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

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ABSTRACT

Background

Changes in the U.S. vaccine advisory process have disrupted immunization guidance, reinforcing the need for an independent evidence review to inform respiratory virus immunization decisions for 2025–2026.

Methods

We conducted a systematic review of U.S.-licensed immunizations against Covid-19, respiratory syncytial virus (RSV), and influenza. We searched PubMed/MEDLINE, Embase, and Web of Science since each disease's most recent Advisory Committee on Immunization Practices Evidence-to-Recommendation review (2023-2024). Outcomes included vaccine efficacy/effectiveness (VE) against hospitalization, other clinical endpoints, and safety.

Results

Of 17,263 identified references, 511 studies met inclusion criteria. XBB.1.5-adapted Covid-19 mRNA vaccines had pooled VE against hospitalization of 46% (95% CI, 34 to 55; cohort) and 50% (95% CI, 43 to 57; case-control) among adults and 37% (95% CI, 29 to 44) among immunocompromised adults. KP.2-adapted vaccines showed VE 68% (95% CI, 42 to 82). Maternal RSV vaccination *(for infant protection),* infant nirsevimab, and RSV vaccines in adults $\geqslant 60$ years showed VE $\geq 68\%$ against hospitalization. Influenza vaccination had pooled VE 48% (95% CI, 39 to 55) in adults and 67% (95% CI, 58 to 75) in children against hospitalization. *Safety profiles were consistent with prior evaluations. Covid-19 vaccine-associated myocarditis occurred at rates of 1.3-3.1 per 100,000 doses in young males, with lower risk associated with longer dosing intervals. RSVPreF was associated with 18.2 excess cases of Guillain-Barré*

syndrome per million doses in older adults; preterm birth was not observed when administered at 32-36 weeks' gestation.

Conclusions

Ongoing peer-reviewed evidence supports the safety and effectiveness of immunizations against Covid-19, RSV, and influenza.

INTRODUCTION

SARS-CoV-2, RSV, and influenza cause substantial U.S. morbidity and mortality. *In the context of fluctuating population immunity and viral evolution, hospitalization rates for these infections vary by season and population (all reported below per 100,000 population). Influenza-associated hospitalization rates have ranged from 8.7 to 102.9 across multiple U.S. seasons (2011-2012 and 2017-2018), and were 83.4 in 2023-2024.[1] Covid-19-associated hospitalization rates have decreased since the onset of the pandemic, but remained 200.1 in 2023-2024, with higher rates among adults ⩾65 years (824.8) and children <1 year (381.3).[2] RSV-associated hospitalization rates among adults have been more stable, with 58.0 during the 2023-2024 season, and remained highest among children <5 years, with hospitalization rates of 1,415 in 2023-2024.[3]*

Recent changes to federal vaccine advisory processes have disrupted immunization guidance and underscore the need for independent evidence assessment. This systematic review synthesizes recent data on respiratory virus epidemiology, vaccine and immunization efficacy and effectiveness, and safety, building upon the Advisory Committee on Immunization Practice's (ACIP) 2023-2024 Evidence-to-Recommendations frameworks to provide clinicians, medical societies, public health professionals, insurers, and policymakers with timely evidence for the 2025-2026 respiratory virus season.

METHODS

Study Design and Registration

We conducted a systematic review and meta-analysis to evaluate the efficacy, effectiveness, and safety of U.S.-licensed immunizations (active and passive) against Covid-19, RSV, and influenza. The protocol was registered prospectively with PROSPERO (CRD420251091346).

Search Strategy

We searched PubMed/MEDLINE, Embase, and Web of Science for English-language articles pertaining to Covid-19, RSV, and influenza epidemiology, immunization efficacy/effectiveness, and immunization safety. Search windows began from the date of each vaccine's last ACIP Evidence-to-Recommendations review: Covid-19 from June 2024, RSV from August 2024, and influenza from August 2023, all through July 31, 2025 (**Tables S1-S3**).

