

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

Supplemental Appendix

Additional Details Available at the [Web Application](#).

Table of contents

Supplemental methods	Page 3
<i>Protocol and search strategy</i>	Page 3
<i>Immunization products</i>	Page 3
<i>Study periods of interest</i>	Page 3
<i>Prespecified adverse events of special interest</i>	Page 3
<i>Definition of immunocompromised</i>	Page 4
<i>Effect estimates</i>	Page 4
<i>Meta-analytic methods</i>	Page 4
<i>Risk of bias assessment</i>	Page 4
Supplemental Results	Page 5
<i>Summary of epidemiology studies identified in this review</i>	Page 5
<i>Summary of safety outcomes not specifically identified as being of special interest</i>	Page 5
<i>Data Visualization</i>	Page 8
Additional Discussion of Limitations and Context not in the Main Text	Page 8
Supplemental Table S1. PubMed Covid-19-related search terms	Page 10
Supplemental Table S2. PubMed RSV-related search terms	Page 12
Supplemental Table S3. PubMed Influenza related search terms	Page 14
Supplemental Table S4. Study characteristics of 511 included studies.	Page 16
Supplemental Table S5. Key findings of epidemiologic studies	Page 39
Supplemental Table S6. Summary results of vaccine effectiveness against medically-attended infection, symptomatic infection, ICU admission, hospitalization >6 months after vaccine administration, long-term symptoms, or death	Page 44
Supplemental Table S7. Summary results of vaccine effectiveness to prevent hospitalization during varying follow-up within 6 months (Covid-19) or one respiratory viral season (RSV and influenza) following vaccine administration.	Page 59
Supplemental Table S8. Summary results of additional vaccine safety outcomes in pregnancy	Page 65
Supplemental Table S9. Summary results of studies regarding key vaccine safety outcomes in studies without an unvaccinated or self-controlled comparator group.	Page 66
Supplemental Table S10. Summary results of included studies reporting on vaccine-related adverse events not specifically identified as being of special interest	Page 76
Supplemental Table S11. Vaccine Co-administration Studies: Immunogenicity, Reactogenicity, and Safety Outcomes	Page 97
Supplemental Table S12. Excluded systematic reviews and meta-analyses identified during the publication window	Page 103
Supplemental Figure S1. PRISMA diagram	Page 113
Supplemental Figure S2. Nirsevimab effectiveness against ICU admission in cohort studies of infants (age < 2 years).	Page 114
Supplemental Figure S3. Nirsevimab effectiveness against medically attended infection in case-control studies of infants	Page 115
Supplemental Figure S4. Influenza vaccine effectiveness against medically attended infection in case-control studies of infants (age < 2 years) children (age 2-17 years).	Page 116

Supplemental Figure S5. Influenza vaccine effectiveness against medically attended infection in case-control studies of younger adults (age 18-64 years).	Page 117
Supplemental Figure S6. Influenza vaccine effectiveness against medically attended infection in case-control studies of older adults (age ≥ 65 years).	Page 118
Supplemental Figure S7. Sensitivity analyses of primary outcome (hospitalization) meta-analyses after excluding studies at high risk of bias	Page 119
Supplemental Figure S8. Influenza vaccine effectiveness against medically attended infection in case-control studies of children 2-17 years of age.	Page 120
Supplemental Figure S9. Influenza vaccine effectiveness against medically attended infection in adults (age ≥ 18).	Page 121
References	Page 122

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 $\leq 200/\mu L$); 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 $(1 - \text{relative effect}) \times 100\%$. 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.

COVID-19 vaccines

New onset seizures after mRNA-1273 - Ko 2025¹⁰

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 2025b¹⁶

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 2024²⁰

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 2025³¹⁻³³

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 S1. 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

ACCEPTED

Supplemental Table S2. 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 ENFLONIA[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 antibody"[tiab] OR ((transplacental[tiab] OR placental[tiab]) AND antibody*[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 S3. 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 of 511 included studies. Additional details available at the [web application](#).

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

Study	Population ¹	Study design ²	Country/region	Setting details	Risk of bias
Almodóvar-Fernández 2024	A, E	Observational - other	Spain	Single-center	High
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		High
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

Study	Population ¹	Study design ²	Country/region	Setting details	Risk of bias
Bahakel 2025	C, IC	Observational - other	US	Multi-center	High
Bajema 2025a	A, E	Cohort	US	Multi-center (VAMC)	Low
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

Study	Population ¹	Study design ²	Country/region	Setting details	Risk of bias
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
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

Study	Population ¹	Study design ²	Country/region	Setting details	Risk of bias
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
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

Study	Population ¹	Study design ²	Country/region	Setting details	Risk of bias
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
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

Study	Population ¹	Study design ²	Country/region	Setting details	Risk of bias
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
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

Study	Population ¹	Study design ²	Country/region	Setting details	Risk of bias
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
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

Study	Population ¹	Study design ²	Country/region	Setting details	Risk of bias
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
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

Study	Population ¹	Study design ²	Country/region	Setting details	Risk of bias
Jeong 2025c	I, C, A, E	Observational - other	Worldwide		High
Jęskowiak-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
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

Study	Population ¹	Study design ²	Country/region	Setting details	Risk of bias
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
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

Study	Population ¹	Study design ²	Country/region	Setting details	Risk of bias
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
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

Study	Population ¹	Study design ²	Country/region	Setting details	Risk of bias
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
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

Study	Population ¹	Study design ²	Country/region	Setting details	Risk of bias
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
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

Study	Population ¹	Study design ²	Country/region	Setting details	Risk of bias
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
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

Study	Population ¹	Study design ²	Country/region	Setting details	Risk of bias
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
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

Study	Population ¹	Study design ²	Country/region	Setting details	Risk of bias
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
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

Study	Population ¹	Study design ²	Country/region	Setting details	Risk of bias
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, Scotland, Denmark		High
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

Study	Population ¹	Study design ²	Country/region	Setting details	Risk of bias
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
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

Study	Population ¹	Study design ²	Country/region	Setting details	Risk of bias
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
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

Study	Population ¹	Study design ²	Country/region	Setting details	Risk of bias
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
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

Study	Population ¹	Study design ²	Country/region	Setting details	Risk of bias
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
Woestenbergh 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
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

Study	Population ¹	Study design ²	Country/region	Setting details	Risk of bias
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
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

Study	Population ¹	Study design ²	Country/region	Setting details	Risk of bias
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. Additional details available at the [web application](#).

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 both JN.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 Choi 2025b	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. 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.

Population	Outcome	Study Label	Findings
			Co-detections were observed in 0.49% of samples, with SARS-CoV-2/influenza A co-detection being the most common.
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
Additional details available at the [web application](#).

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_XB B	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	42 (32 to 51)
					Shrestha 2024, JN.1 predominance	19 (-1 to 35)
	BNT162b2_XB B.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)

Population	Vaccine	Outcome	Study design(s)	# Studies	Study label	VE % (95% CI)
	mRNA XBB1.5	Hospitalization, 7 days - 9 months	Case-control	1	Nham 2025	37 (24 to 48)
	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, 7 days - ~8 months	Case-control	1	Nham 2025	21 (9 to 31)
	BNT162b2_XB B.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_XB B.1.5	Medically-attended infection (ED visit), 0-6 months post-dose	Cohort	1	Andersen 2025a	45 (34 to 54)

Population	Vaccine	Outcome	Study design(s)	# Studies	Study label	VE % (95% CI)
	mRNA XBB1.5	Medically-attended infection (ED visit), 0-4 months post-dose	Cohort	1	Chong 2024	50 (27 to 66)
	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)

Population	Vaccine	Outcome	Study design(s)	# Studies	Study label	VE % (95% CI)
	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)
	BNT162b2_XB B1.5	Symptomatic infection, 9-12 weeks post-dose	Cohort	1	Ward 2025	15 (-8 to 34)
	BNT162b2_XB B1.5	Medically-attended infection (ED visit), 0-6 months post-dose	Cohort	1	Andersen 2025a	48 (33 to 60)
	BNT162b2_XB B.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_XB B.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)

Population	Vaccine	Outcome	Study design(s)	# Studies	Study label	VE % (95% CI)
	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)
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 Alejandre 2024, <1y ^m Jimeno Ruiz 2024, <3m Jimeno Ruiz 2024, 3-6m Marouk 2025, <3m	Unable to calculate effect estimate 9 (9 to 10) to 4 (3 to 6) RSV-bronchiolitis admissions per 100 PICU admissions ^l 69 (44 to 84) 68 (-20 to 91) 51 (11 to 74)

Population	Vaccine	Outcome	Study design(s)	# Studies	Study label	VE % (95% CI)
					Barbas Del Buey 2024, <10m	91 (-4 to 99)
					Coma 2024, <10m	90 (76 to 96)
					Jabagi 2025	74 (56 to 85)
					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 Coma 2024, <10m, primary care attended bronchiolitis Coma 2024, <10m, hospital emergency visits Coma 2024, <10m, all-cause pneumonia Perramon-Malavez 2025a, <4m Perramon-Malavez 2025b, <6m Perramon-Malavez 2025b, 6-11m	17 (-6 to 35) 48 (42 to 53) 55 (48 to 62) 61 (24 to 80) 54 (10 to 77) 44 (42 to 46) 7 (3 to 11)
Infant	Nirsevimab	Medically-attended infection	Case-control	5	Carbajal 2024, 0-12m Moline 2025, 0-8m Lefferts 2024 ⁿ , 1st RSV season, 0-27m Pooled estimate (3 studies)	83 (71 to 90) 89 (79 to 94) 76 (42 to 90) 84 (77 to 89)

Population	Vaccine	Outcome	Study design(s)	# Studies	Study label	VE % (95% CI)
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)
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

Population	Vaccine	Outcome	Study design(s)	# Studies	Study label	VE % (95% CI)
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)
Infant/Child	Any	Medically attended infection	Case-control	22	Shinjo 2024, 6m-15y, Flu A ^a	54 (27 to 71)
					Shinjo 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)
					Shinjo 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)
					Skowronski 2024, 1-19y	60 (34 to 76)
					Smolarchuk 2024, 6m-9y	74 (66 to 99)
					Nguyen 2025, 6m-17y	69 (52 to 81)

Population	Vaccine	Outcome	Study design(s)	# Studies	Study label	VE % (95% CI)
					Sun 2025, 0-5 Pooled estimate (22 studies)	58 (15 to 81) 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)
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	54 (43 to 56) 44 (40 to 47) 38 (24 to 50) 16 (-11 to 41) 42 (41 to 44)

Population	Vaccine	Outcome	Study design(s)	# Studies	Study label	VE % (95% CI)
					Zhu 2025b, 50-64y ^a Zhu 2024b, 18-49y ^a Zhu 2024b, 50-64y ^a	30 (27 to 32) 48 (46-50) 36 (33-39)
					Abou Chakra 2025 Sun 2025b Choi 2024a Erdwiens 2025 Frutos 2025, US Flu VE Frutos 2025, VISION Gào 2024 Kwaah 2025 Kissling 2025 Marron 2024 Maurel 2024 Rose 2025, Denmark Rose 2025, EU Rose 2025, UK Skowronski 2024 Smolarchuk 2024 Whitaker 2024, GB-PC Whitaker 2024, EH-H Whitaker 2024, SC-H Zhang 2025 Lei 2025 Reeves 2025 (female only) Nguyen 2025b Mi 2024 Pooled estimate (19 studies)	53 (49 to 57) 84 (64 to 94) 24 (5 to 40) 6 (-65 to 46) 37 (16 to 53) 56 (53 to 58) 47 (37 to 55) 17 (-35 to 49) 41 (30 to 49) 35 (9 to 54) 40 (22 to 55) 52 (44 to 58) 42 (21 to 58) 47 (36 to 56) 54 (33 to 66) 62 (57 to 67) 55 (43 to 65) 36 (20 to 49) 51 (40 to 59) 72 (57 to 82) 52 (43 to 58) 52 (51 to 56) 50 (29 to 65) 60 (26 to 79) 49 (45 to 53)
	Any	Medically attended	Cohort	1	Tian 2024	61 (2 to 85)

Population	Vaccine	Outcome	Study design(s)	# Studies	Study label	VE % (95% CI)
Adult/Older Adult	Any	Medically attended	Case-control	6	Zeno 2024 Sun 2025b Frutos 2024, US Flu VE Frutos 2024, VISION Lei 2025 Erdwiens 2025 Zhang 2025 Pooled estimate (6 studies)	31 (18 to 42) 53 (8 to 77) 33 (16 to 47) 49 (47 to 51) 75 (59 to 85) 35 (-31 to 68) 50 (18 to 69) 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)
	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 Abou Chakra 2025 Zhu 2024b Choi 2025c Chung 2025 Costantino 2024 Emborg 2025 Choi 2024a Frutos 2024 US Flu VE Frutos 2024 VISION Frutos 2025, US Flu VE Frutos 2025, VISION Gào 2024 Kissling 2025 Lei 2025 Marron 2024	37 (34 to 50) 42 (37 to 47) 30 (27 to 33) 14 (-18 to 37) 37 (5 to 58) 53 (-38 to 84) 31 (17 to 42) 17 (-17 to 42) 51 (14 to 72) 41 (36 to 45) 18 (-69 to 60) 51 (47 to 54) 46 (34 to 49) 49 (35 to 60) 25 (4 to 41) 16 (-83 to 60)

Population	Vaccine	Outcome	Study design(s)	# Studies	Study label	VE % (95% CI)
					Maurel 2024 Rose 2025, Denmark Rose 2025 EU Rose 2025 UK Skowronski 2024 Smolarchuk 2024 Whitaker 2024, GB-PC Whitaker 2024, EH-H Whitaker 2024, SC-H Zhu 2025b Pooled estimate (20 studies)	45 (22 to 62) 55 (44 to 65) 0 (-54 to 34) 38 (18 to 53) 70 (48 to 83) 57 (52 to 61) 55 (32 to 70) 40 (29 to 50) 53 (44 to 61) 26 (24 to 29) 41 (36 to 44)
	Adjuvanted	Medically attended	Case-control	1	Emborg 2025	49 (40 to 75)
	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.

^aPooled 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 providing multiple specific estimates for viral strain or age categories but did not provide an aggregate estimate.

^bNearly all vaccinated children (470 of 474, 99%) received the BNT162b2 vaccine. BNT162b2 or mRNA-1273 not disaggregated.

^cPopulation-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).

^dIncludes XBB1.5, JN.1, and KP.2-specific mRNA vaccines.

^eStudy population limited to adults with end-stage renal disease (ESRD) receiving dialysis without additional immunocompromising conditions; effectiveness may differ in the general adult population.

^fStudy population is adults aged 18-59y in Singapore; results compare bivalent booster versus ancestral mRNA booster.

^gVaccine effectiveness specific to older adults (≥ 60 or ≥ 65 y depending on country-specific recommendations).

^hSee supplemental table S7 for XBB.1.5 booster effectiveness; data shown here for BA.4/5 bivalent formulation only.

ⁱSee supplemental table S7 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.

^jStudy population limited to adults aged ≥ 60 y

^kStudy population limited to adults aged ≥ 60 y; effectiveness reported as percentage of severe cases averted rather than traditional vaccine effectiveness measure.

^lEffect 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.

^mMixed 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.

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

^oIneligible for meta-analysis because study provides multiple estimates by age group within our prespecified populations but no aggregate estimate

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 vaccine effectiveness to prevent hospitalization during varying follow-up within 6 months (Covid-19) or one respiratory viral season (RSV and influenza) following vaccine administration.^{a,b} Additional details available at the [web application](#).

Population	Vaccine	Study design	# Studies	Study label	VE% (95% CI) ^c
a. Covid-19					
Adult	BNT162b2_XBB1.5 ^d	Case-control	2	Nguyen 2025 ^c Caffrey 2024	57 (19 to 77) 58 (33 to 73)
	Mixed XBB1.5 vaccines ^f	Case-control	1	Link-Gelles 2025b	21 (-12 to 45)
Adult/Older Adult	BNT162b2_KP.2	Case-control	1	Appaneal 2025	68 (42 to 82)
	mRNA XBB1.5 ^g	Cohort	3	Andersen 2025a Chong 2024 Wilson 2025	36 (18 to 50) 42 (9 to 63) 51 (48 to 54)
				Pooled estimate (3 studies)	46 (34 to 55)
		Case-control	4	Caffrey 2024 Levy 2025a Nguyen 2025 ^c Tartof 2024a	43 (34 to 51) 52 (34 to 64) 54 (38 to 65) 57 (45 to 66)
				Pooled estimate (4 studies)	50 (43 to 57)
	Mixed XBB1.5 vaccines ^f	Case-control	1	Ma 2024a, JN.1 Ma 2024a, XBB ^h	33 (2 to 54) 54 (36 to 67)
Older Adult	Mixed 2024-2025 vaccines ⁱ	Case-control	1	Link-Gelles 2025a, VISION Link-Gelles 2025a, IVY	45 (36 to 53) 46 (26 to 60)
	mRNA XBB1.5 ^g	Cohort	3	Andersen 2025a Wilson 2025 Andersson 2024	47 (28 to 61) 56 (51 to 61) 58 (50 to 66)
				Pooled estimate (3 studies)	56 (51 to 60)
		Case-control	2	Caffrey 2024 Nguyen 2025 ^c	41 (32 to 50) 54 (40 to 64)

Population	Vaccine	Study design	# Studies	Study label	VE% (95% CI) ^c	
	Mixed XBB1.5 vaccines ^f	Cohort	1	Nunes 2024 ^v , 80+y Nunes 2024 ^v , 65-79y	39 (17 to 54) 47 (32 to 59)	
		Case-control	1	Link-Gelles 2025b	21 (10 to 31)	
Immuno-compromised	Mixed vaccines	Cohort	2	Wilson 2025 Payne 2025	46 (39 to 52) 65 (35 to 82)	
		Case-control	4	Caffrey 2024 Link-Gelles 2024 Link-Gelles 2025a Nguyen 2025c	33 (16 to 47) 36 (25 to 46) 40 (21 to 54) 56 (22 to 75)	
				Pooled estimate (4 studies)		37 (29 to 44)
				b. RSV		
Pregnancy	RSVPreF	RCT	1	Simões 2025	55 (24 to 75)*	
	RSVPreF	Case-control	3	Williams 2025	58 (28 to 75)	
				Pérez Marc 2025	71 (53 to 82)	
				Gentile 2025	79 (51 to 91)	
				Pooled estimate (3 studies)		68 (55 to 78)
Infant	Nirsevimab	Case-control	7 ^{j,k}	Guerrero-del-Cueto 2025	92 (72 to 97)*	
				Silva-Afonso 2025 Rius-Peris 2025 Carbajal 2024 Núñez 2025 ^l Lefferts 2024 Moline 2025	64 (10 to 86) 71 (50 to 83) 83 (72 to 90) 86 (81 to 89) 89 (32 to 98) 93 (82 to 97)	
				Pooled estimate (6 studies) ^j		83 (74 to 88)

Population	Vaccine	Study design	# Studies	Study label	VE% (95% CI) ^c
Infant	Nirsevimab	Cohort	6 ^m	Jabagi 2025 Perramon-Malavez 2025a Torres 2025 Ares-Gómez 2024 Barbas Del Buey 2024 Coma 2024	65 (61 to 69) 74 (62 to 83) 76 (73 to 80) 82 (66 to 90) 88 (68 to 95) 88 (82 to 91)
				Pooled estimate (6 studies)^j	79 (70 to 85)
Infant	Nirsevimab	RCT	1	Munro 2025	83 (68 to 92)
Older Adult	RSVPreF or RSVPreF3	Case-Control	4	Fry 2025	76 (73 to 78)*
				Surie 2024 Payne 2024 Tartof 2024c	75 (50 to 87) 80 (71 to 85) 90 (20 to 99)
				Pooled estimate (3 studies)	79 (72 to 85)
		Cohort	1	Bajema 2025b	80 (66 to 90)
Immuno-compromised	RSVPreF or RSVPreF3	Case-control	2	Fry 2025 Payne 2024	70 (65 to 73)* 73 (48 to 85)
c. Influenza					
Infant/Child	Any	Case-control	8	Shinjo 2024, Flu A ^o Lee 2024c, H1N1 ^o Lee 2024c, H3N2 ^o Shinjo 2024, Flu B ^p Lee 2024c, Flu B ^p	51 (23 to 69) 54 (33 to 69) 55 (30 to 72) 60 (22 to 79) 66 (42 to 80)
				Gharpure 2025, Brazil Frutos 2024, VISION ^{s,u} Tenforde 2024 ⁿ Frutos 2024, NVSN ^{s,t} Frutos 2025, NVSN ^t Gharpure 2025, Chile Shinjo 2025 ^{o,q} Pérez-Gimeno 2024 ^o Frutos 2025, VISION ^u Gharpure 2025, Australia	46 (14 to 66) 52 (16 to 72) 58 (44 to 69) 61 (40 to 75) 63 (41 to 76) 71 (41 to 86) 73 (57 to 83) 77 (21 to 93) 78 (60 to 89) 88 (77 to 93)

Population	Vaccine	Study design	# Studies	Study label	VE% (95% CI) ^c
				Pooled estimate (6 studies)	67 (58 to 75)
Adult	Any	Case-control	5	Tenforde 2024 ^v , 50-64y	40 (32 to 48)
				Lewis 2025 ^v , 50-64y	47 (31 to 60)
				Tenforde 2024 ^v , 18-49y	51 (42 to 60)
				Lewis 2025 ^v , 18-49y	53 (34 to 67)
				Rose 2025, Scotland	28 (13 to 40)
				Rose 2025, Denmark	44 (28 to 57)
				Frutos 2025, IVY	48 (28 to 63)
				Frutos 2025, VISION	51 (41 to 59)
				Rose 2025, EU	52 (16 to 74)
				Maurel 2024 ^o	53 (31 to 68)
				Rose 2025, England	53 (46 to 59)
				Rose 2025, North Ireland	72 (39 to 87)
				Pooled estimate (3 studies)	48 (39 to 55)
Adult/Older Adult	Any	Case-control	1	Domnich 2024, Flu A,^o	40 (-5 to 66)
				Domnich 2024, Flu A(H1N1)	35 (-17 to 63)
			2	Frutos 2024, VISION	41 (34 to 47)
				Frutos 2024, IVY	44 (32 to 54)
				Erdwiens 2025, 60+y	76 (27 to 92)
				Pooled estimate (2 studies)	42 (37 to 48)
Adult/Older Adult	Any	Cohort	2	Acuti Martellucci 2025, 60+y	47 (24 to 63)
				Ruzafa Martinez 2024	78 (24 to 94)
Adult/Older Adult	Adjuvanted	Cohort	1	Acuti Martellucci 2025, 60+y	47 (40 to 54)
Adult/Older Adult	Non-adjuvanted HD	Cohort	1	Acuti Martellucci 2025, 60+y	38 (23 to 50)
Older Adult	Any	Case-control	10	Gharpure 2025, Brazil	14 (-19 to 39)
				Martínez-Baz 2025	28 (6 to 45)
				Rose 2025, Scotland	29 (23 to 36)
				Lewis 2025	31 (16 to 43)
				Maurel 2024 ^m	36 (22 to 47)
				Emborg 2025	36 (23 to 47)

Population	Vaccine	Study design	# Studies	Study label	VE% (95% CI) ^c
				Tenforde 2024	36 (31 to 41)
				Frutos 2025, Ivy	38 (19 to 52)
				Silva-Afonso 2025	39 (15 to 56)
				Gharpure 2025, Chile	40 (12 to 59)
				Frutos 2024, VISION	42 (34 to 50)
				Frutos 2024, IVY	42 (23 to 56)
				Rose 2025, England	48 (42 to 53)
				Rose 2025, EU	49 (34 to 61)
				Rose 2025, Northern Ireland	52 (20 to 72)
				Rose 2025, Denmark	55 (47 to 62)
				Frutos 2025, VISION	57 (52 to 61)
				Gharpure 2025, Australia	59 (45 to 70)
				Gharpure 2025, New Zealand	72 (35 to 88)
				Pooled estimate (10 studies)	42 (36 to 47)
Older Adult	Adjuvanted	Case-control	1	Emborg 2025, 70+y	47 (41 to 53)
Older Adult	Non-adjuvanted HD	Case-control	1	Emborg 2025, 65+y	53 (35 to 66)
Immuno-compromised	Any	Case-control	1	Lewis 2025	32 (7 to 50)

HD: high dose; QIV: quadrivalent inactivated influenza vaccine; RCT: randomized controlled trial; SD: standard dose

^aUnadjusted estimate.

^aPooled analyses were conducted when 3 or more studies were amenable to meta-analysis (see Supplemental Methods). Forest plots of all pooled analyses not already presented in the manuscript can be found in the appendix.

^bData are reported from time frames falling within the first 6 months (Covid-19) or one season (RSV or influenza) following vaccination; when outcomes for multiple time frames were reported within one study *and no aggregate estimate was available*, the latest time frame remaining within 6 months/one season was chosen.

^cUnadjusted estimates (including estimates calculated from raw values from the primary text) and infection strain-specific estimates were not included in the meta-analysis calculations that resulted in pooled estimates presented in this table. For more detailed discussion of the selection of comparable studies for pooled analysis, refer to the Supplemental Methods.

^dAll XBB or other seasonal booster/vaccine studies for adult, adult/elder, and elder categories are presented with 'non-receipt of the studied seasonal booster' as the comparator group.

^eStudy includes data from JN.1-predominant period only.

^fData provided only for mRNA and protein-based vaccines combined

^gIncludes studies of BNT162b2_XBB1.5 alone, mRNA1273_XBB1.5 alone, or combined mRNA XBB1.5 formulations.

^hThis study provided data only for Covid-19 variant-specific hospitalization. Both estimates are provided for 7-89 days post-vaccination. The study also provides data for JN.1-specific hospitalization at 90-189 days post-vaccination (Appendix Table X).

ⁱIncludes mRNA KP.2 formulations, and protein-based JN.1 formulation.

^jThe reported outcomes for Carbajal 2024, Guerrero-del-Cueto 2025, Núñez 2025, Moline 2025, Rius-Peris 2025, Silva-Afonso 2025, Ares-Gómez 2024, Coma 2024, Lefferts 2024, Perramon-Malavez 2025, Barbas Del Buey 2024, Torres 2025, Jabagi 2025 and Munro 2025 are RSV-associated hospitalization. Additional study data on all-cause hospitalization is not reflected in this table (available in Table S7). All studies included in the pooled estimates for this outcome represent ages 0 to 12 months.

^kStudies included for infant vaccine effectiveness to prevent hospitalization reported data within the first RSV season. Duration between nirsevimab dose and hospitalization outcome inconsistently reported in studies. included in this table represents infants' first RSV season.

^lAt-birth immunization for Núñez 2025 used for pooled estimate calculation. Núñez 2025 also presented data on catch-up immunization, hospitalization VE for that group was 88 (83 to 91).

^mPopulation labeled as infant due to age of <20 months at time of dose.VE was calculated based on eligible medical visits in a follow-up window of 8 months, making the full age range 0-27 months.

ⁿOutcome is acute respiratory illness-associated hospitalizations >24h duration.

^oOutcome is hospitalization with influenza A.

^pOutcome is hospitalization with influenza B.

^qOutcome is fever plus hospitalization.

^sFrutos 2024 additionally captured outcomes of influenza A H3N2 in inpatient setting and influenza B in inpatient setting, without VE calculation.

Raw numbers are available in the study's original text.

^tOutcome is for all flu subtypes, ARI in inpatient setting from NVSN.

^uOutcome is for all flu subtypes, ARI in inpatient setting from VISION.

^vIneligible for meta-analysis because study provides multiple estimates by age group within our prespecified populations but no aggregate estimate

Supplemental Table S8. Summary results of additional vaccine safety outcomes in pregnancy. Additional details available at the [web application](#).

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)
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.

^aStudies 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.

^bEffect estimates prefixed with “a” indicate an adjusted effect estimate

°All seasonal influenza vaccines during the time period of the study.

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Supplemental Table S9. Summary results of studies regarding key vaccine safety outcomes in studies without an unvaccinated or self-controlled comparator group. Additional details available at the [web application](#).

