)	Death, 7-209 days post-dose (among end-stage renal disease)	Cohort	1	Payne 2025	60 (38 to 74)
	mRNA XBB1.5	Death, 1-24 weeks post-dose	Cohort	1	Andersson 2024	75 (71 to 80)
	mRNA XBB1.5	Death, 14-179 days post-dose	Cohort	1	Nunes 2024, 65-79y Nunes 2024, ≥80y	58 (42 to 69) 48 (38 to 57)

Population	Vaccine	Outcome	Study design(s)	# Studies	Study label	VE % (95% CI)
	BNT162b2_XBB 1.5	Symptomatic infection, 9-12 weeks post-dose	Cohort	1	Ward 2025	15 (-8 to 34)
	BNT162b2_XBB 1.5	Medically-attended infection (ED visit), 0-6 months post-dose	Cohort	1	Andersen 2025a	48 (33 to 60)
	BNT162b2_XBB .1.5	Medically-attended infection, 15-133 days post-dose	Case-control	1	Caffrey 2024, ED/UC visit Caffrey 2024, outpatient visit	35 (27 to 43) 24 (9 to 36)
	2024-2025 U.S. Licensed vaccines (KP.2 mRNA vaccine or JN.1 Novavax)	Medically-attended infection (ED/UC encounter), 7-119 days post-dose	Case-control	1	Link-Gelles 2025a	35 (29 to 41)
	Combined XBB1.5 vaccines (mRNA or protein)	Medically-attended infection, 7-209 days post-dose	Cohort	1	Payne 2025	44 (37 to 51)
	Combined 2023-2024 booster dose, mRNA or protein-based	Medically-attended infection (ED or UC encounter), 7-299 post-dose	Case-control	1	Link-Gelles 2025b	25 (22 to 28)
Immuno-compromised	Multiple	Critical illness, 120-179 post-dose	Case-control	1	Link-Gelles 2025b	25 (-18 to 52)
	BNT162b2_XBB .1.5	Medically-attended infection, 15-133 days post-dose	Case-control	1	Caffrey 2024, ED/UC visit Caffrey 2024, outpatient visit	34 (22 to 45) 40 (19 to 55)
	Multiple	Medically-attended infection	Cohort	1	Payne 2025	31 (19 to 41)
	Multiple	ICU admission	Cohort	1	Payne 2025	52 (30 to 66)
	Multiple	Death	Cohort	1	Payne 2025	61 (36 to 77)

Population	Vaccine	Outcome	Study design(s)	# Studies	Study label	VE % (95% CI)
b. RSV						
Pregnancy	RSVPreF	RSV-associated Medically-attended lower respiratory tract illness	RCT	1	Simões 2025	49 (31 to 63)
Infant	Nirsevimab	All-cause hospitalization	Observational - other	1	Perramon-Malavez 2025b, <6m Perramon-Malavez 2025b, 6-11m	48 (45 to 52) -9 (-20 to 2)
	Nirsevimab	All-cause hospitalization	Cohort	1	Marouk 2025, <3m	54 (34 to 67)
	Nirsevimab	ICU Admission	Cohort	9	Ares-Gómez 2024[l]	Unable to calculate effect estimate
					Alejandre 2024, <1y[m]	9 (9 to 10) to 4 (3 to 6) RSV-bronchiolitis admissions per 100 PICU admissions[l]
					Jimeno Ruiz 2024, <3m	69 (44 to 84)
					Jimeno Ruiz 2024, 3-6m	68 (-20 to 91)
					Marouk 2025, <3m	51 (11 to 74)
					Barbas Del Buey 2024, <10m	91 (-4 to 99)
					Coma 2024, <10m	90 (76 to 96)
					Jabagi 2025	74 (56 to 85)

Population	Vaccine	Outcome	Study design(s)	# Studies	Study label	VE % (95% CI)
					Perramon-Malavez 2025a, <4m	85 (72 to 92)
					Torres 2025, <10m	85 (79 to 88)
					Pooled estimate (5 studies)	84 (77 to 89)
	Nirsevimab	ICU Admission	Case-control	1	Carbajal 2024	67 (-100 to 95)
	Nirsevimab	Medically-Attended Infection	RCT	1	Arbetter 2024, <1y	78 (64 to 86)
Infant/Child	Nirsevimab	Medically-Attended Infection	Cohort	4	Barbas Del Buey 2024, <10m	17 (-6 to 35)
					Coma 2024, <10m, primary care attended bronchiolitis	48 (42 to 53)
					Coma 2024, <10m, hospital emergency visits	55 (48 to 62)
					Coma 2024, <10m, all-cause pneumonia	61 (24 to 80)
					Perramon-Malavez 2025a, <4m	54 (10 to 77)
					Perramon-Malavez 2025b, <6m	44 (42 to 46)
					Perramon-Malavez 2025b, 6-11m	7 (3 to 11)
Infant	Nirsevimab	Medically-attended infection	Case-control	5	Carbajal 2024, 0-12m	83 (71 to 90)
					Moline 2025, 0-8m	89 (79 to 94)
					Lefferts 2024[n], 1st RSV season, 0-27m	76 (42 to 90)
					Pooled estimate (3 studies)	**84 (77 to 89)**
Infant	Nirsevimab	Symptomatic infection	Cohort	2	Coma 2024, <10m	68.9 (51.7 to 80)
					Marouk 2025, <3m	80 (68 to 87)
Older Adult	RSVPreF3 (single dose)	Hospitalization over 3 seasons	RCT	1	Ison 2025	22 (-46 to 93)

Population	Vaccine	Outcome	Study design(s)	# Studies	Study label	VE % (95% CI)
Older Adult	RSVPreF3 (revaccination)	Hospitalization over 3 seasons	RCT	1	Ison 2025	100 (-55 to 100)
Older Adult	RSVPreF or RSVPreF3	ICU admission and/or death	Case-control	1	Payne 2024	81 (52-92)
Older Adult	RSVPreF3 (single dose)	Medically-attended infection	RCT	1	Ison 2025	70 (50-83)
Older Adult	RSVPreF or RSVPreF3	Medically-attended infection	Case-control	3	Tartof 2024c Fry 2025 Payne 2024	89 (8 to 99) 75 (74 to 77)* 77 (70 to 83)
Older Adult	RSVPreF or RSVPreF3	Medically-attended infection	Cohort	1	Bajema 2025b	79 (72 to 85)
Older Adult	RSVPreF or RSVPreF3	Symptomatic infection	Case-control	1	Fry 2025	70 (68 to 73)*
Older Adult	RSVPreF3 (single dose)	Symptomatic infection over 3 seasons	RCT	1	Ison 2025	51 (40 to 60)
Older Adult	RSVPreF or RSVPreF3	Documented infection	Cohort	1	Bajema 2025b	78 (73 to 84)*
Immuno-compromised	RSVPreF or RSVPreF3	Documented infection	Cohort	1	Bajema 2025b	72 (55 to 85)
Immuno-compromised	RSVPreF or RSVPreF3	Medically-attended infection	Case-control	1	Fry 2025	74 (69 to 78)*
c. Influenza						
Pregnancy	Any	Medically-attended infection	Case-control	1	Reeves 2025	46 (36 to 55)
Infant	Any	Medically-attended infection	Case-control	1	Lei 2025, 6m-2y	64 (54 to 72)
Infant/Child	Any	ICU	Case-control	1	Tenforde 2024, 6m-17y	43 (-6 to 70)

Population	Vaccine	Outcome	Study design(s)	# Studies	Study label	VE % (95% CI)
Infant/Child	Any	Medically attended infection	Case-control	22	Shinjoh 2024, 6m-15y, Flu A[a]	54 (27 to 71)
					Shinjoh 2024, 6m-15y, Flu B[a]	56 (26 to 74)
					Tenforde 2024, 6m-17y	58 (56 to 60)
					Pérez-Gimeno 2024, 6m-<5y	70 (51 to 81)
					Shinjoh 2025, 6m-15y	57 (24 to 75)
					Costantino 2024, 0-14y	38 (-1 to 62)
					Frutos 2024, NVSN, 6m-17y	59 (48 to 67)
					Frutos 2024, US Flu VE, 6m-17y	67 (48 to 80)
					Frutos 2024, VISION, 6m-17y	60 (57 to 64)
					Erdwiens 2025, 0-17y	58 (13 to 80)
					Kissling 2025, 0-17y	70 (61 to 78)
					Jiang 2025, 0-17y	57 (49 to 64)
					Frutos 2025, 6m-17y, NVSN	59 (47 to 68)
					Frutos 2025, 6m-17y, US Flu VE	32 (1 to 54)
					Frutos 2025, 6m-17y, VISION	60 (56 to 63)
					Chung 2025, 8m-8y	68 (51 to 79)
					Abou Chakra 2025, 0-4y	82 (46 to 93)
					Gào 2024, 6m-6y	46 (43 to 49)
					Mi 2024, 6m-6y	63 (33 to 80)
					Zhu 2024b, <18y	56 (54 to 57)
					Zhu 2025a, 6m-2y	32 (19 to 43)
					Zhu 2025b, <18y	53 (51–54)
					Zhang 2025, 0-5y	51 (5 to 75)
					Zeno 2024, 6m-6y	39 (26 to 50)
					Skowronkski 2024, 1-19y	60 (34 to **76)**
					Smolarchuk 2024, 6m-9y	74 (66 to 99)
					Nguyen 2025, 6m-17y	69 (52 to 81)
					Sun 2025, 0-5	58 (15 to 81)
					Pooled estimate (**22 studies**)	**55 (52 to 58)**
Infant/Child	Any	Medically attended	Cohort	1	Dammann 2025, ≤6y	81 (45 to 93)
Child	Any	Medically attended	Cohort	1	Rigamonti 2025, 2-14y	58 (44 to 68)
Child	LAIV	Medically attended	Cohort	1	Rigamonti 2025**,** 2-14y	40 (25 to 52)

Population	Vaccine	Outcome	Study design(s)	# Studies	Study label	VE % (95% CI)
Child	Any	Medically attended	Case-control	8	Lei 2025, 3-9y Lei 2025, 10-17y Zhu 2025a, 3-8y Zhu 2025a, 9-18y	43 (39 to 46) 42 (36 to 48) 41 (34 to 47) 23 (-3 to 43)
					Marron 2024, 2-17y Chung 2025, 9-17y Abou Chakra 2025, 5-17y Gào 2024, 7-17y Mi 2024, 7-17y Zhang 2025, 6-18y Smolarchuck 2024, 10-19y Whitaker 2024, GB-PC, 2-17y Whitaker 2024, EN-H, 2-17y Whitaker 2024, SC-H, 2-17y Sun 2025, 6-17y, 2-17y **Pooled estimate (9 studies)**	68 (30 to 87) 59 (35 to 75) 56 (32 to 72) 39 (36 to 42) -23 (-56 to 35) 34 (21 to 44) 62 (32 to 78) 65 (41 to 79) 63 (46 to 75) 65 (52 to 74) 35 (12 to 62) **49 (45 to 53)**
Child/Adult/ Older Adult	Any	Medically-attended	Case-control	2	Separovic 2025 Choi 2025c	54 (41 to 64) 24 (12 to 35)
Adult	Any	Medically attended	Case-control	23	Tenforde 2024, 18-49y[a] Tenforde 2024, 50-64y[a] Chung 2025, 18-49y[a] Chung 2025, 50-64y[a] Zhu 2025b, 18-49[a] Zhu 2025b, 50-64y[a] Zhu 2024b, 18-49y[a] Zhu 2024b, 50-64y[a]	54 (43 to 56) 44 (40 to 47) 38 (24 to 50) 16 (-11 to 41) 42 (41 to 44) 30 (27 to 32) 48 (46-50) 36 (33-39)
					Abou Chakra 2025 Sun 2025b Choi 2024a Erdwiens 2025	53 (49 to 57) 84 (64 to 94) 24 (5 to 40) 6 (-65 to 46)

Population	Vaccine	Outcome	Study design(s)	# Studies	Study label	VE % (95% CI)
					Frutos 2025, US Flu VE	37 (16 to 53)
					Frutos 2025, VISION	56 (53 to 58)
					Gào 2024	47 (37 to 55)
					Kwaah 2025	17 (-35 to 49)
					Kissling 2025	41 (30 to 49)
					Marron 2024	35 (9 to 54)
					Maurel 2024	40 (22 to 55)
					Rose 2025, Denmark	52 (44 to 58)
					Rose 2025, EU	42 (21 to 58)
					Rose 2025, UK	47 (36 to 56)
					Skowronski 2024	54 (33 to 66)
					Smolarchuk 2024	62 (57 to 67)
					Whitaker 2024, GB-PC	55 (43 to 65)
					Whitaker 2024, EH-H	36 (20 to 49)
					Whitaker 2024, SC-H	51 (40 to 59)
					Zhang 2025	72 (57 to 82)
					Lei 2025	52 (43 to 58)
					Reeves 2025 (female only)	52 (51 to 56)
					Nguyen 2025b	50 (29 to 65)
					Mi 2024	60 (26 to 79)
					Pooled estimate (**19 studies**)	**49 (45 to 53)**
	Any	Medically attended	Cohort	1	Tian 2024	61 (2 to 85)
Adult/Older Adult	Any	Medically attended	Case-control	6	Zeno 2024	31 (18 to 42)
					Sun 2025b	53 (8 to 77)
					Frutos 2024, US Flu VE	33 (16 to 47)
					Frutos 2024, VISION	49 (47 to 51)
					Lei 2025	75 (59 to 85)
					Erdwiens 2025	35 (-31 to 68)
					Zhang 2025	50 (18 to 69)
					Pooled estimate (**6 studies)**	**46 (34 to 56)**
	Any	Death	Cohort	1	Acuti Martellucci 2025	53 (41 to 63)
	Adjuvanted	Death	Cohort	1	Acuti Martellucci 2025	52 (48 to 55)

Population	Vaccine	Outcome	Study design(s)	# Studies	Study label	VE % (95% CI)
	Non-adjuvanted high-dose	Death	Cohort	1	Acuti Martellucci 2025	34 (26 to 41)
	Any	ICU admission	Case-control	1	Teneforde 2024	41 (31 to 40)
Older Adult	Any	Medically attended infection	Case-control	21	Blanquart 2025	22* (13 to 30)
					Tenforde 2024	37 (34 to 50)
					Abou Chakra 2025	42 (37 to 47)
					Zhu 2024b	30 (27 to 33)
					Choi 2025c	14 (-18 to 37)
					Chung 2025	37 (5 to 58)
					Costantino 2024	53 (-38 to 84)
					Emborg 2025	31 (17 to 42)
					Choi 2024a	17 (-17 to 42)
					Frutos 2024 US Flu VE	51 (14 to 72)
					Frutos 2024 VISION	41 (36 to 45)
					Frutos 2025, US Flu VE	18 (-69 to 60)
					Frutos 2025, VISION	51 (47 to 54)
					Gào 2024	46 (34 to 49)
					Kissling 2025	49 (35 to 60)
					Lei 2025	25 (4 to 41)
					Marron 2024	16 (-83 to 60)
					Maurel 2024	45 (22 to 62)
					Rose 2025, Denmark	55 (44 to 65)
					Rose 2025 EU	0 (-54 to 34)
					Rose 2025 UK	38 (18 to 53)
					Skowronski 2024	70 (48 to 83)
					Smolarchuk 2024	57 (52 to 61)
					Whitaker 2024, GB-PC	55 (32 to 70)
					Whitaker 2024, EH-H	40 (29 to 50)
					Whitaker 2024, SC-H	53 (44 to 61)
					Zhu 2025b	26 (24 to 29)
					Pooled estimate (**20 studies**)	**41 (36 to 44)**
	Adjuvanted	Medically attended	Case-control	1	Emborg 2025	49 (40 to 75)

Population	Vaccine	Outcome	Study design(s)	# Studies	Study label	VE % (95% CI)
	Non-adjuvanted high dose	Medically attended	Case-control	1	Emborg 2025	50 (35 to 62)
	Any	Pneumonia	Cohort	1	Mutter 2025	49 (6 to 72)
Immuno-compromised	Any	Medically attended	Case-control	1	Prins 2025, influenza A or B Prins 2025, influenza A Prins 2025, influenza B	7 (-41 to 38) 8 (-46 to 41) -4 (-147 to 56)

RCT: randomized controlled trial, TND: test-negative design, O: Observational, IIV: inactivated influenza vaccine, ED: emergency department, UC: urgent care.

[a]Pooled analyses were conducted when 3 or more studies were amenable to meta-analysis. Forest plots of all pooled analyses not already presented in the manuscript can be found in the appendix. Unadjusted results are not included in the pooled analysis. Studies were excluded from the meta-analysis when outcome metrics (e.g., strain-specific estimates) or age categories were not directly comparable.
[b]Nearly all vaccinated children (470 of 474, 99%) received the BNT162b2 vaccine. BNT162b2 or mRNA-1273 not disaggregated.
[c]Population-level effectiveness includes protection through preventing infection. Mediation analysis showed no significant direct effect of vaccination on long COVID risk among those who became infected (direct effect RR: 1.08 [95% CI, 0.75 to 1.55] for Delta/adolescents; 1.24 [0.92 to 1.66] for Omicron/children; 0.91 [0.69 to 1.19] for Omicron/adolescents).
[d]Includes XBB1.5, JN.1, and KP.2-specific mRNA vaccines.
[e]Study population limited to adults with end-stage renal disease (ESRD) receiving dialysis without additional immunocompromising. conditions; effectiveness may differ in the general adult population.
[f]Study population is adults aged 18-59y in Singapore; results compare bivalent booster versus ancestral mRNA booster.
[g]Vaccine effectiveness specific to older adults (≥60 or ≥65y depending on country-specific recommendations).
[h]See main manuscript Table 1 for XBB.1.5 booster effectiveness; data shown here for BA.4/5 bivalent formulation only.
[i]See Table 1 of main manuscript for XBB.1.5- and JN.1-specific hospitalization effectiveness at 7-89 days post-vaccination; data shown here specific to JN.1 lineage at 90-179 days.
[j]Study population limited to adults aged ≥60y
[k]Study population limited to adults aged ≥60y; effectiveness reported as percentage of severe cases averted rather than traditional vaccine effectiveness measure.
[l]Effect estimate could not be calculated due to zero RSV-associated intensive care unit admissions in nirsevimab-immunized infants versus 10 admissions in non-immunized infants, suggesting high effectiveness.
[m]Mixed reporting formats due to study heterogeneity; Alejandre reported reduction from 9 to 4 RSV-bronchiolitis per 100 pediatric intensive care unit admissions; Ares-Gómez 2024 noted 0 events in the immunized group preventing calculation of effect estimate.