Study Eligibility and Data Extraction

We included randomized controlled trials (RCTs) and observational studies that addressed four domains: U.S. epidemiologic surveillance; vaccine efficacy/effectiveness (VE; *efficacy from RCTs, effectiveness from observational studies*) with laboratory-confirmed outcomes; safety; and vaccine co-administration. Eligible immunizations included U.S.-licensed or emergency-use-authorized vaccines against the three pathogens or licensed RSV monoclonal antibodies. Articles were included only if the data were collected within or spanned pre-defined time periods, varying by disease and domain (**Supplement**). We excluded animal studies, case reports with <10 participants, abstract-only publications, and preprints. Two reviewers independently screened and extracted study characteristics, population demographics, interventions, comparators, and outcomes.

Patient Populations

We stratified results by pre-specified patient populations based on age, pregnancy, and immune status (**Supplement**). We defined infants as ≤24 months, children as 2-17 years, younger adults as 18-64 years, and older adults as aged ≥65 years (≥60 for RSV). Studies reporting age

ranges that could not be disaggregated into prespecified populations were summarized separately.

Outcomes

We reported outcomes for four domains: epidemiology, VE, safety, and co-administration. Epidemiologic data were extracted to contextualize vaccine impact. The primary VE outcome was against laboratory-confirmed, virus-associated hospitalization within 6 months (Covid-19) or one season (RSV and influenza) of immunization; secondary outcomes included VE against medically-attended infection, later hospitalization, intensive care unit (ICU) admission, death, long-term symptoms, and composite endpoints.

Primary safety outcomes included prespecified adverse events (AEs) of special interest by vaccine type and population (**Supplement**).

Statistical Analysis

Effect estimates were reported for VE and safety analyses for which there was an unvaccinated or self-controlled (for safety studies) comparator; *other studies were reported descriptively* (**Supplement**). Random-effects meta-analyses (DerSimonian-Laird method) were conducted when ≥3 comparable studies provided adjusted effect estimates (**Supplement**). Heterogeneity was quantified using the I^2 statistic. Analyses were performed using R version 4.3.0.

Risk of Bias

We assessed risk of bias using validated, study design-specific tools *for all included studies* (**Supplement**). *In sensitivity analyses, we examined the robustness of the pooled estimates by excluding studies with moderate and high risk of bias.*

RESULTS

Study Selection and Characteristics

Of 17,263 identified references, 1,406 underwent full-text review, yielding 511 eligible studies (**Figure 1**)—*12% were RCTs, 24% were cohort studies, 16% were case-control, and 48% used other observational designs; 55% were deemed to have moderate or high risk of bias, including 31% of RCTs and 59% of all observational studies* (**Table S4**).

Epidemiology

*Epidemiologic findings are summarized in the **Supplement** and **Table S5**.*

Vaccine Efficacy/Effectiveness

Covid-19

Children

In a case-control study of children (5-17 years), BNT162b2 XBB.1.5 was associated with VE 65% (95% CI, 36 to 81%) against hospitalization, emergency department, or urgent care visits (**Table S6**).[4] Two pediatric studies found that Covid-19 vaccination was associated with reduced risk of post-Covid symptoms, with VE 57% (95% CI, 2 to 81) against ≥1 symptom *and 73% (95% CI, 31 to 90) against* ≥2 symptoms *in a case-control study,*[5] *and VE 60% (95% CI, 40 to 74) against Long Covid in a cohort study* (**Table S6**).[6]

Adults

Among all adults, pooled VE against hospitalization for multiple XBB.1.5 vaccine products was 46% (95% CI, 34 to 55) across three cohort studies,[7-9] and 50% (95% CI, 43 to 57) across four case-control studies (**Figure 2, Table 1a**).[10-13] XBB.1.5-adapted vaccines were generally associated with lower VE during JN.1-predominant periods—14-54% (**Table 1a, Table S6**).[10,12-15] The KP.2-adapted BNT162b2 vaccine was associated with VE 68% (95% CI, 42 to 82).[16]

Among adults aged 18-64, three case-control studies found mRNA XBB.1.5 VE 57-58% against hospitalization (**Table 1a**).[11,12] A third study found similar effectiveness against hospitalization/death (**Table S6**).[17] Six studies estimated Covid-19 VE against symptomatic or medically-attended infection 22-48% (**Table S6**).[11,12,15,18-20]