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

Population	Outcome(s)	Study label	Findings
			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 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-Hu y 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

Population	Outcome(s)	Study label	Findings
			post-vaccination. No reported cardiac related deaths or need for heart transplantation, but myocardial scarring at a lower severity persisted in most patients.
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 ≥ 18 y, 0 cases of myocarditis were reported within 29 days of vaccination among 50 monovalent (mRNA-1273.815,

Population	Outcome(s)	Study label	Findings
			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 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 ≥ 18 y, 0/53 vaccine recipients (27 adults aged 18-55y, and 26 adults aged >55 y) 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 $\geq 30\%$ decrease in platelets after the first dose.
Adult/Older Adult	Myocarditis	Baden 2024	In an open-label study of a 50 μ g mRNA-1273 booster vaccine, 1/19,609 adults aged ≥ 18 y 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 ≥ 18 y 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

Population	Outcome(s)	Study label	Findings
			cases of transient ischemic attack were reported after BNT162b2 vaccination.
Adult/Older Adult	GBS	Matsuzou no 2024	Among 1,756 patients hospitalized in a neurology division in Japan between 4/2019-3/2022, 1 patient had GBS following BNT162b2 vaccination.
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 ≥ 18 y.
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 ≥ 18 y (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 ± 17 y 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 ≥ 18 y receiving either Pfizer or Moderna bivalent vaccines, and 34.3 per 100,000 (95% CI, 17.7 to 59.9) among patients aged ≥ 65 y

Population	Outcome(s)	Study label	Findings
			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 (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

Population	Outcome(s)	Study label	Findings
			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	Fitzpatrick 2025	In a case series of 60 individuals with neurologic adverse events after Covid-19 vaccines, 1 individual experienced GBS after BNT162b2 vaccine.
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	Mansour 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	

Population	Outcome(s)	Study label	Findings
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 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			

Population	Outcome(s)	Study label	Findings
Pregnant	Gestational hypertension, placental abruption, pre-eclampsia, prematurity, small for gestational age, and stillbirth	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.
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.

Population	Outcome(s)	Study label	Findings
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 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 S10. Summary results of included studies reporting on vaccine-related adverse events not specifically identified as being of special interest. Additional details available at the [web application](#).

Domain	Comparator Type (N=)	Study Label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
a. Covid-19			
Local or Systemic Reactogenicity	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, Jęskowiak-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	
Local or Systemic Reactogenicity <i>cont.</i>			

Domain	Comparator Type (N=)	Study Label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
a. Covid-19			
	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 <i>cont.</i>		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.

Domain	Comparator Type (N=)	Study Label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
a. Covid-19			
Neurologic Events and Conditions <i>cont.</i>		Moisset 2024	BNT162b2 and mRNA-1273: no difference (multiple sclerosis relapse)
	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,	

Domain	Comparator Type (N=)	Study Label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
a. Covid-19			
		Tani 2024, Tetsuka 2024, Werner 2023, Zaidi 2025	
	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 <i>cont</i>	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	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)
Respiratory / ENT Disorders <i>cont.</i>		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

Domain	Comparator Type (N=)	Study Label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
a. Covid-19			
	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 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)

Domain	Comparator Type (N=)	Study Label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
a. Covid-19			
Gastrointestinal Disorders <i>cont.</i>	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, 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 <i>cont.</i>	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%)

Domain	Comparator Type (N=)	Study Label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
a. Covid-19			
Reproductive / Endocrine Disorders <i>cont.</i>	Unvaccinated comparator or self-controlled case series (13) <i>cont.</i>	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-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)
		Licon-Menéndez 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
		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			
Reproductive / Endocrine Disorders <i>Cont.</i>	Unvaccinated comparator or self-controlled case series (13) <i>cont.</i>		
	Active Comparator (9)	Couvillion 2024, Esteban-Cledera 2024, Fatima 2025, Jajou 2024, Jajou 2025, Licona-Menéndez 2024, Mazarakis 2025, Mohamed 2024, Parveen 2024	
	Descriptive only (4)	Aydin 2024, Mantovani 2024, Strid 2024, Yumru Çeliksoy 2024	

Domain	Comparator Type (N=)	Study Label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
a. Covid-19			
Autoimmune & Inflammatory Disorders	Unvaccinated comparator or self-controlled case series (8)	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 (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)
Autoimmune & Inflammatory Disorders <i>cont.</i>	Unvaccinated comparator or self-controlled case series (8) <i>cont.</i>	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

Domain	Comparator Type (N=)	Study Label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
a. Covid-19			
			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)
		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, Kälén 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)

Domain	Comparator Type (N=)	Study Label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
a. Covid-19			
	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	
	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 <i>Cont.</i>		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)
	Unvaccinated comparator or self-controlled		

Domain	Comparator Type (N=)	Study Label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
a. Covid-19			
	case series (3) <i>cont.</i>		
	Active Comparator (11)	Briggs 2025, Dudukina 2025, Lambo 2025, Mohamed 2024, Moscara 2023, Namiki 2024, Peck 2024, Villanueva, Werner 2023, Yildirim 2025, Zaidi 2025	
	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	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)
Ophthalmic Disorders <i>cont.</i>		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)
		Platkowska-Adamska 2024	BNT162b2: no difference (macular degeneration)
		Shemer 2025	BNT162b2: no difference (acute anterior uveitis)
		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

Domain	Comparator Type (N=)	Study Label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
a. Covid-19			
	Unvaccinated comparator or self-controlled case series (6) <i>cont.</i>		
	Active Comparator (4)	Aftab 2024, Kim 2024, Kim 2025a, Kumar 2024	
	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 <i>cont.</i>	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

Domain	Comparator Type (N=)	Study label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
b. RSV			
Local or Systemic Reactogenicity <i>cont.</i>			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 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	Ferguson 2024	RSVPreF3-AS01: 1 case atrial fibrillation vs. 0 (N=1,152)

Domain	Comparator Type (N=)	Study label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
b. RSV			
	self-controlled case series (1)		
	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 case series (N=1)	Ferguson 2024	RSVPreF3-AS01: 1 case cold antibody autoimmune hemolytic anemia vs. 0 (N=1152)
	Descriptive only (1)	Domachowske 2024	
Hematologic Disorders	Unvaccinated comparator or self-controlled case series (N=1)	Fry 2025	RSVPreF and RSVPreF3-AS01: no difference (ITP)
	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)
	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 Miscellaneous cont.	Unvaccinated comparator or self-controlled case series (1)	Grima 2024	Any influenza vaccine: no difference in ED visits

Domain	Comparator Type (N=)	Study label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
C. Influenza			
	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 self-controlled case series (2)	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)
		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	

Domain	Comparator Type (N=)	Study label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
C. Influenza			
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	
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).
Renal / Genitourinary Disorders <i>cont.</i>		Zawiasa-Bryszewska 2025	Quadrivalent split virion inactivated influenza vaccine: no difference (renal function or proteinuria among kidney transplant recipients)
Autoimmune & Inflammatory Disorders	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	

Domain	Comparator Type (N=)	Study label(s)	Differences vaccinated vs. unvaccinated (studies with unvaccinated comparison group only)
C. Influenza			
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)
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 S11. Vaccine Co-administration Studies: Immunogenicity, Reactogenicity, and Safety Outcomes.^a Additional details available at the [web application](#).

Study label	Study design	N (co-admin)	Vaccines	Comparator	Immunogenicity	Reactogenicity	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	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	Immunogenicity	Reactogenicity	Safety	Key findings
							than flu alone	
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), <i>P</i> <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

Study label	Study design	N (co-admin)	Vaccines	Comparator	Immunogenicity	Reactogenicity	Safety	Key findings
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
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-1273.2 14	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

Study label	Study design	N (co-admin)	Vaccines	Comparator	Immuno-genicity	Reacto-genicity	Safety	Key findings
Omole 2025a	RCT	534	QIV + V116	Sequential	Non-inferior	Comparable	No differences	Non-inferior immunogenicity for 20 of 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

^aThree 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.

^bIncludes pediatric participants

^c18-49 years non-pregnant women

^d157 Covid-19+RSV + 158 Covid-19+RSV+QIV

^e213 PPSV23 + 209 PCV15

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Supplemental Table S12. 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-Analysis 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
Shahrehabak 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,Ãs 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-Barré 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-19 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
Milostifá-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-Barré 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

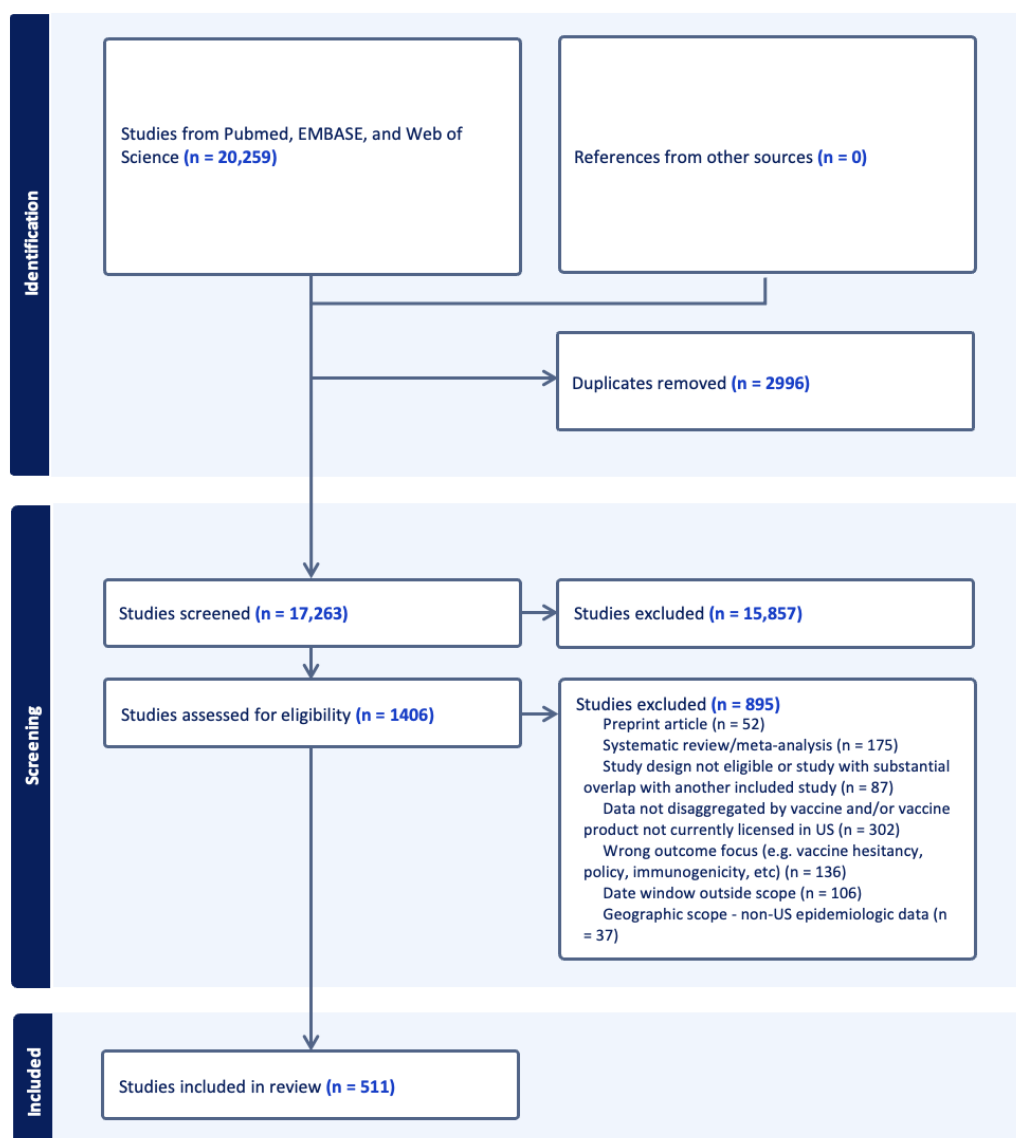
Study label	Study title	Domain(s)
Bandell 2025	Safety of LAIV Vaccination in Asthma or Wheeze: A Systematic Review and GRADE Assessment	S
Liu 2025	Association between influenza vaccination and prognosis in patients with ischemic heart disease: A systematic review and meta-analysis of randomized controlled 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

Study label	Study title	Domain(s)
Veroniki 2024	Trivalent and quadrivalent seasonal influenza vaccine in adults aged 60 and older: a systematic review and network meta-analysis	VE, 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

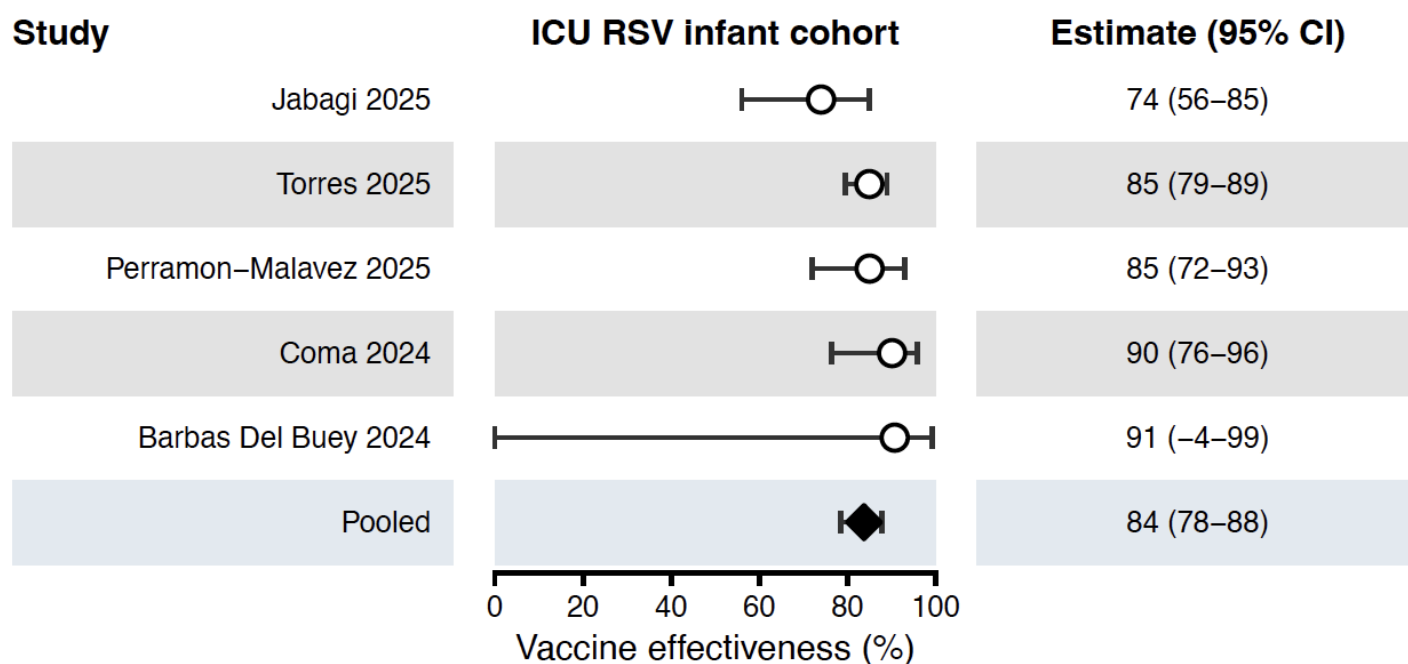
Study label	Study title	Domain(s)
Mulleners 2025	Safety and Efficacy of Vaccination During Lactation: A Comprehensive Review of Vaccines for Maternal and Infant Health Utilizing a Large Language Model Citation Screening System	VE, S
Pan 2025	Vaccination and rheumatoid arthritis: an updated systematic 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. PRISMA diagram. Records were identified by searching for published articles indexed on PubMed, EMBASE, and Web of Science. Abstracts and full texts were each screened by two independent reviewers. The search criteria were intentionally broad to capture all potentially eligible studies. Based on review of the abstracts of the 17,263 references identified by search, 15,857 did not meet eligibility criteria; the remaining 1406 underwent full text review to assess eligibility. Ultimately 511 studies were included in the review. Additional details available at the [web application](#).

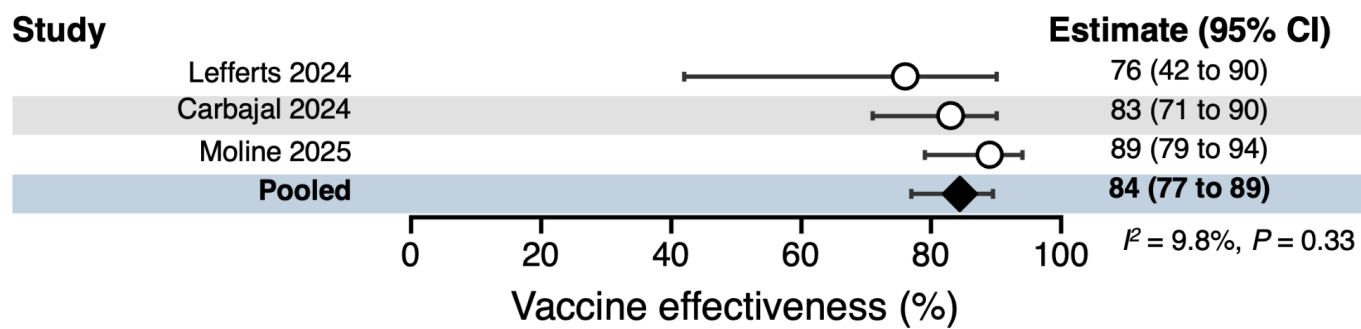


Supplemental Figure S2. Nirsevimab effectiveness against ICU admission in cohort studies of infants (age < 2 years). Arrow indicates lower bound of 95% confidence interval falls below zero. $I^2=14\%$, $p=0.33$.

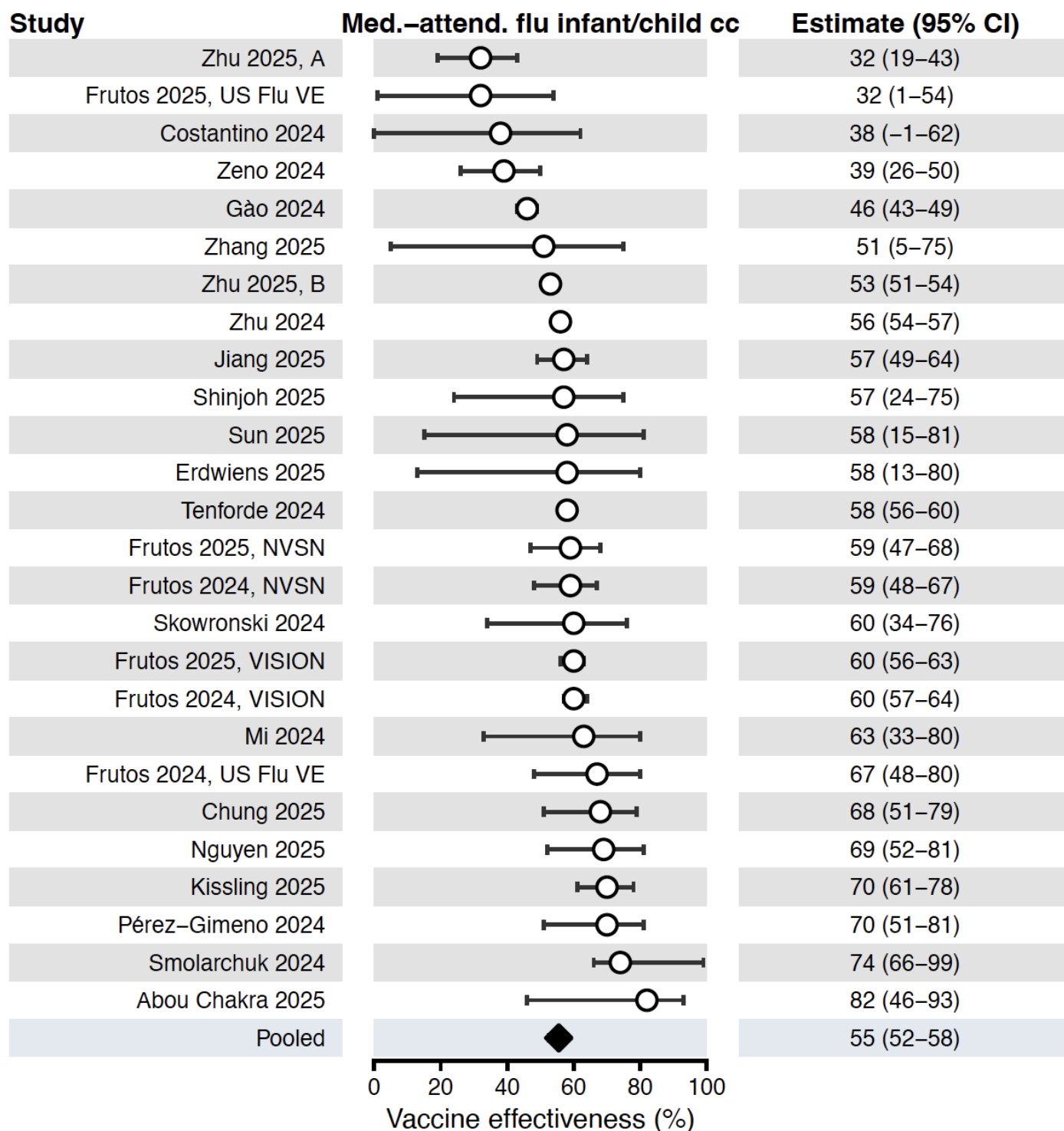


Supplemental Figure S3. Nirsevimab vaccine effectiveness against medically attended infection in case-control studies of infants (age < 2 years).

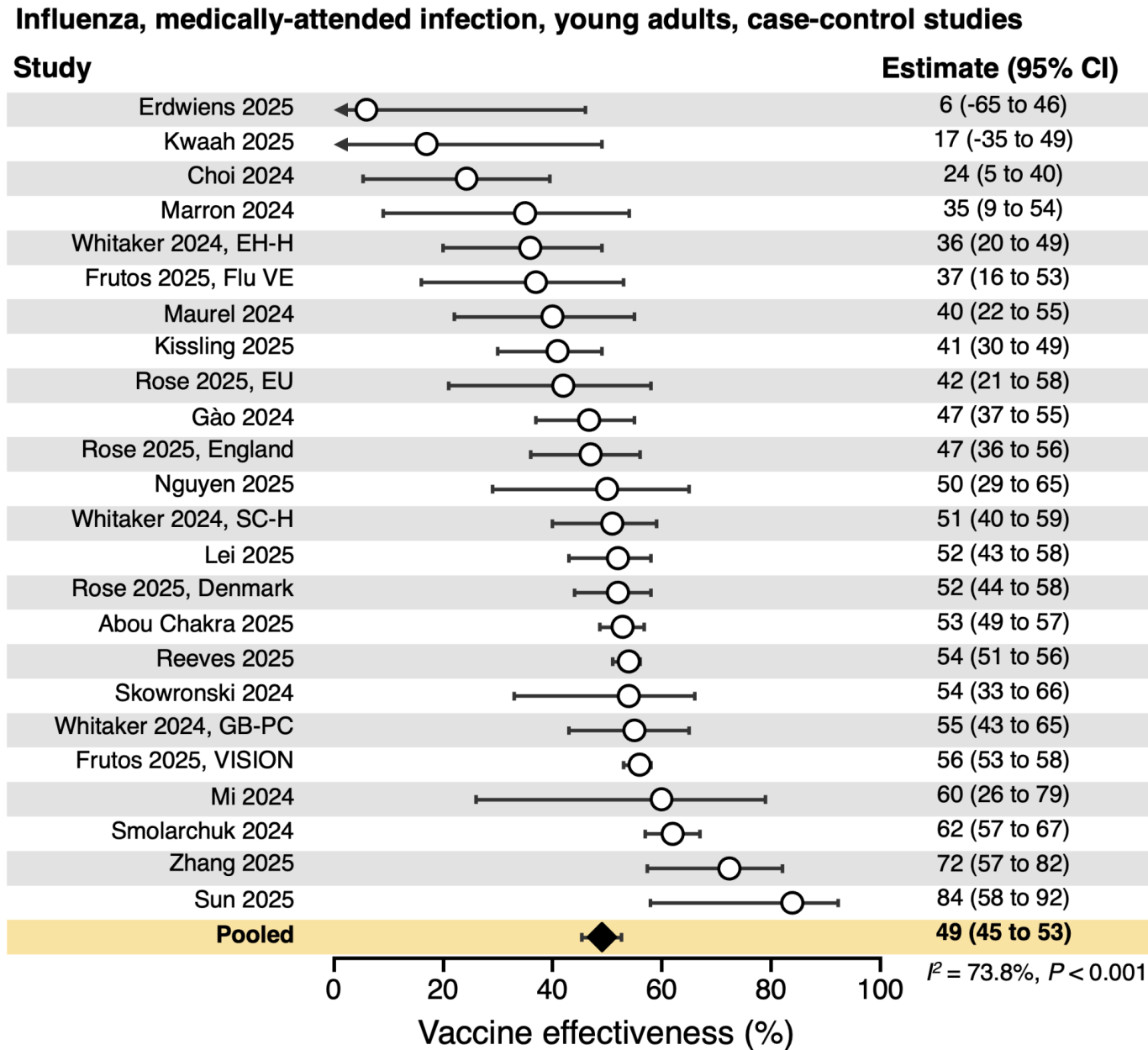
RSV, medically-attended infection, infants, case-control studies



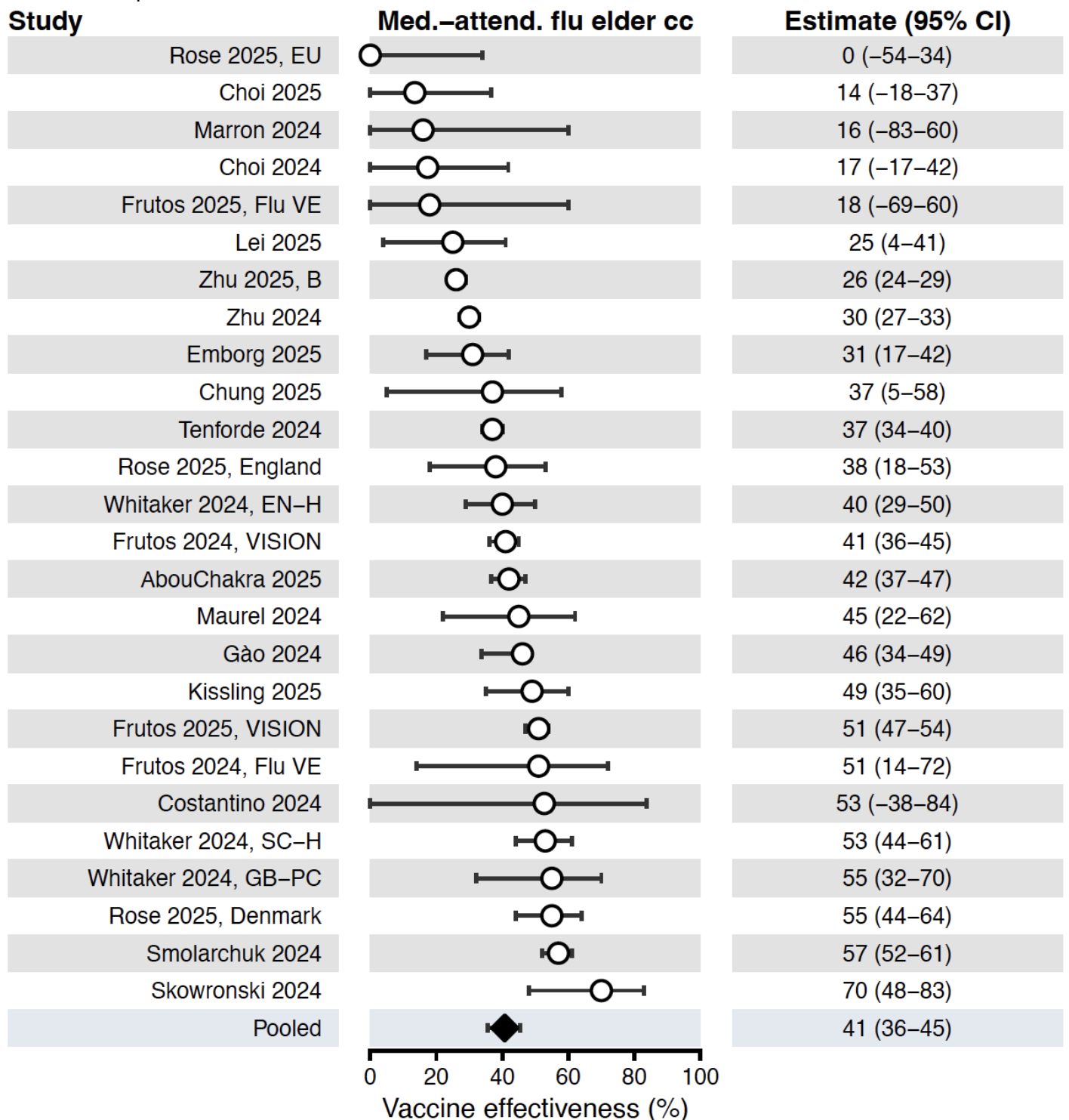
Supplemental Figure S4. Influenza vaccine effectiveness against medically attended infection in case-control studies of infants (age < 2 years) children (age 2-17 years). Arrow indicates lower bound of 95% confidence interval falls below zero. $I^2=81\%$, $p<0.001$



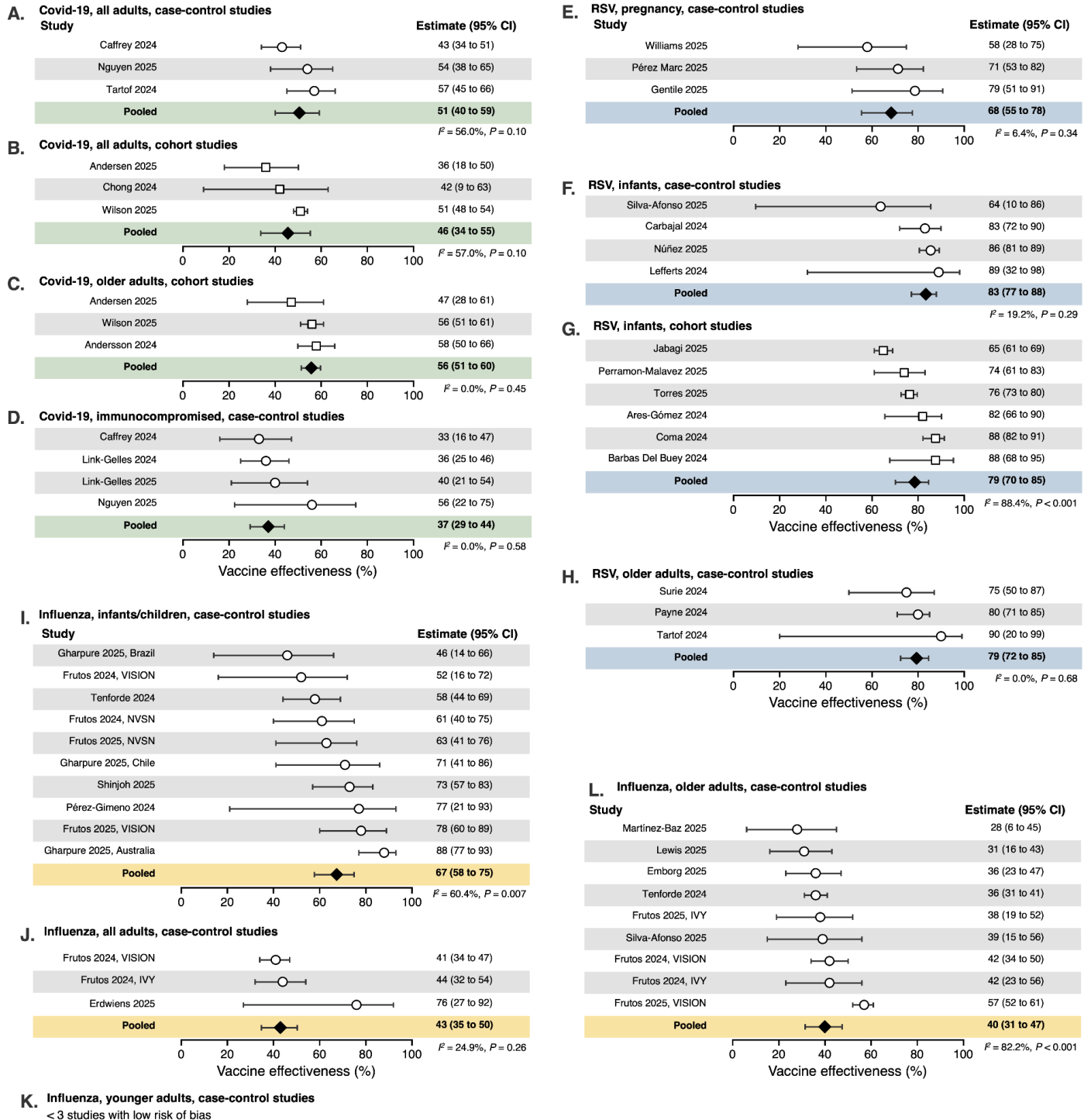
Supplemental Figure S5. Influenza vaccine effectiveness against medically attended infection in case-control studies of younger adults (age 18-64 years). Arrows indicate lower bound of 95% confidence interval falls below zero.