[n]Lefferts 2024 study population primarily included infants aged <24m though age range extended to 27m; all other studies in this group limited to infants <12m. Lefferts 2024 also included RSV season 2 data that showed a VE for medically attended infections of 88 (48 to 97).

Note: Three additional studies evaluated relative VE of different vaccine types. Chemaitelly 2024a found that when comparing BNT162b2 versus mRNA-1273 among individuals of all ages from 2024-2024, the adjusted hazard ratio for Covid-19 incidence was 1.03 (95% CI, 1.02 to 1.05) after the primary series and 1.11 (95% CI, 1.09 to 1.13) after the third booster dose. Yaron 2025 found that in the 2023-2024 influenza season among older adults, the relative VE of high-dose versus standard dose influenza vaccine was 7% (95% CI, -26% to 42%) for reducing hospitalizations. Mombelli 2024 found that when comparing adjuvanted, high-dose, or standard dose influenza vaccine among immunocompromised individuals (solid organ transplant recipients) found comparable incidence of of clinical and subclinical influenza across all 3 groups (6% standard dose, 5% adjuvanted, and 7% high-dose vaccine).

Supplemental Table S7. Summary results of additional vaccine safety outcomes in pregnancy

Safety outcome	Vaccine	# Studies w/ comparison group[a]	Study Label	Effect estimate (95% CI)
a. Covid-19				
Small for gestational age	BNT162b2	3	Hall 2025 Suseeladevi 2024 Tamir-Hostovsky 2024	aHR[b] 0.95 (0.70 to 1.29) aHR 0.93 (0.86 to 1.01) OR 1.00 (0.36 to 2.81)
	mRNA-1273	1	Hall 2025	aHR 1.11 (0.76 to 1.60)
b. RSV				
Placental abruption	RSVPreF	2	Jin Hsieh 2025 Simões 2025	RR 0.98 (0.72 to 1.32) OR 0.33 (0.01 to 8.16)[c]
Small for gestational age	RSVPreF	2	Jin Hsieh 2025 Otsuki 2025	aRR 0.92 (0.82 to 1.03) OR 0.99 (0.14 to 7.10)
Major adverse cardiovascular events	RSVPreF	1	Jin Hsieh 2025	RR 0.75 (0.50 to 1.12)
c. Influenza[c]				
Placental abruption	Seasonal	1	Getahun 2024	aRR 1.01 (0.84 to 1.21)
Small for gestational age	Seasonal	2	Getahun 2024 Fell 2024	aRR 0.99 (0.93 to 1.05) RR 0.79 (0.67 to 0.94)
Guillain-Barré syndrome	Seasonal	1	Lee 2025d	aRR 0.34 (0.04 to 3.11)

HR: hazard ratio, OR: odds ratio, RR: risk ratio. Results are reported to 2 significant digits when at least that many were reported in a study.

[a]Studies were included in the main body of the table if they report data that allows for comparison between a vaccinated group and an unvaccinated (or self-controlled) group; studies with an active comparator (e.g., other vaccine product) are reported in Supplemental Table S8.
[b]Effect estimates prefixed with “a” indicate an adjusted effect estimate
[c]All seasonal influenza vaccines during the time period of the study.

Supplemental Table S8. Summary results of studies regarding key vaccine safety outcomes in studies without an unvaccinated or self-controlled comparator group.

Population	Outcome(s)	Study label	Findings
a. Covid-19			
Pregnant	Preterm birth, fetal death, stillbirth, miscarriage	Garrett 2025	Found that among 119 pregnant individuals who received 1 or 2 doses of mRNA-1273 in the Ubuntu study, rates of adverse birth outcomes were: congenital anomalies: 0%, preterm birth: 8.4%, fetal death and/or stillbirth: 2.5%, and miscarriage: 5.9%.
Pregnant	Miscarriage	LaCroix 2025	Described patient-reported miscarriage incidence of 0.4% and 0.0% following first-trimester BNT162b2 and mRNA-1273, respectively.
Infant/Child	Myocarditis/ pericarditis	Berthaud 2024	Among 53 (6m-5y) and 2519 (6-11y) participants, no cases of myocarditis or pericarditis were reported following mRNA-1273 booster doses at 80 U.S. and 8 Canadian sites.
Infant/Child	Myocarditis/ pericarditis, GBS, coagulation disorder	Dixit 2024	Among the 179 participants receiving one or more doses of mRNA-1273.214 primary series and 539 participants receiving a mRNA-1273.214 booster dose ages 6m-5y, there were no reports of myocarditis or pericarditis, hospitalization for GBS, or coagulation disorder defined as new onset of thrombosis, thromboembolic event, or nontraumatic hemorrhage/bleeding.
Infant/Child	Myocarditis/ pericarditis	Soe 2024a	Among children receiving mRNA Covid-19 vaccines in the Canadian national Vaccine Safety Network, reported myocarditis/pericarditis cases within 0-28 days peaked among male adolescents following second dose, in 3/8,088 (0.037%) 8088 homologous BNT162b2 recipients, and 2/378 (0.529%) homologous mRNA-1273 recipients.
Infant/Child	Myocarditis, myopericarditis , and pericarditis	Top 2025	Among 168 cases of children 16 or under assessed in emergency departments or hospitalized with myocarditis, myopericarditis, and pericarditis 47 (28%) remotely vaccinated, 39 (23%) unvaccinated, and 9 (5%) with unknown vaccination status. Unvaccinated cases appeared more likely to require intensive care unit care (28% vs <7% of vaccine-proximate cases). The adjusted relative incidence of myocarditis/myopericarditis/ pericarditis 0-21 days post-vaccination was 7.1 (95% CI, 4.5 to 11.1).
Child	Myocarditis/ pericarditis	Ahn 2024	Among 3,709,063 adolescents aged 12-19 in South Korea receiving the BNT162b2 vaccine, 184 cases met the Brighton criteria for the case definition of myocarditis and pericarditis. The overall incidence of myocarditis/pericarditis within 42 days after any doses of BNT162b2 was 2.25 (95% CI, 1.94 to 2.60) cases per 100,000 doses, and the incidence of

Population	Outcome(s)	Study label	Findings
			severe cases was 0.25 (95% CI, 0.15 to 3.80) cases per 100,000 doses. When analyzed by vaccination doses, the rates were 1.30 cases (95% CI, 0.95 to 1.73) after the first dose, 3.10 (95% CI 2.50 to 3.71) after the second dose, and 2.76 (95% CI 1.90 to 3.88) after the third dose.
Child	Myocarditis	Figueroa 2024b	Among 2490 participants aged 12-17y receiving the 2-dose mRNA-1273 100-µg primary series, 1 case of nonserious, moderate, probable acute myocarditis resolved within 8 days of symptom onset.
Child	Myocarditis/ pericarditis	Ko 2024	Among individuals aged 12-17y in South Korea, following Pfizer BA.1 or BA.4/5 immunization, the incidence rates per 100,000 person-days for confirmed myocarditis/pericarditis following monovalent and bivalent booster doses were 0.03 and 0.05, respectively.
Child	Myocarditis	Nv 2024	Among a 20 patient cohort at Yale with “Covid-19-related myopericarditis,” 19 had received the BNT162b2 vaccine.
Child	Myocarditis, myopericarditis, perimyocarditis or pericarditis	Pham-Huy 2024	Among all individuals aged 18 years and under seen at the Children’s Hospital of Eastern Ontario and diagnosed with myocarditis, myopericarditis, perimyocarditis or pericarditis based on a standardized protocol based on the Brighton Collaboration criteria, the 17 cases were males, 12 (12/17) patients presented after the 2nd vaccine dose and 4 patients (4/17) after the third vaccine dose. Only 1 patient presented following the first vaccine dose. The rate of cardiac adverse events following immunization was found to be 12.01 cases (90% CI 5.98 to 21.68) per 100,000 doses following the 2nd dose and 16.56 cases (90% CI 5.66 to 37.90) per 100,000 doses following the 3rd dose for males aged 12-17y.
Child/Adult	Myocarditis	Ali 2024	In a case series of 17 patients (age 16-50y) diagnosed with vaccine-induced myocarditis (9 after BNT162b2, 8 after mRNA-1273), onset of myocarditis was typically within 24-96 hours of receiving the vaccine dose and there were minimal long-term effects.
Child/Adult	Myocarditis	Jain 2024	In a longitudinal study of Covid-19 vaccine-associated myocarditis in patients aged <30y, 306 cases were included after BNT162b2 vaccination and 16 cases were included after mRNA-1273 vaccination, 84% of which occurred after 2nd dose with a mean onset of symptoms 3.2 ± 5.2 days post-vaccination. No reported cardiac related deaths or need for heart transplantation, but myocardial scarring at a lower severity persisted in most patients.

Population	Outcome(s)	Study label	Findings
Child/Adult	Myocarditis	Semenza to 2024	In a cohort study of 4,635 patients (aged 12-49y) hospitalized for myocarditis in the France between 12/2020-6/2022, 409 (9%) were post-BNT162b2 (within 7 days post-vaccination), 149 (3%) were post-mRNA-1273 (within 7 days post-vaccination), 298 (6%) were post-Covid-19, and 3,779 (82%) were conventional myocarditis. Weighted HR for rehospitalization for any cause over 18 months of follow-up: 0.74 (95% CI, 0.49 to 1.13) for BNT162b2 and 0.44 (95% CI, 0.22 to 0.89) for mRNA-1273. Weighted HR for composite outcome (rehospitalization for myopericarditis, cardiovascular event, or death from any cause over 18 months of follow-up): 0.68 (95% CI, 0.38 to 1.22) for BNT162b2 and 0.24 (95% CI, 0.05 to 1.18) for mRNA-1273.
Child/Adult	Myocarditis/ pericarditis	Zahrani 2024	In a case series of patients presenting with myocarditis to 2 cardiac centers in Saudi Arabia, 1/7 confirmed myocarditis cases and 1/11 confirmed myopericarditis cases were associated with BNT162b2 or mRNA-1273 vaccination, respectively. The incidence of myocarditis and myopericarditis following Covid-19 vaccination was similar to the background rate during a similar period.
Adult	Myocarditis	Alves 2025 (Vaccine)	In an open-label single-arm study administering NVX-CoV2601, 0/332 adults with prior Covid-19 vaccination and 0/338 adults without prior Covid-19 vaccination experienced myocarditis within 28 days post- vaccination.
Adult	Myocarditis	Bennett 2024a	In an RCT of spike protein booster vaccines among adults age 18-64y, 0/286 NVX-CoV2515 (BA.1) recipients, 0/274 NVX-CoV2373 recipients, and 0/269 bivalent (NVX-CoV2515+NVX-CoV2373) recipients developed myocarditis within 28 days of vaccination.
Adult	Myocarditis	Bennett 2024b	In a Phase 2 RCT of NVX-CoV2373 (2- or 3-dose regimen) among adults aged 18-65y, 0/286 patients with well-controlled HIV and 0/96 patients without HIV developed myocarditis within 180 days.
Adult	Myocarditis	Chalkias 2024	In an open-label study of mRNA-1273 booster vaccines in adults age ≥18y, 0 cases of myocarditis were reported within 29 days of vaccination among 50 monovalent (mRNA-1273.815, XBB.1.5) and 51 bivalent (mRNA-1273.231, BA.4/BA.5) recipients.
Adult	GBS	Choi 2024d	Rates of GBS reported in South Korea between 10/11/22-3/30/23 were 0.2/100,000 doses with mRNA-1273.214 booster, 0/100,000 doses with mRNA-1273.222 booster, 0.1/100,000

Population	Outcome(s)	Study label	Findings
			doses with the BNT162b2 BA.1 booster, and 0/100,000 with the BNT162b2 BA 4/5 booster.
Adult	Myocarditis	Diya 2025a	In a phase 2/3 trial of JN.1-adapted BNT162b2 in adults aged ≥18y, 0/53 vaccine recipients (27 adults aged 18-55y, and 26 adults aged >55y) reported myocarditis within 1 month of vaccination.
Adult	ITP, CVST, GBS, myocarditis, stroke	Fierro 2025	0/60 (0%) recipients of mRNA-1273 vaccine experienced ITP, CVST, GBS, myocarditis, or stroke.
Adult/Older Adult	ITP	Abdurakhmanov 2024	Among 28 individuals with preexisting ITP who received BNT162b2 vaccine, 6 (21%) experienced a ≥ 30% decrease in platelets after the first dose.
Adult/Older Adult	Myocarditis	Baden 2024	In an open-label study of a 50 μg mRNA-1273 booster vaccine, 1/19,609 adults aged ≥18y booster recipients developed myocarditis within 1 day of vaccination but had a respiratory viral infection 1 month prior.
Adult/Older Adult	Myocarditis	Frankenthal 2025	In a cross-sectional survey study of Israeli vaccinated adults aged ≥18y in 2021, 1/2049 volunteers reported myocarditis within 30 days following the third dose of BNT162b2.
Adult/Older Adult	GBS	Gligorov 2025	Through 3/1/22, the French pharmacovigilance database reported 95 cases of GBS following BNT162b2 and 20 cases of GBS following mRNA-1273.
Adult/Older Adult	Myocarditis, stroke	Ito 2025	In a pharmacovigilance study of adults in Japan in 2021, 1 suspected case of myocarditis was reported among 39,463 BNT162b2 doses and 1 suspected case of myocarditis among 26,404 mRNA-1273 doses. Cerebral infarction was reported in 30 cases among 119,808 BNT162b2 recipients.
Adult/Older Adult	Myocarditis, GBS	Karam 2024	In a pharmacovigilance study of vaccine recipients in Lebanon between 2/2021-6/2022, 2 cases of myocarditis and 4 cases of GBS were reported after BNT162b2, occurring in males aged 24-25y occurring within 19-39 days post-vaccination. In addition, 14 cases of ischemic cerebrovascular events and 2 cases of transient ischemic attack were reported after BNT162b2 vaccination.
Adult/Older Adult	GBS	Matsuzouno 2024	Among 1,756 patients hospitalized in a neurology division in Japan between 4/2019-3/2022, 1 patient had GBS following BNT162b2 vaccination.

Population	Outcome(s)	Study label	Findings
Adult/Older Adult	Myocarditis	Okada 2025	In a phase 3 active-controlled comparative study in Japan, there were 0 cases of myocarditis within 28 days post-BNT162b2 (BA.4/BA.5-containing) vaccination among 464 adults aged ≥18y.
Adult/Older Adult	Myocarditis, CVST	Pakanen 2025	In a case series of medicolegal autopsies in Finland between 12/2020-12/2021, 428 reports mentioned Covid-19 vaccination, 1 of which suggested vaccine-associated myocarditis was the cause of death in a patient who received BNT162b2 4 days prior to death. 1 patient was suspected to have died from a CVST 40 days after receiving the second dose of BNT162b2.
Adult/Older Adult	Myocarditis/ pericarditis	Saavedra 2025	In an observational study using administrative data in Brazil, 7 cases of myocarditis and/or pericarditis were reported among 2,948,142 doses of BNT162b2 given to adults aged ≥18y (2.4 cases per million BNT162b2 doses).
Adult/Older Adult	Myocarditis	Talib 2024	In a case-series of adult patients with myocarditis within 14 days of mRNA Covid-19 vaccination, 52/89 patients had received BNT162b2 and 32/89 had received mRNA-1273. Mean age was 34 years and 64% were male. Minimal long-term effects were noted at median clinical follow-up of 232 days.
Adult/Older Adult	Stroke	Karam 2024	In a pharmacovigilance study of adverse events following Covid-19 vaccination in Lebanon between 2/2021-6/2022, 14 cases of ischemic cerebrovascular events and 2 cases of transient ischemic attack were reported following BNT162b2 vaccination. Cases occurred in patients with a mean age of 71 ± 17y for vascular disorders, predominantly after the first dose. 1 hospitalization and 1 fatal outcome were reported among the ischemic stroke cases.
Adult/Older Adult	Stroke	Sharff 2024	In a retrospective cohort study of Kaiser Permanente Northwest patients, the incidence of ischemic stroke or TIA following Covid-19 bivalent booster vaccination was 18.1 per 100,000 (95% CI, 10.9 to 28.2) among all adults aged ≥18y receiving either Pfizer or Moderna bivalent vaccines, and 34.3 per 100,000 (95% CI, 17.7 to 59.9) among patients aged ≥65y receiving the Pfizer bivalent vaccine. Cases were confirmed through physician adjudication with a positive predictive value of 94.7% for the primary diagnosis position.
Infant/Child/ Adult/Older Adult	Myocarditis/ pericarditis, GBS, stroke	Lloyd 2025a	In a retrospective cohort study using administrative health claims data of individuals 6 months and older, incidence of myocarditis/pericarditis following bivalent BNT162b2