Among adults ≥65 years, three cohort studies of mRNA XBB1.5 vaccines had pooled VE 56% (95% CI, 51 to 60) against hospitalization (**Table 1a**, **Figure 2**), and two case-control studies *reported* VE 41% (95% CI, 32 to 50) and 54% (95% CI, 40 to 64) (**Table 1a**).[9,11,12,21,22] Studies combining participants receiving mRNA or protein-based vaccines generally reported lower VE (21-47%) (**Table 1a**).[15,23] A study of the 2024-2025 booster vaccines reported VE 45-46% against hospitalization (**Table 1a**).[20] Two cohort studies evaluated mRNA XBB.1.5 VE against death: one found VE 75% (95% CI, 71 to 80);[22] the other, 58% (95% CI, 42 to 69) among those 65-79 years and 48% (95% CI, 38 to 57) in those ≥80 (**Table S6**).[23] *Across five observational studies, reported VE against symptomatic or medically-attended Covid-19 ranged 15-48%* (**Table S6**).[9,11,15,20,24]

Immunocompromised

Among immunocompromised adults, pooled VE from four case-control studies across vaccine products was 37% (95% CI, 29 to 44) against hospitalization (**Figure 2, Table 1a**).[11,12,20,25] One retrospective cohort study of *immunocompromised adults with end-stage renal disease* reported VE 61% (95% CI, 36 to 77) against death (**Table S6**).[18]

Respiratory Syncytial Virus (RSV)

Pregnancy

A pooled analysis of three case-control studies estimated 68% VE (95% CI, 55 to 78) for maternal RSVPreF vaccination against infant hospitalization (**Figure 2, Table 1b**).[26-28] In an RCT, RSVPreF vaccination during pregnancy had VE of 55% (95% CI, 24 to 75) against infant hospitalization within 180 days of birth (**Table 1b**).[29]

Children

Fourteen studies evaluated nirsevimab effectiveness against hospitalization, with pooled VE 83% (95% CI, 74 to 88; case-control)[30-36] and 79% (95% CI, 70 to 85; cohort)[37-42] (**Figure 2, Table 1b**). In an RCT, nirsevimab had *VE 83% (9*5% CI, 68 to 92) against hospitalization at 180 days (**Table 1b**).[43] Among *five* cohort studies of infants *ranging <4 to <12 months*, pooled VE against ICU admission was 84% (95% CI, 78 to 88) (**Table S6, Figure S1**).[38-42] Three case-control studies yielded pooled VE 84% (95% CI, 77 to 89) against medically-attended infection among infants (**Table S6, Figure S2**).[30,31,36]

Adults aged ⩾60 years

Three case-control studies of RSV vaccines (RSVpreF or RSVPreF3-AS01) *showed pooled* VE 79% (95% CI, 72 to 85) against hospitalization (**Figure 2, Table 1b**).[44-46]

Immunocompromised

Among immunocompromised adults, two case-control studies reported VE 73% (95% CI, 48 to 85)[44] and 70% (95% CI, 65 to 73) for RSV vaccination against hospitalization (**Table 1b**).[47] Effectiveness was higher among solid organ transplant recipients (73%, 95% CI, 62 to 81) than among hematopoietic stem-cell transplant recipients (33%, 95% CI, 12 to 49).[47]

Influenza

Pregnancy

One case-control study reported influenza VE 46% (95% CI, 36 to 55) during pregnancy against influenza-associated emergency department or urgent care visits (**Table S6**).[48]

Children

Six case-control studies yielded a pooled pediatric influenza VE 67% (95% CI, 58 to 75) against hospitalization (**Figure 2, Table 1c).**[49-53] O*ne case-control study reported VE 43% (95% CI, -6 to 70) against ICU admission, with imprecise estimates reflecting the rarity of this outcome (68/74,000 encounters)* (**Table S6**)[53] *Pooled analysis of twenty-one case-control studies showed VE 55% (95% CI, 52 to 68) against medically-attended influenza (**Table S6, Figure S3**).*[49,51-70]