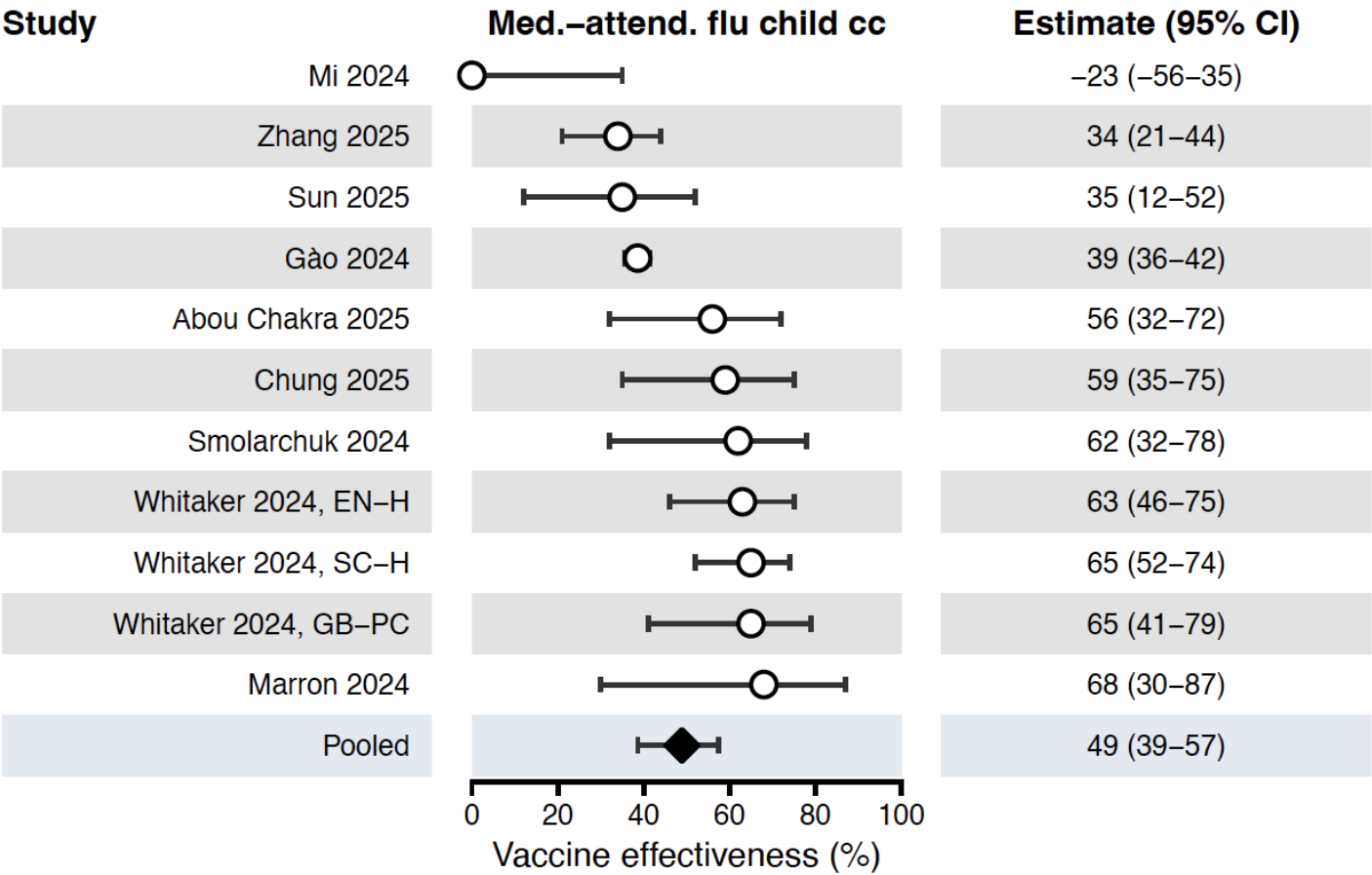
Supplemental Figure S6. Influenza vaccine effectiveness against medically attended infection in case-control studies of older adults (age ≥ 65 years). Arrows indicate lower bound of 95% confidence interval falls below zero. $I^2=91\%$, $p<0.001$



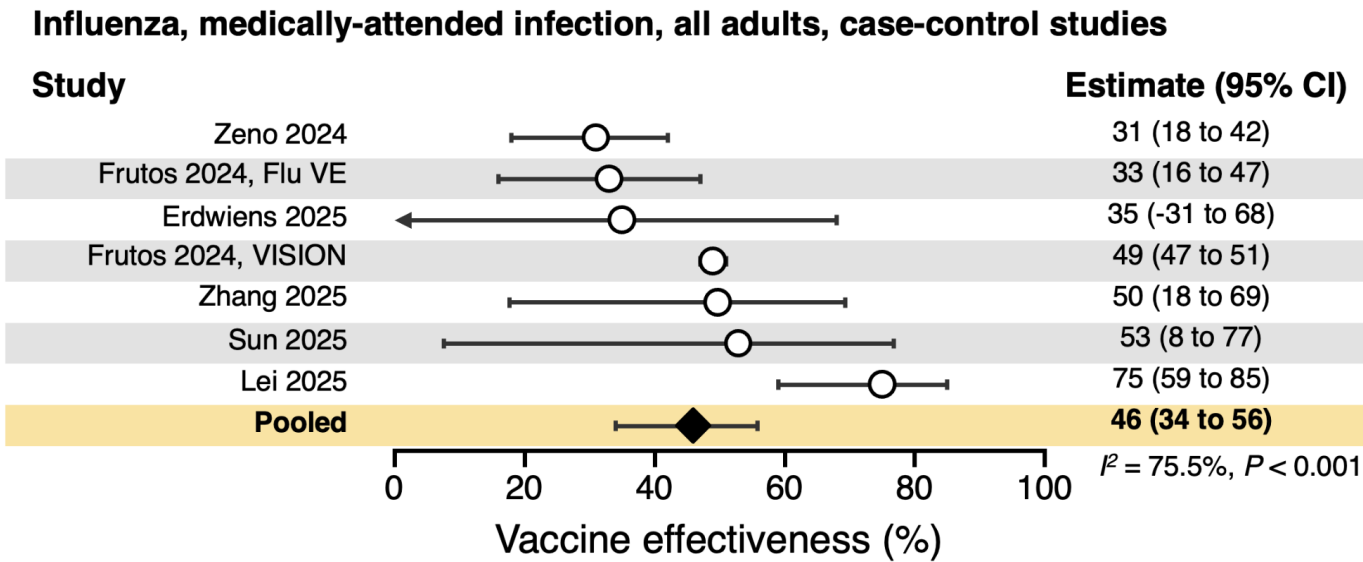
Supplemental Figure S7. Sensitivity analyses of primary outcome (hospitalization) meta-analyses after excluding studies at high risk of bias



Supplemental Figure S8. 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 S9. 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.



REFERENCES

1. Weber F, Knapp G, Ickstadt K, Kundt G, Glass Ä. Zero-cell corrections in random-effects meta-analyses. *Res Synth Methods*. 2020 Nov;11(6):913–9.
2. Cochrane Bias Methods Group. RoB 2: A revised Cochrane risk-of-bias tool for randomized trials [Internet]. [cited 2025 Oct 7]. Available from: <https://methods.cochrane.org/bias/resources/rob-2-revised-cochrane-risk-bias-tool-randomized-trials>
3. Higgins JPT, Altman DG, Gøtzsche PC, Jüni P, Moher D, Oxman AD, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. 2011 Oct 18 [cited 2025 Oct 7]; Available from: <https://www.bmj.com/content/343/bmj.d5928.long>
4. Farrah K, Young K, Tunis MC, Zhao L. Risk of bias tools in systematic reviews of health interventions: an analysis of PROSPERO-registered protocols. *Syst Rev*. 2019 Nov 15;8(1):280.
5. Wells G, Shea B, O'Connell D, Peterson J, Welch V, Losos M, et al. The Newcastle-Ottawa Scale (NOS) for assessing the quality of nonrandomised studies in meta-analyses [Internet]. [cited 2025 Oct 7]. Available from: https://www.ohri.ca/programs/clinical_epidemiology/oxford.asp
6. Carra MC, Romandini P, Romandini M. Risk of Bias Evaluation of Cross-Sectional Studies: Adaptation of the Newcastle-Ottawa Scale. *J Periodontal Res* [Internet]. [cited 2025 Oct 7]; Available from: <https://onlinelibrary.wiley.com/doi/abs/10.1111/jre.13405>
7. Bajema KL, Bui DP, Yan L, Li Y, Rajeevan N, Vergun R, et al. Severity and long-term mortality of COVID-19, influenza, and respiratory syncytial virus. *JAMA Intern Med*. 2025;185(3):324–34.
8. Fazal A, Reinhart K, Huang S, Kniss K, Olson SM, Dugan VG, et al. Reports of encephalopathy among children with influenza-associated mortality - United States, 2010-11 through 2024-25 influenza seasons. *MMWR Morb Mortal Wkly Rep*. 2025;74(6):91–5.
9. Silverman A, Walsh R, Santoro JD, Thomas K, Ballinger E, Fisher KS, et al. Influenza-associated acute necrotizing encephalopathy in US children. *JAMA*. 2025;334:692–701.
10. Ko HY, Yoon D, Kim JH, Jeong HE, Hong SB, Shin WC, et al. Risk of new-onset seizures following immunization against COVID-19: a self-controlled case-series study. *Epidemiol Health*. 2025;e2025024.
11. Rafati A, Jameie M, Amanollahi M, Pasebani Y, Jameie M, Kabiri A, et al. Association of New-Onset Seizures With SARS-CoV-2 Vaccines: A Systematic Review and Meta-Analysis of Randomized Clinical Trials. *JAMA Neurol*. 2024 June 1;81(6):611–8.

12. El Sahly HM, Baden LR, Essink B, Doblecki-Lewis S, Martin JM, Anderson EJ, et al. Efficacy of the mRNA-1273 SARS-CoV-2 Vaccine at Completion of Blinded Phase. *N Engl J Med*. 2021 Nov 3;385(19):1774–85.
13. Hu M, Shoaibi A, Feng Y, Lloyd PC, Wong HL, Smith ER, et al. Safety of Ancestral Monovalent BNT162b2, mRNA-1273, and NVX-CoV2373 COVID-19 Vaccines in US Children Aged 6 Months to 17 Years. *JAMA Netw Open*. 2024 Apr 24;7(4):e248192.
14. Núñez I, García-Grimshaw M, Castillo Valencia CY, Aguilera Callejas DE, Moya Alfaro ML, Saniger-Alba M del M, et al. Seizures following COVID-19 vaccination in Mexico: A nationwide observational study. *Epilepsia*. 2022 Aug 20;10.1111/epi.17390.
15. Rafati A, Jameie M, Amanollahi M, Jameie M, Pasebani Y, Sakhaei D, et al. Association of seizure with COVID-19 vaccines in persons with epilepsy: A systematic review and meta-analysis. *J Med Virol*. 2023;95(9):e29118.
16. Lim E, Kim YH, Jeong NY, Kim SH, Won H, Bae JS, et al. The association between acute transverse myelitis and COVID-19 vaccination in Korea: Self-controlled case series study. *Eur J Neurol*. 2025;32(1):e70020.
17. Morgan HJ, Clothier HJ, Sepulveda Kattan G, Boyd JH, Buttery JP. Acute disseminated encephalomyelitis and transverse myelitis following COVID-19 vaccination – A self-controlled case series analysis. *Vaccine*. 2024 Apr 2;42(9):2212–9.
18. Patone M, Handunnetthi L, Saatci D, Pan J, Katikireddi SV, Razvi S, et al. Neurological complications after first dose of COVID-19 vaccines and SARS-CoV-2 infection. *Nat Med*. 2021 Dec;27(12):2144–53.
19. Lu JYS, Yang SF, Tzeng SL, Lee YT, Wang YH, Yeh CB. Acute transverse myelitis and associate vaccine complication in SARS-CoV-2 patients: a retrospective cohort analysis in real-world database. *Virol J*. 2025 Aug 12;22(1):277.
20. Zethelius B, Attelind S, Westman G, Ljung R, Sundström A. Pulmonary embolism after SARS-CoV-2 vaccination. *Vaccine X*. 2024;21:100571.
21. Botton J, Jabagi MJ, Bertrand M, Baricault B, Drouin J, Le Vu S, et al. Risk for Myocardial Infarction, Stroke, and Pulmonary Embolism Following COVID-19 Vaccines in Adults Younger Than 75 Years in France. *Ann Intern Med*. 2022 Sept 20;175(9):1250–7.
22. Tanislav C, Rosenbauer J, Zingel R, Kostev K. No increased incidence of venous thrombosis or pulmonary embolism after SARS-CoV-2 vaccination in Germany. *Public Health*. 2022 June 1;207:14–8.
23. Barda N, Dagan N, Ben-Shlomo Y, Kepten E, Waxman J, Ohana R, et al. Safety of the BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Setting. *N Engl J Med*. 2021 Sept 15;385(12):1078–90.
24. Shoaibi A, Lloyd PC, Wong HL, Clarke TC, Chillarige Y, Do R, et al. Evaluation of potential adverse events following COVID-19 mRNA vaccination among adults aged 65 years and older: Two self-controlled studies in the U.S. *Vaccine*. 2023 July 19;41(32):4666–78.

25. Klein NP, Lewis N, Goddard K, Fireman B, Zerbo O, Hanson KE, et al. Surveillance for Adverse Events After COVID-19 mRNA Vaccination. *JAMA*. 2021 Oct 12;326(14):1390–9.
26. Lai D, Zhang YD, Lu J. Venous Thromboembolism following Two Doses of COVID-19 mRNA Vaccines in the US Population, 2020–2022. *Vaccines*. 2022 Aug;10(8):1317.
27. Harris DA, Hayes KN, Zullo AR, Mor V, Chachlani P, Deng Y, et al. Comparative Risks of Potential Adverse Events Following COVID-19 mRNA Vaccination Among Older US Adults. *JAMA Netw Open*. 2023 Aug 2;6(8):e2326852.
28. Hippisley-Cox J, Patone M, Mei XW, Saatci D, Dixon S, Khunti K, et al. Risk of thrombocytopenia and thromboembolism after covid-19 vaccination and SARS-CoV-2 positive testing: self-controlled case series study. 2021 Aug 27 [cited 2025 Oct 7]; Available from: <https://www.bmj.com/content/374/bmj.n1931>
29. Nicholson M, Goubran H, Chan N, Siegal D. No apparent association between mRNA COVID-19 vaccination and venous thromboembolism. *Blood Rev*. 2022 Nov 1;56:100970.
30. Knight R, Walker V, Ip S, Cooper JA, Bolton T, Keene S, et al. Association of COVID-19 With Major Arterial and Venous Thrombotic Diseases: A Population-Wide Cohort Study of 48 Million Adults in England and Wales. *Circulation*. 2022 Sept 20;146(12):892–906.
31. Bea S, Ahn HY, Woo J, Shin JY, Cho SW. The Impact of COVID-19 Vaccination on Thyroid Disease in 7 Million Adult and 0.2 Million Adolescent Vaccine Recipients. *J Clin Endocrinol Metab*. 2024;
32. Cheng KL, Yu WS, Wang YH, Ibarburu GH, Lee HL, Wei JC. Long-term Thyroid Outcomes After COVID-19 Vaccination: A Cohort Study of 2,333,496 Patients from the TriNetX Network. *J Clin Endocrinol Metab*. 2025;
33. Shani M, Hermesh I, Feldhamer I, Reges O, Lavie G, Arbel R, et al. The association between BNT162b2 vaccinations and incidence of immune-mediated comorbidities. *Vaccine*. 2024;42(18):3830–7.
34. Wong CKH, Lui DTW, Xiong X, Chui CSL, Lai FTT, Li X, et al. Risk of thyroid dysfunction associated with mRNA and inactivated COVID-19 vaccines: a population-based study of 2.3 million vaccine recipients. *BMC Med*. 2022 Oct 14;20(1):339.
35. Zarkesh M, Sanoie M, Heydarzadeh S, Abooshahab R, Daneshafrooz A, Hosseinpanah F, et al. Thyroid Function in the Time of COVID-19: A Systematic Review of Disease Progression and Vaccination Effect [Internet]. *International Journal of Endocrinology and Metabolism*; 2024 Mar [cited 2025 Oct 7] p. e155247. Report No.: 22. Available from: <https://brieflands.com/articles/ijem-146857#abstract>

36. Jung SW, Jeon JJ, Kim YH, Choe SJ, Lee S. Long-term risk of autoimmune diseases after mRNA-based SARS-CoV2 vaccination in a Korean, nationwide, population-based cohort study. *Nat Commun.* 2024;15(1):6181.
37. Woo J, Kim MK, Lim H, Kim JH, Jung H, Kim HA, et al. Risk of new-onset polymyalgia rheumatica following COVID-19 vaccination in South Korea: a self-controlled case-series study. *RMD Open.* 2025;11(2).
38. Wu PC, Huang IH, Wang CW, Tsai CC, Chung WH, Chen CB. New Onset and Exacerbations of Psoriasis Following COVID-19 Vaccines: A Systematic Review. *Am J Clin Dermatol.* 2022 Nov 1;23(6):775–99.
39. Khanahmadi M, Khayatan D, Guest PC, Hashemian S, Abdolghaffari AH, Sahebkar A. The Relationship Between Psoriasis, COVID-19 Infection and Vaccination During Treatment of Patients. In: Guest PC, editor. *Application of Omic Techniques to Identify New Biomarkers and Drug Targets for COVID-19* [Internet]. Cham: Springer International Publishing; 2023 [cited 2025 Oct 7]. p. 339–55. Available from: https://doi.org/10.1007/978-3-031-28012-2_18
40. Liakou AI, Tsantes AG, Routsi E, Agiasofitou E, Kalamata M, Bompou EK, et al. Could Vaccination against COVID-19 Trigger Immune-Mediated Inflammatory Diseases? *J Clin Med.* 2024 Jan;13(16):4617.
41. Ergun T, Hosgoren Tekin S, Apti Sengun O, Akin Cakici O, Seckin D, Adiyay C, et al. Immunogenicity, efficacy, and safety of CoronaVac and Pfizer/BioNTech mRNA vaccines in patients with psoriasis receiving systemic therapies: A prospective cohort study. *Vaccine.* 2023 June 29;41(29):4287–94.
42. El-Qushayri AE, Nardone B. Psoriasis exacerbation after COVID-19 vaccines: A brief report of the reported cases. *Dermatol Ther.* 2022;35(12):e15900.

References. ALL 511 INCLUDED STUDIES IN THE SYSTEMATIC REVIEW (ALSO SUMMARIZED IN TABLE S4); ADDITIONAL DETAILS AVAILABLE AT THE [WEB APPLICATION](#).

1. Ab Rahman N, King TL, Peariasamy KM, Sivasampu S. Risk of major adverse cerebro-cardiovascular events following BNT162b2, CoronaVac, and ChAdOx1 vaccination and SARS-CoV-2 infection: a self-controlled case-series study. *Vaccine*. 2024;42(26):126465.
2. Abdul Rahim NS, Lim XJ, Leong EL, Lim SY, Amri NA, Lim CC, et al. Association of COVID-19 infection and COVID-19 vaccination with idiopathic sudden sensorineural hearing loss in Malaysia: a case-control study. *BMC Public Health*. 2025;25(1):920.
3. Abdurakhmanov D, Yanik AM, Menguc M, Arian F, Toptas T, Atagunduz IK, et al. Effect of inactivated and mRNA COVID-19 vaccines on thrombocytopenia in immune thrombocytopenia patients. *VacciMonitor*. 2024;33.
4. Abou Chakra CN, Blanquart F, Vieillefond V, Enouf V, Visseaux B, Haim-Boukobza S, et al. Vaccine effectiveness dynamics against influenza and SARS-CoV-2 in community-tested patients in France 2023-2024. *Emerg Microbes Infect*. 2025;14(1):2466699.
5. Abukhalil AD, Abushehadeh RR, Shatat SS, Al-Shami N, Naseef HA, Ladadweh H, et al. COVID-19 Vaccines Breakthrough Infections and Adverse Effects Reported by the Birzeit University Community in Palestine. *International Journal of General Medicine*. 2024;17:3349–60.
6. Acuti Martellucci C, Rosso A, Zauli E, Bianconi A, Fiore M, Soldato G, et al. The effectiveness of four quadrivalent, inactivated influenza vaccines administered alone or in combination with pneumococcal and/or SARS-CoV-2 vaccines: a population-wide cohort study. *Vaccines*. 2025;13(3):309.
7. Adelglass JM, Bradley P, Cai MR, Chau G, Kalkeri R, Cloney-Clark S, et al. Immunogenicity of adjuvanted recombinant SARS-CoV-2 spike protein vaccine after earlier mRNA vaccine doses. *J Allergy Clin Immunol*. 2025;155(6):2063-2074.e6.
8. Adin ME, Isufi E, Wu J, Pang Y, Nguyen D, Simsek Has D, et al. Reactive axillary lymph nodes after COVID-19 mRNA vaccination: comparison of mRNA vs. attenuated whole-virus vaccines. *Nucl Med Commun*. 2024;45(6):474–80.
9. Aftab OM, Dupaguntla A, Hughes P, Langer PD, Zarbin MA, Bhagat N. Ophthalmologic Complications in Coronavirus Disease 2019 Immunization: A National Vaccine Adverse Event Reporting System Analysis. *Ophthalmology*. 2024;131(6):741–3.
10. Ahmed Al Qahtani A, Korairi HA, Alzaedy MA, Al Nasher MA, Alshahrani AS, Mohamed NS, et al. Short and long-term side effects of eligible COVID-19 vaccines in Saudi Arabia, Southern Region, 2023. *Clinical Epidemiology and Global Health*. 2025;33.
11. Ahn B, Shin SH, Hwang MJ, Choi H, Na S, Park S, et al. Epidemiological characteristics and outcome of myocarditis and pericarditis temporally associated with BNT162b2 COVID-19 vaccine in adolescents: Korean national surveillance. *J Korean Med Sci*. 2024;39(49):e317.

12. Al-Haddad HS, Mossa HAL, Muhammed AA, Jumaah AS, McAllister KA, Yasseen AA. The impact of SARS-CoV-2 mRNA vaccine on intracytoplasmic sperm injection outcomes at a fertility center in Iraq: A prospective cohort study. *Health Science Reports*. 2024;7(5).
13. Al-Rousan N, Al-Najjar H. Evaluation of the effects of MERCK, MODERNA, PFIZER/BioNTech, and JANSSEN COVID-19 vaccines on vaccinated people: A metadata analysis. *Informatics in Medicine Unlocked*. 2024;49.
14. Alami A, Pérez-Lloret S, Mattison DR. Safety surveillance of respiratory syncytial virus (RSV) vaccine among pregnant individuals: a real-world pharmacovigilance study using the Vaccine Adverse Event Reporting System. *BMJ Open*. 2025;15(4):e087850.
15. Alawfi SA. Health of Saudi Women in the Post-Pandemic Era: Candidiasis Incidence and Post COVID-19 and COVID-19-Vaccination. *International Journal of Women's Health*. 2024;16:1687–97.
16. Albahari D, Abdallah O, Alqam SMI, Mohammed MFH, Ahmed MAS, Wadoo O. Impact of mRNA COVID-19 vaccination on hematological parameters in patients maintained on clozapine: A retrospective study from Qatar. *Exploratory Research in Clinical and Social Pharmacy*. 2025;19.
17. Alejandre C, Penela-Sánchez D, Alsina J, Agüera M, Soler A, Moussalam S, et al. Impact of universal immunization program with monoclonal antibody nirsevimab on reducing the burden of serious bronchiolitis that need pediatric intensive care. *Eur J Pediatr*. 2024;183(9):3897–904.
18. Ali MT, Chapra A, Mohamed SFA, Ghareeb AN, Al Kuwari M, Karim SA, et al. A Case Series Examining the 1-year Follow-up Outcomes of Myocarditis Associated with COVID-19 Vaccination. *Heart Views*. 2024;25(4):197–211.
19. Almeida NC, Parameswaran L, DeHaan EN, Wyper H, Rahman F, Jiang Q, et al. Immunogenicity and Safety of the Bivalent Respiratory Syncytial Virus Prefusion F Subunit Vaccine in Immunocompromised or Renally Impaired Adults. *Vaccines*. 2025;13(3).
20. Almodóvar-Fernández I, Real-Fernández A, Romero Atanes MJ, Andreu-Villarraig C, Beltrán-Viciano MÁ, Monreal-Pérez MF. SARS-CoV-2 vaccination effect over coagulation in 60s patients treated with acenocumarol. *Vacunas*. 2024;25(3):323–30.
21. Alves K, Kouassi A, Plested JS, Kalkeri R, Smith K, Kaba M, et al. Immunogenicity and safety of a monovalent Omicron XBB.1.5 SARS-CoV-2 recombinant spike protein vaccine in previously unvaccinated, SARS-CoV-2 seropositive participants: Primary day-28 analysis of a phase 2/3 open-label study. *Vaccine*. 2025;55:127046.
22. Amaral de Avila Machado M, Gallo S, Goldstein A, Vachhani P, Byrareddy RM, Kantele A, et al. Enhanced passive safety surveillance of standard-dose and high-dose influenza vaccines in Finland and Germany 2023-24 season. *Hum Vaccin Immunother*. 2025;21(1):2475616.
23. Amicizia D, Domnich A, Lai PL, Orsi A, Icardi G, Tkach-Motulyak O, et al. Enhanced passive safety surveillance of the MF59-adjuvanted quadrivalent influenza vaccine in the elderly during the 2021/22 influenza season. *Hum Vaccin Immunother*. 2023;19(1):2190279.