Population	Outcome(s)	Study label	Findings
			(BA.4/BA.5-containing) vaccination was 131.4 cases per 100,000 person-years for people aged 18-35y. Relative to historical controls, no statistically significant signal was observed for other age groups or following mRNA-1273.222 (BA.4/BA.5-containing) vaccination. Similarly, relative to historical controls there was no statistically significant safety signal identified for GBS or stroke with BNT162b2 or mRNA-1273.222 vaccines.
Infant/Child/ Adult/Older Adult	Myocarditis	Nazar 2024	In a cross-sectional study in Europe (overlap with Nazar 2025), myopericarditis frequency was reported as 2.1 per million BNT162b2 doses, 3.2 per million mRNA-1273 doses, and 17.8 per million NVX-COV2373 doses (records included 567,203,616 doses of BNT162b2 [combination of original, XBB.1.5, BA.1, and BA.4/BA.5], 132,734,949 doses of mRNA-1273 [combination of original, BA.1, and BA.4/BA.5], and 225,312 doses of NVX-CoV2373).
Infant/Child/ Adult/Older Adult	ITP, CVST, GBS, myocarditis, pericarditis	Nazar 2025	In the EudraVigilance Database, the estimated incidence of ITP was 0.9/million doses after 533,217,626 doses of BNT162b2 vaccine, and 0.8/million doses after 128,567,876 doses of mRNA-1273 vaccine. Estimated incidence of CVST was 0.7/million doses and 0.6/million doses after BNT162b2 and mRNA-1273 vaccines respectively. Cerebral thrombosis was reported at 0.3/million doses for BNT162b2 and 0.2/million doses for mRNA-1273. Estimated incidence of GBS was 1.5/million doses and 1.4/million doses after BNT162b2 and mRNA-1273 vaccines respectively. Myocarditis frequency was reported as 8.3 per million BNT162b2 doses and 10.4 per million mRNA-1273 doses (records included 533,217,626 doses of BNT162b2 and 128,567,876 doses of mRNA-1273). Myopericarditis frequency was reported as 2.1 per million BNT162b2 doses and 3.2 per million mRNA-1273 doses.
Child/Adult/ Older Adult	Myocarditis/ pericarditis, GBS	Clothier 2024	In an observational real-world study of vaccine safety surveillance system data in Australia between 2022-2023 following NVX-CoV2373 vaccination to all ages, myocarditis was reported twice (both with onset within 14 days of dose 2), suggesting an overall reporting rate of 1.95 per 100,000 vaccinations (95% CI, 0.1 to 7.0). Pericarditis: 19.5 per 100,000 vaccinations (95% CI, 11.9 to 30.1), more commonly after dose 1 compared to dose 2 and boosters. GBS was reported after 0 cases after 102,946 doses.
Child/Adult/ Older Adult	GBS	Fitzpatric k 2025	In a case series of 60 individuals with neurologic adverse events after Covid-19 vaccines, 1 individual experienced GBS after BNT162b2 vaccine.

Population	Outcome(s)	Study label	Findings
Child/Adult/ Older Adult	Myocarditis/ pericarditis	Lu 2024c	In a case series of adverse events following Covid-19 immunization in Taiwan between 1/2021-6/2023, 0 cases of GBS were identified after BNT162b2 and 7 cases after mRNA-1273 thought to be associated or indeterminately associated with vaccination, none of which were associated with death. 15 cases of myocarditis/pericarditis were identified after BNT162b2 and 12 cases after mRNA-1273 thought to be associated or indeterminately associated with vaccination.
Child/Adult/ Older Adult	GBS	Mansou 2024	Among 3,527,106 individuals who received a Covid-19 vaccine between 12/14/20-4/30/22 in Alberta, Canada, there were 6 reported cases of GBS with BNT162b2 and 1 reported case with mRNA-1273.
Child/Adult/ Older Adult	ITP, myocarditis/ pericarditis, GBS, stroke	Sankar 2025	In a pharmacovigilance study in South Africa, disproportionate reporting signals were identified for ITP and myocarditis/pericarditis, but not for GBS or stroke with BNT162b2.
Child/Adult/ Older Adult	Myocarditis	Smith 2025	In a cross-sectional study of confirmed myocarditis cases with symptom onset within 14 days of vaccination in Australia, 171 cases were reported after BNT162b2 (77% were male, 64% were <24 years of age) and 30 cases were reported after mRNA-1273 (67% were male, 60% were <24 years of age).
Child/Adult/ Older Adult	Myocarditis	Takada 2025	In a pharmacovigilance study in Japan including people aged >12 years between 4/2004-12/2023, myocarditis was reported more frequently after BNT162b2 and mRNA-1273 vaccination than after other drugs used as controls in the study. Most cases were <30 years of age or male and time-to-symptom onset was 5.89 days (95% CI, 4.91 to 7.05) after BNT162b2 and 8.40 days (95% CI, 7.23 to 9.72) after mRNA-1273. Most patients recovered or were in remission, but death was reported in 13% after BNT162b2 and 8% after mRNA-1273.
Child/Adult/ Older Adult	Stroke	Nazar 2025	
Child/Adult/ Older Adult	GBS, Stroke	Top 2024	In a prospective cohort study in Canada, there was 1 reported case of GBS following the second dose of BNT162b2 among 250,431 recipients. For stroke (any type) and/or TIA, there were 8/442,371 cases after the first dose of BNT162b2, 27/250,431 cases after the 2nd dose of BNT162b2, 1/49,176 cases after the 3rd dose of BNT162b2, 0/203,933 cases after the first dose of mRNA-1273, 8/137,451 cases after the 2nd

Population	Outcome(s)	Study label	Findings
			dose of mRNA-1273, and 3/77,410 cases after the third dose of mRNA-1273.
Child/Adult/ Older Adult	Myocarditis, GBS	Wan 2024	In a target trial emulation study of patients aged >12y in 2022, 9/319,909 patients (incidence rate of 0.013 per 10,000 person days [95% CI, 0.006 to 0.025]) and 6/902,194 (incidence rate of 0.003 per 10,000 person days [95% CI, 0.001 to 0.007]) experienced myocarditis after second and third doses of BNT162b2, respectively. There were 0 cases of GBS in 6,710,804 days of follow up (incidence: 0.0, 95% CI, 0.0 to 0.0).
Age not specified	Myocarditis	Shah 2024	Among 832 Team USA athletes competing in the 2020 and 2022 Olympics and Paralympics, 0 cases of myocarditis were reported during >1 year of follow-up (244 had received mRNA-1273, 444 had received BNT162b2).
Immuno-compromised	Myocarditis, GBS, stroke, CVST, ITP	Bellitto 2024	In a survey of patients who self-reported an immunocompromised state across 11 European countries that included 130 patients who received BNT162b2 and 75 who received mRNA-1273, 0 cases of myocarditis, GBS, stroke, or CVST were reported. 1 case of ITP was reported following the second dose mRNA-1273.
Immuno-compromised	Myocarditis	Goodyear 2024	In an RCT comparing the immunogenicity of a third dose of BNT162b2, mRNA-1273, and NVX-CoV2373, 0 episodes of myocarditis were reported among 354 patients who received BNT162b2 and 50 patients who received NVX-CoV2373 during 28 days of follow up. Among 347 patients who received mRNA-1273, 1 case (0.3%) of myocarditis was reported.
b. RSV			
Pregnant	Gestational hypertension, placental abruption, pre-eclampsia, prematurity, small for gestational	Alami 2025	VAERS data from 9/1/23-2/23/24: 2 gestational hypertension, 2 pre-eclampsia, 1 stillbirth, 27 preterm births, and 2 placental abruptions following RSV vaccination.

Population	Outcome(s)	Study label	Findings
	age, and stillbirth		
Pregnant	Placental abruption, pre-eclampsia/ eclampsia, prematurity, and stillbirth	Li 2025b	VAERS data from 5/2023-12/2024: 7 pre-eclampsia, 2 eclampsia, 4 stillbirths, 88 preterm births, and 3 placental abruptions following RSV vaccination.
Pregnant	Placental abruptions	Simões 2025	Frequency of placental abruption was 0/3698 (0%) among vaccinated and 1/3687 (0.03%) among unvaccinated.
Adult/Older Adult	GBS, MI, stroke	Fierro 2025	Among 61 adults receiving mRNA-1345 in a Phase I trial, incidence of GBS, MI, and stroke were 0/61 (0%), 0/61 (0%), and 1/61 (1.6%), respectively.
Adult	GBS	Shaw 2024a	In a Phase I study of mRNA-1345, 0/80 (0%) of healthy young adults experienced GBS.
Older Adult	GBS	Shaw 2024b	In a Phase I study of mRNA-1345, 0/60 (0%) of older adults experienced GBS.
Immuno-compromised	GBS	Almeida 2025	In a Phase 3 single-arm study of RSVpreF in immunocompromised or renally impaired adults, 0/203 participants developed GBS.
c. Influenza			
Pregnant	Congenital defects, placental abruption, preeclampsia/ eclampsia, prematurity, small for gestational age, stillbirth	Hsiao 2024	Risk of adverse birth outcomes (gestational hypertension, pre-eclampsia, eclampsia, stillbirth, placental abruption), small for gestational age, and congenital anomalies similar with age-appropriate inactivated influenza vaccination or recombinant influenza vaccination.
Pregnant	Congenital defects	Malange 2025	Found possible protective effect of seasonal influenza vaccination against cleft lip ± cleft palate and gastroschisis.
Adult/Older Adult	GBS	Gligorov 2025	Among 375 cases of GBS reported to occur within 4 weeks of vaccination between 1/1/85-3/1/22 in France, 94/375 (25%) of cases occurred after influenza vaccination.
Adult/Older Adult	MI	Fonseca 2024	In the VIP-ACS trial in which individuals with acute coronary syndrome within the past 7 days were randomized to double-dose quadrivalent inactivated influenza vaccine vs. standard dose influenza vaccine, there was no statistically significant

Population	Outcome(s)	Study label	Findings
			difference between groups in the incidence of major cardiovascular events.
Older Adult	GBS	Li 2025a	Among older adults receiving influenza vaccines between 2018-2024 in the US, there were 81 reports of GBS following influenza vaccination in the VAERS database.
Infant/Child/ Adult/Older Adult	GBS	Giang 2024	Four reports of possible GBS were identified following receipt of a seasonal influenza vaccine. After applying the Brighton Collaboration Case Definition (BCCD), one report was classified as level 3; the remaining three reports could not be classified according to BCCD, mainly due to incomplete medical information within the report. The single report described GBS after receipt of more than one vaccine.
Infant/Child/ Adult/Older Adult	GBS	Jeong 2024a	Analysis of VigiBase (WHO adverse event database), found GBS reporting was more frequent after influenza vaccination than after comparator drugs.
Infant/Child/ Adult/Older Adult	Stroke	Rogers 2024	Between 1/1/90-12/31/23, there were 52 cerebral thromboembolic events reported following influenza vaccination.
d. Coadministration			
Pregnant	Preeclampsia, preterm birth, and placental abruption	Choi 2025a	Found similar frequency of preeclampsia, preterm birth, and placental abruption noted between women who had Covid-19 vaccine only vs. influenza vaccine only in pregnancy.

CVST: Cerebral Venous Sinus Thrombosis, GBS: Guillain-Barré syndrome, ITP: Immune Thrombocytopenic Purpura, MI: myocardial infarction, VAERS: Vaccine Adverse Event Reporting System

Supplemental Table S9. Summary results of included studies reporting on vaccine-related adverse events not specifically identified as being of special interest

Domain	Comparator Type (N=)	Study Label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
a. Covid-19			
Local or Systemic Reactogenicity Local or Systemic	Active Comparator (43)	Abukhalil 2024, Adelglass 2025, Ann Costa Clemens 2024, Barnay 2025, Beller 2025, Ben Kridis 2024, Bennett 2025, Briggs 2025, da Silva 2025, Darko 2024, Diya 2025b, Elemuwa 2024, ElHilali 2024, Garrett 2025, Grieshaber 2025, Jęśkowiak-Kossakowska 2024, Kikuchi 2024, Kurucu 2024, Lambo 2025, Madni 2024, Marchese 2025, Mazarakis 2025, McLeod 2024, Mok 2025, Moreira Puga 2025, Moscara 2023, Namiki 2024, Naqid 2024, Park 2024b, Pinto 2024, Prabhu 2025, Reynolds 2024, Rousculp 2024, Sher 2024, Sodagari 2025, Subaiea 2025, Tani 2024, Tetsuka 2024, Villanueva, Werner 2023, Yechezkel 2024, Yildirim 2025, Zaidi 2025	

Domain	Comparator Type (N=)	Study Label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
a. Covid-19			
Reactogenicity *cont.*	Descriptive only (26)	Ahmed Al Qahtani 2025, Al-Rousan 2024, Amstutz 2024, Bolu 2025, Chalkias 2024, Chewaskulyong 2024, Ferraioli 2025, Figueroa 2024a, Figueroa 2025a, Figueroa 2025b, Hammam 2024, Holzwarth 2025, Itamochi 2024, Konishi 2025, Lafleur 2024, Li 2024b, López-Contreras 2023, Moor 2024, Petr 2024, Rossier 2024, Shoji 2024, Thanborisutkul 2025, van Ewijk 2025, Vita 2025, Woestenberg 2025, Yamamoto 2024, Yin 2024	
Miscellaneous	Unvaccinated comparator or self-controlled case series (1)	Soe 2024b	mRNA-1273: health events requiring change in activities or medical consultation OR 2.91 (95% CI, 2.24 to 3.79) after homologous dose 2 and 1.50 (95% CI, 1.12 to 2.02) after heterologous dose 2; BNT162b2: no differences; no differences in serious health events, which were rare; N=173,038 older adults
	Descriptive only (4)	Al-Rousan 2024, Churilla 2024, Hikichi 2024, Mantovani 2024	
	Active comparator (5)	Ferrari 2024, Manniche 2024, Mazarakis 2025, Shaharir 2025, Sodagari 2025	
Musculoskeletal & Joint Disorders	Unvaccinated comparator or self-controlled case series (1)	Nong 2025	BNT162b2 and mRNA-1273: no difference (osteoarthritis flare)

Domain	Comparator Type (N=)	Study Label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
a. Covid-19			
	Active comparator (14)	Mackenzie 2025, Mazarakis 2025, Mok 2025, Namiki 2024, Naqid 2024, Nong 2025, Prabhu 2025, Sher 2024, Subaiea 2025, Tani 2024, Tetsuka 2024, Werner 2023, Yechezkel 2024, Zaidi 2025	
	Descriptive only (6)	Hikichi 2024, Holzwarth 2025, López-Contreras 2023, Mantovani 2024, Yamamoto 2024, Yin 2024	
Neurologic Events and Conditions	Unvaccinated comparator (6)	Abdul Rahim 2025	mRNA-1273: no difference (sensorineural hearing loss)
		Ganelin-Cohen 2024	BNT162b2: post-hoc analysis of patients with multiple sclerosis flares after vaccination showed greater proportion of vaccinated patients exhibiting increased multiple sclerosis lesions OR 7.11 (95% CI, 1.29 to 49.16); N=33
		Ko 2025	mRNA-1273: new-onset seizure IRR 1.21 (95% CI, 1.04 to 1.42); BNT162b2: no difference; self-controlled case series with a risk period of days 1-28 and control period of days 29-240 post-vaccination. Incidence of NOS was 1.52/person-year in risk window, 1.54/person-year in control window.
Neurologic Events and Conditions *cont.*		Lee 2025c	BNT162b2: no difference (composite outcome in children: Bell's palsy, idiopathic thrombocytopenia, acute disseminated encephalomyelitis, myocarditis, pericarditis, GBS, transverse myelitis, acute MI, anaphylaxis, stroke, deep vein thrombosis, pulmonary embolism, narcolepsy, appendicitis, disseminated intravascular coagulation, febrile seizures, Kawasaki disease)
		Lim 2025b	BNT162b2: transverse myelitis IRR 1.99 (95% CI, 1.30 to 3.03); mRNA-1273 2.57 (95% CI, 1.14 to 5.79). Self-controlled case series with a risk period of days 1-42 and control period of days 43-270 post-vaccination.
		Moisset 2024	BNT162b2 and mRNA-1273: no difference (multiple sclerosis relapse)

Domain	Comparator Type (N=)	Study Label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
a. Covid-19			
Neurologic Events and Conditions *cont.*	Active comparator (25)	Barnay 2025, ElHilali 2024, Göbel 2025, Grieshaber 2025, Jaffry 2023, Katatbeh 2024, Ko 2025, Leung 2024, Lim 2025b, Liu 2025, López de Las Huertas 2025, Mohamed 2024, Moisset 2024, Moscara 2023, Naqid 2024, Okoye 2024, Park 2024b, Prabhu 2025, Rouleau 2025, Sher 2024, Sodagari 2025, Tani 2024, Werner 2023, Yechezkel 2024, Zaidi 2025	
	Descriptive only (8)	Aşkın Turan 2024, Boulefaa 2025, Granja López 2024, Holzwarth 2025, Mantovani 2024, Thanborisutkul 2025, Yamamoto 2024, Yin 2024	
Dermatologic / Cutaneous Events	Active Comparator (19)	ElHilali 2024, Grieshaber 2025, Jęśkowiak-Kossakowska 2024, Kyung 2025, Lambo 2025, Lin 2024, Mazarakis 2025, Mok 2025, Moon 2024, Namiki 2024, Naqid 2024, Prabhu 2025, Reynolds 2024, Subaiea 2025, Tani 2024, Tetsuka 2024, Werner 2023, Zaidi 2025	