Adults aged 18-64 years

Three case-control studies yielded a pooled influenza VE 48% (95% CI, 39 to 55) against hospitalization (**Figure 2, Table 1c**).[71-73] Among 19 case-control studies, pooled influenza VE against medically-attended infection was 49% (95% CI, 45 to 53) (**Table S6, Figure S4**).[48,55,59,61,63,64,66-78]

Adults aged ≥65 years

In adults aged ≥65 years, one case-control study reported VE 53% (95% CI, 35 to 66), *47% (95% CI, 41 to 53)*, and 36% (95% CI, 23 to 47) for the high-dose, *adjuvanted*, and standard-dose inactivated influenza vaccines (**Table 1c**).[79] Ten case-control studies of varied standard-dose vaccine formulations yielded pooled VE 42% (95% CI, 36 to 47) against hospitalization (**Figure 2, Table 1c**).[34,49,50,53,71-73,79-81] *Twenty* case-control studies had pooled influenza *VE 41% (95% CI, 35 to 45*) against medically-attended infection (**Table S6, Figure S5**).[49,53,57-61,63,65,67,68,71-76,78,79,82]

Immunocompromised

Among immunocompromised adults, one multicenter U.S. case-control study reported influenza VE 32% (95% CI, 7 to 50) against hospitalization (**Table 1c**).[80]

Sensitivity Analyses

*Pooled estimates were similar after excluding studies with moderate or high risk of bias (**Figure S6**).*

Safety

Covid-19

Pregnancy

Across *seven* observational studies, Covid-19 vaccination was not associated with risk of miscarriage, stillbirth, congenital anomalies, or small for gestational age (**Table 2a, Table S7**).[83-88] For preterm birth, BNT162b2 was associated with reduced risk in three of four studies: (odds ratio (OR) 0.72 (95% CI, 0.63 to 0.82),[88] adjusted odds ratio (aOR) 0.86 (95% CI, 0.83 to 0.90),[85] and adjusted hazard ratio (aHR) 0.79-0.93 by gestational age;[86] one study showed no

association (**Table 2a**).[89] MRNA-1273 vaccine *was associated with* reduced risk of preterm birth in one study (aOR 0.86, 95% CI, 0.81 to 0.93)[85] and no association in two others (**Table 2a**).[88,89]

Children

Studies reporting myocarditis incidence after Covid-19 vaccination in children are available in **Table 3a** and **Table S8**.[90-92] In South Korea, among 3,709,063 adolescents (12-19 years) who received 8,135,240 BNT162b2 doses, 184 cases of myocarditis/pericarditis were identified—82% in males—with incidence rates per 100,000 doses of 1.30 (95% CI, 0.95 to 1.73), 3.10 (95% CI, 2.50 to 3.71), and 2.76 (95% CI, 1.90 to 3.88) after the first, second, and third doses.[91] A second South Korean study also evaluated myocarditis rates in adolescents following COVID-19 vaccination.[92] In England, a self-controlled case series (SCCS) including 581,356 younger children (5-11 years) and 2,870,403 adolescents (12-17 years) receiving ≥1 BNT162b2 dose found no *association with* increased myocarditis risk in younger children and increased risk in adolescents (first dose incidence rate ratio [IRR] 1.92; 95% CI, 1.08 to 3.43; second dose IRR 2.96; 95% CI, 1.65 to 5.32)[90] *There was no association with increased risk of Idiopathic Thrombocytopenia Purpura (ITP), and there were too few GBS cases to provide effect estimates.*

Adults and Overlapping Populations

Myocarditis

An English cohort study evaluated myocarditis risk after BNT162b2 and mRNA-1273 vaccination among individuals ≥12 years, encompassing 45.7 million individuals between December 2020 and January 2022 (**Table 3a**).[93] Elevated myocarditis risk was observed within one week following BNT162b2 doses compared with baseline: first dose (aHR 2.05, 95% CI,

1.28 to 3.29), second (aHR 3.14, 95% CI, 2.04 to 4.85), and third (aHR 1.65, 95% CI, 1.07 to 2.57). For mRNA-1273, *increased risk was observed* within one week of the first dose (aHR 4.64, 95% CI, 1.40 to 15.31) and four weeks of the second (aHR 10.8, 95% CI, 3.79 to 30.83), but not following the third (aHR 0.86, 95% CI, 0.49 to 1.51).