24. Amstutz A, Chammartin F, Audigé A, Eichenberger AL, Braun DL, Amico P, et al. Antibody and T-Cell Response to Bivalent Booster SARS-CoV-2 Vaccines in People With Compromised Immune Function: COVERALL-3 Study. *J Infect Dis.* 2024;230(4):e847–59.
25. (a) Andersen KM, Allen KE, Nepal RM, Mateus JS, Yu T, Zhou A, et al. Effectiveness of BNT162b2 XBB.1.5 vaccine in immunocompetent adults using tokenization in two U.S. states. *Vaccine.* 2025;52:126881.
26. (b) Andersen KM, Porter TM, Fell DB, Reimbaeva M, Moran MM, Cane A, et al. Clinical Outcomes in Children <5 Years of Age Hospitalized for Respiratory Syncytial Virus, COVID-19 or Influenza in the United States. *Pediatr Infect Dis J.* 2025;
27. Andersson NW, Thieson EM, Pihlström N, Perälä J, Faksova K, Gram MA, et al. Comparative effectiveness of monovalent XBB.1.5 containing covid-19 mRNA vaccines in Denmark, Finland, and Sweden: target trial emulation based on registry data. *BMJ Med.* 2024;3(1):e001074.
28. Ann Costa Clemens S, Weckx L, Milan EP, Smolenov I, Clemens R. Interchangeability of different COVID-19 vaccine platforms as booster doses: A phase 3 study mimicking real-world practice. *Vaccine.* 2024;42(19):3989–98.
29. Appaneal HJ, Lopes VV, Puzniak L, Zasowski EJ, Jodar L, McLaughlin JM, et al. Early effectiveness of the BNT162b2 KP.2 vaccine against COVID-19 in the US Veterans Affairs healthcare system. *Nat Commun.* 2025;16(1):4033.
30. Arbetter D, Gopalakrishnan V, Aksyuk AA, Ahani B, Chang Y, Dagan R, et al. Lower respiratory tract infections following respiratory syncytial virus monoclonal antibody nirsevimab immunization versus placebo: Analysis from a Phase 3 randomized clinical trial (MELODY). *Clin Infect Dis.* 2024;
31. Arcolaci A, Guidolin L, Olivieri E, Bilò MB, Bonadonna P, Braschi MC, et al. A real-life multicenter experience for the post-pandemic management of hypersensitivity reactions to Covid-19 vaccines. *Vaccine.* 2025;61:127337.
32. Arepalli S, Kopplin L, Tsui E, Brill D, Sobrin L, Papaliodis G, et al. THE HETEROGENEOUS PRESENTATIONS OF DE NOVO AND RECURRENT OCULAR INFLAMMATION AFTER COVID-19 VACCINATION : A Multicenter Report and a Review of the Literature. *Retina.* 2025;45(6):1175–83.
33. Ares-Gómez S, Mallah N, Santiago-Pérez MI, Pardo-Seco J, Pérez-Martínez O, Otero-Barrós MT, et al. Effectiveness and impact of universal prophylaxis with nirsevimab in infants against hospitalisation for respiratory syncytial virus in Galicia, Spain: initial results of a population-based longitudinal study. *Lancet Infect Dis.* 2024;24(8):817–28.
34. Asiri A, Alotaibi HM, Alotaibi NA, Alsaleem AA. Adverse Cutaneous Reactions Following COVID-19 Vaccination Among Patients with Pre-Existing Urticaria: A Cross-Sectional Study at a Tertiary Care Center in Saudi Arabia. *IJGM.* 2025 June 17;18:3227–37.
35. Aşkın Turan S, Aydın Ş. A retrospective cohort study: is COVID-19 BNT162b2 mRNA vaccination a trigger factor for cluster headache? *Acta Neurol Belg.* 2024;124(5):1535–42.

36. Athan E, Baber J, Quan K, Scott RJ, Jaques A, Jiang Q, et al. Safety and immunogenicity of bivalent RSVpreF vaccine coadministered with seasonal inactivated influenza vaccine in older adults. *Clin Infect Dis*. 2024;78(5):1360–8.
37. Aydillo T, Balsera-Manzanero M, Rojo-Fernandez A, Escalera A, Salamanca-Rivera C, Pachón J, et al. Concomitant administration of seasonal influenza and COVID-19 mRNA vaccines. *Emerg Microbes Infect*. 2024;13(1):2292068.
38. Aydin MF, Afşin M, Yeleç S, Bakay K, Özçelik Otcu SM. Effect of COVID-19 mRNA vaccine on serum AMH, TSH, FSH and LH concentrations. *Journal of Experimental and Clinical Medicine (Turkey)*. 2024;41(2):300–2.
39. Baba A, Yamada K, Kanekura T. Cutaneous adverse events following COVID-19 vaccination: A case series of 30 Japanese patients and a review of 93 Japanese studies. *J Dermatol*. 2024;51(6):827–38.
40. Babalola TK, Clouston SAP, Sekendiz Z, Chowdhury D, Soriolo N, Kawuki J, et al. SARS-COV-2 re-infection and incidence of post-acute sequelae of COVID-19 (PASC) among essential workers in New York: a retrospective cohort study. *The Lancet Regional Health - Americas*. 2025;42.
41. Baden LR, El Sahly HM, Essink B, Follmann D, Hachigian G, Strout C, et al. Long-term safety and effectiveness of mRNA-1273 vaccine in adults: COVE trial open-label and booster phases. *Nat Commun*. 2024;15(1):7469.
42. Bahakel H, Spieker AJ, Hayek H, Schuster JE, Hamdan L, Dulek DE, et al. Immunogenicity and Reactogenicity of High- or Standard-Dose Influenza Vaccine in a Second Consecutive Influenza Season. *J Infect Dis*. 2025;231(1):e123–31.
43. (a) Bajema KL, Bui DP, Yan L, Li Y, Rajeevan N, Vergun R, et al. Severity and long-term mortality of COVID-19, influenza, and respiratory syncytial virus. *JAMA Intern Med*. 2025;185(3):324–34.
44. (b) Bajema KL, Yan L, Li Y, Argraves S, Rajeevan N, Fox A, et al. Respiratory syncytial virus vaccine effectiveness among US veterans, September, 2023 to March, 2024: a target trial emulation study. *Lancet Infect Dis*. 2025;25(6).
45. Barbas Del Buey JF, Íñigo Martínez J, Gutiérrez Rodríguez M, Alonso García M, Sánchez-Gómez A, Lasheras Carbajo MD, et al. The effectiveness of nirsevimab in reducing the burden of disease due to respiratory syncytial virus (RSV) infection over time in the Madrid region (Spain): a prospective population-based cohort study. *Front Public Health*. 2024;12:1441786.
46. Barnay M, Foubert-Samier A, Violleau MH, Campana-Salort E, Cintas P, Laforêt P, et al. The safety of COVID-19 vaccines in a large French series of patients with neuromuscular conditions and the impacts of vaccination on their daily lives. *Rev Neurol (Paris)*. 2025;181(6):571–8.
47. Barouch SE, Chiczy TM, Blanc R, Barbaty DR, Parker LJ, Tong X, et al. Concurrent administration of COVID-19 and influenza vaccines enhances spike-specific antibody responses. *Open Forum Infectious Diseases*. 2024;11(4).

48. Battis N, Ekstein SF, Cosky EEP, Neeley AB. Patient-Reported Association Between COVID-19 Infection or Vaccination and Onset of Allergic Contact Dermatitis®. *Dermatitis*. 2024;35(6):614–7.
49. Baum HE, Thirard R, Halliday A, Baos S, Thomas AC, Harris RA, et al. Detection of SARS-CoV-2-specific mucosal antibodies in saliva following concomitant COVID-19 and influenza vaccination in the ComFluCOV trial. *Vaccine*. 2024;42(12):2945–50.
50. Bea S, Ahn HY, Woo J, Shin JY, Cho SW. The Impact of COVID-19 Vaccination on Thyroid Disease in 7 Million Adult and 0.2 Million Adolescent Vaccine Recipients. *J Clin Endocrinol Metab*. 2024;
51. Beller NS, Beller M, Murmann JJ, Crisp RW. Impact of the medical briefing and vaccine type on adverse events following COVID-19 vaccination: A randomized clinical trial. *Vaccine*. 2025;61:127392.
52. Bellitto C, Luxi N, Ciccimarra F, L'Abbate L, Raethke M, van Hunsel F, et al. What is the Safety of COVID-19 Vaccines in Immunocompromised Patients? Results from the European “Covid Vaccine Monitor” Active Surveillance Study. *Drug Saf*. 2024;47(10):1011–23.
53. Ben Kridis W, Boudawara O, Khanfir A. Local and systemic side effects of COVID-19 vaccine in Tunisian cancer patients: A prospective single center study. *J Oncol Pharm Pract*. 2024;10781552241285034.
54. (a) Bennett C, Rivers EJ, Woo W, Bloch M, Cheung K, Griffin P, et al. Immunogenicity and Safety of Heterologous Omicron BA.1 and Bivalent SARS-CoV-2 Recombinant Spike Protein Booster Vaccines: A Phase 3 Randomized Clinical Trial. *J Infect Dis*. 2024;230(1):e4–16.
55. (b) Bennett C, Hoosain Z, Koen A, Lalloo U, Louw C, Maluleke V, et al. Immunogenicity and safety of SARS-CoV-2 recombinant spike protein vaccine in South African people living with and without HIV-1 infection: A phase 2 randomised trial. *Journal of Infection*. 2024 Dec;89(6):106285.
56. Bennett C, Chau G, Clayton E, Chu L, Alvarez J, Hidalgo AB, et al. Safety and immunogenicity of Omicron protein vaccines in mRNA-vaccinated adolescents: A phase 3, randomised trial. *J Infect*. 2025;90(2):106428.
57. Berthaud V, Creech CB, Rostad CA, Carr Q, de Leon L, Dietrich M, et al. Safety and Immunogenicity of an mRNA-1273 Booster in Children. *Clin Infect Dis*. 2024;79(6):1524–32.
58. Beurrier M, Conart JB, Antoine ML, Facile A, Bagheri H, Gras-Champel V, et al. Retinal vascular occlusion after COVID-19 vaccination: Analysis of the French pharmacovigilance database. *Therapie*. 2025;80(3):295–303.
59. Biegus J, Szenborn L, Zymliński R, Zakliczyński M, Reczuch K, Guzik M, et al. The early safety profile of simultaneous vaccination against influenza and Respiratory Syncytial Virus (RSV) in patients with high-risk heart failure. *Vaccine*. 2024;42(12):2937–40.
60. Blanquart F, Vieillefond V, Visseaux B, Abou Chakra CN, Nunes MC, Jacques A, et al. Influenza vaccine effectiveness against detected infection in the community, France, October 2024 to February 2025. *Euro Surveill*. 2025;30(7).

61. Blauvelt CA, Zeme M, Natarajan A, Epstein A, Roh ME, Morales A, et al. RSV vaccine and nirsevimab uptake among pregnant people and their neonates. *JAMA Netw Open*. 2025;8(2):e2460735.
62. Bolu O, Alo OD, Iwara E, Longley AT, Hadley I, Ogar CK, et al. Feasibility of cohort event monitoring and assessment of reactogenicity and adverse events among a cohort of AstraZeneca and Moderna COVID-19 vaccine recipients in Nigeria, 2021. *Vaccine*. 2025;52:126907.
63. Bosch W, Speiser LJ, Wi CI, King KS, Natoli TL, Ihrke KD, et al. Incidence of Respiratory Syncytial Virus in Community-Dwelling Adults Aged 18-64 Years Over 2 Seasons, 2022-2024, in a North American Community. *Open Forum Infectious Diseases*. 2024;11(10).
64. Boulefaa D, Bagheri H, Salvo F, Rabier MB, Geniaux H, Lepelley M, et al. Early Detection of Hearing Impairment Signals Post-mRNA COVID-19 Vaccination: A Disproportionality Analysis Study on French Pharmacovigilance Database. *Drug Saf*. 2025;48(3):251–63.
65. Briggs FBS, Schmidt H, Mateen FJ, Buxhoeveden S, Bebo BF, Fiol J, et al. Self-reported longitudinal COVID-19 vaccination reactogenicity profiles in persons with multiple sclerosis. *Mult Scler Relat Disord*. 2025;94:106253.
66. Buynak R, Cannon K, DeAtkine D, Kirby J, Usdan L, Bhavsar A, et al. Randomized, open-label phase 3 study evaluating immunogenicity, safety, and reactogenicity of RSVPreF3 OA coadministered with FLU-QIV-HD in adults aged ≥ 65 . *Infectious Diseases and Therapy*. 2024;13(8):1789–805.
67. Byoun HS, Lee SU, Won YD, Choi TW, Lee SH, Kim YD, et al. Nationwide cohort observational study on the safety and efficacy of COVID-19 vaccination in patients with Moyamoya disease. *Sci Rep*. 2024;14(1):24400.
68. Caffrey AR, Appaneal HJ, Lopes VV, Puzniak L, Zasowski EJ, Jodar L, et al. Effectiveness of BNT162b2 XBB vaccine in the US veterans affairs healthcare system. *Nat Commun*. 2024;15(1):9490.
69. Carazo S, Skowronski DM, Brousseau N, Guay CA, Sauvageau C, Racine É, et al. Monovalent mRNA XBB.1.5 vaccine effectiveness against COVID-19 hospitalization in Quebec, Canada: Impact of variant replacement and waning protection during 10-month follow-up. *PLoS One*. 2025;20(6):e0325269.
70. Carbajal R, Boelle PY, Pham A, Chazette Y, Schellenberger M, Weil C, et al. Real-world effectiveness of nirsevimab immunisation against bronchiolitis in infants: a case-control study in Paris, France. *Lancet Child Adolesc Health*. 2024;8(10):730–9.
71. Carcione D, Spencer P, Pettigrew G, Leeb A, Drake-Brockman C, Ford T, et al. ACTIVE POST-MARKETING SAFETY SURVEILLANCE OF NIRSEVIMAB ADMINISTERED TO CHILDREN IN WESTERN AUSTRALIA, APRIL-JULY 2024. *Pediatr Infect Dis J*. 2025;
72. Chalkias S, McGhee N, Whatley JL, Essink B, Brosz A, Tomassini JE, et al. Interim Report of the Reactogenicity and Immunogenicity of Severe Acute Respiratory Syndrome Coronavirus 2 XBB-Containing Vaccines. *J Infect Dis*. 2024;230(2):e279–86.

73. Chandler R, Montenegro N, Llorach C, Aguirre LN, Germain S, Kuriyakose SO, et al. Immunogenicity, reactogenicity, and safety of AS01E-adjuvanted RSV prefusion F protein-based candidate vaccine (RSVPreF3 OA) when co-administered with a seasonal quadrivalent influenza vaccine in older adults: results of a phase 3, open-label, randomized controlled trial. *Clin Infect Dis*. 2024;ciad786.
74. (a) Chemaitelly H, Ayoub HH, Coyle P, Tang P, Hasan MR, Yassine HM, et al. BNT162b2 Versus mRNA-1273 Vaccines: Comparative Analysis of Long-Term Protection Against SARS-CoV-2 Infection and Severe COVID-19 in Qatar. *Influenza Other Respir Viruses*. 2024;18(10):e13357.
75. (b) Chemaitelly H, Akhtar N, Jerdi SA, Kamran S, Joseph S, Morgan D, et al. Association between COVID-19 vaccination and stroke: a nationwide case-control study in Qatar. *Int J Infect Dis*. 2024;145:107095.
76. (a) Chen CH, Chiu YW, Chen BD, Wu MJ, Tsai SF. De Novo Biopsy-Proven Glomerular Disease Following COVID-19 Vaccination. *Journal of Clinical Medicine*. 2024;13(15).
77. (b) Chen DT, Copland E, Hirst JA, Mi E, Dixon S, Coupland C, et al. Uptake, effectiveness and safety of COVID-19 vaccines in individuals at clinical risk due to immunosuppressive drug therapy or transplantation procedures: a population-based cohort study in England. *BMC Med*. 2024;22(1):237.
78. Chen CY, Hsieh MHC, Huang WT, Lai ECC. Interaction between influenza vaccine and statins affecting the risk of rhabdomyolysis in Taiwan: a nationwide case-centred analysis. *eClinicalMedicine*. 2025;82.
79. Cheng TM, Chen YS, Wei KC, Chang YC, Huang YT, Chen CL. Assessment of the herpes zoster risk among renal transplant recipients administered the influenza vaccine. *Vaccine*. 2024;42(24):126075.
80. Cheng KL, Yu WS, Wang YH, Ibarburu GH, Lee HL, Wei JC. Long-term Thyroid Outcomes After COVID-19 Vaccination: A Cohort Study of 2,333,496 Patients from the TriNetX Network. *J Clin Endocrinol Metab*. 2025;
81. Chewaskulyong B, Satjaritanun P, Ketpueak T, Suksombooncharoen T, Charoentum C, Nuchpong N, et al. Neutralizing antibodies and safety of a COVID-19 vaccine against SARS-CoV-2 wild-type and Omicron variants in solid cancer patients. Harapan H, editor. *PLoS ONE*. 2024 Nov 7;19(11):e0310781.
82. Chime N, Anspach B, Jain V, Laajalahti O, Ollinger T, Yaplee D, et al. Phase 3 Study Assessing Lot-to-Lot Consistency of Respiratory Syncytial Virus Prefusion Protein F3 Vaccine and Its Immune Response, Safety, and Reactogenicity When Co-administered With Quadrivalent Influenza Vaccine. *J Infect Dis*. 2025;231(1):e144–53.
83. Cho H, Lim E, Kim HJ, Jeong NY, Choi NK. Association Between Influenza Vaccination and Acute Kidney Injury Among the Elderly: A Self-Controlled Case Series. *Pharmacoepidemiol Drug Saf*. 2024;33(9):e70006.

84. Cho J, Jo H, Kim H, Park J, Pizzol D, Kim MS, et al. Global Burden of Vaccine-Associated Cerebrovascular Venous Sinus Thrombosis, 1968-2024: A Critical Analysis From the WHO Global Pharmacovigilance Database. *J Korean Med Sci.* 2025;40(11):e101.
85. (a) Choi YJ, Sohn JW, Choi WS, Wie SH, Lee J, Lee JS, et al. Interim estimates of 2023-2024 seasonal influenza vaccine effectiveness among adults in Korea. *J Korean Med Sci.* 2024;39(15):e146.
86. (b) Choi MJ, Yu YJ, Kim JW, Ju HJ, Shin SY, Yang YJ, et al. Immunogenicity and safety of concomitant bivalent COVID-19 and quadrivalent influenza vaccination: implications of immune imprinting and interference. *Clin Microbiol Infect.* 2024;30(5):653–9.
87. (c) Choi YJ, Lim J, Bea S, Lee J, Choi JY, Rho SY, et al. Thromboembolism after coronavirus disease 2019 vaccination in atrial fibrillation/flutter: a self-controlled case series study. *Eur Heart J.* 2024;45(32):2983–91.
88. (d) Choi SK, Kim S, Ko M, Heo Y, Kim TE, Lee Y, et al. Safety of the bivalent COVID-19 mRNA booster vaccination among persons aged over 18 years in the Republic of Korea. *Osong Public Health and Research Perspectives.* 2024;15(6):542–9.
89. (a) Choi YJ, Jung J, Kang M, Choi MJ, Choi WS, Seo YB, et al. The risk of pregnancy related adverse outcomes after COVID-19 vaccination: Propensity score-matched analysis with influenza vaccination. *Vaccine.* 2025;44:126506.
90. (b) Choi T, Xie Y, Al-Aly Z. Rates of Hospitalization and Death due to COVID-19 in US Veterans with SARS-CoV-2 Infection in the XBB-, JN.1-, and KP-Predominant Eras. *Open Forum Infectious Diseases.* 2025;12(3).
91. (c) Choi YJ, Song JY, Wie SH, Lee J, Lee JS, Jeong HW, et al. Early and late influenza vaccine effectiveness in South Korea during the 2023–2024 season. *Vaccines.* 2025;13(2).
92. Chong C, Wee LE, Jin X, Zhang M, Malek MIA, Ong B, et al. Risks of SARS-CoV-2 JN.1 infection and COVID-19-associated emergency department visits/hospitalizations following updated boosters and prior infection: a population-based cohort study. *Clin Infect Dis.* 2024;79(5):1190–6.
93. Chung JR, Price AM, Zimmerman RK, Geffel KM, House SL, Curley T, et al. Influenza vaccine effectiveness against medically attended outpatient illness, United States, 2023-24 season. 2024;
94. Churilla T, Crane C, Sreedharan R, Alzarka BJ, Charnaya O, Jain NG, et al. Safety and infectious outcomes in pediatric kidney transplant recipients after COVID-19 vaccination: A pediatric nephrology research consortium study. *Pediatr Transplant.* 2024;28(4):e14786.
95. Clark R, Davies S, Labrador J, Loubet P, Natalini Martínez S, Moríñigo HM, et al. Safety and immunogenicity of respiratory syncytial virus prefusion F protein vaccine when co-administered with adjuvanted seasonal quadrivalent influenza vaccine in older adults: a phase 3 randomized trial. *Clin Infect Dis.* 2024;79(4):1088–98.

96. Clothier HJ, Parker C, Mallard JH, Effler P, Bloomfield L, Carcione D, et al. Nuvaxovid NVX-CoV2373 vaccine safety profile: real-world data evidence after 100,000 doses, Australia, 2022 to 2023. *Euro Surveill.* 2024;29(50).
97. Coma E, Martinez-Marcos M, Hermosilla E, Mendioroz J, Reñé A, Fina F, et al. Effectiveness of nirsevimab immunoprophylaxis against respiratory syncytial virus-related outcomes in hospital and primary care settings: a retrospective cohort study in infants in Catalonia (Spain). *Arch Dis Child.* 2024;109(9):736–41.
98. Copland E, Patone M, Saatci D, Handunnetthi L, Hirst J, Hunt DPJ, et al. Safety outcomes following COVID-19 vaccination and infection in 5.1 million children in England. *Nat Commun.* 2024;15(1):3822.
99. Costantino C, Mazzucco W, Graziano G, Maida CM, Vitale F, Tramuto F. Mid-term estimates of influenza vaccine effectiveness against the A(H1N1)pdm09 prevalent circulating subtype in the 2023/24 season: data from the Sicilian RespiVirNet surveillance system. *Vaccines.* 2024;12(3):305.
100. Couvillion SP, Nakayasu ES, Webb-Robertson BM, Yang IH, Eder JG, Nicora CD, et al. Associations between SARS-CoV-2 Infection or COVID-19 Vaccination and Human Milk Composition: A Multi-Omics Approach. *J Nutr.* 2024;154(12):3566–74.
101. da Silva ESFI, Silva RL, Filho C, Santos M, Martins LES, de Abreu TC, et al. Vaccine adherence and adverse events of the SARS-COV vaccine in patients with inflammatory bowel disease. *Gastroenterol Hepatol.* 2025;48(1):502202.
102. Dammann MT, Kraft H, Stichtenoth G, Hanke K, Zemlin M, Soler Wenglein J, et al. Influenza Immunization in Very-Low-Birth-Weight Infants: Epidemiology and Long-Term Outcomes. *Vaccines (Basel).* 2025;13(1).
103. Darko DM, Seaneke SK, Karikari-Boateng E, Nkansah E, Amponsa-Achiano K, Mohamed NT, et al. Safety of mRNA COVID-19 vaccines among persons 15- years and above in Ghana: A cohort event monitoring study. *Vaccine.* 2024;42(26):126460.
104. Davis M, Towner W, DeHaan E, Jiang Q, Li W, Rahman F, et al. Bivalent RSVpreF Vaccine in Adults 18 to <60 Years Old With High-Risk Conditions. *Clin Infect Dis.* 2025;80(4):911–20.
105. de la Cueva IS, Gerber JE, Hastie A, Brotons C, Panzer F, Pirçon JY, et al. Enhanced Safety Surveillance of GSK's Inactivated Quadrivalent Seasonal Influenza Vaccine in Belgium, Germany, and Spain During the 2022/2023 Influenza Season. *Drug Saf.* 2024;47(11):1137–48.
106. de-la-Plaza-San-Frutos M, García-García E, Martínez-Pascual B, Esteban IM, Domínguez-Balmaseda D, Sosa-Reina MD. Effects of vaccination against COVID-19 on overactive bladder symptoms on young population. *Frontiers in Medicine.* 2024;11.
107. Denoble AE, Vazquez-Benitez G, Sheth SS, Ackerman-Banks CM, DeSilva MB, Zhu J, et al. Coronavirus disease 2019 (COVID-19) vaccination and stillbirth in the Vaccine Safety Datalink. *Obstet Gynecol.* 2024;144(2):215–22.

108. Deshmukh AJ, Ahmad R, Cha YM, Mulpuru SK, DeSimone CV, Killu AM, et al. Association between COVID-19 vaccination and atrial arrhythmias in individuals with cardiac implantable electronic devices. *J Cardiovasc Electrophysiol*. 2024;35(9):1828–36.
109. Dixit A, Bennett R, Ali K, Griffin C, Clifford RA, Turner M, et al. Interim safety and immunogenicity of COVID-19 omicron BA.1 variant-containing vaccine in children in the USA: an open-label non-randomised phase 3 trial. *Lancet Infect Dis*. 2024;24(7):687–97.
110. (a) Diya O, Gayed J, Lowry FS, Ma H, Bangad V, Mensa F, et al. A phase 2/3 trial to investigate the safety and immunogenicity of monovalent Omicron JN.1-adapted BNT162b2 COVID-19 vaccine in adults ≥18 years old. *Vaccine*. 2025;52:126869.
111. (b) Diya O, Gayed J, Lowry FS, Ma H, Bangad V, Mensa F, et al. Safety and Immunogenicity of Monovalent Omicron KP.2-Adapted BNT162b2 COVID-19 Vaccine in Adults: Single-Arm Substudy from a Phase 2/3 Trial. *Infect Dis Ther*. 2025;
112. Domachowske J, Hamrén UW, Banu I, Baronio R, Basavaraju B, Koen A, et al. Safety and Pharmacokinetics of Nirsevimab in Immunocompromised Children. *Pediatrics*. 2024;154(4).
113. Domnich A, Icardi G, Panatto D, Scarpaleggia M, Trombetta CS, Ogliastro M, et al. Influenza epidemiology and vaccine effectiveness during the 2023/2024 season in Italy: a test-negative case-control study. *Int J Infect Dis*. 2024;147:107202.
114. Domnich A, Orsi A, Lai PL, Massaro E, Trombetta CS, Pastorino J, et al. Enhanced safety surveillance of the adjuvanted respiratory syncytial virus vaccine among Italian older adults. *VACCINE: X*. 2025;24.
115. Dos Santos G, Devadiga R, Kim CS, Bang J. An 8-Year Prospective, Observational, Multi-centre Post-Marketing Safety Surveillance Study Conducted in South Korea (2014-2022) Following the Introduction of GSK's Inactivated Quadrivalent Seasonal Influenza Vaccine (Fluarix Tetra) for Subjects Aged 6 Months and Older. *Drug Saf*. 2024;47(4):365–75.
116. Dudukina E, Bräuner EV, Christiansen CB, Mogensen SH, Hervig ME, Ulsø S, et al. Associations between mRNA COVID-19 vaccination and urticaria: a nationwide registry-based cohort study in Denmark. *Scand J Public Health*. 2025;53(5):533–43.
117. Dulfer EA, Geckin B, Taks EJM, GeurtsvanKessel CH, Dijkstra H, van Emst L, et al. Timing and sequence of vaccination against COVID-19 and influenza (TACTIC): a single-blind, placebo-controlled randomized clinical trial. *The Lancet Regional Health - Europe*. 2023;29.
118. Duskin-Bitan H, Robenshtok E, Peretz A, Beckenstein T, Tsur N, Netzer D, et al. Subacute Thyroiditis Following COVID-19 and COVID-19 Vaccination. *Endocr Pract*. 2024;30(8):731–6.
119. Elbaz M, Hoffman T, Yahav D, Dovrat S, Ghanem-Zoubi N, Atamna A, et al. Varicella-Zoster Virus-Induced Neurologic Disease After COVID-19 Vaccination: A Multicenter Observational Cohort Study. *Open Forum Infectious Diseases*. 2024;11(6).
120. Elemuwa UG, Bitrus F, Abubakar A, Abiodun AS, Faniyi AE, Oreagba IA, et al. TRENDS OF COVID-19 VACCINE ADVERSE EVENT FOLLOWING IMMUNIZATION (AEFI): A ONE-YEAR RETROSPECTIVE REVIEW USING THE PASSIVE SURVEILLANCE DATA IN

THE NIGERIAN NATIONAL DATABASE (VIGIFLOW). *Journal of Population Therapeutics and Clinical Pharmacology*. 2024;31(8):1693–702.