Domain	Comparator Type (N=)	Study Label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
a. Covid-19			
	Descriptive only (7)	Asiri 2025, Baba 2024, Holzwarth 2025, Jirawattanadon 2024, López-Contreras 2023, Mantovani 2024, Sodagari 2025, Thanborisutkul 2025	
Cardiovascular Disorders	Unvaccinated comparator or self-controlled case series (3)	Deshmukh 2024	BNT162b2, mRNA-1273: no difference (atrial arrhythmia)
		Ip 2025	BNT162b2: no difference (cerebral small vessel disease)
		Lee 2025c	BNT162b2: no difference (composite outcome in children: Bell's palsy, idiopathic thrombocytopenia, acute disseminated encephalomyelitis, myocarditis, pericarditis, GBS, transverse myelitis, acute MI, anaphylaxis, stroke, deep vein thrombosis, pulmonary embolism, narcolepsy, appendicitis, disseminated intravascular coagulation, febrile seizures, Kawasaki disease)
Cardiovascular Disorders *cont*	Active Comparator (10)	ElHilali 2024, Grieshaber 2025, Lambo 2025, Lee 2024d, Mazarakis 2025, Mok 2025, Pudasaini 2024, Sodagari 2025, Werner 2023, Yechezkel 2024	
	Descriptive only (5)	Holzwarth 2025, López-Contreras 2023, Mantovani 2024, Memon 2024, Sodagari 2025, Yoon 2025	

Domain	Comparator Type (N=)	Study Label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
a. Covid-19			
Respiratory / ENT Disorders Respiratory / ENT Disorders *cont.*	Unvaccinated comparator or self-controlled case series (3)	Lee 2025c	BNT162b2: no difference (composite outcome in children: Bell's palsy, idiopathic thrombocytopenia, acute disseminated encephalomyelitis, myocarditis, pericarditis, GBS, transverse myelitis, acute MI, anaphylaxis, stroke, deep vein thrombosis, pulmonary embolism, narcolepsy, appendicitis, disseminated intravascular coagulation, febrile seizures, Kawasaki disease)
		Xu 2025b	Pfizer and Moderna mRNA XBB.1.5 vaccines: no difference (tinnitus)
		Zethelius 2024	BNT162b2: pulmonary embolism after first dose HR 1.19 (95% CI, 1.06 to 1.34) (361 cases after 4,708,284 doses, 0.01%), no difference for other doses; mRNA-1273: second dose after first dose BNT162b2 3.82 (95% CI, 1.43 to 10.19) (4 cases after 26,689 doses, 0.01%), no difference for other doses; N=7,512,450
	Active Comparator (15)	ElHilali 2024, Grieshaber 2025, Lambo 2025, Lee 2023, Mazarakis 2025, Mohamed 2024, Namiki 2024, Prabhu 2025, Sodagari 2025, Wang 2024a, Werner 2023, Yechezkel	

Domain	Comparator Type (N=)	Study Label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
a. Covid-19			
		2024, Yih 2024, Zaidi 2025, Zethelius 2024	
	Descriptive only (5)	Hikichi 2024, Holzwarth 2025, López-Contreras 2023, Mantovani 2024, Memon 2024	
Gastrointestinal Disorders	Unvaccinated comparator or self-controlled case series (3)	Lee 2025c	BNT162b2: no difference (composite outcome in children: Bell's palsy, idiopathic thrombocytopenia, acute disseminated encephalomyelitis, myocarditis, pericarditis, GBS, transverse myelitis, acute MI, anaphylaxis, stroke, deep vein thrombosis, pulmonary embolism, narcolepsy, appendicitis, disseminated intravascular coagulation, febrile seizures, Kawasaki disease)
		Morciano 2024	BNT162b2 and mRNA-1273: no difference (appendicitis)
		Rossier 2024	BNT162b2, mRNA-1273: no difference (inflammatory bowel disease flare)
	Active Comparator (22)	ElHilali 2024, Grieshaber 2025, McLeod 2024, Mok 2025, Morciano 2024, Moscara 2023, Namiki 2024, Naqid 2024, Park 2024b, Pinto 2024, Prabhu 2025, Reynolds 2024, Rossier 2024, Sher 2024, Sodagari 2025, Subaiea 2025, Tani 2024,	

Domain	Comparator Type (N=)	Study Label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
a. Covid-19			
Gastrointestinal Disorders *cont.*		Tetsuka 2024, Villanueva, Werner 2023, Yechezkel 2024, Zaidi 2025	
	Descriptive only (7)	Fontana 2024, Hikichi 2024, López-Contreras 2023, Mantovani 2024, Obeng 2025, Thanborisutkul 2025, Yamamoto 2024	
Renal / Genitourinary Disorders	Active Comparator (2)	Alawfi 2024, de-la-Plaza-San-Frutos 2024	
	Descriptive only (4)	Chen 2024a, Hikichi 2024, Sodagari 2025, Umezawa 2025	
Reproductive / Endocrine Disorders	Unvaccinated comparator or self-controlled case series (13)	Al-Haddad 2024	BNT162b2: no difference (fertility parameters)
		Bea 2024 Bea 2024 *cont.*	BNT162b2: new-onset hypothyroidism IRR 0.88 (95% CI, 0.80 to 0.96) after first dose; mRNA-1273: new-onset hypothyroidism 0.74 (95% CI, 0.62 to 0.89) first dose, 0.82 (95% CI, 0.70 to 0.96) second dose; new-onset subacute thyroid disease 2.57 (95% CI, 1.16 to 5.72) second dose; new-onset thyroid eye disease 0.19 (95% CI, 0.06 to 0.64) first dose; no differences for other thyroid outcomes. Overall rates: new-onset hypothyroidism 7,685/5,407,214 (0.1%), new-onset subacute thyroid disease 363/5,407,214 (0.01%), new-onset thyroid eye disease 540/5,407,214 (0.01%)
		Cheng 2025	BNT162b2: hyperthyroidism HR 1.16 (95% CI, 1.06 to 1.28), hypothyroidism 1.85 (95% CI, 1.79 to 1.92); mRNA-1273: hyperthyroidism 1.40 (95% CI, 1.23 to 1.59), hypothyroidism 2.13 (95% CI, 2.04 to 2.23); no differences for subacute thyroiditis; follow-

Domain	Comparator Type (N=)	Study Label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
a. Covid-19			
Reproductive / Endocrine Disorders *cont.*	Unvaccinated comparator or self-controlled case series (13) *cont.*		up was 1 year post-vaccination, overall rates: hyperthyroidism 2,806/1,705,422 (0.2%), hypothyroidism 23,296/1,705,422 (1.4%)
		Couvillion 2024	BNT162b2: compositional changes in 4 proteins in human milk 3 days after vaccination; mRNA-1273 8 proteins 1-6 hours after vaccination; no changes in other proteins or any lipids or metabolites in extensive multi-omics approach (N=48)
		Duskin-Bitan 2024	BNT162b2: no difference (subacute thyroiditis)
		Jajou 2024	BNT162b2: menstrual disorders over 12 months after vaccination IRR 0.87 (95% CI, 0.84 to 0.90); mRNA-1273 menstrual disorders over 12 months after vaccination 0.85 (95% CI, 0.78 to 0.94); Overall rate 18,986/631,802 (3%)
		Jajou 2025	mRNA-1273, BNT162b2: no differences (clinic visits for postmenopausal bleeding)
		Licona-Menínde z 2024	BNT162b2: menstrual cycle alterations first dose OR 0.57 (95% CI, 0.36 to 0.89); mRNA-1273: no difference for first dose; N=522 females of reproductive age
		Magnus 2024a	BNT162b2, mRNA-1273: no difference (menstrual disorders)
		Magnus 2024b	BNT162b2 and mRNA-1273: no difference (postpartum hemorrhage)
		Safrai 2024	BNT162b2: no difference (in vitro fertilization performance and outcomes)
		Shani 2024	BNT162b2: hypothyroid aged 18-44y HR 0.87 (95% CI, 0.81 to 0.95) (overall rate 440/100,000). Retrospective electronic health record study of largest health care organization in Israel, included N=2,455,207 vaccinated, N=594,879 unvaccinated
Reproductive / Endocrine Disorders		Youngster 2024	BNT162b2: no difference (in vitro fertilization performance and outcomes)

Domain	Comparator Type (N=)	Study Label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
a. Covid-19			
Cont.	Unvaccinated comparator or self-controlled case series (13) *cont.*		
	Active Comparator (9)	Couvillion 2024, Esteban-Cledera 2024, Fatima 2025, Jajou 2024, Jajou 2025, Licona-Menínde z 2024, Mazarakis 2025, Mohamed 2024, Parveen 2024	
	Descriptive only (4)	Aydin 2024, Mantovani 2024, Strid 2024, Yumru Çeliksoy 2024	
Autoimmune & Inflammatory Disorders	Unvaccinated comparator or	Jung 2024	BNT162b2: primary cicatricial alopecia aHR 0.81 (99% CI, 0.68 to 0.98); psoriasis 0.84 (95% CI, 0.80 to 0.89), Behcet disease 0.75 (95% CI 0.62 to 0.91), rheumatoid arthritis 0.88 (95% CI, 0.85 to 0.91), systemic lupus erythematosus 1.18 (95% CI, 1.02 to 1.36); mRNA-1273 primary cicatricial alopecia aHR 0.75 (99% CI, 0.58 to 0.96), psoriasis 0.73 (95% CI, 0.67 to 0.78), ulcerative colitis 0.83

Domain	Comparator Type (N=)	Study Label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
a. Covid-19			
Autoimmune & Inflammatory Disorders *cont.*	self-controlled case series (8)		(95% CI, 0.70 to 0.99), rheumatoid arthritis 0.81 (95% CI, 0.78 to 0.85). Nationwide, population-based cohort study including 9,258,803 individuals.
		Kälin 2024	BNT162b2, mRNA-1273: no difference (autoantibody positivity in autoimmune hepatitis)
		Kim 2025b	BNT162b2, NVX-CoV2372: no difference (Kawasaki disease / MIS-C)
		Lee 2025c	BNT162b2: no difference (composite outcome in children: Bell's palsy, idiopathic thrombocytopenia, acute disseminated encephalomyelitis, myocarditis, pericarditis, GBS, transverse myelitis, acute MI, anaphylaxis, stroke, deep vein thrombosis, pulmonary embolism, narcolepsy, appendicitis, disseminated intravascular coagulation, febrile seizures, Kawasaki disease)
		Prasertsakul 2025	BNT162b2: no difference (MIS-C)
	Unvaccinated comparator or self-controlled case series (8) *cont.*	Shani 2024	BNT162b2: psoriasis age 12-17y HR 1.53 (95% CI, 1.18 to 1.98) (overall rate 154/100,000), 18-44y 1.44 (95% CI, 1.24 to 1.60) (overall rate 440/100,000), 45-64 1.69 (95% CI, 1.38 to 2.07) (overall rate 307/100,000), ≥65y 1.62 (95% CI, 1.25 to 2.1) (overall rate 291/100,000); colitis age 12-17y HR 1.93 (95% CI, 1.27 to 2.93) (overall rate 63/100,000), 18-44y 1.38 (95% CI, 1.13 to 1.7) (overall rate 84/100,000), 45-64y 1.5 (95% CI, 1.1 to 2.04) (overall rate 109/100,000); vitiligo age 45-64y HR 2.82 (95% CI, 1.57 to 5.08) (overall rate 50/100,000); polymyalgia rheumatica age ≥65 HR 2.12 (95% CI, 1.3 to 3.47) (overall rate 100/100,000); no differences for other age groups and diseases (inflammatory bowel disease, uveitis, Grave's disease, rheumatoid arthritis, fibromyalgia, Sjögren's syndrome, giant cell arteritis). Retrospective electronic health record study of largest health care organization in Israel, included N=2,455,207 vaccinated, N=594,879 unvaccinated
		Woo 2025	BNT162b2 and mRNA-1273: no difference (polymyalgia rheumatica)

Domain	Comparator Type (N=)	Study Label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
a. Covid-19			
		Yoon 2024	BNT162b2: Bell's palsy IRR 1.15 (95% CI, 1.09 to 1.20); mRNA-1273: no difference; 4 cases per 1 million vaccine doses, N=44,564,345 vaccine doses
	Active Comparator (12)	Farisogullari 2024, Fraenza 2025, Jarrot 2024, Kälin 2024, Kikuchi 2024, Namiki 2024, Pathak 2025, Shaharir 2025, Thepveera 2025, Woo 2025, Yildirim 2025, Yoon 2024	
	Descriptive only (9)	Ferraioli 2025, Hammam 2024, Mantovani 2024, Ng 2024, Öcek 2024, Özdemir 2024, Pekdiker 2024, Pira 2024, Primicerio 2025	
Hematologic Disorders	Unvaccinated comparator or self-controlled case series (2)	Kern 2025	BNT162b2: no difference (leukocyte count)
		Lee 2025c	BNT162b2: no difference (composite outcome in children: Bell's palsy, idiopathic thrombocytopenia, acute disseminated encephalomyelitis, myocarditis, pericarditis, GBS, transverse myelitis, acute MI, anaphylaxis, stroke, deep vein thrombosis, pulmonary embolism, narcolepsy, appendicitis, disseminated intravascular coagulation, febrile seizures, Kawasaki disease)
	Active Comparator (11)	Adin 2024, Almodóvar-Fernández 2024, ElHilali 2024, Gaddh 2023, Huang 2025a, Maan 2024, Namiki 2024, Subaiea 2025, Werner 2023, Yechezkel 2024, Zaidi 2025	

Domain	Comparator Type (N=)	Study Label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
a. Covid-19			
	Descriptive only (3)	Albahari 2025, Mantovani 2024, Nelli 2025	
Allergic / Hypersensitivity Reactions	Unvaccinated comparator or self-controlled case series (3)	Dudukina 2025	BNT162b2: chronic urticaria standardized incidence rate 0.61 (95% CI, 0.50 to 0.73), other urticaria 0.84 (95% CI, 0.74 to 0.94); mRNA-1273: chronic urticaria 3.00 (95% CI, 2.27 to 3.88), other urticaria 3.65 (95% CI, 3.06 to 4.31); BNT162b2 then mRNA-1273: chronic urticaria 0.46 (95% CI, 0.12 to 1.20), other urticaria 0.79 (95% CI, 0.39-1.38). Overall event rates chronic urticaria 0.02/person-year, other urticaria 0.04/person-year; N=4,700,301 vaccinated, N=5,480,146 pre-pandemic comparators
		Khalid 2024	BNT162b2: no difference (recurrent systemic allergic reaction)
Allergic / Hypersensitivity Reactions *Cont.*	Unvaccinated comparator or self-controlled case series (3) *cont.*	Lee 2025c	BNT162b2: no difference (composite outcome in children: Bell's palsy, idiopathic thrombocytopenia, acute disseminated encephalomyelitis, myocarditis, pericarditis, GBS, transverse myelitis, acute MI, anaphylaxis, stroke, deep vein thrombosis, pulmonary embolism, narcolepsy, appendicitis, disseminated intravascular coagulation, febrile seizures, Kawasaki disease)
	Active Comparator (11)	Briggs 2025, Dudukina 2025, Lambo 2025, Mohamed 2024, Moscara 2023, Namiki 2024, Peck 2024, Villanueva, Werner 2023, Yildirim 2025, Zaidi 2025	

Domain	Comparator Type (N=)	Study Label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
a. Covid-19			
	Descriptive only (11)	Arcolaci 2025, Battis 2024, Fitzpatrick 2024, Hikichi 2024, Konishi 2025, Lim 2025a, López-Contreras 2023, Padilla-Pantoja 2024, Petr 2024, Thanborisutkul 2025, Tursinov 2025	
Ophthalmic Disorders Ophthalmic Disorders *cont*.	Unvaccinated comparator or self-controlled case series (6)	Hwang 2025b	mRNA-1273, BNT162b2: no difference (retinal artery occlusion, retinal vein occlusion, non-infectious uveitis, non-infectious scleritis, optic neuritis, ischemic optic neuropathy)
		Kim 2024	BNT162b2: uveitis in patients with history of uveitis HR 1.23 (95% CI, 1.19 to 1.27), overall event rate 0.03 per person-month; mRNA-1273: 1.22 (95% CI, 1.13 to 1.31), N=473,934, overall event rate 0.03 per person-month
		Kumar 2024	mRNA-1274 and BNT162b2: no difference (recurrent non-infectious uveitis)
		Płatkowska-Adamska 2024	BNT162b2: no difference (macular degeneration)
		Shemer 2025	BNT162b2: no difference (acute anterior uveitis)
	Unvaccinated comparator or self-controlled case series (6) *cont.*	Sumer 2025	BNT162b2: pre- and post-vaccination (2.5 months) in healthy volunteers, comparison of corneal topographic and specular microscopic parameters showed increase in central corneal thickness (542 vs. 528), coefficient of variation (42 vs. 39), central corneal thickness (548 vs. 533); decrease in endothelial cell density (2,597 vs. 2,378), hexagonality (48 vs. 50); N=64
	Active Comparator (4)	Aftab 2024, Kim 2024, Kim 2025a, Kumar 2024	

Domain	Comparator Type (N=)	Study Label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
a. Covid-19			
	Descriptive only (3)	Arepalli 2025, Beurrier 2025, Testi 2024a, Testi 2024b	
Infectious Complications / Reactivations	Unvaccinated comparator or self-controlled case series (1):	Elbaz 2024	BNT162b2: no difference (varicella zoster-induced neurologic disease)
Infectious Complications / Reactivations *cont*.	Active Comparator (1)	Werner 2023	
	Descriptive only (1)	López-Contreras 2023	
Oncologic	Descriptive only (1)	Gordon 2024	