A French case-control study of 7,911 myocarditis cases among individuals ⩾12 years, conducted during administration of >80 million BNT162b2 and mRNA-1273 doses, found that longer dosing intervals *were associated with lower* myocarditis risk.[94] For BNT162b2, the aOR fell from 6.5 (95% CI, 3.8 to 11) when the third dose was given <153 days after the second to 1.6 (95% CI, 0.61 to 4.2) when >213 days; findings were consistent for mRNA-1273. Two US-based SCCS found no significant increase in myocarditis following either BNT162b2 or mRNA-1273 XBB.1.5 vaccines.[95,96]

Stroke and Cerebral Venous Sinus Thrombosis (CVST)

Most studies showed either inverse or no significant associations with stroke depending on subtype (ischemic stroke, hemorrhagic stroke, or transient ischemic attack) and vaccine formulation (**Table 3a**).[93,95-100] An Italian SCCS found increased risk with mRNA-1273 (IRR 1.40, 95% CI, 1.23 to 1.60) but not BNT162b2.[101]

For CVST, *one English cohort study* found no association with either mRNA vaccine,[93] *while an Italian SCCS reported an increased risk associated with mRNA-1273 (IRR 4.84, 95% CI 1.47 to 15.89), but not BNT162b2.*[101]

Guillain-Barré Syndrome

A multinational SCCS observed no increased risk with BNT162b2 or mRNA-1273.[102] A US-based SCCS and a French case-control study reached similar conclusions.[95,103] In contrast, a

nationwide South Korean cohort comparing vaccinated individuals with historical controls identified an elevated risk after BNT162b2 (aHR 1.91, 95% CI, 1.35 to 2.70) but not mRNA-1273 (aHR 1.08, 95% CI, 0.64 to 1.81) during extended follow-up (mean 471 days) (**Table 3a**).[104]

Immunocompromised

A UK-based case-control study including 583,541 immunocompromised individuals (~2% organ transplant, >90% immune-modifying drugs), found either a reduced risk (e.g., IRR 0.68, 95% CI, 0.53 to 0.89 for dose 1) or no association with stroke in the 28 days following the first 3 doses of BNT162b2 (**Table 3**).[105] The same study found no increased risk of ITP following BNT162b2.

RSV

Pregnancy

Two studies found no association between RSVPreF vaccination and hypertensive disorders of pregnancy (**Table 2b**).[29,106] Others reported no association with stillbirth or congenital anomalies, placental abruption, or small for gestational age (**Table S7**).[29,106,107] For preterm birth, two cohort studies and one large RCT found no significant association with RSVPreF, *though effect estimates varied by timing of vaccination* (**Table 2b**).[106,108,109]

Adults aged ≥60 years

In a US multicenter RCT of 36,862 patients ≥60 years, myocardial infarction rates did not differ between RSVpreF and placebo (**Table 3b**).[110] A large U.S. SCCS of adults ≥60 years found 18.2 (95% CI, 9.8 to 23.3) excess GBS cases per million RSVPreF doses, with no statistically

300 significant increased risk for RSVPreF3-AS01 (5.2 excess cases per million doses).[47] The same
301 study found no increased risk of ITP for either RSV vaccine.