121. El Hilali S, Benmlih S, Haroun AE, Zeghari Z, Khalis M, Frindy M, et al. Adverse effects of COVID-19 vaccines in the Moroccan adults and children during the pandemic. *Clinical Epidemiology and Global Health*. 2024;28.

122. Emborg HD, Valentiner-Branth P, Trebbien R, Bolt Botnen A, Grove Krause T, Søborg B. Enhanced influenza vaccines impact effectiveness in individuals aged 65 years and older, Denmark, 2024/25 influenza season up to 4 March 2025. *Euro Surveill*. 2025;30(12).

123. Erdwiens A, Hackmann C, Wedde M, Biere B, Reiche J, Preuß U, et al. Interim estimates of 2024-2025 seasonal influenza vaccine effectiveness in Germany-data from primary care and hospital sentinel surveillance. *Influenza Other Respir Viruses*. 2025;19(5):e70115.

124. Esteban-Cledera L, Bissacco CA, Pallejá-Millán M, Villalobos M, Villalobos F. Association between COVID-19 Vaccines and Menstrual Disorders: Retrospective Cohort Study of Women Aged 12-55 Years Old in Catalonia, Spain. *Int J Environ Res Public Health*. 2024;21(8).

125. Estrella-Porter P, Correcher-Martínez E, Orrico-Sánchez A, Carreras JJ. Post-Marketing Surveillance of Nirsevimab: Safety Profile and Adverse Event Analysis from Spain's 2023-2024 RSV Immunisation Campaign. *Vaccines (Basel)*. 2025;13(6).

126. Fabbri A, Ruggeri EM, Virtuoso A, Giannarelli D, Raso A, Chegai F, et al. Periodic boosters of COVID-19 vaccines do not affect the safety and efficacy of immune checkpoint inhibitors for advanced non-small cell lung cancer: a longitudinal analysis of the vax-on-third study. *Cancers (Basel)*. 2025;17(12).

127. Farisogullari B, Lawson-Tovey S, Hyrich KL, Gossec L, Carmona L, Strangfeld A, et al. Factors associated with disease flare following SARS-CoV-2 vaccination in people with inflammatory rheumatic and musculoskeletal diseases: results from the physician-reported EULAR Coronavirus Vaccine (COVAX) Registry. *Ann Rheum Dis*. 2024;83(11):1584–95.

128. Fatima N, Mohsin W, Vasanth U, Waheed S, Khalid L, Makhdoom T, et al. MENSTRUAL IRREGULARITIES IN WOMEN AFTER COVID-19 INFECTION AND VACCINATION: A COMMUNITY BASED STUDY AMONG DUBAI HOSPITAL FEMALE STAFF AND WOMEN ATTENDING GYNECOLOGY CLINIC AND EMERGENCY. *Journal of Population Therapeutics and Clinical Pharmacology*. 2025;32(2):50–9.

129. Fazal A, Reinhart K, Huang S, Kniss K, Olson SM, Dugan VG, et al. Reports of encephalopathy among children with influenza-associated mortality - United States, 2010-11 through 2024-25 influenza seasons. *MMWR Morb Mortal Wkly Rep*. 2025;74(6):91–5.

130. Fell DB, Russell M, Fung SG, Swayze S, Chung H, Buchan SA, et al. Effectiveness of influenza vaccination during pregnancy against laboratory-confirmed seasonal influenza among infants under 6 months of age in Ontario, Canada. *J Infect Dis*. 2024;230(1):e80–92.

131. Ferguson M, Schwarz TF, Núñez SA, Rodríguez-García J, Mital M, Zala C, et al. Noninferior Immunogenicity and Consistent Safety of Respiratory Syncytial Virus Prefusion F Protein Vaccine in Adults 50-59 Years Compared to ≥60 Years of Age. *Clin Infect Dis*. 2024;79(4):1074–84.

132. Ferraioli M, Aiello A, Prevete I, Chimenti MS, De Marco L, Meschi S, et al. Anti-SARS-CoV-2 B and T-Cell Immune Responses Persist 12 Months After mRNA Vaccination with BNT162b2 in Systemic Lupus Erythematosus Patients Independently of Immunosuppressive Therapies. *Vaccines*. 2025;13(4).
133. Ferrari F, Sodi F, Madotto F, Carlesso E, Florio G, Pelliccia MR, et al. Medical occurrence and safety of SARS-CoV-2 vaccination outside of the hospital setting. *Intern Emerg Med*. 2024;19(6):1593–604.
134. Fierro C, Sanchez-Crespo N, Makrinos D, Zhang W, Sun Y, Rohilla P, et al. Shared clinical and immunologic features of mRNA vaccines: preliminary results from a comparative clinical study. *Front Immunol*. 2025;16:1501275.
135. (a) Figueroa AL, Azzi JR, Eghtesad B, Priddy F, Stolman D, Siangphoe U, et al. Safety and Immunogenicity of the mRNA-1273 Coronavirus Disease 2019 Vaccine in Solid Organ Transplant Recipients. *J Infect Dis*. 2024;230(3):e591–600.
136. (b) Figueroa AL, Ali K, Berman G, Zhou H, Deng W, Xu W, et al. Safety and durability of mRNA-1273–induced SARS-CoV-2 immune responses in adolescents: results from the phase 2/3 TeenCOVE trial. *eClinicalMedicine*. 2024;74.
137. (a) Figueroa AL, Ali K, Berman G, Xu W, Deng W, Girard B, et al. Safety and immunogenicity of an mRNA-1273 vaccine booster in adolescents. *Hum Vaccin Immunother*. 2025;21(1):2436714.
138. (b) Figueroa AL, Torres D, Reyes-Acuna C, Matherne P, Yeakey A, Deng W, et al. Safety and immunogenicity of a single-dose omicron-containing COVID-19 vaccination in adolescents: an open-label, single-arm, phase 2/3 trial. *Lancet Infect Dis*. 2025;25(2):208–17.
139. Fitzpatrick T, Yamoah P, Lacuesta G, Sadarangani M, Cook V, Pourshahnazari P, et al. Revaccination outcomes among adolescents and adults with suspected hypersensitivity reactions following COVID-19 vaccination: A Canadian immunization research network study. *Vaccine*. 2024;42(24):126078.
140. Fitzpatrick T, Yamoah P, Summerby-Murray D, Cowan J, Sadarangani M, Wright A, et al. Neurological adverse events following COVID-19 vaccination among Canadians referred to the special immunization clinic network. *Vaccine*. 2025;59:127254.
141. Folegatti PM, Pepin S, Tabar C, Fries K, Talanova O, See S, et al. Comparative assessment of immunogenicity and safety of recombinant influenza vaccine in children, adolescents, and adults: results from a phase 3, immunobridging, open-label, non-randomised study. *Lancet Infect Dis*. 2025;
142. Fonseca HAR, Zimmerman A, Monfardini F, Guimarães HP, Pedrosa RP, Patriota RLS, et al. In-Hospital influenza vaccination to prevent cardiorespiratory events in the first 45 days after acute coronary syndrome: A prespecified analysis of the VIP-ACS trial. *Vaccine*. 2024;42(3):496–504.
143. Fontana RJ, Li YJ, Vuppalachchi R, Kleiner DE, Gu J, Shroff H, et al. ERAP-1 and ERAP-2 Variants in Liver Injury After COVID-19 mRNA Vaccination: A US Multicenter Study. *Am J Gastroenterol*. 2024;119(8):1496–505.

144. Fotakis EA, Picasso E, Sacco C, Petrone D, Del Manso M, Bella A, et al. Impact of the 2023/24 autumn-winter COVID-19 seasonal booster campaign in preventing severe COVID-19 cases in Italy (October 2023-March 2024). *Vaccine*. 2024;42(26):126375.
145. Fraenza F, Cagnotta C, Gaio M, Sportiello L, Scavone C, Capuano A, et al. Disproportionality analysis of European safety reports on autoimmune and rheumatic diseases following COVID-19 vaccination. *Sci Rep*. 2025;15(1):14740.
146. Frankenthal D, Zatlawi M, Karni-Efrati Z, Keinan-Boker L, Glatman-Freedman A, Bromberg M. Evaluation of adverse events and comorbidity exacerbation following the COVID-19 booster dose: A national survey among randomly-selected booster recipients. *PLoS One*. 2025;20(7):e0326231.
147. Frutos AM, Price AM, Harker E, Reeves EL, Ahmad HM, Murugan V, et al. Interim estimates of 2023-24 seasonal influenza vaccine effectiveness - United States. *MMWR Morb Mortal Wkly Rep*. 2024;73(8):168–74.
148. Frutos AM, Cleary S, Reeves EL, Ahmad HM, Price AM, Self WH, et al. Interim estimates of 2024-2025 seasonal influenza vaccine effectiveness - four vaccine effectiveness networks, United States, October 2024-February 2025. *MMWR Morb Mortal Wkly Rep*. 2025;74(6):83–90.
149. Fry SE, Terebuh P, Kaelber DC, Xu R, Davis PB. Effectiveness and safety of respiratory syncytial virus vaccine for US adults aged 60 years or older. *JAMA Netw Open*. 2025;8(5):e258322.
150. Gaddh M, Scott D, Wysokinski WE, McBane RD, Casanegra AI, Baumann Kreuziger L, et al. Comparison of Venous Thromboembolism Outcomes after COVID-19 and Influenza Vaccinations. *TH Open*. 2023;7(4):E303–8.
151. Gallagher TJ, Parikh M, Herrera K, Lin ME, Hur K. Association of COVID-19 Vaccination With Changes in Smell and Taste. *Otolaryngol Head Neck Surg*. 2024;171(4):1240–4.
152. Ganelin-Cohen E, Buxbaum C, Bosak N, Sobol S, Vaknin-Dembinsky A, Hellmann MA, et al. The effect of COVID-19 vaccination on multiple sclerosis activity as reflected by MRI. *Brain Behav*. 2024;14(7):e3587.
153. Gao Y, Yang X, Li X, Chen H, Li Y, Tan X, et al. Lot-to-lot consistency, immunogenicity and safety of a quadrivalent split virion inactivated influenza vaccine in healthy population aged 9-59 years: a randomized, double-blind, controlled, phase IV clinical trial. *Vaccine*. 2024;42(21):126182.
154. Gào X, Sun Y, Shen P, Guo J, Chen Y, Yin Y, et al. Population-Based Influenza Vaccine Effectiveness Against Laboratory-Confirmed Influenza Infection in Southern China, 2023-2024 Season. *Open Forum Infectious Diseases*. 2024;11(9).
155. Garrett N, Tapley A, Hudson A, Dadabhai S, Zhang B, Mgodini NM, et al. Hybrid versus vaccine immunity of mRNA-1273 among people living with HIV in East and Southern Africa: a prospective cohort analysis from the multicentre CoVPN 3008 (Ubuntu) study. *EClinicalMedicine*. 2025;80:103054.

156. Gentile A, Juárez MDV, Lucion MF, Gregorio G, López O, Fernández T, et al. Maternal immunization with RSVpreF vaccine: effectiveness in preventing respiratory syncytial virus-associated hospitalizations in infants under 6 months in Argentina: multicenter case-control study. *Pediatr Infect Dis J*. 2025;44(10):988–94.
157. Getahun D, Liu IA, Sy LS, Glanz JM, Zerbo O, Vazquez-Benitez G, et al. Safety of the seasonal influenza vaccine in 2 successive pregnancies. *JAMA Netw Open*. 2024;7(9):e2434857.
158. Gharpure R, Regan AK, Nogareda F, Cheng AC, Blyth CC, George SS, et al. Effectiveness of 2023 southern hemisphere influenza vaccines against severe influenza-associated illness: pooled estimates from eight countries using the test-negative design. *Lancet Glob Health*. 2025;13(2):e203–11.
159. Giang E, Xu Y, Naganathan T, Abraham N, Bawolak MT, Salim BS, et al. Canadian vaccine safety surveillance reports following immunization with seasonal influenza vaccines, 2021–2022. *Can Commun Dis Rep*. 2024;50(1–2):16–24.
160. Giovanetti M, Ali S, Slavov SN, Azarian T, Cella E. Epidemiological Transitions in Influenza Dynamics in the United States: Insights from Recent Pandemic Challenges. *Microorganisms*. 2025;13(3).
161. Gligorov M, Lebrun-Vignes B, Masmoudi K, Vial T, Junot H, Pourcher V, et al. Vaccines and the risk of Guillain-Barré syndrome: A French pharmacovigilance analysis. *Thérapie*. 2025;
162. Göbel CH, Heinze A, Heinze-Kuhn K, Karstedt S, Morscheck M, Tashiro L, et al. Comparison of Phenotypes of Headaches After COVID-19 Vaccinations Differentiated According to the Vaccine Used. *Vaccines (Basel)*. 2025;13(2).
163. Gonen T, Barda N, Asraf K, Joseph G, Weiss-Ottolenghi Y, Doolman R, et al. Immunogenicity and Reactogenicity of Coadministration of COVID-19 and Influenza Vaccines. *JAMA Netw Open*. 2023;6(9):e2332813.
164. Goodyear CS, Patel A, Barnes E, Willicombe M, Siebert S, de Silva TI, et al. Immunogenicity of third dose COVID-19 vaccine strategies in patients who are immunocompromised with suboptimal immunity following two doses (OCTAVE-DUO): an open-label, multicentre, randomised, controlled, phase 3 trial. *Lancet Rheumatol*. 2024;6(6):e339–51.
165. Gordon ER, Adeuyan O, Kwinta BD, Schreidah CM, Fahmy LM, Queen D, et al. Exploring cutaneous lymphoproliferative disorders in the wake of COVID-19 vaccination. *Skin Health Dis*. 2024;4(3):e367.
166. Goswami J, Cardona JF, Hsu DC, Simorellis AK, Wilson L, Dhar R, et al. Safety and immunogenicity of mRNA-1345 RSV vaccine coadministered with an influenza or COVID-19 vaccine in adults aged 50 years or older: an observer-blinded, placebo-controlled, randomised, phase 3 trial. *Lancet Infect Dis*. 2025;25(4):411–23.
167. Granja López J, Estebas Armas C, Lorenzo Dieguez M, Puertas Muñoz I, De Celis Ruiz E, Rigual R, et al. Neurological manifestations of immune origin after COVID-19 vaccination: retrospective case study. *Frontiers in Pharmacology*. 2024;15.

168. Grieshaber V, Strumann C, Holzwarth S, Toepfner N, von Meißner WCG, Konstantopoulos N, et al. The Long-Term Tolerability of BNT162b2 in Children and Adolescents (the CoVacU18 Study). *Dtsch Arztebl Int.* 2025;122(10):257–63.
169. Grima AA, Kwong JC, Richard L, Reid J, Raphael J, Basta NE, et al. The safety of seasonal influenza vaccination among adults prescribed immune checkpoint inhibitors: A self-controlled case series study using administrative data. *Vaccine.* 2024;42(7):1498–505.
170. Grimaldi L, Papeix C, Hamon Y, Buchard A, Moride Y, Benichou J, et al. Vaccines and the Risk of Hospitalization for Multiple Sclerosis Flare-Ups. *JAMA Neurol.* 2023;80(10):1098–104.
171. Grisanti SG, Garbarino S, Bellucci M, Schenone C, Candiani V, Di Lillo S, et al. Neurological long COVID in the outpatient clinic: Is it so long? *Eur J Neurol.* 2025;32(3):e16510.
172. Guerrero-Del-Cueto F, Lobato-Lopez S, Lozano-Duran D, Sanchez-Duran B, Ramirez-Martin L, Esteban-San-Narciso B, et al. Assessing the impact of nirsevimab immunization on RSV bronchiolitis hospital admissions and their severity: a case-control study and comparison with pre- and post-COVID-19 seasons in a tertiary pediatric hospital. *Pediatr Pulmonol.* 2025;60(7):e71059.
173. Hall C, Lanning J, Romano CJ, Bukowinski AT, Gumbs GR, Conlin AMS. COVID-19 vaccine initiation in pregnancy and risk for adverse neonatal outcomes among United States military service members, January-December 2021. *Vaccine.* 2025;51:126894.
174. Hammam N, Mosad D, Ibrahim AM, Abdel-Fattah YH, Aly HM, El-Saadany HM, et al. Safety of COVID-19 Vaccination in Patients with Rheumatic and Musculoskeletal Diseases: A Cross-sectional Study in Egypt. *Oman Medical Journal.* 2024;39(5).
175. Hashimoto Y, Iwagami M, Yamana H, Ono S, Takeuchi Y, Michihata N, et al. Ocular Adverse Events After Influenza Vaccination in Older Adults: Self-Controlled Case Series Using a Large Database in Japan. *Ophthalmic Epidemiol.* 2024;31(5):448–53.
176. Havers FP, Whitaker M, Chatwani B, Patton ME, Taylor CA, Chai SJ, et al. COVID-19-Associated Hospitalizations and Maternal Vaccination Among Infants Aged <6 Months - COVID-NET, 12 States, October 2022-April 2024. *MMWR Morb Mortal Wkly Rep.* 2024;73(38):830–6.
177. Havlin J, Skotnicova A, Dvorackova E, Palavandishvili N, Smetanova J, Svorcova M, et al. Respiratory syncytial virus prefusion F3 vaccine in lung transplant recipients elicits CD4+ T cell response in all vaccinees. *Am J Transplant.* 2025;25(7):1452–60.
178. Hikichi H, Fujioka Y, Saga A, Watanabe K, Hasegawa R, Moritoki Y, et al. Comparison of Transient and Persistent Adverse Events After COVID-19 Vaccination: A Retrospective Analysis. *Cureus.* 2024;16(6):e63410.
179. Holzwarth S, Saadat K, Jorczyk M, Dreßen S, Kotsias-Konopelska S, Schlegtendal A, et al. PaedVacCOVID - safety of the BNT162b2 vaccine against the SARS-CoV-2 in children with and without comorbidities aged 5 to 11 years. *Infection.* 2025;53(2):615–24.

180. Hospital Español de Pachuca Research Group, Licona-Menéndez RD, Peón AN. Anti-COVID-19 Vaccination Alters the Menstrual Cycle and Dose Accumulation Enhances the Effect. *Medicina (Kaunas)*. 2024;60(6).
181. Hsiao A, Yee A, Izikson R, Fireman B, Hansen J, Lewis N, et al. Safety of quadrivalent recombinant influenza vaccine in pregnant persons and their infants. *AJOG Global Reports*. 2024;4(4).
182. (a) Huang PC, Chen CH, Chien CH, Chen CH, Chen CY. Reactive Axillary Lymphadenopathy Among Different COVID-19 Vaccines: A Retrospective Study in Breast Sonography. *International Journal of Breast Cancer*. 2025;2025(1).
183. (b) Huang L, Li G, Zhang Y, Zhao X, Wang K, Jia C, et al. The Safety and Immunogenicity of a Quadrivalent Influenza Subunit Vaccine in Healthy Children Aged 6–35 Months: A Randomized, Blinded and Positive-Controlled Phase III Clinical Trial. *Vaccines*. 2025;13(5).
184. (a) Hwang HS, Lee H, Yoon SY, Kim JS, Jeong K, Kronbichler A, et al. Global burden of vaccine-associated kidney injury using an international pharmacovigilance database. *Sci Rep*. 2025;15(1):5177.
185. (b) Hwang S, Kang SW, Choi J, Park KA, Lim DH, Shin JY, et al. COVID-19 Vaccination and Ocular Adverse Events: A Self-Controlled Case Series Study From the Entire South Korean Population. *Am J Ophthalmol*. 2025;269:69–77.
186. Ioannou GN, Berry K, Rajeevan N, Li Y, Yan L, Huang Y, et al. Effectiveness of the 2023-to-2024 XBB.1.5 COVID-19 Vaccines Over Long-Term Follow-up : A Target Trial Emulation. *Ann Intern Med*. 2025;178(3):348–59.
187. Ip S, North TL, Torabi F, Li Y, Abbasizanjani H, Akbari A, et al. Cohort study of cardiovascular safety of different COVID-19 vaccination doses among 46 million adults in England. *Nat Commun*. 2024;15(1):6085.
188. Ip YMB, Pang S, Yao A, Lau L, Miu A, Chiu K, et al. COVID-19 vaccination and cerebral small vessel disease progression-A prospective cohort study. *Int J Infect Dis*. 2025;151:107324.
189. Ison MG, Papi A, Athan E, Feldman RG, Langley JM, Lee DG, et al. Efficacy, safety, and immunogenicity of the AS01(E)-adjuvanted respiratory syncytial virus prefusion F protein vaccine (RSVPreF3 OA) in older adults over three respiratory syncytial virus seasons (AReSVi-006): a multicentre, randomised, observer-blinded, placebo-controlled, phase 3 trial. *Lancet Respir Med*. 2025;13(6):517–29.
190. Itamochi M, Yazawa S, Saga Y, Shimada T, Tamura K, Maenishi E, et al. COVID-19 mRNA booster vaccination induces robust antibody responses but few adverse events among SARS-CoV-2 naïve nursing home residents. *Sci Rep*. 2024;14(1):23295.
191. Ito S, Tsuchida N, Kusunoki S, Kaneko Y, Naito T, Hori S, et al. Safety comparison between Pfizer BNT162b2, Moderna mRNA-1273, and AstraZeneca AZD1222 in a Nationwide prospective cohort survey at the beginning of the severe acute respiratory syndrome coronavirus 2 vaccination in Japan. *Vaccine*. 2025;49:126754.

192. Jabagi MJ, Cohen J, Bertrand M, Chalumeau M, Zureik M. Nirsevimab Effectiveness at Preventing RSV-Related Hospitalization in Infants. *NEJM Evid.* 2025 Mar;4(3):EVIDoa2400275.
193. Jaffry M, Aftab OM, Mostafa FB, Faiz I, Jaffry K, Mandava K, et al. Optic Neuritis After COVID-19 Vaccination: An Analysis of the Vaccine Adverse Event Reporting System. *J Neuroophthalmol.* 2023;43(4):499–503.
194. Jain SS, Anderson SA, Steele JM, Wilson HC, Muniz JC, Soslow JH, et al. Cardiac manifestations and outcomes of COVID-19 vaccine-associated myocarditis in the young in the USA: longitudinal results from the Myocarditis After COVID Vaccination (MACiV) multicenter study. *eClinicalMedicine.* 2024;76.
195. Jajou R, Lieber T, van Puijenbroek EP, Mulder E, Overbeek J, Hek K, et al. GP consultations for menstrual disorders after COVID-19 vaccination - A self-controlled cohort study based on routine healthcare data from the Netherlands. *Vaccine.* 2024;42(25):126130.
196. Jajou R, van Puijenbroek EP, Veldkamp R, Overbeek JA, van Hunsel F, Kant AC. General practitioner consultation for postmenopausal bleeding after COVID-19 vaccination-a self-controlled cohort study. *Br J Clin Pharmacol.* 2025;
197. Jarrot PA, Mirouse A, Ottaviani S, Cadiou S, Salmon JH, Liozon E, et al. Polymyalgia rheumatica and giant cell arteritis following COVID-19 vaccination: Results from a nationwide survey. *Hum Vaccin Immunother.* 2024;20(1):2334084.
198. (a) Jeong YD, Park S, Lee S, Jang W, Park J, Lee K, et al. Global burden of vaccine-associated Guillain-Barré syndrome over 170 countries from 1967 to 2023. *Sci Rep.* 2024;14(1):24561.
199. (b) Jeong YD, Lee K, Lee S, Park J, Kim HJ, Lee J, et al. Global and regional burden of vaccine-associated facial paralysis, 1967-2023: Findings from the WHO international pharmacovigilance database. *J Med Virol.* 2024;96(6):e29682.
200. (a) Jeong J, Kim H, Jo H, Park J, Cho J, Lee H, et al. Global burden of vaccine-associated Raynaud's phenomenon, 1968-2024: A comprehensive analysis of the pharmacovigilance database. *Eur J Clin Pharmacol.* 2025;
201. (b) Jeong J, Jo H, Son Y, Park J, Oh J, Lee S, et al. Global and regional estimates of vaccine-associated herpes zoster and their related vaccines from 1969 to 2023. *Sci Rep.* 2025;15(1):13285.
202. (c) Jeong YD, Jo H, Yim Y, Lee S, Park J, Lee J, et al. Global estimates of vaccine-associated narcolepsy from 1967 to 2023. *Sci Rep.* 2025;15(1):21331.
203. Jęśkowiak-Kossakowska I, Nowotarska P, Grosman-Dziewiszek P, Szelać A, Wiatrak B. Impact of Comorbidities and Skin Diseases on Post-Vaccination Reactions: A Study on COVID-19 Vaccinations in Poland. *Journal of Clinical Medicine.* 2024;13(20).
204. Jiang Y, Sun J, Huang F, Xie X, Wang X, Wu X, et al. Influenza vaccine effectiveness among primary and secondary school students in Shenzhen during the 2023/24 influenza season. *Emerg Microbes Infect.* 2025;14(1):2490531.

205. Jimeno Ruiz S, Peláez A, Labourt A, Acuña FM, Linares L, Llana Martín I, et al. Evaluating the Effectiveness of Nirsevimab in Reducing Pediatric RSV Hospitalizations in Spain. *Vaccines (Basel)*. 2024 Oct 11;12(10).
206. Jin Hsieh TY, Cheng-Chung Wei J, Collier AR. Investigation of maternal outcomes following respiratory syncytial virus vaccination in the third trimester: insights from a real-world U.S. electronic health records database. *Am J Obstet Gynecol*. 2025;S0002-9378(25):00298–4.
207. Jirawattanadon P, Leeyaphan C, Koomanachai P, Pudchakan P, Bunyaratavej S, Kulthanan K, et al. Clinical presentation, associated factors, and course of cutaneous reaction after the booster dose of COVID-19 vaccination. *Clinical and Experimental Vaccine Research*. 2024;13(4):309–14.
208. Jobe NB, Rose E, Winn AK, Goldstein L, Schneider ZD, Silk BJ. Human Metapneumovirus Seasonality and Co-Circulation with Respiratory Syncytial Virus - United States, 2014-2024. *MMWR Morb Mortal Wkly Rep*. 2025;74(11):182–7.
209. Jorda A, Prager M, Pracher L, Haselwanter P, Jackwerth M, Al Jalali V, et al. Immunogenicity, safety, and reactogenicity of concomitant administration of the novavax vaccine against Omicron XBB.1.5 (NVX-CoV2601) and a 20-valent pneumococcal conjugate vaccine in adults aged ≥60 years: A randomised, double-blind, placebo-controlled, non-inferiority trial. *J Infect*. 2025;90(2):106405.
210. Jorgensen SCJ, Drover SSM, Fell DB, Austin PC, D'Souza R, Guttmann A, et al. Association between maternal mRNA covid-19 vaccination in early pregnancy and major congenital anomalies in offspring: population based cohort study with sibling matched analysis. *BMJ Med*. 2024;3(1):e000743.
211. Jung SW, Jeon JJ, Kim YH, Choe SJ, Lee S. Long-term risk of autoimmune diseases after mRNA-based SARS-CoV2 vaccination in a Korean, nationwide, population-based cohort study. *Nat Commun*. 2024;15(1):6181.
212. Kálin T, Passarin K, Filipowicz-Sinnreich M, Semela D, Seifert T, Sallusto F, et al. SARS-CoV-2 mRNA vaccines do not worsen autoimmunity in patients with autoimmune liver diseases. *J Autoimmun*. 2024;149:103325.
213. Kang J, Park J, Jo H, Lee H, Lee K, Kim S, et al. Global Burden of Vaccine-Associated Chronic Urticaria, 2010-2023: From the Global Pharmacovigilance Database. *Allergy Asthma Immunol Res*. 2024;16(6):613–25.
214. Karam R, Iskandar K, Watfa M, Zeitoun A. Serious adverse events following immunization with COVID-19 vaccines in Lebanon: a retrospective analysis of the National Pharmacovigilance Database. *BMC Public Health*. 2024;24(1):2905.
215. Katatbeh MA, Al-Mashakbeh Y, Freihat H, Gharam H, Mohammad R, Aldalki R, et al. Incidence of narcolepsy symptoms after taking COVID-19 vaccines: a Jordanian cross-sectional study. *Clinical and Experimental Vaccine Research*. 2024;13(3):218–24.
216. Kawai N, Ikematsu H, Bando T, Lee WJ, Matsuura S, Tetsunari M, et al. Comparison of adverse reactions to COVID-19 XBB.1.5 and influenza vaccination in the 2023-24 Japanese influenza season. *J Infect Chemother*. 2025;31(8):102728.