Domain	Comparator Type (N=)	Study label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
b. RSV			
Local or Systemic Reactogenicity	Unvaccinated comparator or self-controlled case series (4)	Davis 2024	RSVpreF RCT: more local reactions than placebo recipients (37% vs 12%), frequency of AEs to 1 month after vaccination similar in RSVpreF and placebo. 1 participant in RSVpreF group had mild nonserious urticaria resolving in 2 days. Severe AEs to 1 month after vaccination were in 0.2% RSVpreF and 1.8% placebo, SAEs through 6 months were in 1.1% RSVpreF and 3.1% placebo. 1 death in RSVpreF recipient (cardiopulmonary arrest on day 106 assessed as not related to vaccination)
		Ocana de Sentuary 2025	Nirsevimab: no difference
		Walsh 2024	RSVPreF: with revaccination, higher rates of injection site pain, redness, swelling compared to placebo, most mild and moderate. 1 participant each vs. 0 with severe muscle pain and severe fatigue/tiredness. 5 vs. 0 with fever. 24 vs. 11 with AEs, 16 vs. 3 with major AEs, 1 vs. 0 severe AE (lactic acidosis not considered related to vaccination) within 1 month. Severe AEs 1 month after revaccination 3

Domain	Comparator Type (N=)	Study label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
b. RSV			
Local or Systemic Reactogenicity *cont.*			vs. 0. Healthy adults randomized to vaccination and revaccination 1 year later with placebo or vaccine (N=263).
		Ferguson 2024	RSVPreF3-AS01: no difference
	Active Comparator (2)	Carcione 2025, Mayer 2025	
	Descriptive only (8)	Almeida 2025, Biegus 2024, Buynak 2024, Domnich 2025, Estrella-Porter 2025, Havlin 2025, Levy 2025b, Nguyen 2025a, van Heesbeen 2024	
Miscellaneous	Unvaccinated comparator or self-controlled case series (1)	Mao 2025	Nirsevimab: Small (N=24) phase I study found AEs including, increased urine urobilinogen (2), increased serum creatinine (1), decreased complement factor (1), decreased platelet count (1), vs. 0 in placebo arm
	Descriptive only (2)	Domachowske 2024, Estrella-Porter 2025	
Dermatologic / Cutaneous Events	Descriptive only (1)	Estrella-Porter 2025	
Cardiovascular Disorders	Unvaccinated comparator or self-controlled case series (1)	Ferguson 2024	RSVPreF3-AS01: 1 case atrial fibrillation vs. 0 (N=1,152)
	Descriptive only (1)	Biegus 2024	
Gastrointestinal Disorders	Active Comparator (1)	Carcione 2025	
	Descriptive only (2)	Estrella-Porter 2025, Nguyen 2025a	
Autoimmune & Inflammatory Disorders	Unvaccinated comparator or self-controlled	Ferguson 2024	RSVPreF3-AS01: 1 case cold antibody autoimmune hemolytic anemia vs. 0 (N=1152)

Domain	Comparator Type (N=)	Study label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
b. RSV			
	case series (N=1):		
	Descriptive only (1)	Domachowske 2024	
Hematologic Disorders	Descriptive only (1)	Domachowske 2024	
Allergic / Hypersensitivity Reactions	Descriptive only (4)	Biegus 2024, Domachowske 2024, Domnich 2025, Estrella-Porter 2025	

Domain	Comparator Type (N=)	Study label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
C. Influenza			
Local or Systemic Reactogenicity	Unvaccinated comparator or self-controlled case series (2)	Nakayama 2025	Quadrivalent live attenuated influenza vaccine: no difference (solicited and unsolicited AEs)
		Prasert 2024	TIV: higher rates of some solicited events (pain, tenderness, headache, malaise, myalgia most common); frequency of adverse events over 1 year similar (N=3,672)

Domain	Comparator Type (N=)	Study label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
C. Influenza			
	Active Comparator (20)	Bahakel 2025, Gao 2024, Huang 2025b, Kandinov 2025, Kawai 2024, Kothari 2024, Li 2024a, Meidani 2024, Mombelli 2024, Moscara 2023, Omole 2025a, Poder 2023, Prasert 2024, Shi 2023, Sodagari 2025, Thomas 2023, Wang 2024b, Wen 2025, Yechezkel 2024, Zornoza Moreno 2024	
	Descriptive only (11)	Amaralde de Avila Machado 2025, Amicizia 2023, de la Cueva 2024, Dos Santos 2024, Folegatti 2025, Nakashima 2023, Shapiro 2023, Slingerland 2023, Wu 2025a, Yin 2024, Zawiasa-Bryszewska 2025	
Miscellaneous	Unvaccinated comparator or self-controlled case series (1)	Grima 2024	Any influenza vaccine: no difference in ED visits
Miscellaneous *cont.*	Active Comparator (3)	Mombelli 2024, Omole 2025a, Sodagari 2025	
	Descriptive only (2)	Slingerland 2023, Wu 2025a	
Musculoskeletal & Joint Disorders	Active Comparator (2)	Poder 2023, Yechezkel 2024	
	Descriptive only (N=3):	Slingerland 2023, Wu 2025a, Yin 2024	
Neurologic Events and Conditions	Unvaccinated comparator or	Grimaldi 2023	Any influenza vaccine: no difference (multiple sclerosis hospitalization)
		Lophatananon 2023	Any influenza vaccine: dementia HR 0.96 (95% CI, 0.94 to 0.97)

Domain	Comparator Type (N=)	Study label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
C. Influenza			
	self-controlled case series (2)	Ogawa 2025	Any influenza vaccine: no difference (composite outcome of hospitalizations related to epilepsy, paralysis, facial paralysis, neuralgia, neuritis, optic neuritis, migraine, extrapyramidal disorders, Guillain-Barré Syndrome, or narcolepsy; epilepsy alone)
	Active Comparator (7)	Grimaldi 2023, Jeong 2025c, Lee 2025a, Moscara 2023, Poder 2023, Sodagari 2025, Yechezkel 2024	
	Descriptive only (4)	Slingerland 2023, Woo 2024, Wu 2025a, Yin 2024	
Dermatologic / Cutaneous Events	Active Comparator (3)	Kyung 2025, Poder 2023, Sodagari 2025	
Cardiovascular Disorders	Active Comparator (3)	Lee 2024b, Sodagari 2025, Yechezkel 2024	
Respiratory / ENT Disorders	Active Comparator (3)	Gallagher 2024, Sodagari 2025, Yechezkel 2024	
	Descriptive only (2)	Machado 2024, Slingerland 2023	
Gastrointestinal Disorders	Unvaccinated comparator or self-controlled case series (1)	Nakafero 2024	Inactivated influenza vaccine: no difference (inflammatory bowel disease flare)
	Active Comparator (6)	Mombelli 2024, Moscara 2023, Poder 2023, Sodagari 2025, Thomas 2023, Yechezkel 2024	
	Descriptive only (1)	Machado 2024	

Domain	Comparator Type (N=)	Study label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
C. Influenza			
Renal / Genitourinary Disorders	Unvaccinated comparator or self-controlled case series (2)	Cho 2024	Any influenza vaccine: acute kidney injury: 2018-2019 IRR 0.83 (95% CI, 0.79 to 0.87), 2018-2019 IRR 0.86 (95% CI, 0.82 to 0.90). Self-controlled case series with incidence in risk period 1.45 cases/person-years (2018-19) and 1.51 cases/person-years (2019-20); incidence in control period 1.83 cases/person-years (2018-19) and 1.80 cases/person-years (2019-20).
		Zawiasa-Bryszewska 2025	Quadrivalent split virion inactivated influenza vaccine: no difference (renal function or proteinuria among kidney transplant recipients)
Renal / Genitourinary Disorders *cont.*	Active Comparator (2)	Hwang 2025a, Sodagari 2025	
	Descriptive only (1)	Machado 2024	
Autoimmune & Inflammatory Disorders	Active Comparator (5)	Chen 2025, Jeong 2025a, Jeong 2024b, Mombelli 2024, Oh 2024	
	Descriptive only (2)	Dos Santos 2024, Wu 2025a	
Hematologic Disorders	Active Comparator (2)	Gaddh 2023, Yechezkel 2024	
	Descriptive only (2)	Machado 2024, Zawiasa-Bryszewska 2025	
Allergic / Hypersensitivity Reactions	Active Comparator (3)	Kang 2024, Lee 2024a, Moscara 2023	
	Descriptive only (1)	Machado 2024	
Ophthalmic Disorders	Unvaccinated comparator or self-controlled case series (1)	Hashimoto 2024	Any influenza vaccine: no difference (uveitis, scleritis, retinal vein occlusion, retinal artery occlusion, optic neuritis)

Domain	Comparator Type (N=)	Study label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
C. Influenza			
Infectious Complications / Reactivations	Unvaccinated comparator or self-controlled case series (1)	Cheng 2024	Inactivated influenza vaccine: no difference (herpes zoster)
	Active Comparator (1)	Jeong 2025b	

Supplemental Table S10. Vaccine Co-administration Studies: Immunogenicity, Reactogenicity, and Safety Outcomes[a]

Study label	Study design	N (co-admin)	Vaccines	Comparator	Immuno-genicity	Reacto-genicity	Safety	Key findings
a. Covid-19 + Influenza Vaccine (17 studies)								
Aydillo 2024	Observational	128	BNT162b2 bivalent + QIV	Solo vaccines	Non-inferior	Increased	No SAEs	Higher H3N2 antibodies when vaccines administered in different arms (vs. same arm)
Barouch 2024	Non-RCT	42	mRNA vaccines + Fluarix/Fluzone	Sequential	Superior	Not reported	No concerns	Enhanced spike antibodies with co-administration (vs. sequential)
Baum 2024	RCT	138	BNT162b2 + QIV or aTIV	BNT162b2 alone	Non-inferior	Not reported	Not reported	No difference in salivary anti-spike IgG and IgA levels with co-administration.
Choi 2024b	Non-RCT	154	BNT162b2 bivalent + QIV	Sequential	Mixed	Comparable	Comparable	Co-administration did not meet non-inferiority criteria for seroconversion rates (titers were non-inferior)
Dulfer 2023	RCT	38	BNT162b2 + QIV	Solo vaccines	Reduced	Comparable	No concerns	Lower Covid-19 antibodies with co-admin
Gonen 2023	Observational	146	BNT162b2 bivalent + flu	Solo vaccines	Non-inferior	Increased	No concerns	Reactogenicity higher in co-admin group vs. Covid-19 alone, but lower than flu alone
Moscara 2023	Observational	610	BNT162b2 + flu	Solo vaccines	N/A	Increased	Similar to Covid-19 alone, lower than flu alone	OR 0.35 (95% CI, 0.22 to 0.55) for any AE vs flu alone

Study label	Study design	N (co-admin)	Vaccines	Comparator	Immuno-genicity	Reacto-genicity	Safety	Key findings
Moss 2023	Observational	18	BNT162b2 bivalent + QIV	Solo vaccines	Non-inferior	Not reported	No concerns	Similar titers in all groups
Murdoch 2023	RCT	560	BNT162b2 + SIIV	Sequential	Non-inferior	Increased	Comparable	77.7% systemic events with co-administration, 63.7% with Covid-19 alone
Naficy 2024	RCT	498	mRNA-1273 + QIV	Sequential	Non-inferior	Comparable	No concerns	No immunological interference or safety concerns in co-administration group.
Park 2024a[b]	Observational	7,783	XBB.1.5 + QIV	Covid-19 alone	N/A	No increase	No differences	Healthcare visits: 1.2% (co-admin) vs. 1.5% (Covid-19 alone), *P* <0.05
Pasquale 2025	Observational	346	BNT162b2 XBB.1.5 + QIVe or QIVc	Flu alone or Covid-19 alone	N/A	Increased	Similar to Covid-19	More local/systemic reactions in co-admin groups vs. Covid-19 alone
Pattinson 2024	Observational	116	Bivalent Covid-19 vaccine + IIV	N/A	Non-inferior	Not reported	No concerns	Ipsilateral = contralateral
Ramsay 2023	RCT	119	Covid-19 mRNA vaccines + IIV	Sequential	N/A	Comparable	No concerns	Safety focus study
Riccomi 2024	Observational	54	Covid-19 mRNA vaccine + QIV	Covid-19 alone	Superior	Not reported	No concerns	Increased anti-spike titer in co-administration group
Sun 2025a[b]	SCCS	10,071	BNT162b2 XBB.1.5 + IIV	Covid-19 alone	N/A	N/A	No increased AESI	Self-controlled case series

Study label	Study design	N (co-admin)	Vaccines	Comparator	Immuno-genicity	Reacto-genicity	Safety	Key findings
Walter 2024[b]	RCT	169	Covid-19 mRNA + IIV4	Sequential	N/A	Comparable	No concerns	Age ≥5y included
b. RSV + Influenza Vaccines (9 studies)								
Athan 2024	RCT	702	RSVpreF + SIIV	Sequential	Non-inferior	Increased	No concerns	Systemic events: 44.7% (co-admin) vs. 41.4% (sequential)
Buynak 2024	RCT	516	RSVPreF3 OA + FLU-QIV-HD	Sequential	Non-inferior	Increased	Comparable	Local AEs within 4 days of visit 1: 62.4% (co-admin) vs. 44.4% (sequential)
Chandler 2024	RCT	442	RSVPreF3 OA + FLU-QIV	Sequential	Non-inferior	Increased	No concerns	Local AEs: 53.4% (co-admin) vs. 20.8% (sequential)
Chime 2025	RCT	438[c]	RSVPreF3 + FLU-D-QIV	Sequential	Mixed	Increased	Acceptable	Acceptable immunogenicity outcomes for 3/4 influenza strains
Clark 2024	RCT	523	RSVPreF3 OA + FLU-aQIV	Sequential	Mixed	Increased	No concerns	Non-inferior for 3/4 influenza strains
Won 2024	Observational	87,899	QIV + PPSV23	Sequential	N/A	Mixed	Mixed	Allergic reactions: aIRR 0.71 (95% CI, 0.58-0.87); Paralysis: aIRR 1.63 (95% CI, 1.05 to 2.52)

Study label	Study design	N (co-admin)	Vaccines	Comparator	Immuno-genicity	Reacto-genicity	Safety	Key findings
Zhu 2024a	RCT	160	IIV4 + PPSV23	Sequential	Non-inferior	Comparable	No SAEs	All immunogenicity endpoints met
c. Multiple Vaccine Combinations (9 studies)								
Goswami 2025 (Covid-19)	RCT	564	mRNA-1345 RSV + Covid-19 mRNA-1273.214	Sequential	Non-inferior	Comparable	No concerns	Co-administration of two mRNA vaccines does not negatively impact immune outcomes
Goswami 2025 (Flu)	RCT	685	mRNA-1345 RSV + SIIV4	Sequential	Mixed	Comparable	No concerns	5/6 non-inferiority criteria met in co-administration group (all but RSV-A nAbs)
Jorda 2025	RCT	64	NVX-CoV2601 + PCV20	Sequential	Non-inferior	Increased	No concerns	More reactogenic than placebo
Neutel 2025	RCT	315[d]	BNT162b2 + RSVpreF with or without QIV	Solo vaccines	Non-inferior	Increased	Comparable	Local reactions were more common among the concomitant groups, vs. RSVPreF-alone, but were similar to those of the BNT162n2-alone and QIV-alone groups
Omole 2025b	RCT	422[e]	mRNA-1273 + PPSV23 or PCV15	Sequential	Comparable	Comparable	Comparable	Co-administration with either pneumococcal formula in adults age ≥50y was immunogenic and well tolerated
Omole 2025a	RCT	534	QIV + V116	Sequential	Non-inferior	Comparable	No differences	Non-inferior immunogenicity for 20 of

Study label	Study design	N (co-admin)	Vaccines	Comparator	Immuno-genicity	Reacto-genicity	Safety	Key findings
								21 pneumococcal serotypes in V11620/21 serotypes met criteria
Schmader 2024	RCT	267	RZV + aIIV4 or HD-IIV4	Sequential	N/A	No differences	No SAE differences	Safety focus study
Xu 2024	SCCS	NR	Covid-19 vaccine + IIV	Covid-19 alone	N/A	N/A	No increased stroke	Stroke RR 0.99 (95% CI, 0.68 to 1.45) among all ages; among ages <65 years stroke RR 2.14 (95% CI, 1.02 to 4.49) by electronic-data-base outcome, not confirmed after chart review (RR 2.25. 95% CI, 0.98 to 5.65)
Xu 2025b[b]	SCCS	922[e]	Covid-19 mRNA XBB.1.5 + IIV	Covid-19 alone	N/A	N/A	No increased tinnitus	No increased first-ever tinnitus risk: RI 0.78 (95% CI, 0.67 to 0.90) at 14 days, RI 0.87 (95% CI, 0.78 to 0.96) at 28 days

aIIV4 = Adjuvanted quadrivalent inactivated influenza vaccine, AESI = Adverse event of special interest, HD-IIV4 = High-dose quadrivalent inactivated influenza vaccine, IIV = Inactivated influenza vaccine, N/A = Not applicable, PCV = Pneumococcal conjugate vaccine, PCV20 = 20-valent pneumococcal conjugate vaccine, PPSV = Pneumococcal polysaccharide vaccine, QIV = Quadrivalent influenza vaccine, RCT = Randomized controlled trial, RZV = Recombinant zoster vaccine, SAE = Serious adverse event, SCCS = Self-controlled case series, SIIV = Seasonal inactivated influenza vaccine

[a]Three studies without comparator groups were not included in the table: Moro 2024 analyzed 3,689 VAERS reports following co-administration of Covid-19 and influenza vaccines, finding 29 deaths at expected rates and no unusual or unexpected patterns of AEs; Biegus 2024 reported injection site pain (63%) and systemic reactions (33%) following co-administration of RSV and influenza vaccines and no heart failure exacerbations among 105 patients with high-risk heart failure; Li 2025a examined 791 VAERS reports following co-administration of influenza vaccines and recombinant zoster vaccine among older adults without identifying any new safety signals.