302 Influenza

303 *Pregnancy*

304 *Six* studies provided new data on influenza vaccine safety during pregnancy (**Table 2c, Table**
305 **S7**)[111-116] One reported a reduced miscarriage risk,[114] while another found no association.[115]
306 *Three studies had mixed results regarding influenza vaccine and hypertensive disorders of*
307 *pregnancy. A US-based cohort found no association,[112] a South Korean cohort found reduced*
308 *risk,[113] and a different US-based cohort found increased unadjusted risk (OR 1.08, 95% CI, 1.03*
309 *to 1.13).[114]* Other studies also reported no association between influenza vaccination and
310 stillbirth,[114] congenital abnormalities, [113] placental abruption, or small for gestational age (**Table**
311 **S7**).[112] A case-control study reported no association with spina bifida, and *inverse associations*
312 *with* cleft lip/palate (aOR 0.6, 95% CI, 0.4 to 0.9) and gastroschisis (aOR 0.4, 95% CI, 0.2 to
313 0.7) (**Table 2**).[116] For preterm birth, one cohort study found a reduced risk,[112] and another found
314 no significant association.[111]

315 *Adults aged ⩾65 years*

316 Two US SCCS found no increased risk of GBS among adults aged ⩾65 years (**Table 3c**)[91,117]

317 An SCCS including people on Medicare found no increased risk of ischemic or hemorrhagic
318 stroke following various influenza vaccines (**Table 3c**), but identified a statistically significant
319 increased risk of a composite of ischemic stroke or TIA occurring 22-42 days after high-dose
320 influenza vaccination (e.g., Medicare Advantage population, IRR 1.11, 95% CI, 1.01 to 1.22).[117]
321 Conversely, a Canadian cohort study found influenza vaccine within 30 days was *associated*
322 *with a reduced risk of* stroke (aHR 0.66, 95% CI, 0.65 to 0.68).[118]

Other Safety Events

Additional descriptive safety studies of adverse events of special interest without comparators and adverse events not of special interest are presented in **Tables S8 and S9.**

Coadministration

Seventeen studies of Covid-19 and influenza vaccine co-administration *showed* comparable immunogenicity and safety to sequential dosing (**Table S10**).[96,119-133] Five RCTs in adults aged ⩾65 years showed similar results for RSV and influenza co-administration.[134-138] Triple co-administration of Covid-19, RSV, and influenza vaccines, as well as co-administration with non-respiratory vaccines, maintained acceptable immunogenicity and safety profiles.[139]

Data Visualization

An interactive web application containing additional information about the included studies can be found here (**Supplement***)*.

DISCUSSION

This systematic review provides an updated, independent, and interactive evidence synthesis for respiratory virus immunizations ahead of the 2025-2026 season. Conducted over twelve weeks by academic researchers and clinical experts, it reflects a rigorous, transparent effort to support data-driven guidance following changes to federal advisory processes. This review includes only data published since the most recent comprehensive ACIP Evidence-to-Recommendations reviews. *These incremental data build upon different evidence foundations: decades for influenza vaccines, several years for COVID-19 vaccines, and emerging evidence for newly-licensed RSV immunizations.*[140] Updated findings affirm immunizations are associated

with substantial risk reduction against severe outcomes across populations, with *key* severe vaccine-related safety events *like myocarditis and GBS* remaining rare. *Although effectiveness estimates around 40% against hospitalizations in some populations (e.g., Covid-19 vaccines in immunocompromised, influenza vaccines in adults) may appear modest, they still represent substantial reductions in severe outcomes at the population level and are similar to influenza VE seen over the last fifteen years.*[140]

XBB.1.5-adapted Covid-19 vaccines *showed moderate to high effectiveness* against hospitalization across age groups, including clinically meaningful effectiveness among older and immunocompromised adults. Although *effectiveness* varied by time since vaccination, study population, and vaccine formulation, *it remained substantial* within six months of vaccination. Lower VE for XBB.1.5-adapted vaccines against JN.1 underscores the importance of timely strain-specific updates, *a strategy long used for influenza.*[10,12-15] *S*ome evidence suggested vaccination *may be associated with reduced* risk of Post-Covid-19-Condition among children. We did not identify new studies of Covid-19 VE during pregnancy, though prior evidence supports maternal vaccination to prevent severe disease and adverse maternal and child outcome.[141,142]

RSV prevention has advanced substantially in recent years. Maternal immunization with RSVPreF and infant nirsevimab both *showed strong effectiveness* against *infant* RSV-associated hospitalization. Among adults ⩾60 years, RSVPreF3 AS01 and RSVPreF *were similarly associated with high effectiveness* against hospitalization; *effectiveness among immunocompromised adults was lower but still substantial*.