217. Kern M, Hamm SR, Pedersen CR, Møller DL, Loft JA, Hasselbalch RB, et al. Leukocyte Count in Solid Organ Transplant Recipients After SARS-CoV-2 mRNA Vaccination and Infection. *Vaccines*. 2025;13(2).
218. Khalid MB, Zektser E, Chu E, Li M, Utoh J, Ryan P, et al. A randomized double-blinded trial to assess recurrence of systemic allergic reactions following COVID-19 mRNA vaccination. *J Allergy Clin Immunol*. 2024;153(6):1634–46.
219. Kikuchi J, Kondo Y, Kojima S, Kasai S, Sakai Y, Takeshita M, et al. Risk of disease flares after SARS-CoV-2 mRNA vaccination in patients with systemic lupus erythematosus. *Immunol Med*. 2024;47(2):76–84.
220. Kim J, Kwon HY, Ahn SJ. COVID-19 Vaccine-Associated Uveitis in Patients With a History of Uveitis. *JAMA Ophthalmol*. 2024;142(6):522–8.
221. (a) Kim Y, Han K, Kim JH. Retinal Vascular Occlusions After COVID-19 Vaccination in South Korea: A Nation-Wide Population-Based Study. *Ophthalmic Epidemiol*. 2025;32(4):403–11.
222. (b) Kim S, Ko HY, Oh J, Yoon D, Kim JH, Choe YJ, et al. Risk of Kawasaki Disease/Multisystem Inflammatory Syndrome Following COVID-19 Vaccination in Korean Children: A Self-Controlled Case Series Study. *J Korean Med Sci*. 2025;40(3):e10.
223. (c) Kim K, Bolormaa E, Gwak E, Shin JY, Choi NK, Choe YJ, et al. Maternal exposures to COVID-19 vaccine and adverse birth outcomes: national population study in Korea. *J Korean Med Sci*. 2025;40(17):e63.
224. Kirwan PD, Foulkes S, Munro K, Sparkes D, Singh J, Henry A, et al. Protection of vaccine boosters and prior infection against mild/asymptomatic and moderate COVID-19 infection in the UK SIREN healthcare worker cohort: October 2023 to March 2024. *J Infect*. 2024;89(5):106293.
225. Kissling E, Maurel M, Pozo F, Pérez-Gimeno G, Buda S, Sève N, et al. Influenza vaccine effectiveness in Europe and the birth cohort effect against influenza A(H1N1)pdm09: VEBIS primary care multicentre study, 2023/24. *Euro Surveill*. 2025;30(23).
226. Ko M, Kim S, Choi SK, Shin SH, Lee YK, Kwon Y. Comparative safety of monovalent and bivalent mRNA COVID-19 booster vaccines in adolescents aged 12 to 17 years in the Republic of Korea. *Osong Public Health and Research Perspectives*. 2024;15(4):364–74.
227. Ko HY, Yoon D, Kim JH, Jeong HE, Hong SB, Shin WC, et al. Risk of new-onset seizures following immunization against COVID-19: a self-controlled case-series study. *Epidemiol Health*. 2025;e2025024.
228. Konishi A, Fukushima W, Matsuura T, Ohfuji S, Kase T, Kondo K, et al. Adverse reactions following first three doses of the BNT162b2 mRNA COVID-19 vaccine: A prospective cohort study on relationships with individual characteristics and previous experience of adverse reactions. *Hum Vaccin Immunother*. 2025;21(1):2518646.
229. Kothari K, Shah S, Gill VK, Ray RK, Kumar NR, Sanmukhani J, et al. A prospective, randomized, parallel, active controlled, phase III Indian study of immunogenicity and safety of

two inactivated influenza vaccines - Vaxiflu-4 and Fluarix tetra in children aged 6 months to 35 months. *Hum Vaccin Immunother.* 2024;20(1):2416329.

230. Kumar A, Miller DC, Sun Y, Arnold BF, Acharya NR. Risk of Recurrent Noninfectious Uveitis After Coronavirus Disease 2019 Vaccination in the United States. *Ophthalmol Sci.* 2024;4(4):100474.

231. Kurucu N, Kutluk T, Kartal İ, Yeşil Ş, Vural Ö, Dinçer OS, et al. Safety and efficacy of COVID-19 vaccines in children and adolescents with cancer. *Turk J Pediatr.* 2024;66(4):412–20.

232. Kwaah B, DeMarcus LS, Thervil JW, Jenkins WN, Gruner WE, Hartless TR, et al. Mid-season vaccine effectiveness estimates for influenza: the Department of Defense Global Respiratory Pathogen Surveillance Program, 2024-2025 season. *Msmr.* 2025;32(5):42–3.

233. Kyung S, Rahmati M, Kang J, Lee K, Lee H, Yon DK. Global and Regional Burden of Vaccine-Associated Erythema Multiforme and Their Related Vaccines, 1967-2023: An In-Depth Analysis of the World Health Organization Pharmacovigilance Database. *Med Princ Pract.* 2025;34(1):25–38.

234. LaVerriere E, Behar S, Sher-Jan C, Liang YM, Sagar M, Connor JH. Genomic Epidemiology of Respiratory Syncytial Virus in a New England Hospital System, 2024. 2025;

235. Lacroix I, Caillet A, Delteil L, Ameur H, Padelli N, Hurault-Delarue C, et al. COVACPREG, a French prospective cohort study of women vaccinated against COVID-19 during pregnancy. *Therapie.* 2025;80(3):271–8.

236. Lafleur B, Fung J, Verschoor CP, Dubois S, MacDonald NE, Taddio A. Omission of alcohol skin cleansing and risk of adverse events in long-term care residents undergoing COVID-19 vaccination: A cohort study. *Hum Vaccin Immunother.* 2024;20(1):2368681.

237. Lambo J, Keli S, Kaplan SK, Njideaka-Kevin T, Arja SB, Khedir Omer Altahir A, et al. The descriptive epidemiology of adverse events following two doses of mRNA COVID-19 vaccination in Curaçao, the Caribbean. *Infect Dis (Lond).* 2025;57(2):137–49.

238. Laniece Delaunay C, Verdasca N, Monge S, Domegan L, Sève N, Buda S, et al. COVID-19 Vaccine Effectiveness Against Medically Attended Symptomatic SARS-CoV-2 Infection Among Target Groups in Europe, October 2024-January 2025, VEBIS Primary Care Network. *Influenza Other Respir Viruses.* 2025;19(5):e70120.

239. Lauring AS, Edson C, Surie D, Dawood FS, Self WH, Lucero-Obusan C, et al. Genomic Characterization of RSV in the US by Vaccination Status. *Jama.* 2025;333(17):1540–3.

240. Lee MT, Lee JW, Lee HJ, Lee JM, Choi JC, Gu KM, et al. Interstitial lung disease following COVID-19 vaccination: a disproportionality analysis using the Global Scale Pharmacovigilance Database (VigiBase). *BMJ Open Respir Res.* 2023;10(1).

241. (a) Lee K, Lee H, Kwon R, Shin YH, Yeo SG, Lee YJ, et al. Global burden of vaccine-associated anaphylaxis and their related vaccines, 1967-2023: A comprehensive analysis of the international pharmacovigilance database. *Allergy.* 2024;79(3):690–701.

242. (b) Lee S, Jo H, Lee H, Lee H, Lee J, Kim HJ, et al. Global estimates on the reports of vaccine-associated myocarditis and pericarditis from 1969 to 2023: Findings with critical reanalysis from the WHO pharmacovigilance database. *J Med Virol*. 2024;96(6):e29693.
243. (c) Lee SL, Kwan MYW, Murphy C, Chan ELY, Wong JSC, Sullivan SG, et al. Influenza vaccine effectiveness against influenza-associated hospitalizations in children, Hong Kong, November 2023 to June 2024. *Vaccine: X*. 2024;20.
244. (d) Lee N, Kim KH, Park JH, Cho JY, Cho SH, Kim DK, et al. COVID-19 Vaccination-Related Pericarditis: A Korean Nationwide Study. *Mayo Clin Proc*. 2024;99(10):1577–88.
245. (a) Lee JE, Jo H, Cho H, Oh J, Jeong YD, Lee S, et al. Global and Regional Burden of Vaccine-Associated Transverse Myelitis and Potentially Associated With Vaccines From 1967 to 2023: An Analysis of the International Pharmacovigilance Data. *J Med Virol*. 2025;97(6):e70408.
246. (b) Lee N, Nguyen L, Nasreen S, Austin PC, Brown KA, Buchan SA, et al. Limited durability of protection conferred by XBB.1.5 vaccines against omicron-associated severe outcomes among community-dwelling adults, Ontario, Canada. *Vaccine*. 2025;60:127300.
247. (c) Lee JJY, Bernatsky S, Benchimol EI, Kwong JC, Li Q, Yeung RSM, et al. Safety and health care utilization following COVID-19 vaccination (BNT162b2) among children and youth with juvenile idiopathic arthritis and inflammatory bowel disease: A population-based study. *PAEDIATRICS & CHILD HEALTH*. 2025;
248. (d) Lee H, Yoon D, Kim JH, Noh Y, Joo EJ, Han JY, et al. Association of influenza vaccination during pregnancy with health outcomes in mothers and children: a population-based cohort study. *Clin Pharmacol Ther*. 2025;117(5):1381–92.
249. Lefferts B, Bressler S, Keck JW, Desnoyers C, Hodges E, January G, et al. Nirsevimab effectiveness against medically attended respiratory syncytial virus illness and hospitalization among Alaska native children - Yukon-Kuskokwim Delta region, Alaska, October 2023-June 2024. *MMWR Morb Mortal Wkly Rep*. 2024;73(45):1015–21.
250. Lei H, Niu B, Sun Z, Wang Y, Che X, Du S, et al. Influenza vaccine effectiveness against medically-attended influenza infection in 2023/24 season in Hangzhou, China. *Hum Vaccin Immunother*. 2025;21(1):2435156.
251. Leung WCY, Ho RWH, Leung AKL, Chu FHN, Lo CNR, Chan AA, et al. Risk of Seizure Aggravation after COVID-19 Vaccinations in Patients with Epilepsy. *Vaccines*. 2024;12(6).
252. LeVu S, Bertrand M, Botton J, Jabagi MJ, Drouin J, Semenzato L, et al. Risk of Guillain-Barré syndrome following COVID-19 vaccines: a nationwide self-controlled case series study. *Neurology*. 2023;101(21):e2094–102.
253. LeVu S, Bertrand M, Semenzato L, Jabagi MJ, Botton J, Drouin J, et al. Influence of mRNA Covid-19 vaccine dosing interval on the risk of myocarditis. *Nat Commun*. 2024;15(1):7745.
254. Levy ME, Chilunda V, Davis RE, Heaton PR, Pawloski PA, Goldman JD, et al. Reduced Likelihood of Hospitalization With the JN.1 or HV.1 Severe Acute Respiratory Syndrome Coronavirus 2 Variants Compared With the EG.5 Variant. *J Infect Dis*. 2024;230(5):1197–201.

255. (a) Levy ME, Chilunda V, Heaton PR, McKeen D, Goldman JD, Davis RE, et al. XBB.1.5 mRNA COVID-19 vaccine protection against inpatient or emergency department visits among adults infected with SARS-CoV-2 JN.1 and XBB-lineage variants. *Front Immunol*. 2025;16:1470609.
256. (b) Levy L, Yahav D, Benzmira M, Bezalel Y, Hoffman T, Shirin N, et al. Neutralizing Antibody Response to the AreXvy Respiratory Syncytial Virus Vaccine in Lung Transplant Recipients: Assessment Against Reference and Seasonal Strains. *Vaccines*. 2025;13(4).
257. Lewis NM, Harker EJ, Cleary S, Zhu Y, Grijalva CG, Chappell JD, et al. Vaccine effectiveness against influenza A(H1N1), A(H3N2), and B-associated hospitalizations-United States, September 1, 2023-May 31, 2024. *J Infect Dis*. 2025;jiaf185.
258. Lewnard JA, Mahale P, Malden D, Hong V, Ackerson BK, Lewin BJ, et al. Immune escape and attenuated severity associated with the SARS-CoV-2 BA.2.86/JN.1 lineage. *Nat Commun*. 2024;15(1):8550.
259. (a) Li X, Kou Z, Liu T, An W, An W, Zhang W, et al. Exploratory Study of the Phase IV Immunization Schedule of Quadrivalent Influenza Split-Virion Vaccine in Children Aged 3–8 Years. *Vaccines*. 2024;12(3).
260. (b) Li Y, Li J, Dang Y, Chen Y, Tao C. Adverse Events of COVID-19 Vaccines in the United States: Temporal and Spatial Analysis. *JMIR Public Health Surveill*. 2024;10:e51007.
261. (a) Li Y, Xia H, Zhang H, Lu Y, Zhou H, Yu R, et al. The safety of co-administration of recombinant zoster vaccine (Shingrix) and influenza vaccines in the elderly in VAERS during 2018-2024. *Hum Vaccin Immunother*. 2025;21(1):2525603.
262. (b) Li J, Zhang Z, Wang M. Post-licensure safety of respiratory syncytial virus vaccines, Vaccine Adverse Event Reporting System, United States, May 2023-December 2024. *Prev Med Rep*. 2025;56:103150.
263. (a) Lim QY, Lau TM, Lai SHY, Chua GT, Zhang K, Lam JHY, et al. Outcomes of pediatric patients with suspected allergies to COVID-19 vaccines. *J Allergy Clin Immunol Glob*. 2025;4(1):100387.
264. (b) Lim E, Kim YH, Jeong NY, Kim SH, Won H, Bae JS, et al. The association between acute transverse myelitis and COVID-19 vaccination in Korea: Self-controlled case series study. *Eur J Neurol*. 2025;32(1):e70020.
265. Lin TH, Keowmani T, Moon TM. Risk Factors Associated with Cutaneous Reactions Following COVID-19 Vaccine Immunisation: A Registry-Based Case-Control Study. *Malaysian Journal of Medical Sciences*. 2024;31(3):133–48.
266. Link-Gelles R, Rowley EAK, DeSilva MB, Dascomb K, Irving SA, Klein NP, et al. Interim effectiveness of updated 2023-2024 (Monovalent XBB.1.5) COVID-19 vaccines against COVID-19-associated hospitalization among adults aged ≥18 years with immunocompromising conditions - VISION network, September 2023-February 2024. *MMWR Morb Mortal Wkly Rep*. 2024;73(12):271–6.

267. (a) Link-Gelles R, Chickery S, Webber A, Ong TC, Rowley EAK, DeSilva MB, et al. Interim estimates of 2024-2025 COVID-19 vaccine effectiveness among adults aged ≥ 18 years - VISION and IVY networks, September 2024-January 2025. *MMWR Morb Mortal Wkly Rep*. 2025;74(6):73–82.
268. (b) Link-Gelles R, Rowley EAK, Irving SA, Klein NP, Grannis SJ, Ong TC, et al. Estimated 2023-2024 COVID-19 vaccine effectiveness in adults. *JAMA Netw Open*. 2025;8(6):e2517402.
269. Liu Y, He J, Zhou X, Wu Y, Cai H, Sun Y, et al. Analysis of new-onset seizures following use of COVID-19 vaccinations in children based on VAERS. *Expert Opin Drug Saf*. 2025;24(2):177–82.
270. (a) Lloyd PC, Smith ER, Gruber JF, Ondari M, Wong HL, Hu M, et al. Safety monitoring of bivalent COVID-19 mRNA vaccines among recipients 6 months and older in the United States. *Pharmacoepidemiol Drug Saf*. 2025;34(5):e70151.
271. (b) Lloyd PC, Acharya G, Zhao H, Shah N, Anguzu G, Ambarsoomzadeh D, et al. Safety monitoring of health outcomes following influenza vaccination during the 2023-2024 season among U.S. Medicare beneficiaries aged 65 years and older. *Vaccine*. 2025;53:127069.
272. López de Las Huertas AG, Stewart S, Elizalde MU, Guijarro-Eguinoa J, Seco-Meseguer E, Diago-Sempere E, et al. Disproportionality Analysis of the Five Most Widespread Neurological Effects of COVID-19 Vaccines from 2021 to 2023: Insights from EudraVigilance. *Pharmaceuticals (Basel)*. 2025;18(5).
273. López-Contreras JE, Paredes-Casillas P, Morales-Romero J, Castillo-Vélez FE, Lona-Reyes JC, Bedolla-Barajas M. Incidence and factors associated with early and late adverse reactions after the first dose of Pfizer-BioNTech vaccine among healthcare workers. *Cirugia y Cirujanos*. 2023;91(1):34–40.
274. Lophatananon A, Carr M, McMillan B, Dobson C, Itzhaki R, Parisi R, et al. The association of herpes zoster and influenza vaccinations with the risk of developing dementia: a population-based cohort study within the UK Clinical Practice Research Datalink. *BMC Public Health*. 2023;23(1):1903.
275. (a) Lu Y, Matuska K, Ma Y, Laniyan L, Chillarige Y, Anderson SA, et al. Stroke after influenza vaccines in older adults in the US, 2016 to 2019. *JAMA Netw Open*. 2024;7(7):e2423926.
276. (b) Lu Y, Matuska K, Nadimpalli G, Ma Y, Duma N, Zhang HT, et al. Stroke Risk After COVID-19 Bivalent Vaccination Among US Older Adults. *Jama*. 2024;331(11):938–50.
277. (c) Lu YA, Huang FY, Chi H, Lin CY, Chiu NC. Preliminary Report of Nationwide COVID-19 Vaccine Compensation in Taiwan. *Healthcare (Basel)*. 2024;12(13).
278. (a) Ma KC, Surie D, Lauring AS, Martin ET, Leis AM, Papalambros L, et al. Effectiveness of updated 2023-2024 (monovalent XBB.1.5) COVID-19 vaccination against SARS-CoV-2 omicron XBB and BA.2.86/JN.1 lineage hospitalization and a comparison of clinical severity-IVY network, 26 hospitals, October 18, 2023-March 9, 2024. *Clin Infect Dis*. 2024 Aug 6;ciae405.

279. (b) Ma KC, Castro J, Lambrou AS, Rose EB, Cook PW, Batra D, et al. Genomic Surveillance for SARS-CoV-2 Variants: Circulation of Omicron XBB and JN.1 Lineages - United States, May 2023-September 2024. *MMWR Morb Mortal Wkly Rep.* 2024;73(42):938–45.
280. Maan R, Lauw MN, China L, Patch D, Baiges A, Garcia-Pagan JC, et al. Extensive splanchnic vein thrombosis after SARS-CoV-2 vaccination: A Vascular Liver Disease Group (VALDIG) initiative. *Hepatology.* 2024;80(5):1147–57.
281. Machado MAA, Gandhi-Banga S, Gallo S, Cousseau TG, Byraredy RM, Nissilä M, et al. Enhanced passive safety surveillance of high-dose and standard-dose quadrivalent inactivated split-virion influenza vaccines in Germany and Finland during the 2022/23 influenza season. *Hum Vaccin Immunother.* 2024;20(1):2322196.
282. Mackenzie LJ, Bousie JA, Newman P, Cunningham J, Woodward AP, Silk-Jones J, et al. What three years of COVID-19 vaccine administration reveals about the incidence of shoulder injury related to vaccine administration (SIRVA). *Vaccine.* 2025;51:126892.
283. Madhi SA, Kampmann B, Simões EAF, Zachariah P, Pahud BA, Radley D, et al. Preterm birth frequency and associated outcomes from the MATISSE (Maternal Immunization Study for Safety and Efficacy) maternal trial of the bivalent respiratory syncytial virus prefusion F protein vaccine. *Obstet Gynecol.* 2025;145(2):147–56.
284. Madni SA, Strickland K, Konrad V, Zauche LH, Olson CK, Sharma AJ. COVID-19 Vaccine Reactogenicity Among Young Children. *JAMA Netw Open.* 2024;7(11):e2447492.
285. (a) Magnus MC, Caspersen IH, Wensaas KA, Eide HN, Örtqvist AK, Oakley L, et al. Covid-19 vaccination and menstrual bleeding disturbances among women of fertile age: a Norwegian registry study. *Eur J Epidemiol.* 2024;39(10):1127–38.
286. (b) Magnus MC, Rasmussen TD, Örtqvist AK, Oakley LL, Urhoj SK, Stephansson O, et al. COVID-19 vaccination during pregnancy is not associated with an increased risk of severe postpartum hemorrhage. *Am J Obstet Gynecol.* 2024;231(3):e99–100.
287. Malange V, Mohaissen T, Conway KM, Rhoads A, Morris JK, Ailes EC, et al. Influenza vaccination during early pregnancy and risk of major birth defects, US birth defects study to evaluate pregnancy exposures, 2014-2019. *Vaccine.* 2025;59:127297.
288. Manniche V, Schmeling M, Gilthorpe JD, Hansen PR. Reports of Batch-Dependent Suspected Adverse Events of the BNT162b2 mRNA COVID-19 Vaccine: Comparison of Results from Denmark and Sweden. *Medicina (Kaunas).* 2024;60(8).
289. Mansou Y, Kumaran M, Farmer G, Kemp K, Usman H, Strong D, et al. Reported Adverse Events Following SARS-CoV-2 Vaccinations in the Canadian Province of Alberta and Associated Risk Factors: A Retrospective Cohort Study. *Vaccines.* 2024;12(12).
290. Mantovani M, Bellavite P, Fazio S, Di Fede G, Tomasi M, Belli D, et al. Autoantibodies Targeting G-Protein-Coupled Receptors and RAS-Related Molecules in Post-Acute COVID Vaccination Syndrome: A Retrospective Case Series Study. *Biomedicines.* 2024;12(12).

291. Mao X, Hua X, Wu C, Ge X, Zhang J, Wu X, et al. A phase I, randomized, placebo-controlled trial to evaluate the pharmacokinetics, safety, and tolerability of nirsevimab in healthy Chinese adults. *Clin Transl Sci*. 2025;18(1):e70095.
292. Marchese AM, Beyhaghi H, Rousculp MD, Huang V, Liu X, Toback S, et al. Local and systemic reactogenicity after mRNA and protein-based COVID-19 vaccines compared to meningococcal vaccine (MenACWY) in a UK blinded, randomized phase 2 trial (COV-BOOST). *Vaccine*. 2025;44:126569.
293. Marouk A, Verrat B, Pontais I, Cojocaru D, Chappuy H, Craiu I, et al. Effectiveness of nirsevimab in reducing hospitalizations in emergency departments due to bronchiolitis among infants under 3 months: a retrospective study. *Eur J Pediatr*. 2025;184(3):229.
294. Marron L, McKenna A, O'Donnell J, Joyce M, Bennett C, Connell J, et al. Influenza vaccine effectiveness against symptomatic influenza in primary care: a test negative case control study over two influenza seasons 2022/2023 and 2023/2024 in Ireland. *Influenza Other Respir Viruses*. 2024;18(12):e70023.
295. Martínez-Baz I, Navascués A, Trobajo-Sanmartín C, Pozo F, Fernández-Huerta M, Olazabal-Arruiz M, et al. Effectiveness of influenza vaccination in preventing confirmed influenza cases and hospitalizations in Northern Spain, 2023/24 season: a population-based test-negative case-control study. *Int J Infect Dis*. 2025;151:107364.
296. Matsuzono K, Mieno M, Mashiko T, Anan Y, Ozawa T, Koide R, et al. Effect of COVID 19 pandemic on the neurology department hospitalization with analysis of the neurological complications secondary to COVID 19 and vaccination against COVID 19. *SAGE Open Medicine*. 2024;12.
297. Maurel M, Howard J, Kissling E, Pozo F, Pérez-Gimeno G, Buda S, et al. Interim 2023/24 influenza A vaccine effectiveness: VEBIS European primary care and hospital multicentre studies, September 2023 to January 2024. *Euro Surveill*. 2024;29(8).
298. Mayer EF, Falsey AR, Clark R, Ferguson M, Cardona J, She F, et al. Safety, Tolerability, and Immunogenicity of mRNA-1345 in Adults at Increased Risk for RSV Disease Aged 18 to 59 Years. *Clin Infect Dis*. 2025;
299. Mazarakis N, Toh ZQ, Neal E, Bright K, Luu S, Quah L, et al. The immunogenicity, reactogenicity, and safety of a bivalent mRNA or protein COVID-19 vaccine given as a fourth dose. *J Infect*. 2025;90(3):106447.
300. McLeod C, Dymock M, Flanagan KL, Plebanski M, Marshall HS, Estcourt MJ, et al. The Platform Trial In COVID-19 priming and BOOsting (PICOBOO): The immunogenicity, reactogenicity, and safety of licensed COVID-19 vaccinations administered as a second booster in BNT162b2 primed individuals aged 18-<50 and 50-<70 years old. *J Infect*. 2024;89(6):106346.
301. Meidani M, Khatami M, Abdollahi A, Mirzapour P, Karimian E, SeyedAlinaghi S. SAFETY AND EFFECTIVENESS OF SINGLE- VERSUS DOUBLE-DOSE OF SEASONAL INFLUENZA VACCINE IN KIDNEY TRANSPLANT RECIPIENTS: A RANDOMIZED CLINICAL TRIAL. *Russian Journal of Infection and Immunity*. 2024;14(1):125–32.

302. Memon D, Dafalla I, Raba AA, Krebit I. Cardiac Investigations in Paediatric Patients with Chest Pain Following COVID-19 mRNA Vaccination. *Ir Med J.* 2024;117(9):1026.
303. Mensah AA, Stowe J, Jardine JE, Kirsebom FCM, Clare T, Kall M, et al. COVID-19 vaccine safety in pregnancy, a nested case-control study in births from April 2021 to March 2022, England. *BJOG.* 2024;131(13):1882–93.
304. Metz TD, Reeder HT, Clifton RG, Flaherman V, Aragon LV, Baucom LC, et al. Post-Acute Sequelae of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) After Infection During Pregnancy. *Obstet Gynecol.* 2024;144(3):411–20.
305. Mi J, Wang J, Chen L, Guo Z, Lei H, Chong MK, et al. Real-world effectiveness of influenza vaccine against medical-attended influenza infection during 2023/24 season in Ili Kazakh autonomous prefecture, China: a test-negative, case-control study. *Hum Vaccin Immunother.* 2024;20(1):2394255.
306. Mohamed S, Elkarim MA, Al-Jaberi SA. Safety of COVID-19 Vaccines in Patients With Multiple Sclerosis: A Cross-Sectional Study From a Tertiary Rehabilitation Center in Saudi Arabia. *Cureus.* 2024;16(12):e75889.
307. Moisset X, Leray E, Chenaf C, Taithe F, Vukusic S, Mulliez A, et al. Risk of Relapse After COVID-19 Vaccination Among Patients With Multiple Sclerosis in France: A Self-Controlled Case Series. *Neurology.* 2024;103(5):e209662.
308. Mok CKP, Tang YS, Tan CW, Chong KC, Chen C, Sun Y, et al. Comparison of safety and immunogenicity in the elderly after receiving either Comirnaty or Spikevax monovalent XBB1.5 COVID-19 vaccine. *J Infect.* 2025;90(1):106374.
309. Moline HL, Toepfer AP, Tannis A, Weinberg GA, Staat MA, Halasa NB, et al. Respiratory syncytial virus disease burden and nirsevimab effectiveness in young children from 2023-2024. *JAMA Pediatr.* 2025;179(2):179–87.
310. Mombelli M, Neofytos D, Huynh-Do U, Sánchez-Céspedes J, Stampf S, Golshayan D, et al. Immunogenicity of High-Dose Versus MF59-Adjuvanted Versus Standard Influenza Vaccine in Solid Organ Transplant Recipients: The Swiss/Spanish Trial in Solid Organ Transplantation on Prevention of Influenza (STOP-FLU Trial). *Clin Infect Dis.* 2024;78(1):48–56.
311. Moon IJ, Lee WJ, Ko HC, Kim H, Na CH, Park J, et al. Cutaneous Manifestations of COVID-19 Vaccination and COVID-19 Infection: a Questionnaire-based, Multi-center Study in Korea. *Journal of Mycology and Infection.* 2024;29(3):117–36.
312. Moor J, Toepfner N, von Meißner WCG, Berner R, Moor MB, Kublickiene K, et al. Sex differences in symptoms following the administration of BNT162b2 mRNA COVID-19 vaccine in children below 5 years of age in Germany (CoVacU5): a retrospective cohort study. *Biol Sex Differ.* 2024;15(1):74.
313. Morciano C, Massari M, Cutillo M, Belleudi V, Trifirò G, Mores N, et al. Acute Appendicitis After COVID-19 Vaccines in Italy: A Self-Controlled Case Series Study. *Drug Saf.* 2024;47(11):1157–69.