[b]Includes pediatric participants
[c]18-49 years non-pregnant women
[d]157 Covid-19+RSV + 158 Covid-19+RSV+QIV
[e]213 PPSV23 + 209 PCV15

Supplemental Table S11. Excluded systematic reviews and meta-analyses identified during the publication window

Study label	Study title	Domain(s)
a. Covid-19		
Al-Omoush 2025	Sarcoidosis and Covid-19 Vaccines: A Systematic Review of Case Reports and Case Series	S
Alinaghi 2025	Feasibility and Effectiveness of Vaccines for Covid-19: An Umbrella Review	VE
Azeem 2025	Efficacy and limitations of SARS-CoV-2 vaccines - A systematic review	VE, S
Bachmann 2025	Disparities in response to mRNA SARS-CoV-2 vaccines according to sex and age: A systematic review	VE
Beck 2025	Indirect comparison of the relative vaccine effectiveness of mRNA-1283 vs. BNT162b2 vaccines against symptomatic Covid-19 among US adults	VE
Berad 2025	Systematic Review: Long-Term Effects of Covid-19 on Cardiovascular Health	Epi
Bushi 2025	Impact of Covid-19 Vaccination on Menstrual Irregularities, Bleeding Patterns, and Cycle Duration: A Systematic Review and Meta-Analysis	S
Cahuapaza-Gutierrez 2025	New-onset hematologic disorders following Covid-19 vaccination: a systematic review	S
Dorjee 2025	Menstrual disturbance associated with Covid-19 vaccines: A comprehensive systematic review and meta-analysis	S
Fahrbach 2025	Comparative effectiveness of Omicron XBB 1.5-adapted Covid-19 vaccines: a systematic literature review and network meta-analysis	VE
Gomes 2025	Portal-splenic-mesenteric venous thrombosis in Covid-19 patients: a systematic review	Epi
Jafari 2025	Updates on Auditory Outcomes of Covid-19 and Vaccine Side Effects: An Umbrella Review	S
Kalantari 2025	A Systematic Review of Vascular Injuries: A Review of Petechiae, Purpura, and Ecchymosis in Critical Situations Following Covid-19 Vaccination	S
Karimi 2025	Covid-19 Vaccination and Cardiovascular Events: A Systematic Review and Bayesian Multivariate Meta‚ÄëAnalysis of Preventive Benefits and Risks	S
Kitano 2025	Age- and sex-stratified risks of myocarditis and pericarditis attributable to Covid-19 vaccination: a systematic review and meta-analysis	S
Mahneva 2025	Systematic Review of Covid-19 and Covid-19 mRNA Vaccine Myocarditis in Athletes: Incidence, Diagnosis, Prognosis, and Return-to-Play Principles	S
Mirza 2025	Facial Nerve Palsy Amid the SARS-CoV-2 Pandemic: A Pooled Analysis	S
Padhi 2025	Incidence and Association of Uveitis with Covid-19 Vaccination: A Systematic Review and Meta-Analysis	S
Peine 2025	Efficacy and Effectiveness of Covid-19 Vaccines Against Post Covid-19 Condition/Long Covid-19: Systematic Review and Meta-Analysis	VE
Qi 2025	A scoping review on adult patients with de novo glomerular diseases following Covid-19 infection or vaccine	S

Study label	Study title	Domain(s)
Ragni 2025	Covid-19 infection and vaccination and the risk of pituitary apoplexy: an entangled yarn	S
Rudolph 2025	Factors affecting the impact of Covid-19 vaccination on post Covid-19 conditions among adults: A systematic literature review	VE
Samatha 2025	Global impact of the Covid-19-10 JN1 variant on transmission, immunity, and therapeutic response: a systematic review	VE
Satyam 2025	Unraveling Cardiovascular Risks and Benefits of Covid-19 Vaccines: A Systematic Review	S
Shahrebabak 2025	The efficacy of Covid-19 vaccination in cystic fibrosis patients: a systematic review	VE
Sterian 2025	Evidence on the associations and safety of Covid-19 vaccination and post Covid-19 condition: an updated living systematic review	VE, S
Syed 2025	Comparative effectiveness of three common SARS-COV-2 vaccines: A network meta-analysis of randomized trials	VE
Taiyeb Khosroshahi 2025	Post-Covid-19 Vaccination Meningitis and Meningoencephalitis: A Systematic Review of Case Series and Case Reports	S
Wu 2025	Erythema Multiforme and Epidermal Necrolysis Following Covid-19 Vaccines: A Systematic Review	S
Yella 2025	A Systematic Review of the Covid-19 Vaccine's Impact on the Nervous System	S
Zeng 2025	Causal relationship between Covid-19, vaccination, and 20 digestive diseases: a comprehensive two-sample Mendelian randomization study	S
Zhang 2025	Growing attention of immunogenicity among patients with autoimmune diseases post-SARS-CoV-2 vaccination: meta-analysis and systematic reviews of the current studies	S
Zhang 2025	Immunogenicity and Safety of Covid-19 Vaccines in Patients with Lung Cancer: Results of a Systematic Review and Meta-Analysis	S
Abuhammad 2024	Covid-19 vaccine-associated vasculitis: A systematic review	S
AlShahrani 2024	Prevalence of menstrual alterations following Covid-19 vaccination: systematic review & meta-analysis	S
Alper 2024	Idiopathic sudden sensorineural hearing loss after Covid-19 vaccination: a systematic review and meta-analysis	S
Arabzadeh Bahri 2024	Anosmia or Ageusia Following Covid-19 Vaccination: A Systematic Review	S
Asante 2024	Heterologous versus homologous Covid-19 booster vaccinations for adults: systematic review with meta-analysis and trial sequential analysis of randomised clinical trials	VE
Atefi 2024	Meningitis after Covid-19 vaccination, a systematic review of case reports and case series	S
Basutkar 2024	Maternal and Neonatal Outcomes after Vaccination with SARS-CoV-2: A Systematic Review and Meta-analysis of Cohort Studies	VE, S
Bushi 2024	Postural orthostatic tachycardia syndrome after Covid-19 vaccination: A systematic review	S

Study label	Study title	Domain(s)
Cahuapaza-Gutierrez 2024	Aplastic Anemia Following Covid-19 Vaccination: A Systematic Review of Case Reports and Case Series	S
Chow 2024	The effect of pre-Covid-19 and post-Covid-19 vaccination on long Covid-19: A systematic review and meta-analysis	VE, S
Chue 2024	Immune thrombocytopenia exacerbation post Covid-19 vaccination: a systematic review and meta-analysis	S
Ciapponi 2024	Safety and Effectiveness of Covid-19 Vaccines During Pregnancy: A Living Systematic Review and Meta-analysis	VE, S
Dang 2024	Effectiveness of Covid-19 Vaccines in People with Severe Mental Illness: A Systematic Review and Meta-Analysis	VE
Dasara 2024	Status epilepticus as a complication of SARS-CoV-2 vaccination: Two case reports and systematic review with individual patients' data analysis	S
Dhanasekaran 2024	Safety, efficacy, and immunogenicity of SARS-CoV-2 mRNA vaccination in children and adult patients with rheumatic diseases: a comprehensive literature review	VE
Dorgalaleh 2024	Congenital Bleeding Disorders and Covid-19-A Systematic Literature Review	S
Duzett 2024	Pityriasis following Covid-19 vaccinations: a systematic review	S
Florek 2024	Myocarditis Associated with Covid-19 Vaccination	S
Galgut 2024	Covid-19 vaccines are effective at preventing symptomatic and severe infection among healthcare workers: A clinical review	S
Gerede 2024	Safety of Covid-19 Vaccination in Pregnancy: A Systematic Review	S
Hoxha 2024	Covid-19 vaccine and the risk of flares in inflammatory arthritis: a systematic literature review and meta-analysis	S
Hua 2024	Immune response of Covid-19 vaccines in solid cancer patients: A meta-analysis	VE
Huang 2024	Adverse Cardiovascular Effects of Covid-19 Vaccination: A Systematic Review	S
Lam 2024	Systematic Review: Safety and Efficacy of mRNA Covid-19 Vaccines in Pregnant Women	VE, S
Lamichhane 2024	Immediate impacts of Covid-19 vaccination on glycemic control in type 1 diabetes mellitus: A systematic review and meta-analysis	S
Lee 2024	Cardiac and Neurological Complications Post Covid-19 Vaccination: A Systematic Review of Case Reports and Case Series	S
Li 2024	Takotsubo syndrome and vaccines: a systematic review	S
Martora 2024	Pemphigus and Bullous Pemphigoid Following Covid-19 Vaccination: A Systematic Review	S
Meo 2024	Exploring the adverse events of Oxford-AstraZeneca, Pfizer-BioNTech, Moderna, and Johnson and Johnson Covid-19 vaccination on Guillain-Barre Syndrome	S
Mirzakhani 2024	The Assessment of Anti-SARS-CoV-2 Antibodies in Different Vaccine Platforms: A Systematic Review and Meta-Analysis of Covid-19 Vaccine Clinical Trial Studies	VE
Mitsikostas 2024	Headaches and facial pain attributed to SARS-CoV-2 infection and vaccination: a systematic review	S

Study label	Study title	Domain(s)
Mohammadi 2024	Covid-19 Vaccine Safety Studies among Vulnerable Populations: A Systematic Review and Meta-analysis of 120 Observational Studies and Randomized Clinical Trials	S
Moradiya 2024	Systematic Review of Individual Patient Data Covid-19 Infection and Vaccination-Associated Thrombotic Microangiopathy	S
Ng 2024	Localised swelling at sites of dermal filler injections following administration of Covid-19 vaccines: a systematic review	S
Oliveira 2024	Neonatal and maternal outcomes of mRNA versus Non-mRNA Covid-19 vaccines in pregnant patients: a systematic review and meta-analysis	S
Parmar 2024	Ocular Implications of Covid-19 Infection and Vaccine-Related Adverse Events	S
Payne 2024	Association between Covid-19 vaccination and menstruation: a state of the science review	S
Peinemann 2024	Adverse Menstrual Events Reported After and Before (or Without) Covid-19 Vaccination: A Systematic Review and Meta-Analysis of Comparative Observational Studies	S
Politis 2024	The Global Burden of Absenteeism Related to Covid-19 Vaccine Side Effects Among Healthcare Workers: A Systematic Review and Meta-Analysis	S
Pyarali 2024	Bell,Äôs Palsy, an Adverse Event Following Covid-19 Vaccines	S
Rafati 2024	Association of New-Onset Seizures With SARS-CoV-2 Vaccines: A Systematic Review and Meta-Analysis of Randomized Clinical Trials	S
Rafati 2024	Association of new onset seizure and Covid-19 vaccines and long-term follow-up: A systematic review and meta-analysis	S
Rayner 2024	Efficacy and safety of Covid-19 vaccination in solid organ transplant recipients: A systematic review and network meta-analysis	VE
Riemma 2024	Susceptibility to Infection and Impact of Covid-19 Vaccines on Symptoms of Women with Endometriosis: A Systematic Review and Meta-Analysis of Available Evidence	VE
Rustagi 2024	SARS-CoV-2 pathophysiology and post-vaccination severity: a systematic review	S
Sanker 2024	Post Covid-19 vaccination medium vessel vasculitis: a systematic review of case reports	S
SeyedAlinaghi 2024	The immunologic outcomes and adverse events of Covid-19 vaccine booster dose in immunosuppressed people: A systematic review	S
Shaheen 2023	Guillain-Barr√© syndrome following Covid-19 vaccination: An updated systematic review of cases	S

Study label	Study title	Domain(s)
Soltanzadi 2024	Incidence of Bell's palsy after coronavirus disease (Covid-19) vaccination: a systematic review and meta-analysis	S
Sood 2024	Effects of post-Covid-19 vaccination in oral cavity: a systematic review	S
Stella 2024	Foe Or Friend? Systemic Lupus Erythematosus (Sle) Patients And Covid-19 Vaccination: A Systematic Review	S
Tian 2024	Immunogenicity and risk factors for poor humoral immune response to SARS-CoV-2 vaccine in patients with autoimmune hepatitis: a systematic review and meta-analysis	VE
Verrienti 2024	Pituitary and Covid-19 vaccination: a systematic review	S
Wang 2024	Covid-19 vaccination during pregnancy and adverse perinatal outcomes: a systematic review and meta-analysis	S
Yang 2024	An overview and single-arm meta-analysis of immune-mediated adverse events following Covid-19 vaccination	S
Zarkesh 2024	Thyroid Function in the Time of Covid-19: A Systematic Review of Disease Progression and Vaccination Effect	S
Zeng 2024	Comprehensive insights into Covid-19 vaccine-associated multiple evanescent white dot syndrome (MEWDS): A systematic analysis of reported cases	S
Zheng 2024	Meta-analysis of hybrid immunity to mitigate the risk of Omicron variant reinfection	VE
Zhu 2024	Alopecia areata following Covid-19 vaccine: a systematic review	S
Wang 2023	Comparative effectiveness of mRNA-1273 and BNT162b2 Covid-19 vaccines in immunocompromised individuals: a systematic review and meta-analysis using the GRADE framework	VE
Angeles 2024	Covid-19 Vaccine-Related Movement Disorders: A Systematic Review	S
Choi 2024	Myocarditis and Pericarditis are Temporally Associated with BNT162b2 Covid-19 Vaccine in Adolescents: A Systematic Review and Meta-analysis	S
Ghafari 2024	Covid-1919 Vaccination Considerations for Pregnant Women: A Systematic Review	S
Gupta 2024	Risk of Corneal Transplant Rejection Following Covid-19 Vaccination: A Systematic Review and Meta-analysis	S
Åysak 2024	ANCA-Positive Small-Vessel Vasculitis Following SARS-CoV-2 Vaccination-A Systematic Review	S
Milosti*f*á-Srb 2024	The Effect of Covid-19 and Covid-19 Vaccination on Assisted Human Reproduction Outcomes: A Systematic Review and Meta-Analysis	S
Rosca 2024	Parsonage-Turner Syndrome following Covid-19 Vaccination: A Systematic Review	S

Study label	Study title	Domain(s)
Sharma 2024	Pathophysiology of oral lesions subsequent to SARS-CoV-2 vaccination: A systematic review	S
Thenpandiyan 2024	Myopericarditis following Covid-19 vaccination in children: a systematic review and meta-analysis	S
Wilburn 2024	Effectiveness of Pfizer Vaccine BNT162b2 Against SARS-CoV-2 in Americans 16 and Older: A Systematic Review	VE
Wong 2024	Systematic review and meta-analysis of Covid-19 mRNA vaccine effectiveness against hospitalizations in adults	VE
Yazdani 2024	Incidence of Guillain-Barr√© Syndrome (GBS) after Covid-19 Vaccination: a Systematic Review and Meta-Analysis	S
Abourjeili 2025	Myocarditis Following Covid-19 Vaccine: What Did We Learn?	S
Abumayyaleh 2025	Covid-19 and Myocarditis: Trends, Clinical Characteristics, and Future Directions	S
Banerjee 2025	Cardiac Complications Associated With Covid-19 Vaccination: A Systematic Review of Cohort Studies	S
Etesami 2025	Drug- and Vaccine-Induced Cutaneous T-Cell Lymphoma: A Systematic Review of the Literature	S
Justiz-Vaillant 2025	Covid-19 Vaccines Effectiveness and Safety in Trinidad and Tobago: A Systematic Review and Meta-Analysis	VE, S
Kawabata 2025	Olfactory disorder after Covid-19 vaccination	S
Lei 2025	The Effectiveness and Influence of Covid-19 Vaccination on Perinatal Individuals and Their Newborns: An Updated Meta-Analysis	VE
Mohammadi 2025	Covid-19 vaccine safety studies among special populations: A systematic review and meta-analysis of 120 observational studies and randomized clinical trials	S
Muayad 2025	Herpes zoster ophthalmicus temporally after Covid-19 vaccination: a systematic review of uncontrolled case reports and case series	S
Nitz 2025	Cardiovascular Sequelae of the Covid-19 Vaccines	S
Patel 2025	Protective effects of booster dose of SARS-COV-2 vaccination against post-acute Covid-19 syndrome: A systematic review	VE
Perelli 2025	Preterm Birth and SARS-CoV-2: Does a Correlation Exist?	Epi
Volkman 2025	Effectiveness of a single Covid-19 mRNA vaccine dose in individuals with prior SARS-CoV-2 infection: a systematic review	VE
Gandhi 2025	Safety of Covid-19 Vaccines Among Pregnant Women in India: A Systematic Review and Meta-Analysis	S