Across age groups, influenza vaccines *showed effectiveness* against symptomatic infection and hospitalization, with the recommended high-dose formulations *associated with added benefit* for

older adults.[79] The high proportion of unvaccinated children among influenza-associated encephalopathy cases and fatalities underscores missed opportunities for prevention.[143,144]

Covid-19 vaccination during pregnancy was not associated with miscarriage, congenital anomalies, or stillbirth, and was associated with reduced preterm birth risk in most studies. Covid-19 vaccine-associated myocarditis occurred at rates of 1.3-3.1 per 100,000 doses in young males, with longer dosing intervals *associated with substantially lower risk,*[94] and *no significant excess myocarditis risk observed for XBB1.5-adapted vaccines.*[95,96]

For RSV vaccines, trial and real-world data *found no associations* with hypertensive disorders of pregnancy, stillbirth, or congenital anomalies. Initial concerns about preterm birth for RSVPreF were not observed in subsequent studies when vaccination occurred at the newly recommended 32-36 weeks' gestation. While GBS remained rare, a small increased risk was observed among adults aged ⩾60 years.

Influenza vaccines continued to *show* excellent safety across age groups and in pregnancy. Several studies identified *inverse associations between vaccination* and miscarriage, preterm birth, and congenital anomalies. A small increased risk of stroke observed in one Medicare study after high-dose vaccination merits further investigation. No excess GBS risk was observed.

Coadministration of respiratory virus vaccines preserved immunogenicity with similar reactogenicity to separate administration. Trials of concurrent Covid-19, RSV, and influenza vaccination demonstrated non-inferior immunogenicity and comparable safety, supporting single-visit vaccination strategies to facilitate access.

Although most included studies were observational, those rated low risk of bias attempted to control for known confounders using robust design and analytic methods. Evolving viral epidemiology and vaccine formulations may limit the durability of specific point estimates. *Our focus on the peer-reviewed literature excludes as-yet-unpublished, real-time data typically summarized for ACIP from systems such as the Vaccine Safety Datalink*. Prespecified search windows necessarily omitted studies published outside the review period, including later regulatory analyses and safety assessments. Several major randomized trials published subsequently report findings consistent with our primary results.[45,145-148] With compressed timelines and screening of 17,263 references, some data may have been inadvertently excluded. All extracted data are publicly available via a web application for user review and interpretation. *Further limitations are detailed in the* **Supplement**.

CONCLUSIONS

Immunizations against Covid-19, RSV, and influenza *have shown consistent effectiveness and safety and are associated with substantially reduced risk of hospitalization and severe disease across populations*. These findings underscore the enduring value of respiratory virus immunization as a cornerstone of preventive care and *support* the feasibility of maintaining rigorous, evidence-based guidance during periods of institutional disruption.

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Table 1. 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]

Population	Vaccine	Study design	# Studies	Study label	VE% (95% CI)[c]
a. Covid-19					
Adult	BNT162b2_ XBB1.5[d]	Case-control	2	Nguyen 2025[e,12] Caffrey 2024[11]	57 (19 to 77) 58 (33 to 73)
	Mixed XBB1.5 vaccines[f]	Case-control	1	Link-Gelles 2025[15]	21 (-12 to 45)
Adult/Older Adult	BNT162b2_KP.2	Case-control	1	Appaneal 2025[16]	68 (42 to 82)
	mRNA XBB1.5[g]	Cohort	3	Andersen 2025[9] Chong 2024[8] Wilson 2025[21]	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[11] Levy 2025[13] Nguyen 2025[e,12] Tartof 2024[10]	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 2024[14], JN.1 Ma 2024[14], XBB[h]	33 (2 to 54) 54 (36 to 67)
Older Adult	Mixed 2024-2025 vaccines[i]	Case-control	1	Link-Gelles 2025[20], VISION Link-Gelles 2025[20], IVY	45 (36 to 53) 46 (26 to 60)
	mRNA XBB1.5[g]	Cohort	3	Andersen 2025[9] Wilson 2025[21] Andersson 2024[22]	47 (28 to 61) 56 (51 to 61) 58 (50 to 66)
				Pooled estimate (3 studies)	**56 (51 to 60)**