314. Moreira Puga MA, Dias de Oliveira R, Vieira da Silva P, Charu V, Hedlin H, Lu D, et al. Immunogenicity and reactogenicity of fractional vs. full booster doses of COVID-19 vaccines: a non-inferiority, randomised, double-blind, phase IV clinical trial in Brazil. *The Lancet Regional Health - Americas*. 2025;44.
315. Moro PL, Ennulat C, Brown H, Woody G, Zhang B, Marquez P, et al. Safety of simultaneous administration of bivalent mRNA COVID-19 and influenza vaccines in the Vaccine Adverse Event Reporting System (VAERS). *Drug Saf*. 2024;47(5):487–93.
316. Moscara L, Venerito V, Martinelli A, Di Lorenzo A, Toro F, Violante F, et al. Safety profile and SARS-CoV-2 breakthrough infections among HCWs receiving anti-SARS-CoV-2 and influenza vaccines simultaneously: an Italian observational study. *Vaccine*. 2023;41(38):5655–61.
317. Moss S, Jurkowicz M, Nemet I, Atari N, Kliker L, Abd-Elkader B, et al. Immunogenicity of co-administered Omicron BA.4/BA.5 bivalent COVID-19 and quadrivalent seasonal influenza vaccines in Israel during the 2022–2023 winter season. *Vaccines*. 2023;11(10).
318. Mukherjee S, Singer T, Venkatesh A, Choudhury NA, Perez Giraldo GS, Jimenez M, et al. Vaccination prior to SARS-CoV-2 infection does not affect the neurologic manifestations of long COVID. *Brain Commun*. 2025;7(1):fcae448.
319. Munro APS, Drysdale SB, Cathie K, Flamein F, Knuf M, Collins AM, et al. 180-day efficacy of nirsevimab against hospitalisation for respiratory syncytial virus lower respiratory tract infections in infants (HARMONIE): a randomised, controlled, phase 3b trial. *Lancet Child Adolesc Health*. 2025;9(6):404–12.
320. Murdoch L, Quan K, Baber JA, Ho AWY, Zhang Y, Xu X, et al. Safety and Immunogenicity of the BNT162b2 Vaccine Coadministered with Seasonal Inactivated Influenza Vaccine in Adults. *Infectious Diseases and Therapy*. 2023;12(9):2241–58.
321. Mutter P, Romem A. Association between influenza vaccine effectiveness and chronic diseases among older adults with dementia. *Sci Rep*. 2025;15(1):24702.
322. Naficy A, Kuxhausen A, Seifert H, Hastie A, Leav B, Miller J, et al. No immunological interference or concerns about safety when seasonal quadrivalent influenza vaccine is co-administered with a COVID-19 mRNA-1273 booster vaccine in adults: a randomized trial. *Hum Vaccin Immunother*. 2024;20(1):2327736.
323. Nakafero G, Grainge MJ, Card T, Mallen CD, Nguyen Van-Tam JS, Abhishek A. Uptake, safety and effectiveness of inactivated influenza vaccine in inflammatory bowel disease: A UK-wide study. *BMJ Open Gastroenterology*. 2024;11(1).
324. Nakashima K, Homma Y, Taniguchi J, Kubota N, Otsuki A, Ito H, et al. Immunogenicity and safety of influenza vaccine in patients with lung cancer receiving immune checkpoint inhibitors: A single-center prospective cohort study. *J Infect Chemother*. 2023;29(11):1038–45.
325. Nakayama T, Hayashi T, Makino K, Oe K. The efficacy and safety of a quadrivalent live attenuated influenza nasal vaccine in Japanese children: A phase 3, randomized, placebo-controlled study. *J Infect Chemother*. 2025;31(2):102460.

326. Namiki T, Takada K, Hayakawa S, Komine-Aizawa S. Comparison of adverse events following the second/third dose of BNT162b2 in a medical institute in Japan. *Heliyon*. 2024;10(14):e34347.
327. Naqid IA. Evaluating the Adverse Effects and Associated Risk Factors of COVID-19 Vaccines Among Healthcare Workers: A Retrospective Study in the Duhok Province, Iraq. *Cureus*. 2024;16(10):e71671.
328. Nasreen S, Jiang Y, Lu H, Lee A, Cutland CL, Gentile A, et al. Risk of Guillain-Barré syndrome after COVID-19 vaccination or SARS-CoV-2 infection: a multinational self-controlled case series study. *Vaccine*. 2025;60:127291.
329. Nazar W, Romantowski J, Niedożytko M, Daniłowicz-Szymanowicz L. Cardiac adverse drug reactions to COVID-19 vaccines. A cross-sectional study based on the Europe-wide data. *Eur Heart J Cardiovasc Pharmacother*. 2024;10(7):599–607.
330. Nazar W, Romantowski J, Nazar G, Niedożytko M, Braun-Dullaeus R, Daniłowicz-Szymanowicz L. Serious adverse drug reactions associated with anti-SARS-CoV-2 vaccines and their reporting trends in the EudraVigilance database. *Sci Rep*. 2025;15(1):18582.
331. Nelli F, Ruggeri EM, Virtuoso A, Giannarelli D, Barbuta J, Chegai F, et al. Venous Thromboembolic Risk Does Not Increase After a Third Dose of SARS-CoV-2 mRNA-BNT162b2 Vaccine in Cancer Patients Receiving Active Systemic Therapies: Updated Results from the Vax-On-Third-Profile Study. *Vaccines*. 2025;13(4).
332. Neutel JM, Erdem R, Jiang Q, Cannon K, Stacey H, Newton R, et al. Safety and immunogenicity of concomitant administration and combined administration of bivalent BNT162b2 COVID-19 vaccine and bivalent RSVpreF respiratory syncytial virus vaccine with or without quadrivalent influenza vaccine in adults ≥ 65 years of age. *Vaccines*. 2025;13(2).
333. Ng AJJ, Teo DCH, Dorajoo SR, Yap AJY, Chow WC, Ng NKM, et al. Acute autoimmune hepatitis following COVID-19 mRNA vaccination: A population-based study using electronic health records in Singapore. *Vaccine*. 2024;42(26):126462.
334. (a) Nguyen T, Dawes L, Huang YA, Tay E, Dymock M, O'Moore M, et al. Short term safety profile of respiratory syncytial virus vaccine in adults aged ≥ 60 years in Australia. *Lancet Reg Health West Pac*. 2025;56:101506.
335. (b) Nguyen HQ, Alonge OD, Hanson KE, Stefanski E, Petrie JG, Ambrose K, et al. Effectiveness of cell culture-based influenza vaccine, 2023-2024. *J Pediatric Infect Dis Soc*. 2025;14:piaf069.
336. (c) Nguyen JL, Mitratza M, Volkman HR, de Munter L, Tran TMP, Marques C, et al. Effectiveness of the BNT162b2 XBB.1.5-adapted vaccine against COVID-19 hospitalization related to the JN.1 variant in Europe: a test-negative case-control study using the id.DRIVE platform. *EClinicalMedicine*. 2025;79:102995.
337. Nham E, Song JY, Sohn JW, Choi WS, Wie SH, Lee J, et al. Real-world effectiveness of COVID-19 XBB.1.5 monovalent mRNA vaccine: Analysis over nine months. *Vaccine*. 2025;59:127275.

338. Nong M, Barbhaiya M, Braverman G, Bykerk VP, Hupert N, Lewis C th, et al. Association of COVID-19 vaccinations with osteoarthritis flares: A case-crossover study. *Osteoarthritis Cartilage*. 2025;33(4):500–8.
339. Nunes B, Humphreys J, Nicolay N, Braeye T, Van Evercooren I, Hansen CH, et al. Monovalent XBB.1.5 COVID-19 vaccine effectiveness against hospitalisations and deaths during the Omicron BA.2.86/JN.1 period among older adults in seven European countries: a VEBIS-EHR network study. *Expert Rev Vaccines*. 2024;1085–190.
340. Núñez O, Olmedo C, Moreno-Perez D, Lorusso N, Fernández Martínez S, Pastor Villalba PE, et al. Effectiveness of catch-up and at-birth nirsevimab immunisation against RSV hospital admission in the first year of life: a population-based case-control study, Spain, 2023/24 season. *Euro Surveill*. 2025;30(5).
341. Nv B, McCollum S, Faherty E, Steele JM, Karnik R. Longitudinal Assessment of Left Ventricular Function in Patients with Myopericarditis After mRNA COVID-19 Vaccination. *Pediatr Cardiol*. 2024;45(7):1524–32.
342. Obeng RC, Escobar DJ, Vadasz B, Zheng W, Ju JY, Booth AL, et al. Histologic Features of Liver Injury Associated With SARS-CoV-2 Messenger RNA Vaccines. *Arch Pathol Lab Med*. 2025;149(6):556–60.
343. Ocana de Sentuary C, Testard C, Lagrée M, Leroy M, Gasnier L, Enes-Dias A, et al. Acceptance and safety of the RSV-preventive treatment of newborns with nirsevimab in the maternity department: a prospective longitudinal cohort study in France. *eClinicalMedicine*. 2025;79.
344. Öcek L, Demir Özen T, Öcek Ö, Sariteke A, Şener U. Evaluation of Clinical Effects of COVID-19 Infection and Vaccines on Myasthenia Gravis. *Noropsikiyatri Arsivi*. 2024;61(3):213–20.
345. Ogawa M, Takeuchi Y, Iida Y, Iwagami M, Uemura K, Ono S, et al. Safety Assessment of Influenza Vaccination for Neurological Outcomes Among Older Adults in Japan: A Self-Controlled Case Series Study. *Pharmacoepidemiol Drug Saf*. 2025;34(1):e70082.
346. Oh J, Jo H, Park J, Lee H, Kim HJ, Lee H, et al. Global burden of vaccine-associated rheumatic diseases and their related vaccines, 1967-2023: A comprehensive analysis of the international pharmacovigilance database. *Int J Rheum Dis*. 2024;27(8):e15294.
347. Okada Y, Kumagai Y, Okura I, Otsuki M, Ishida N, Iwama Y, et al. Immunogenicity of a booster dose of a bivalent (Asp614Gly and omicron BA.4/5 variant) self-amplifying mRNA SARS-CoV-2 booster vaccine versus the BNT162b2 omicron BA.4/5 mRNA vaccine: a randomised phase 3 trial. *Lancet Infect Dis*. 2025;25(3):290–300.
348. Okoye C, Zazzara MB, Ceolin C, Fedele G, Palmieri A, Abbatecola AM, et al. Delirium Incidence and Predictors in SARS-CoV-2 Vaccinated Residents in Long-Term Care Facilities (LTCF): Insights from the GeroCovid Vax Study. *J Am Med Dir Assoc*. 2024;25(11):105251.
349. (a) Omole T, Weinberg AS, Azizad M, Greenberg D, Grijalva CG, Orenstein WA, et al. A phase 3 randomized, double-blind clinical study to evaluate the safety and immunogenicity of

V116 when administered concomitantly with influenza vaccine in adults 50 years of age or older. *Vaccine*. 2025;62:127514.

350. (b) Omole T, Pelayo E, Weinberg AS, Chalkias S, Endale Z, Tamms G, et al. Safety, Tolerability, and Immunogenicity of the Pneumococcal Vaccines PPSV23 or PCV15 Co-Administered with a Booster Dose of mRNA-1273 SARS-CoV-2 Vaccine in Healthy Adults ≥ 50 Years of Age. *Vaccines*. 2025;13(2).

351. Otsuki T, Akada S, Anami A, Kosaka K, Munjal I, Baber J, et al. Efficacy and safety of bivalent RSVpreF maternal vaccination to prevent RSV illness in Japanese infants: subset analysis from the pivotal randomized phase 3 MATISSE trial. *Vaccine*. 2024;42(22):126041.

352. Özdemir Ö, Dikici Ü. The effect of COVID-19 and COVID-19 vaccines on chronic spontaneous urticaria: single center experience. *Allergologia Polska - Polish Journal of Allergology*. 2024;11(2):180–3.

353. Padilla-Pantoja FD, Fakh-Gomez N, Muñoz-Gonzalez C, Prazeres S, Galindo-Ferreiro A. Temporary Delayed Hypersensitivity Reaction to Botulinum Toxin-A After COVID-19 Vaccination: A Case Series. *Aesthetic Plast Surg*. 2024;48(23):5162–70.

354. Pakanen L, Nieminen T, Kuvaja P, Nohynek H, Goebeler S, Artama M, et al. COVID-19 vaccination as a rare potential etiology for cause of death after medicolegal autopsy. A Finnish nationwide study. *VACCINE: X*. 2025;24.

355. Pan Y, Han Y, Zhou C, Zhao L, Zheng J, Ye X, et al. Evaluating the safety of XBB.1.5-containing COVID-19 mRNA vaccines using a self-controlled case series study. *Nat Commun*. 2025;16(1):6514.

356. (a) Park B, Lee HA, Kim Y, Kim CH, Park H, Jun S, et al. Active Surveillance for Safety Monitoring of XBB.1.5-Containing COVID-19 mRNA Vaccines in Korea. *J Korean Med Sci*. 2024;39(43):e309.

357. (b) Park H, Lim E, Jun S, Lee H, Lee HA, Park H, et al. Reported adverse events and associated factors in Korean Coronavirus Disease 2019 vaccinations. *J Korean Med Sci*. 2024;39(42):e274.

358. Parveen N. COVID-19 vaccination and menstrual disturbances: A prospective study from Pakistan. *Pak J Med Sci*. 2024;40(7):1345–8.

359. Pasquale S, Moscara L, Palmieri C, Martinelli A, Fontanelli S, Bellomo C, et al. Safety of SARS-CoV-2 XBB.1.5 and seasonal influenza vaccines co-administration: data from a perspective observational active surveillance study. Puglia (Italy), season 2023/2024. *Virology*. 2025;610:110613.

360. Pathak GN, Sanabria B, Pathak AN, Lohani DM, Razi S, Rao B. Vitiligo development following COVID-19 vaccination: A retrospective analysis of 128 cases using the Vaccine Adverse Events Reporting System. *J Am Acad Dermatol*. 2025;93(1):272–4.

361. Pattinson D, Jester P, Gu C, Guan L, Armbrust T, Petrie JG, et al. Ipsilateral and contralateral coadministration of influenza and COVID-19 vaccines produce similar antibody responses. *EBioMedicine*. 2024;103:105103.

362. Patton ME, Moline HL, Whitaker M, Tannis A, Pham H, Toepfer AP, et al. Interim Evaluation of Respiratory Syncytial Virus Hospitalization Rates Among Infants and Young Children After Introduction of Respiratory Syncytial Virus Prevention Products - United States, October 2024-February 2025. *MMWR Morb Mortal Wkly Rep.* 2025;74(16):273–81.
363. Payne AB, Watts JA, Mitchell PK, Dascomb K, Irving SA, Klein NP, et al. Respiratory syncytial virus (RSV) vaccine effectiveness against RSV-associated hospitalisations and emergency department encounters among adults aged 60 years and older in the USA, October, 2023, to March, 2024: a test-negative design analysis. *Lancet.* 2024;404(10462):1547–59.
364. Payne AB, Novosad S, Sung HM, Zhang Y, Wiegand R, Gomez Victor CS, et al. Effectiveness of 2023-2024 COVID-19 vaccines against COVID-19-associated hospitalizations among adults aged ≥18 years with end stage kidney disease - United States, September 2023-April 2024. *Vaccine.* 2025;55:127010.
365. Peck LF, Poh WW, Lim AT, Soh SBL, Tham MY, Foo BPQ, et al. Anaphylaxis post-COVID-19 vaccinations in Singapore. *Singapore Med J.* 2024;
366. Pekdiker M, Ketenci S. ASIA syndrome after BNT162b2 vaccination: Is it a distinct rheumatoid arthritis phenotype? *Immunol Res.* 2024;72(6):1424–31.
367. Pérez Marc G, Vizzotti C, Fell DB, Di Nunzio L, Olszevicki S, Mankiewicz SW, et al. Real-world effectiveness of RSVpreF vaccination during pregnancy against RSV-associated lower respiratory tract disease leading to hospitalisation in infants during the 2024 RSV season in Argentina (BERNI study): a multicentre, retrospective, test-negative, case-control study. *Lancet Infect Dis.* 2025;25(9):1044–54.
368. Pérez-Gimeno G, Mazagatos C, Lorusso N, Basile L, Martínez-Pino I, Corpas Burgos F, et al. Effectiveness of influenza vaccines in children aged 6 to 59 months: a test-negative case-control study at primary care and hospital level, Spain 2023/24. *Euro Surveill.* 2024;29(40).
369. (a) Perramon-Malavez A, Hermosilla E, Coma E, Fina F, Reñé A, Martínez-Marcos M, et al. Effectiveness of nirsevimab immunoprophylaxis against respiratory syncytial virus-related outcomes in hospital care settings: a seasonal cohort study of infants in Catalonia, Spain. *Pediatr Infect Dis J.* 2025;44(5):394–8.
370. (b) Perramon-Malavez A, Buonsenso D, Morello R, Coma E, Foster S, Leonard P, et al. Real-world impact of nirsevimab immunisation against respiratory disease on emergency department attendances and admissions among infants: a multinational retrospective analysis. *Lancet Reg Health Eur.* 2025;
371. Petr V, Zahradka I, Modos I, Roder M, Fialova M, Machkova J, et al. Safety and Immunogenicity of SARS-CoV-2 mRNA Vaccine Booster Doses in Kidney Transplant Recipients: Results of a 12-mo Follow-up From a Prospective Observational Study. *Transplant Direct.* 2024;10(6):e1645.
372. Pham-Huy A, Bowes J, Russell K, Amira A, Lai L. Short- and long-term outcomes of cardiac adverse events following COVID-19 immunization managed in a Canadian pediatric center. *Vaccine.* 2024;42(24):126090.

373. Pinto A, Silva MFS, Oliveira FCE, Garcia MML, Melo VB, Damasceno GA, et al. Comparison of Adverse Events and Antibody Responses Among Different COVID-19 Vaccination Schedules. *Viral Immunol.* 2024;37(7):337–45.
374. Pira A, Mariotti F, Moro F, Didona B, Scaglione GL, Panebianco A, et al. COVID-19 Vaccine: A Potential Risk Factor for Accelerating the Onset of Bullous Pemphigoid. *Vaccines.* 2024;12(9).
375. Płatkowska-Adamska B, Bociek A, Kal M, Zarębska-Michaluk D, Odrobina D. BNT162b2 vaccine booster dose did not influence the activity of the exudative form of age-related macular degeneration during anti-vascular endothelial growth factor therapy. *Minerva Med.* 2024;115(6):643–50.
376. Poder A, Oberije J, Meyer J, Heymer P, Molrine D, Versage E, et al. Immunogenicity and Safety of MF59-Adjuvanted Quadrivalent Influenza Vaccine Compared with a Nonadjuvanted, Quadrivalent Influenza Vaccine in Adults 50–64 Years of Age. *Vaccines.* 2023;11(10).
377. Popham K, St George K, Felsen C, Dumyati G, Tesini BL. Disproportionate Impact of Respiratory Syncytial Virus (RSV) Among Older Adults in Long-Term Care Settings. *J Am Med Dir Assoc.* 2025;26(9):105760.
378. Prabhu R, Prabhu G, Htay MNN, Thundakattil AV, Moe S, Das S. Safety comparison of mRNA, viral vector, and inactivated Covid-19 vaccines: incidence of adverse events following primary and booster doses among medical professionals in Malaysia. *BMC Infect Dis.* 2025;25(1):898.
379. Prasert K, Praphasiri P, Lerdsamran H, Nakphook S, Ditsungnoen D, Chawalchitiporn S, et al. Safety and immunogenicity of locally produced trivalent inactivated influenza vaccine (Tri Fluvac) in healthy Thai adults aged 18-64 years in Nakhon Phanom: A Phase III double blinded, three-arm, randomized, controlled trial. *Vaccine.* 2024;42(1):24–32.
380. Prasertsakul B, Sitthikarnkha P, Ngamjarus C, Jakeaw C, Sutra S. Factors Associated with COVID-19 Infection Related Multisystem Inflammatory Syndrome in Children: A Multicenter Matched Case-Control Study. *Children (Basel).* 2025;12(6).
381. Pratt GW, Wong CL, Rao LV. Prevalence and Co-Detection Rates of SARS-CoV-2, Influenza, and Respiratory Syncytial Virus: A Retrospective Analysis. *APMIS.* 2025;133(3).
382. Primicerio GC, Bille MB, Lund EL, Birk S. Small fiber neuropathy following COVID-19 vaccination: A case series. *J Neurol Sci.* 2025;474:123536.
383. Prins MLM, van Dokkum ED, de Vries APJ, Tushuizen ME, van der Helm D, Spithoven EM, et al. A Retrospective Test-Negative Case-Control Study to Evaluate Influenza Vaccine Effectiveness in Preventing Influenza Among Immunocompromised Adults With a Solid Organ Transplant. *Transpl Int.* 2025;38:14187.
384. Pudasaini S, Le NH, Huscher D, Holert F, Hillus D, Tober-Lau P, et al. Levels of high-sensitive troponin T and mid-regional pro-adrenomedullin after COVID-19 vaccination in vulnerable groups: monitoring cardiovascular safety of COVID-19 vaccination. *Frontiers in Cardiovascular Medicine.* 2024;11.

385. Ramsay JA, Jones M, Vande More AM, Hunt SL, Williams PCM, Messer M, et al. A single blinded, phase IV, adaptive randomised control trial to evaluate the safety of coadministration of seasonal influenza and COVID-19 vaccines (the FluVID study). *Vaccine*. 2023;41(48):7250–8.
386. Reeves EL, Dascomb K, Irving SA, Klein NP, Tartof SY, Grannis SJ, et al. Effectiveness of 2023-2024 seasonal influenza vaccine against influenza-associated emergency department and urgent care encounters among pregnant and non-pregnant women of reproductive age. *Vaccine*. 2025;62:127483.
387. Regan AK, Wesselink AK, Wang TR, Savitz DA, Yland JJ, Rothman KJ, et al. Risk of miscarriage in relation to seasonal influenza vaccination before or during pregnancy. *Obstet Gynecol*. 2023;142(3):625–35.
388. Regan AK, Sullivan SG, Arah OA. Maternal influenza vaccination and associated risk of fetal loss: a claims-based prospective cohort study. *Vaccine*. 2024;42(26):126256.
389. Reynolds R, Tay E, Dymock M, Deng L, Glover C, Lopez LK, et al. Short-Term Active Safety Surveillance of the Spikevax and Nuvaxovid Priming Doses in Australia. *Vaccines (Basel)*. 2024;12(9).
390. Riccomi A, Trombetta CM, Dorrucchi M, Di Placido D, Sanarico N, Farchi F, et al. Effects of influenza vaccine on the immune responses to SARS-CoV-2 vaccination. *Vaccines*. 2024;12(4).
391. Rigamonti V, Torri V, Morris SK, Ieva F, Giaquinto C, Donà D, et al. Real-world effectiveness of influenza vaccination in preventing influenza and influenza-like illness in children. *Vaccine*. 2025;53:126946.
392. Rius-Peris JM, Palomo-Atance E, Muro-Díaz E, Llorente-Ruiz C, Murcia-Clemente L, Alcaraz R. Nirsevimab immunisation significantly reduces respiratory syncytial virus-associated bronchiolitis hospitalisations and alters seasonal patterns. *Acta Paediatr*. 2025;114:1963–76.
393. Rogers C, Thorp J, Cosgrove K, McCullough P. COVID-19 Vaccines: A Risk Factor for Cerebral Thrombotic Syndromes. *ijirms*. 2024 Nov 1;9(11):621–7.
394. Rose AM, Lucaccioni H, Marsh K, Kirsebom F, Whitaker H, Emborg HD, et al. Interim 2024/25 influenza vaccine effectiveness: eight European studies, September 2024 to January 2025. *Euro Surveill*. 2025;30(7).
395. Rossier LN, Décosterd NP, Matter CB, Staudenmann DA, Moser A, Egger B, et al. SARS-CoV-2 vaccination in inflammatory bowel disease patients is not associated with flares: a retrospective single-centre Swiss study. *Ann Med*. 2024;56(1):2295979.
396. Rouleau I, Issa Kana KDN, Zafack JG, Viger YB, De Serres G. New-onset anesthesia/paresthesia following the administration of COVID-19 vaccines in Quebec, Canada. *Vaccine*. 2025;57:127217.
397. Rousculp MD, Hollis K, Ziemiecki R, Odom D, Marchese AM, Montazeri M, et al. Reactogenicity Differences between Adjuvanted, Protein-Based and Messenger Ribonucleic Acid (mRNA)-Based COVID-19 Vaccines. *Vaccines (Basel)*. 2024;12(7).

398. Ruzafa Martinez C, Valero S, García Villalba E, Tomás C, Muñoz Á, Alcaraz A, et al. Vaccine effectiveness in patients admitted for influenza during the 2023-2024 season. *Med Clin (Barc)*. 2024;163(12):589–94.
399. Saavedra RDC, Paixao ES, Ichihara MYT, Costa MDCN, Carvalho-Sauer R, de Castro CT, et al. Prevalence of Adverse Events Reported Following the First Dose of COVID-19 Vaccines in Bahia State, Brazil, from 2021 to 2022. *Vaccines*. 2025;13(2).
400. Safrai M, Kremer E, Atias E, Ben-Meir A. BNT162b2 COVID-19 vaccine does not affect fertility as explored in a pilot study of women undergoing IVF treatment. *Minerva Obstet Gynecol*. 2024;76(3):215–21.
401. Salmaggi A, Bortolan F, Ercolanoni M, Vrabie PS, Cideni F, Leoni O, et al. Impact of COVID-19 disease and COVID-19 vaccinations on hospital admissions for neurological diseases in the Lombardia over-12 population. Data from a self-controlled case series analysis. *Neurol Sci*. 2025;46(1):25–32.
402. Sankar C, Evans S, Meyer JC, Gunter HM, Sekiti V, McCarthy K. Signal Monitoring for Adverse Events Following Immunisation with COVID-19 Vaccines During the SARS-CoV-2 Pandemic: An Evaluation of the South African Surveillance System. *Drug Saf*. 2025;
403. Schmader KE, Walter EB, Talaat KR, Rountree W, Poniewierski M, Randolph E, et al. Safety of Simultaneous Vaccination With Adjuvanted Zoster Vaccine and Adjuvanted Influenza Vaccine: A Randomized Clinical Trial. *JAMA Netw Open*. 2024;7(10):e2440817.
404. Semenzato L, Le Vu S, Botton J, Bertrand M, Jabagi MJ, Drouin J, et al. Long-term prognosis of patients with myocarditis attributed to COVID-19 mRNA vaccination, SARS-CoV-2 infection, or conventional etiologies. *Jama*. 2024;332(16):1367–77.
405. Separovic L, Zhan Y, Kaweski SE, Sabaiduc S, Carazo S, Olsha R, et al. Interim estimates of vaccine effectiveness against influenza A(H1N1)pdm09 and A(H3N2) during a delayed influenza season, Canada, 2024/25. *Euro Surveill*. 2025;30(4).
406. Shah AB, Rizzo SM, Finnoff JT, Baggish AL, Adams WM. Cardiovascular safety of the COVID-19 vaccine in team USA athletes. *Sports Health*. 2024;16(4):504–6.
407. Shaharir SS, Nawi AM, Mariamutu TN, Kamaruzaman L, Said MSM, Rajalingham S, et al. Self-reported delayed adverse events and flare following COVID-19 vaccination among patients with autoimmune rheumatic disease (AIRD) in Malaysia: results from the COVAD-2 Study. *Int J Rheum Dis*. 2025;28(1):e70043.
408. Shani M, Hermesh I, Feldhamer I, Reges O, Lavie G, Arbel R, et al. The association between BNT162b2 vaccinations and incidence of immune-mediated comorbidities. *Vaccine*. 2024;42(18):3830–7.
409. Shapiro JR, Seddu K, Park HS, Lee JS, Creisher PS, Yin A, et al. The intersection of biological sex and gender in adverse events following seasonal influenza vaccination in older adults. *Immunity & Ageing*. 2023 Aug 29;20(1):43.
410. Sharff KA, Tandy TK, Lewis PF, Johnson ES. Incidence of ischemic stroke after COVID-19 bivalent booster vaccination in an integrated health system. *Vaccine*. 2024;42(26):126440.