Study label	Study title	Domain(s)
Sadowski 2025	Association between Guillain-Barre syndrome and SARS-CoV-2 virus infection, including the impact of Covid-19 vaccination in the context of the development and general clinical characteristics of the disease	S
Ma 2025	Effectiveness of the monovalent XBB.1.5 Covid-19 vaccines: A systematic review and meta-analysis	VE
Park 2025	Long Covid-19: A Systematic Review of Preventive Strategies	VE
b. RSV		
Sumsuzzman 2025	Real-World Effectiveness of Nirsevimab Against Respiratory Syncytial Virus Disease in Infants: A Systematic Review and Meta-Analysis	VE
Tanashat 2025	Efficacy and safety of nirsevimab for preventing respiratory syncytial virus infection in infants: an updated systematic review and meta-analysis encompassing 11,001 participants	VE, S
Wang 2025	Effectiveness of nirsevimab immunization against RSV infection in preterm infants: a systematic review and meta-analysis	VE
Moreira 2024	Efficacy of anti-RSV vaccination in preventing respiratory syncytial virus disease and severe illness in older adults: a systematic review of randomized controlled trials	VE
Wu 2024	Efficacy, Safety, and Immunogenicity of Subunit Respiratory Syncytial Virus Vaccines: Systematic Review and Meta-Analysis of Randomized Controlled Trials	VE, S
Zeng 2024	Efficacy and safety of vaccines to prevent respiratory syncytial virus infection in infants and older adults: A systematic review and meta-analysis	VE, S
Marchand 2024	RSVpreF vaccination in pregnancy: a meta-analysis of maternal-fetal safety and infant efficacy	S
Kuitunen 2025	Respiratory Syncytial Virus Vaccination Is Associated With Increased Odds of Preterm Birth	S
Duan 2025	Global outbreaks of respiratory syncytial virus infections from 1960 to 2025: a systematic review and meta-analysis	Epi
Garegnani 2025	Palivizumab for preventing severe respiratory syncytial virus (RSV) infection in children	VE
Manzoni 2025	Systematic Review and Expert Consensus on the Use of Long-acting Monoclonal Antibodies for Prevention of Respiratory Syncytial Virus Disease: ARMADA (Advancing RSV Management And Disease Awareness) Taskforce	VE
c. Influenza		
Askar 2025	Relative Efficacy, Effectiveness and Safety of Newer and/or Enhanced Seasonal Influenza Vaccines for the Prevention of Laboratory-Confirmed Influenza in Individuals Aged 18 years and Over: Update of a Systematic Review	VE, S

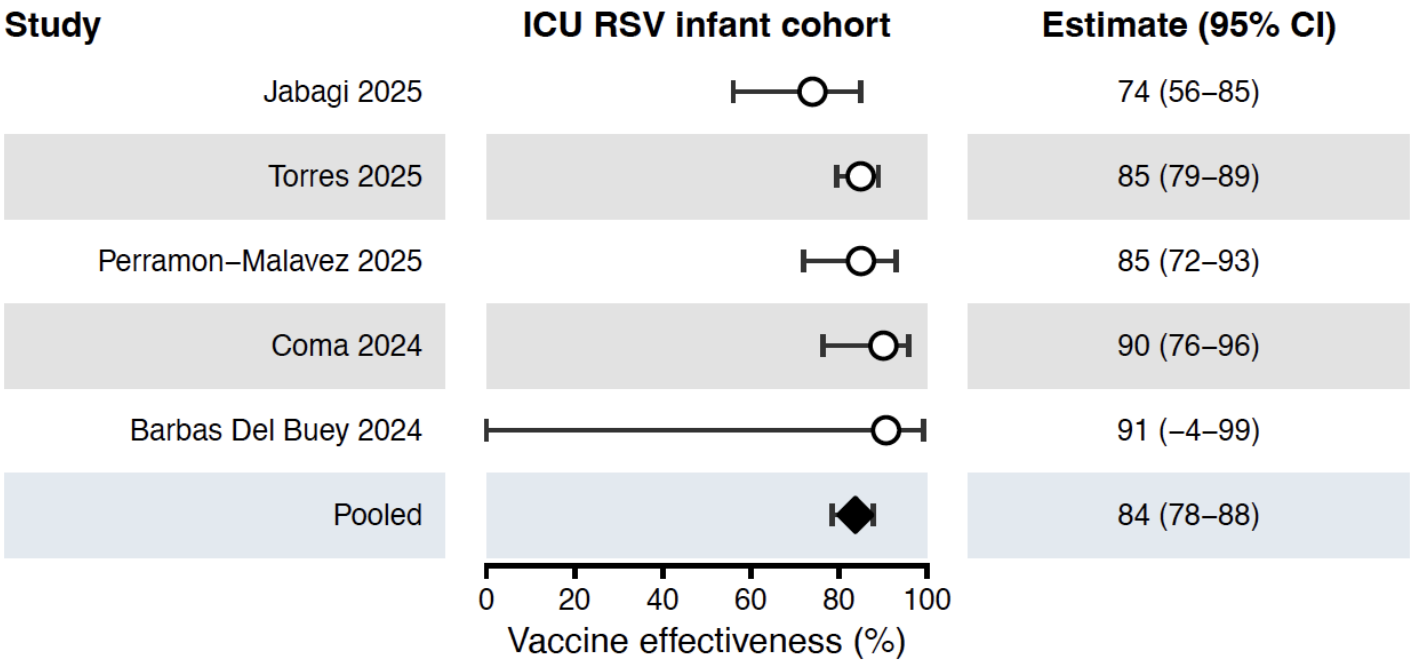
Study label	Study title	Domain(s)
Bandell 2025	Safety of LAIV Vaccination in Asthma or Wheeze: A Systematic Review and GRADE Assessment	S
Liu 2025	Association between influenza vaccination and prognosis in patients with ischemic heart disease: A systematic review and meta-analysis of randomized controlled trials	VE
Zorger 2025	Vaccines for preventing infections in adults with haematological malignancies	VE
Addario 2023	Impact of influenza, herpes zoster, and pneumococcal vaccinations on the incidence of cardiovascular events in subjects aged over 65 years: a systematic review	S
Carregaro 2023	Immunogenicity and safety of inactivated quadrivalent influenza vaccine compared with the trivalent vaccine for influenza infection: an overview of systematic reviews	S
Domnich 2024	Immunogenicity and safety of the MF59-adjuvanted seasonal influenza vaccine in non-elderly adults: A systematic review and meta-analysis	S
Elsaid 2023	Immune thrombocytopenic purpura after influenza vaccine administration; a systematic review and meta-analysis	S
Ferdinands 2024	Protection against influenza hospitalizations from enhanced influenza vaccines among older adults: A systematic review and network meta-analysis	VE
Guo 2024	Real-world effectiveness of seasonal influenza vaccination and age as effect modifier: A systematic review, meta-analysis and meta-regression of test-negative design studies	VE
Gupta 2024	Role of Influenza Vaccination in Cardiovascular Disease: Systematic Review and Meta-Analysis	VE, S
Kiely 2023	Sex differences in adverse events following seasonal influenza vaccines: a meta-analysis of randomised controlled trials	S
Liu 2024	Association Between Influenza Vaccine and Immune Thrombocytopenia: A Systematic Review and Meta-Analysis	S
Martins 2023	Seasonal Influenza Vaccine Effectiveness in Persons Aged 15-64 Years: A Systematic Review and Meta-Analysis	VE
Mashkoor 2024	Neurological complications of influenza vaccination: Navigating the spectrum with a focus on acute disseminated encephalomyelitis (ADEM)	S
Moa 2023	Systematic review of influenza vaccine effectiveness against laboratory-confirmed influenza among older adults living in aged care facilities	VE
Modin 2023	Influenza vaccination and cardiovascular events in patients with ischaemic heart disease and heart failure: A meta-analysis	S
Omidi 2024	Comparing higher-dose and single standard-dose influenza vaccines in preventing cardiovascular events: a meta-analysis with 68,713 patients	VE
Skaarup 2024	The relative vaccine effectiveness of high-dose vs standard-dose influenza vaccines in preventing hospitalization and mortality: A meta-analysis of evidence from randomized trials	VE
Veroniki 2024	Trivalent and quadrivalent seasonal influenza vaccine in adults aged 60 and older: a systematic review and network meta-analysis	VE, S

Study label	Study title	Domain(s)
Veroniki 2023	Comparing trivalent and quadrivalent seasonal influenza vaccine efficacy in persons 60 years of age and older: A systematic review and network meta-analysis	VE
Wolfe 2023	Safety of influenza vaccination during pregnancy: a systematic review	S
Zhang 2024	A meta-analysis of immunogenicity and safety of two versus single-doses of influenza A (H1N1) vaccine in person living with HIV	VE, S
Nakabembe 2024	The safety and immunogenicity of vaccines administered to pregnant women living with HIV: a systematic review and meta-analysis	VE, S
Pennisi 2025	Post-Vaccination Anaphylaxis in Adults: A Systematic Review and Meta-Analysis	S
Rivera-Izquierdo 2025	High-dose versus standard-dose influenza vaccine for immunocompromised patients: A systematic review and meta-analysis of randomised clinical trials	VE
Yang 2025	Influenza vaccination and risk of dementia: a systematic review and meta-analysis	S
Wang 2024	Vaccination and the risk of systemic lupus erythematosus: a meta-analysis of observational studies	S
d. Multiple		
Aksar 2025	Vaccination and clozapine use: a systematic review and an analysis of the VAERS database	VE, S
Boikos 2025	Co-Administration of BNT162b2 Covid-19 and Influenza Vaccines in Adults: A Global Systematic Review	C
Ma 2025	Severe Cutaneous Adverse Reactions Following Vaccination: A Systematic Review and Meta-Analysis	S
Rahimi 2025	Immunogenicity and adverse effects of pneumococcal vaccines co-administered with influenza or SARS-CoV-2 vaccines in adults: A systematic review and Meta-analysis	VE, C
deBruin 2023	Are maternal vaccines effective and safe for mothers and infants? A systematic review and meta-analysis of randomised controlled trials	VE, S
DelRiccio 2024	Influenza vaccination and Covid-19 infection risk and disease severity: A systematic review and multilevel meta-analysis of prospective studies	VE
Lu 2023	Evaluation of the efficacy, safety and influencing factors of concomitant and sequential administration of viral respiratory infectious disease vaccines: a systematic review and meta-analysis	VE, S, C
Marantos 2024	Immunogenicity and safety of vaccines in multiple sclerosis: A systematic review and meta-analysis	VE, S
Pontiroli 2024	Vaccination against influenza viruses reduces infection, not hospitalization or death, from respiratory Covid-19: A systematic review and meta-analysis	VE
Mulleners 2025	Safety and Efficacy of Vaccination During Lactation: A Comprehensive Review of Vaccines for Maternal and Infant Health Utilizing a Large Language Model Citation Screening System	VE, S

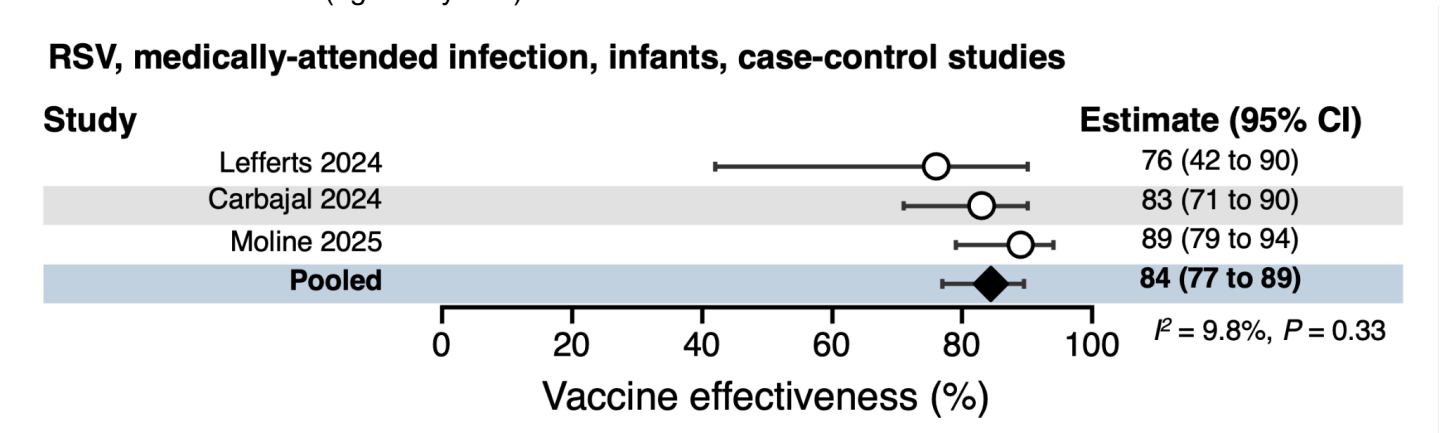
Study label	Study title	Domain(s)
Pan 2025	Vaccination and rheumatoid arthritis: an updated systematic review and meta-analysis of data from 25,949,597 participants	S
Rezahosseini 2025	Safety and Immunogenicity of Co-Administration of Herpes Zoster Vaccines with Other Vaccines in Adults: A Systematic Review and Meta-Analysis	S, C
Chittajallu 2025	Safety and Efficacy of Vaccines During Pregnancy: A Systematic Review	VE, S
Messina 2024	Oral manifestations after vaccinations: A systematic review of observational studies	S

Epi: Epidemiology, VE: vaccine effectiveness, S: Safety, C: Co-administration

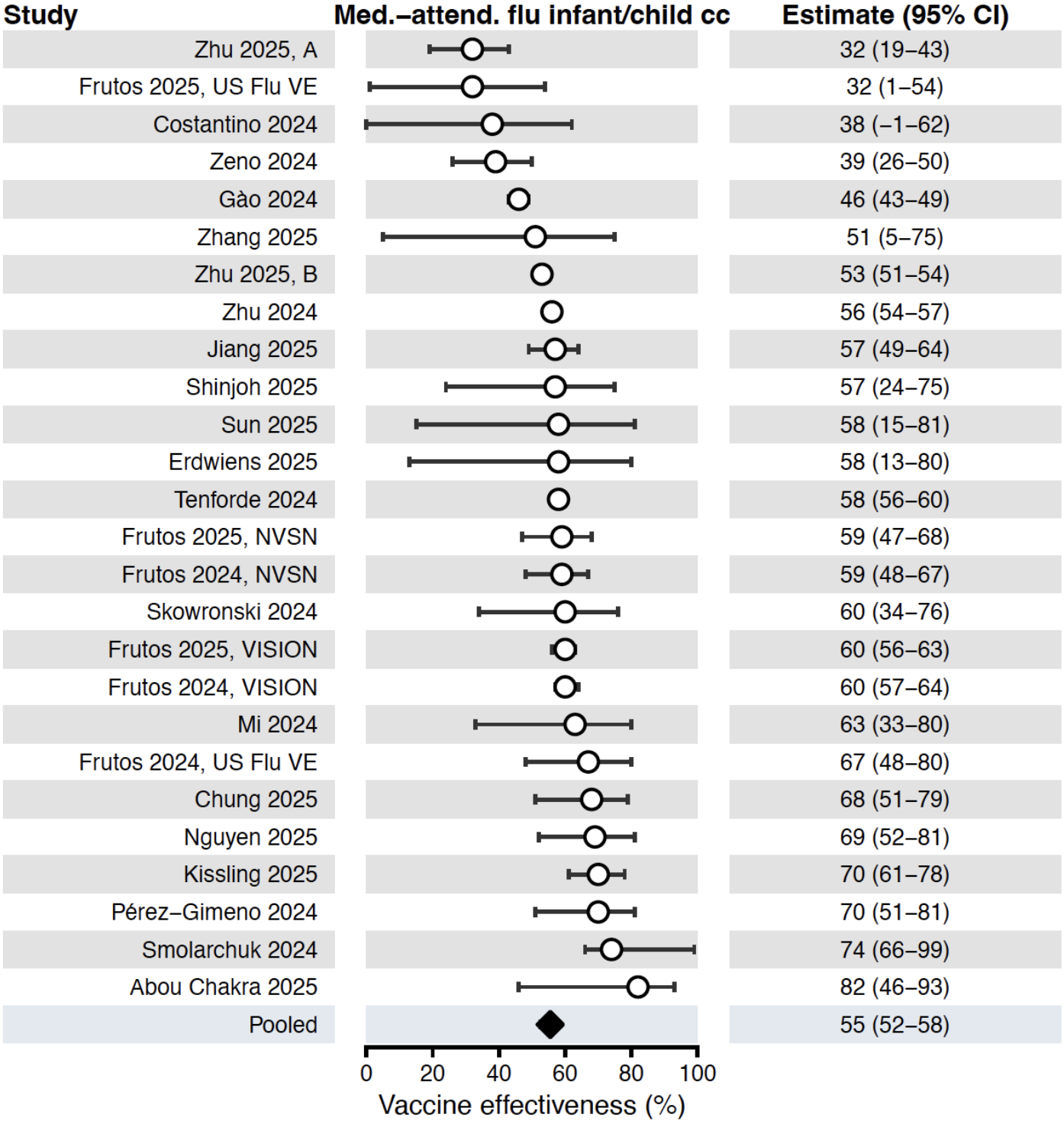
Supplemental Figure S1. Nirsevimab effectiveness against ICU admission in cohort studies of infants (age < 2 years). Arrow indicates lower bound of 95% confidence interval falls below zero. I^2=14%, p=0.33.