411. (a) Shaw CA, Mithani R, Kapoor A, Dhar R, Wilson L, El Asmar L, et al. Safety, tolerability, and immunogenicity of an mRNA-based respiratory syncytial virus vaccine in healthy young adults in a phase 1 clinical trial. *J Infect Dis.* 2024;230(3):e637–46.
412. (b) Shaw CA, Essink B, Harper C, Mithani R, Kapoor A, Dhar R, et al. Safety and immunogenicity of an mRNA-based RSV vaccine including a 12-month booster in a phase 1 clinical trial in healthy older adults. *J Infect Dis.* 2024;230(3):e647–56.
413. Shemer A, Toledano A, Altarescu A, Dubinsky-Pertzov B, Rozenberg A, Hecht I, et al. COVID-19 vaccination and acute anterior uveitis-a case control study. *Vaccines (Basel).* 2025;13(2).
414. Sher LD, Boakye-Appiah JK, Hill S, Wasserman E, Xu X, Maldonado Y, et al. Bivalent Omicron BA.4/BA.5 BNT162b2 vaccine in 6-month- to <12-year-olds. *J Pediatric Infect Dis Soc.* 2024;13(8):421–9.
415. Sheth SS, Vazquez-Benitez G, DeSilva MB, Zhu J, Seburg EM, Denoble AE, et al. Coronavirus disease 2019 (COVID-19) vaccination and spontaneous abortion. *Obstet Gynecol.* 2025;146(1):129–37.
416. Shi Y, Yang W, Li X, Chu K, Wang J, Tang R, et al. Immunogenicity and safety of one versus two doses of quadrivalent inactivated influenza vaccine (IIV4) in vaccine-unprimed children and one dose of IIV4 in vaccine-primed children aged 3–8 years. *Vaccines.* 2023;11(10).
417. Shi XC, Gruber JF, Ondari M, Lloyd PC, Freyria Duenas P, Clarke TC, et al. Assessment of potential adverse events following the 2022-2023 seasonal influenza vaccines among U.S. adults aged 65 years and older. *Vaccine.* 2024;42(15):3486–92.
418. Shinjoh M, Yaginuma M, Yamaguchi Y, Tamura K, Furuichi M, Tsumura Y, et al. Effectiveness of inactivated influenza vaccine in children during the 2023/24 season: the first season after relaxation of intensive COVID-19 measures. *Vaccine.* 2024;42(23):126241.
419. Shinjoh M, Tamura K, Yamaguchi Y, Fukushima H, Kuremoto N, Tezuka M, et al. Influenza vaccination in Japanese children, 2024/25: effectiveness of inactivated vaccine and limited use of newly introduced live-attenuated vaccine. *Vaccine.* 2025;61:127429.
420. Shoji N, Ito S, Nojiri S, Urasaki W, Nara T, Okuzawa A, et al. Adverse reactions to mRNA COVID-19 vaccine in people with allergies in Japan. *Glob Health Med.* 2024;6(6):363–74.
421. Shrestha NK, Burke PC, Nowacki AS, Gordon SM. Effectiveness of the 2023-2024 formulation of the COVID-19 messenger RNA vaccine. *Clin Infect Dis.* 2024;79(2):405–11.
422. Silva-Afonso RDF, Platas-Abenza G, Guerrero-Soler M, Gallardo-Rodríguez P, Gil-Sánchez F, Pérez-Paz G, et al. Effectiveness of immunization strategies for preventing severe acute respiratory infection during the 2023/2024 season in a Spanish health department. *Enferm Infecc Microbiol Clin.* 2025;43(7):435–43.
423. Silverman A, Walsh R, Santoro JD, Thomas K, Ballinger E, Fisher KS, et al. Influenza-associated acute necrotizing encephalopathy in US children. *JAMA.* 2025;334:692–701.

424. Simões EAF, Pahud BA, Madhi SA, Kampmann B, Shittu E, Radley D, et al. Efficacy, safety, and immunogenicity of the MATISSE (Maternal Immunization Study for Safety and Efficacy) maternal respiratory syncytial virus prefusion F protein vaccine trial. *Obstet Gynecol.* 2025;145(2):157–67.
425. Skowronski DM, Zhan Y, Kaweski SE, Sabaiduc S, Khalid A, Olsha R, et al. 2023/24 mid-season influenza and Omicron XBB.1.5 vaccine effectiveness estimates from the Canadian Sentinel Practitioner Surveillance Network (SPSN). *Euro Surveill.* 2024;29(7).
426. Slingerland P, van Hunsel F, Lieber T, van Balveren L, Duijster JW. The Effect of Sex on the Incidence, Latency, Duration and Perceived Burden of Adverse Events Following Seasonal Influenza Vaccination in the Netherlands. *Drug Saf.* 2023;46(12):1323–34.
427. Smith J, Schrader S, Morgan H, Shenton P, Alafaci A, Cox N, et al. Clinical phenotype of COVID-19 vaccine-associated myocarditis in Victoria, 2021-22: a cross-sectional study. *Med J Aust.* 2025;222(1):23–9.
428. Smolarchuk C, Ickert C, Kwong JC, Buchan SA. Early influenza vaccine effectiveness estimates using routinely collected data, Alberta, Canada, 2023/24 season. *Euro Surveill.* 2024;29(2).
429. Sodagari S, Sodagari N. Examining vaccination-related adverse events in frequent neurodegenerative diseases. *Brain, Behavior, and Immunity - Health.* 2025;43.
430. (a) Soe P, Vanderkooi OG, Sadarangani M, Naus M, Muller MP, Kellner JD, et al. mRNA COVID-19 vaccine safety among children and adolescents: a Canadian National Vaccine Safety Network cohort study. *Lancet Reg Health Am.* 2024;40:100949.
431. (b) Soe P, Wong H, Naus M, Muller MP, Vanderkooi OG, Kellner JD, et al. mRNA COVID-19 vaccine safety among older adults from the Canadian National Vaccine Safety Network. *Vaccine.* 2024;42(18):3819–29.
432. Strid P, Abara WE, Clark E, Moro PL, Olson CK, Gee J. Postmenopausal Bleeding After Coronavirus Disease 2019 (COVID-19) Vaccination: Vaccine Adverse Event Reporting System. *Obstet Gynecol.* 2024;144(2):283–7.
433. Subaiea GM, Alkhateeb N, Sahman F, Alsudayri A, Almudayni AM, Alrashidi H, et al. Charting the COVID-19 vaccination journey in Saudi Arabia: Insights into post-vaccination adverse effects and immunization dynamics. *Front Pharmacol.* 2025;16:1561410.
434. Sumer F, Subasi S. Evaluation of the Effects of mRNA-COVID 19 Vaccines on Corneal Endothelium. *Ophthalmic Epidemiol.* 2025;1–8.
435. (a) Sun JW, Dodge LE, Kim EJ, Zhou L, Mather S, Goebe H, et al. Risk of adverse events after Omicron XBB-adapted BNT162b2 COVID-19 vaccination in the United States. *Vaccine.* 2025;45:126629.
436. (b) Sun Y, Shi W, Zhang D, Ma C, Feng Z, Zhang J, et al. Early vaccine effectiveness estimates against medically attended laboratory-confirmed influenza based on influenza surveillance, Beijing, China, 2024/25 season. *Euro Surveill.* 2025;30(7).

437. Surie D, Self WH, Zhu Y, Yuengling KA, Johnson CA, Grijalva CG, et al. RSV vaccine effectiveness against hospitalization among US adults 60 years and older. *JAMA*. 2024;332(13):1105–7.
438. Suseeladevi AK, Denholm R, Retford M, Raffetti E, Burden C, Birchenall K, et al. COVID-19 vaccination and birth outcomes of 186,990 women vaccinated before pregnancy: an England-wide cohort study. *The Lancet Regional Health - Europe*. 2024;45.
439. Swift MD, Breeher LE, Dierkhising R, Hickman J, Johnson MG, Roellinger DL, et al. Association of COVID-19 Vaccination With Risk of Medically Attended Postacute Sequelae of COVID-19 During the Ancestral, Alpha, Delta, and Omicron Variant Eras. *Open Forum Infectious Diseases*. 2024;11(9).
440. Takada K, Taguchi K, Samura M, Igarashi Y, Okamoto Y, Enoki Y, et al. SARS-CoV-2 mRNA vaccine-related myocarditis and pericarditis: An analysis of the Japanese Adverse Drug Event Report database. *J Infect Chemother*. 2025;31(1):102485.
441. Talib N, Fronza M, Marschner CA, Thavendiranathan P, Karur GR, Hanneman K. Cardiovascular magnetic resonance imaging and clinical follow-up in patients with clinically suspected myocarditis after COVID-19 vaccination. *J Cardiovasc Magn Reson*. 2024;26(1):101036.
442. Tamir-Hostovsky L, Maayan-Metzger A, Gavri-Beker A, Watson D, Leibovitch L, Strauss T. Association of BNT162b2 SARS-CoV-2 vaccination during pregnancy with postnatal outcomes in premature infants. *Acta Paediatr*. 2024;113(10):2275–81.
443. Tanaka K, Demchuk AM, Malo S, Hill MD, Holodinsky JK. Risk of stroke within 3, 7, 14, 21 and 30 days after influenza vaccination in Alberta, Canada: a population-based study. *Eur J Neurol*. 2024;31(4):e16172.
444. Tani N, Ikematsu H, Watanabe H, Goto T, Yanagihara Y, Kurata Y, et al. Reduction of adverse reactions and correlation between post-vaccination fever and specific antibody response across successive SARS-CoV-2 mRNA vaccinations. *Vaccine X*. 2024;18:100489.
445. (a) Tartof SY, Slezak JM, Puzniak L, Frankland TB, Ackerson BK, Jodar L, et al. Effectiveness of BNT162b2 XBB vaccine against XBB and JN.1 sublineages. *Open Forum Infect Dis*. 2024;11(7):ofae370.
446. (b) Tartof SY, Frankland TB, Puzniak L, Slezak JM, Ackerson BK, Hong V, et al. BNT162b2 XBB vaccine for COVID-19 among children 5-17 years of age. *JAMA Netw Open*. 2024;7(12):e2449944.
447. (c) Tartof SY, Aliabadi N, Goodwin G, Slezak J, Hong V, Ackerson B, et al. Estimated vaccine effectiveness for respiratory syncytial virus-related lower respiratory tract disease. *JAMA Netw Open*. 2024;7(12):e2450832.
448. Taylor CA, Patel K, Pham H, Kirley PD, Kawasaki B, Meek J, et al. COVID-19-Associated Hospitalizations Among U.S. Adults Aged ≥18 Years - COVID-NET, 12 States, October 2023-April 2024. *MMWR Morb Mortal Wkly Rep*. 2024;73(39):869–75.

449. Tenforde MW, Reeves EL, Weber ZA, Tartof SY, Klein NP, Dascomb K, et al. Influenza vaccine effectiveness against hospitalizations and emergency department or urgent care encounters for children, adolescents, and adults during the 2023-2024 season, United States. *Clin Infect Dis*. 2024;81(3):667–78.
450. (a) Testi I, Brandão-de-Resende C, De-La-Torre A, Concha-Del-Rio LE, Cheja-Kalb R, Mahendradas P, et al. Ocular inflammatory events following COVID-19 vaccination in the paediatric population: a multinational case series. *Ocul Immunol Inflamm*. 2024;32(7):1237–42.
451. (b) Testi I, Soomro T, Pavesio C, Solebo AL. Ocular inflammatory events following COVID-19 vaccination: reporting of suspected adverse drug reactions to regulatory authorities in the UK. *Br J Ophthalmol*. 2024;108(9):1200–3.
452. Tetsuka N, Suzuki K, Suzuki K, Ishihara T, Miwa T, Tajirika S, et al. Adverse events of COVID-19 vaccination during 2021–2022 suppressed by breakfast consumption and favorable sleeping habit among Japanese university students. *VACCINE: X*. 2024;19.
453. Thanborisutkul K, Kulalert P, Methaset K, Nanthapisal S, Chunthatikul T, Phangpanya N, et al. Incidence and Factors Associated with Self-Reported Skin Symptoms of Allergic Reactions to COVID-19 Vaccines. *Vaccines*. 2025;13(3).
454. Thepveera S, Charuvani S, Sukharomana M, Thunsiribuddhichai Y, Lomjansook K, Chaiyapak T, et al. Disease exacerbation and COVID-19 following mRNA COVID-19 vaccination in adolescents with Systemic Lupus Erythematosus. *Lupus*. 2025;34(6):562–70.
455. Thomas LD, Batarseh E, Hamdan L, Haddadin Z, Dulek D, Kalams S, et al. Comparison of Two High-Dose Versus Two Standard-Dose Influenza Vaccines in Adult Allogeneic Hematopoietic Cell Transplant Recipients. *Clin Infect Dis*. 2023;77(12):1723–32.
456. Tian Y, Ma Y, Ran J, Yuan L, Zeng X, Tan L, et al. Protective Impact of Influenza Vaccination on Healthcare Workers. *Vaccines*. 2024;12(11).
457. Top KA, Shulha HP, Muller MP, Valiquette L, Vanderkooi OG, Kellner JD, et al. Participant-reported neurological events following immunization in the Canadian National Vaccine Safety Network-COVID-19 vaccine (CANVAS-COVID) study. *Vaccine*. 2024;42(26):126445..
458. Top KA, Bettinger JA, Embree JE, Jadavji T, Purewal R, Sauv   L, et al. Active Surveillance for Myocarditis and Pericarditis in Canadian Children from 2021 to 2022: A Canadian Immunization Monitoring Program ACTive Study. *J Pediatr*. 2025;284:114642.
459. Torres JP, Saur   D, Goic M, Thraves C, Pacheco J, Burgos J, et al. Effectiveness and impact of nirsevimab in Chile during the first season of a national immunisation strategy against RSV (NIRSE-CL): a retrospective observational study. *Lancet Infect Dis*. 2025;S1473-3099(25)00233-6.
460. Tursinov Y, Horth R, Kurbonov B, Denebayeva A, Adambekov S, Nabirova D. COVID-19 vaccination pharmacovigilance in Khojaly district, Uzbekistan: an epidemiological evaluation. *Front Public Health*. 2025;13:1520821.

461. Umezawa Y, Suzuki H, Hirose H, Takahara H, Tomita S, Suzuki Y. A Series of Glomerular Diseases That Developed After COVID-19 Vaccination. *Cureus*. 2025;17(3):e81085.
462. van Ewijk CE, Suárez Hernández S, Jacobi RHJ, Knol MJ, Hahné SJM, Wijmenga-Monsuur AJ, et al. Innate immune response after BNT162b2 COVID-19 vaccination associates with reactogenicity. *Vaccine X*. 2025;22:100593.
463. Villanueva P, McDonald E, Croda J, Croda MG, Dalcolmo M, Dos Santos G, et al. Factors influencing adverse events following COVID-19 vaccination. *Hum Vaccin Immunother*. 2024;20(1):2323853.
464. Vita E, Monaca F, Mastrantonio L, Piro G, Moretti G, Sparagna I, et al. COVALENCE STUDY: Immunogenicity and Reactogenicity of a COVID-19 mRNA Vaccine in an Open-Label Cohort of Long-Survivor Patients with Metastatic Lung Cancer. *Vaccines*. 2025 Mar 5;13(3):273.
465. Walsh EE, Falsey AR, Zareba AM, Jiang Q, Gurtman A, Radley D, et al. Respiratory Syncytial Virus Prefusion F Vaccination: Antibody Persistence and Revaccination. *J Infect Dis*. 2024;230(4):e905–16.
466. Walsh EE, Eiras D, Woodside J, Jiang Q, Patton M, Marc GP, et al. Efficacy, immunogenicity, and safety of the bivalent RSV prefusion F (RSVpreF) vaccine in older adults over 2 RSV seasons. *Clin Infect Dis*. 2025;ciaf061.
467. Walter EB, Schlaudecker EP, Talaat KR, Rountree W, Broder KR, Duffy J, et al. Safety of simultaneous vs sequential mRNA COVID-19 and inactivated influenza vaccines: a randomized clinical trial. *JAMA Netw Open*. 2024;7(11):e2443166.
468. Wan EYF, Wang B, Lee AL, Zhou J, Chui CSL, Lai FTT, et al. Comparative effectiveness and safety of BNT162b2 and CoronaVac in Hong Kong: A target trial emulation. *Int J Infect Dis*. 2024;146:107149.
469. (a) Wang W, Yellamsetty A, Edmonds RM, Barcavage SR, Bao S. COVID-19 vaccination-related tinnitus is associated with pre-vaccination metabolic disorders. *Frontiers in Pharmacology*. 2024;15.
470. (b) Wang S, Wang Y, Chen D, Xu W, Duan P, Ji W, et al. Safety and immunogenicity of full-dose quadrivalent influenza vaccine in children 6-35 months of age in China: A randomized, double-blind, clinical trial. *Hum Vaccin Immunother*. 2024;20(1):2425149.
471. Ward T, Paton RS, Overton CE, Mellor J, Aziz NA, Charlett A, et al. Understanding the effectiveness of the Comirnaty monovalent and bivalent vaccines during the Winter Coronavirus (COVID-19) Infection Study. *J Infect*. 2025;90(5):106461.
472. Wee LE, Lim JT, Goel M, Malek MIA, Chiew CJ, Ong B, et al. Bivalent Boosters and Risk of Postacute Sequelae Following Vaccine-Breakthrough SARS-CoV-2 Omicron Infection: A Cohort Study. *Clin Infect Dis*. 2025;80(3):520–8.
473. Wen F, Liu S, Zhou L, Zhu Y, Wang W, Wei M, et al. Immunogenicity and safety of 1 versus 2 doses of quadrivalent-inactivated influenza vaccine in children aged 3-8 years with or without previous influenza vaccination histories. *Hum Vaccin Immunother*. 2025;21(1):2468074.

474. Werner F, Zeschick N, Kühlein T, Steininger P, Überla K, Kaiser I, et al. Patient-reported reactogenicity and safety of COVID-19 vaccinations vs. comparator vaccinations: a comparative observational cohort study. *BMC Med.* 2023;21(1):358.
475. Whitaker H, Findlay B, Zitha J, Goudie R, Hassell K, Evans J, et al. Interim 2023/2024 season influenza vaccine effectiveness in primary and secondary care in the United Kingdom. *Influenza Other Respir Viruses.* 2024;18(5):e13284.
476. Williams TC, Marlow R, Cunningham S, Drysdale SB, Groves HE, Hunt S, et al. Bivalent prefusion F vaccination in pregnancy and respiratory syncytial virus hospitalisation in infants in the UK: results of a multicentre, test-negative, case-control study. *Lancet Child Adolesc Health.* 2025;9(9):655–62.
477. Wilson A, Rahai N, Beck E, Beebe E, Conroy B, Esposito D, et al. Evaluating the effectiveness of mRNA-1273.815 against COVID-19 hospitalization among adults aged ≥ 18 years in the United States. *Infect Dis Ther.* 2025;14(1):199–216.
478. Woestenbergh PJ, Terpstra AW, van Hunsel F, Lieber T, Maas VYF. Comparison of Perceived Adverse Events After COVID-19 Vaccination Between Pregnant and NonPregnant Women Using Two Cohort Studies in the Netherlands. *Birth Defects Res.* 2025;117(6):e2490.
479. Won H, Kim JA, Jeong NY, Choi NK. Safety of concomitant administration of 23-valent polysaccharide pneumococcal vaccine and influenza vaccine among the elderly. *Vaccine.* 2024;42(13):3190–6.
480. Woo EJ, Miller ER, Stroud E. Syncope after live attenuated influenza vaccine: Reports to the Vaccine Adverse Event Reporting System (2003-2024). *Vaccine.* 2024;42(24):126290.
481. Woo J, Kim MK, Lim H, Kim JH, Jung H, Kim HA, et al. Risk of new-onset polymyalgia rheumatica following COVID-19 vaccination in South Korea: a self-controlled case-series study. *RMD Open.* 2025;11(2).
482. (a) Wu H, He X, Cao Y, Gao W. Adverse events affecting recovery from seasonal influenza vaccination in the hypertensive population: A population-based pharmacovigilance analysis. *PLoS One.* 2025;20(5):e0310474.
483. (b) Wu Q, Zhang B, Tong J, Bailey LC, Bunnell HT, Chen J, et al. Real-world effectiveness and causal mediation study of BNT162b2 on long COVID risks in children and adolescents. *EClinicalMedicine.* 2025;79:102962.
484. Xiang Y, Feng Y, Qiu J, Zhang R, So HC. Association of COVID-19 vaccination with risks of hospitalization due to cardiovascular and other diseases: a study using data from the UK Biobank. *Int J Infect Dis.* 2024;145:107080.
485. Xie Y, Choi T, Al-Aly Z. Mortality in Patients Hospitalized for COVID-19 vs Influenza in Fall-Winter 2023-2024. *Jama.* 2024;331(22):1963–5.
486. Xu S, Sy LS, Hong V, Holmquist KJ, Qian L, Farrington P, et al. Ischemic stroke after bivalent COVID-19 vaccination: self-controlled case series study. *JMIR Public Health Surveill.* 2024 June 25;10:e53807.

487. (a) Xu Y, Li H, Santosa A, Wettermark B, Fall T, Björk J, et al. Cardiovascular events following coronavirus disease 2019 vaccination in adults: a nationwide Swedish study. *Eur Heart J*. 2025;46(2):147–57.
488. (b) Xu S, Sy LS, Hong V, Qian L, Holmquist KJ, Bruxvoort KJ, et al. Tinnitus risk after COVID-19 XBB.1.5 vaccination: A self-controlled case series study. *Vaccine*. 2025;62:127548.
489. Yamamoto C, Kobashi Y, Kawamura T, Nishikawa Y, Saito H, Oguro F, et al. Group of longitudinal adverse event patterns after the fourth dose of COVID-19 vaccination with a latent class analysis. *Front Public Health*. 2024;12:1406315.
490. Yaron S, Yechezkel M, Yamin D, Razi T, Borochoy I, Shmueli E, et al. Incremental benefit of high dose compared to standard dose influenza vaccine in reducing hospitalizations. *npj Vaccines*. 2025;10(1).
491. Yechezkel M, Qian G, Levi Y, Davidovitch N, Shmueli E, Yamin D, et al. Comparison of physiological and clinical reactions to COVID-19 and influenza vaccination. *Commun Med (Lond)*. 2024;4(1):169.
492. Yih WK, Duffy J, Su JR, Bazel S, Fireman B, Hurley L, et al. Tinnitus after COVID-19 vaccination: Findings from the vaccine adverse event reporting system and the vaccine safety datalink. *Am J Otolaryngol*. 2024;45(6):104448.
493. Yildirim TD, Akleyek C, Yildirim D, Cinakli H, Hakbilen S, Coşkun BN, et al. COVID-19 vaccination in patients on biologic or targeted-synthetic disease modifying anti-rheumatic drug therapy: A multi center real-world data. *Asian Pacific Journal of Tropical Medicine*. 2025;18(2):77–83.
494. Yin A, Wang N, Shea PJ, Rosser EN, Kuo H, Shapiro JR, et al. Sex and gender differences in adverse events following influenza and COVID-19 vaccination. *Biol Sex Differ*. 2024;15(1):50.
495. Yoon D, Jung K, Kim JH, Ko HY, Yoon BA, Shin JY. Risk for Facial Palsy after COVID-19 Vaccination, South Korea, 2021-2022. *Emerg Infect Dis*. 2024;30(11):2313–22.
496. Yoon Y, Hwang MJ, Shin SH, Choi H, Na S, Park S, et al. Health-related quality of life in adolescents with myocarditis and pericarditis after BNT162b2 COVID-19 vaccination: Korean national surveillance. *Eur J Cardiovasc Nurs*. 2025;
497. Youngster M, Maman O, Kedem A, Avraham S, Rabbi ML, Gat I, et al. The effect of COVID-19 vaccination during IVF stimulation on cycle outcomes- a retrospective cohort study. *J Reprod Immunol*. 2024;163:104246.
498. Yousaf AR, Mak J, Gwynn L, Lutrick K, Bloodworth RF, Rai RP, et al. COVID-19 vaccination and odds of post-COVID-19 condition symptoms in children aged 5 to 17 years. *JAMA Netw Open*. 2025;8(2):e2459672.
499. Yumru Çeliksoy H. Impact of Pfizer-BioNTech COVID-19 Vaccination on the Menstrual Cycle. *Bagcilar Medical Bulletin*. 2024;9(2):99–105.

500. Yunker M, Villafuerte DA, Fall A, Norton JM, Abdullah O, Rothman RE, et al. Genomic evolution of influenza during the 2023-2024 season, the Johns Hopkins Health System. *J Clin Virol.* 2024;174:105718.
501. Zahrani EMA, Elsafi SH, Alkharraz RS, Sahal NH, Almansori M, Alhababi AI, et al. Occurrence of Myopericarditis Following COVID-19 Vaccination Among Adults in the Eastern Region, Saudi Arabia: A Multicenter Study. *International Journal of General Medicine.* 2024;17:3231–7.
502. Zaidi S, Qayyum HA, Qayyum IA, Khan Z, Islam T, Ahmed N, et al. COVID-19 vaccines side effects among the general population during the pandemic: a cross-sectional study. *Front Public Health.* 2025;13:1420291.
503. Zawiasa-Bryszewska A, Nowicka M, Górka M, Edyko P, Edyko K, Tworek D, et al. Safety and Efficacy of Influenza Vaccination in Kidney Graft Recipients in Late Period After Kidney Transplantation. *Vaccines.* 2025;13(2).
504. Zeno EE, Nogareda F, Regan A, Couto P, Rondy M, Jara J, et al. Interim Effectiveness Estimates of 2024 Southern Hemisphere Influenza Vaccines in Preventing Influenza-Associated Hospitalization - REVELAC-i Network, Five South American Countries, March-July 2024. *MMWR Morb Mortal Wkly Rep.* 2024;73(39):861–8.
505. Zethelius B, Attelind S, Westman G, Ljung R, Sundström A. Pulmonary embolism after SARS-CoV-2 vaccination. *Vaccine X.* 2024;21:100571.
506. Zhang J, Zhang L, Li J, Ma J, Wang Y, Sun Y, et al. Moderate effectiveness of influenza vaccine in outpatient settings: a test-negative study in Beijing, China, 2023/24 season. *Vaccine.* 2025;46:126662.
507. (a) Zhu Z, Sun J, Xie Y, Lu X, Tang W, Zhao Y, et al. Immunogenicity and Safety of an Inactivated Quadrivalent Influenza Vaccine Administered Concomitantly with a 23-Valent Pneumococcal Polysaccharide Vaccine in Adults Aged 60 Years and Older. *Vaccines.* 2024;12(8).
508. (b) Zhu S, Quint J, León TM, Sun M, Li NJ, Tenforde MW, et al. Interim Influenza Vaccine Effectiveness Against Laboratory-Confirmed Influenza - California, October 2023-January 2024. *MMWR Morb Mortal Wkly Rep.* 2024;73(8):175–9.
509. (a) Zhu L, Han Y, Lu J, Tan J, Liao C, Guo C, et al. Evaluation of Influenza Vaccine Effectiveness from 2021 to 2024: A Guangdong-Based Test-Negative Case–Control Study. *Vaccines.* 2025;13(1).
510. (b) Zhu S, Quint J, León T, Sun M, Li NJ, Yen C, et al. Estimating influenza vaccine effectiveness against laboratory-confirmed influenza using linked public health information systems, California, 2023-2024 Season. *J Infect Dis.* 2025;jiaf248.
511. Zornoza Moreno M, Pérez Martín JJ, Gómez Moreno MC, Valcárcel Gómez MD, Pérez Martínez M, Tornel Miñarro FI. Adverse Effects Related to Paediatric Influenza Vaccination and Its Influence on Vaccination Acceptability. The FLUTETRA Study: A Survey Conducted in the Region of Murcia, Spain. *Influenza Other Respir Viruses.* 2024;18(6):e13331.