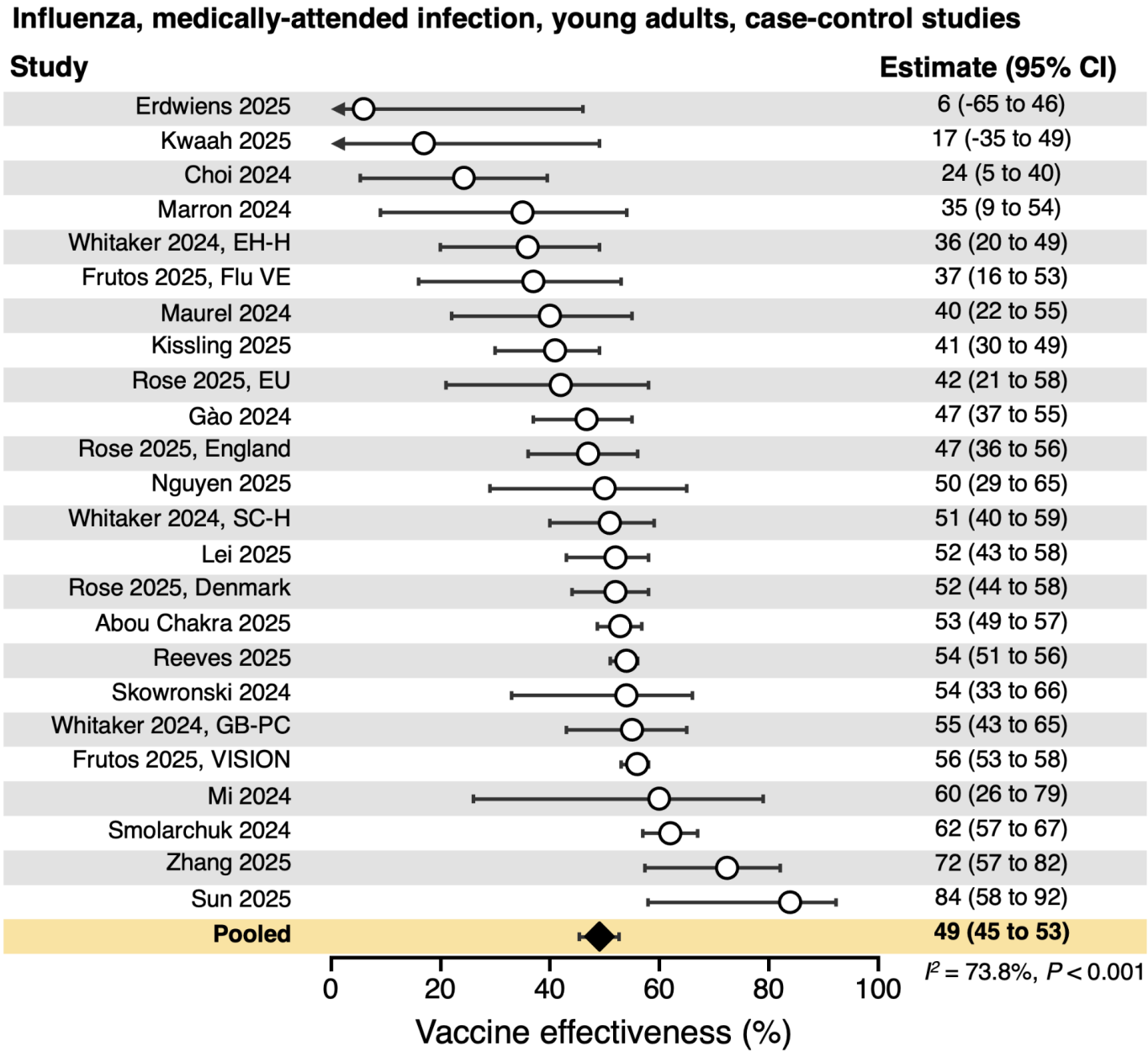
Supplemental Figure S2. Nirsevimab vaccine effectiveness against medically attended infection in case-control studies of infants (age < 2 years).



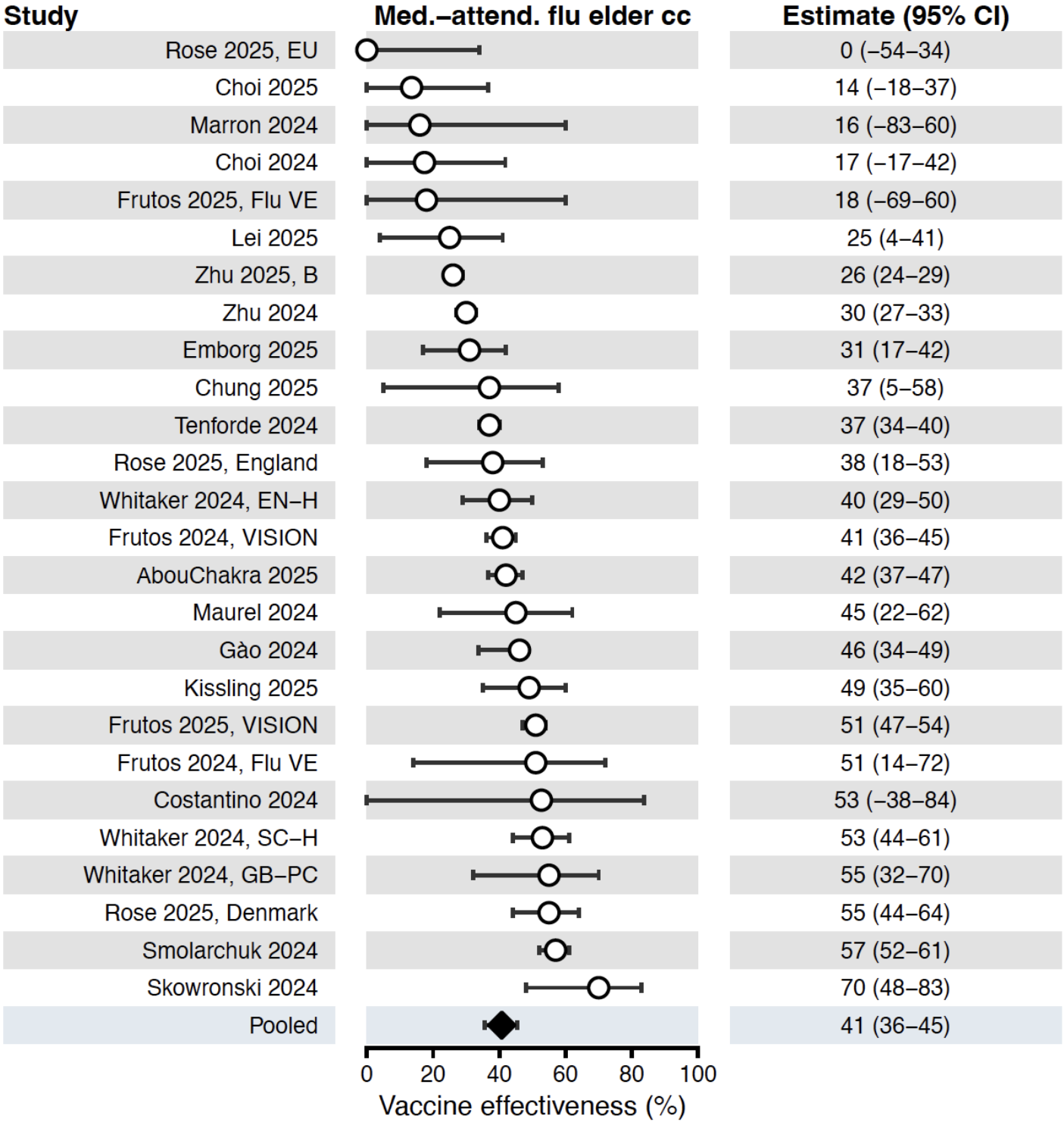
Supplemental Figure S3. Influenza vaccine effectiveness against medically attended infection in case-control studies of infants (age < 2 years) children (age 2-17 years). Arrow indicates lower bound of 95% confidence interval falls below zero. I^2=81%, p=<0.001



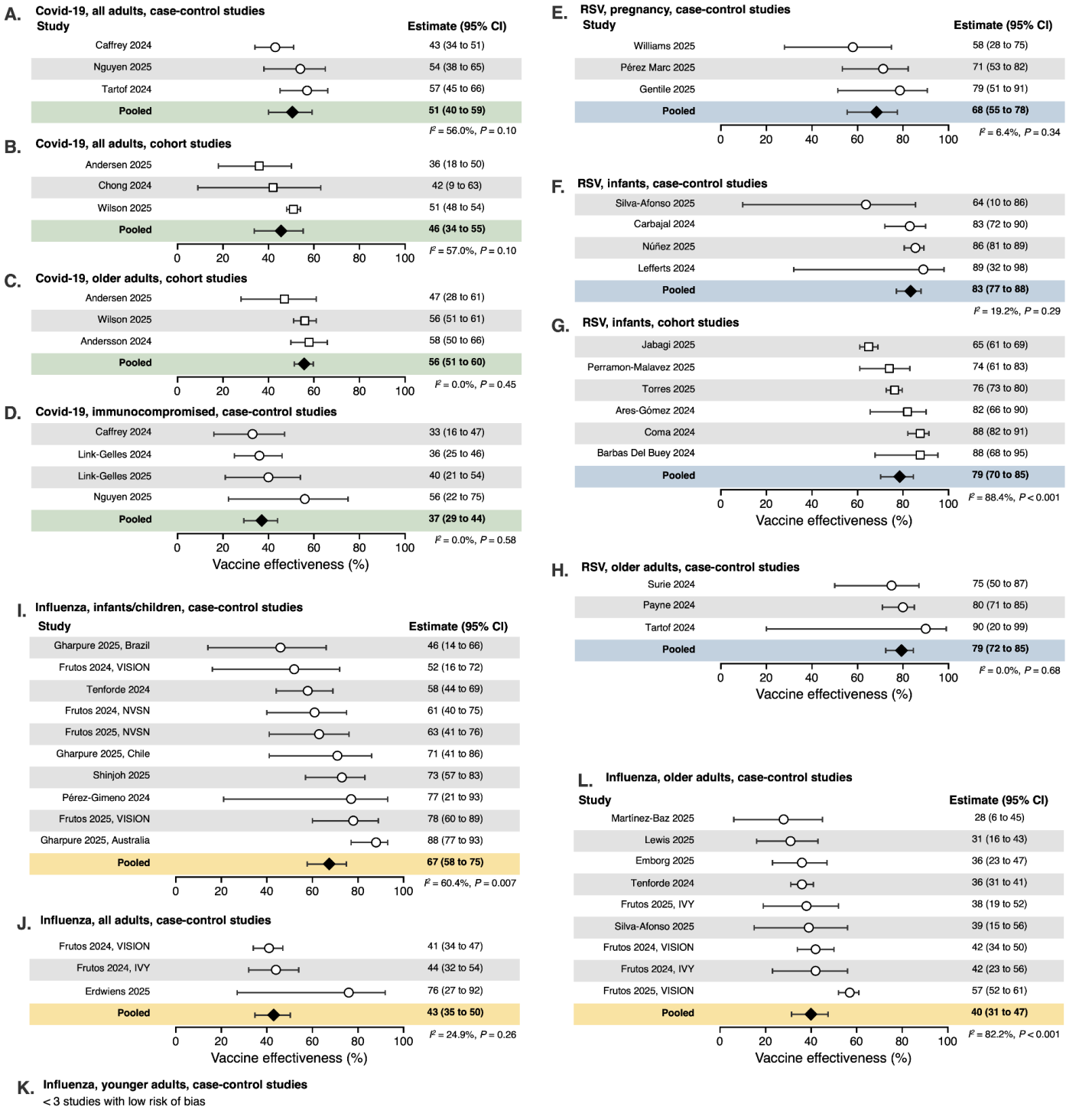
Supplemental Figure S4. Influenza vaccine effectiveness against medically attended infection in case-control studies of younger adults (age 18-64 years). Arrows indicate lower bound of 95% confidence interval falls below zero.



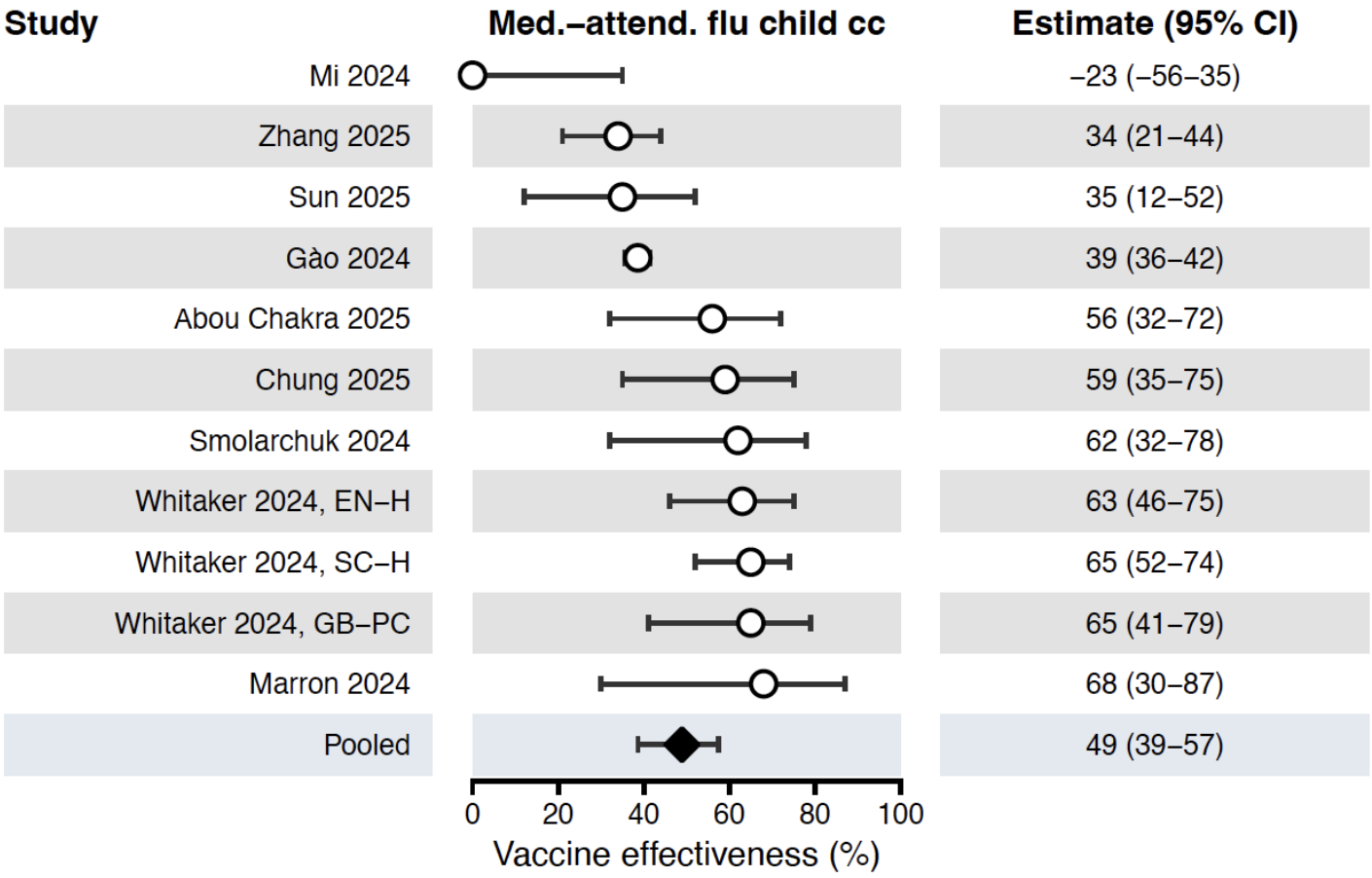
Supplemental Figure S5. Influenza vaccine effectiveness against medically attended infection in case-control studies of older adults (age ≥ 65 years). Arrows indicate lower bound of 95% confidence interval falls below zero. I^2=91%, p=<0.001



Supplemental Figure S6. Sensitivity analyses of primary outcome (hospitalization) meta-analyses after excluding studies at high risk of bias

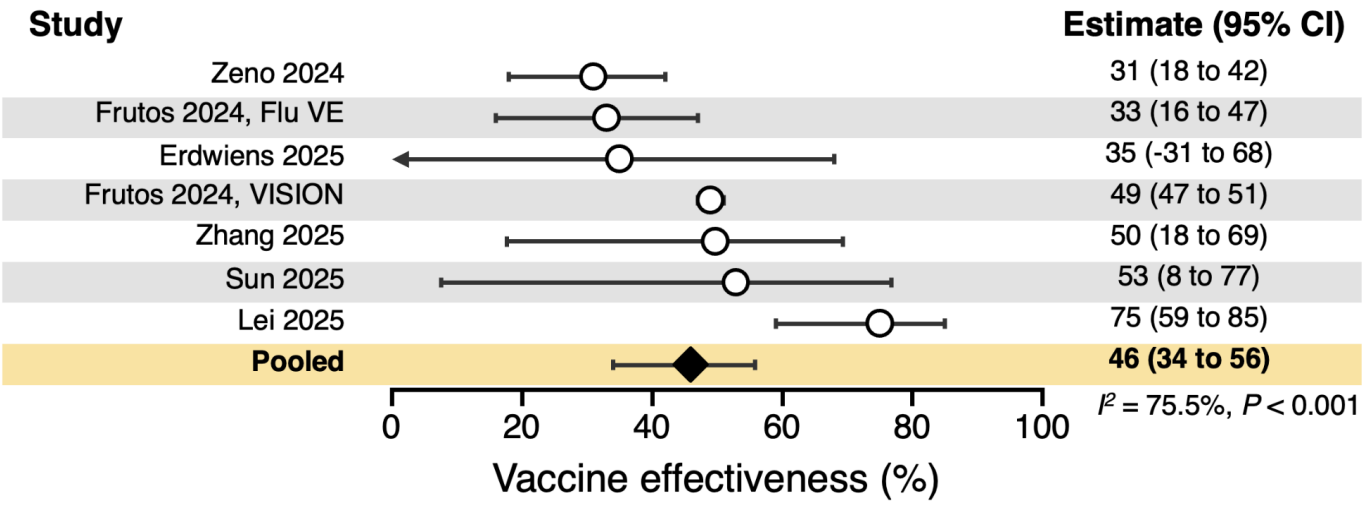


Supplemental Figure S7. Influenza vaccine effectiveness against medically attended infection in case-control studies of children 2-17 years of age. Arrow indicates lower bound of 95% confidence interval falls below zero. I^2=77%, p=<0.001



Supplemental Figure S8. Influenza vaccine effectiveness against medically attended infection in case-control studies of adults (age ≥ 18 years). Arrow indicates lower bound of 95% confidence interval falls below zero.

Influenza, medically-attended infection, all adults, case-control studies



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