Population	Vaccine	Study design	# Studies	Study label	VE% (95% CI)[c]
		Case-control	2	Caffrey 2024[11] Nguyen 2025[e,12]	41 (32 to 50) 54 (40 to 64)
	Mixed XBB1.5 vaccines[f]	Cohort	1	Nunes 2024[23], 80+y Nunes 2024[23], 65-79y	39 (17 to 54) 47 (32 to 59)
		Case-control	1	Link-Gelles 2025[15]	21 (10 to 31)
Immuno-compromised	Mixed vaccines	Cohort	2	Wilson 2025[21] Payne 2025[18]	46 (39 to 52) 65 (35 to 82)
		Case-control	4	Caffrey 2024[11] Link-Gelles 2024[25] Link-Gelles 2025[20] Nguyen 2025[12]	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[29]	55 (24 to 75)*
	RSVPreF	Case-control	3	Williams 2025[28] Pérez Marc 2025[27] Gentile 2025[26]	58 (28 to 75) 71 (53 to 82) 79 (51 to 91)
				Pooled estimate (3 studies)	**68 (55 to 78)**
Infant	Nirsevimab	Case-control	7[j,k]	Guerrero-del-Cueto 2025[35]	92 (72 to 97)*

Population	Vaccine	Study design	# Studies	Study label	VE% (95% CI)[c]
				Silva-Afonso 2025[34] Rius-Peris 2025[33] Carbajal 2024[30] Nunez 2025[l,32] Lefferts 2024[36] Moline 2025[31]	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)**
Infant	Nirsevimab	Cohort	6[m]	Jabagi[40] 2025 Perramon-Malavez 2025[41] Torres 2025[42] Ares-Gómez 2024[37] Barbas Del Buey 2024[38] Coma 2024[39]	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[149]	83 (68 to 92)
Older Adult	RSVPreF or RSVPreF3	Case-Control	4	Fry 2025[47]	76 (73 to 78)*
				Surie 2024[45] Payne 2024[44] Tartof 2024[46]	75 (50 to 87) 80 (71 to 85) 90 (20 to 99)
				Pooled estimate (3 studies)	**79 (72 to 85)**
		Cohort	1	Bajema 2025[150]	80 (66 to 90)
Immuno-compromised	RSVPreF or RSVPreF3	Case-control	2	Fry 2025[47] Payne 2024[44]	70 (65 to 73)* 73 (48 to 85)
c. Influenza					
Infant/Child	Any	Case-control	8	Shinjoh 2024[151], Flu A[o] Lee 2024[152], H1N1[o] Lee 2024[152], H3N2[o] Shinjoh 2024[151], Flu B[p] Lee 2024[152], Flu B[p]	51 (23 to 69) 54 (33 to 69) 55 (30 to 72) 60 (22 to 79) 66 (42 to 80)

Population	Vaccine	Study design	# Studies	Study label	VE% (95% CI)[c]
				Gharpure 2025[50], Brazil	46 (14 to 66)
				Frutos 2024[49], VISION[s,u]	52 (16 to 72)
				Tenforde 2024[n,53,]	58 (44 to 69)
				Frutos 2024[49], NVSN[s,t]	61 (40 to 75)
				Frutos 2025[71], NVSN[t]	63 (41 to 76)
				Gharpure 2025, Chile	71 (41 to 86)
				Shinjoh 2025[o,q,52]	73 (57 to 83)
				Pérez-Gimeno 2024[o,51]	77 (21 to 93)
				Frutos 2025[71], VISION[u]	78 (60 to 89)
				Gharpure 2025[50], Australia	88 (77 to 93)
				Pooled estimate (6 studies)	**67 (58 to 75)**
Adult	Any	Case-control	5	Tenforde 2024[53], 50-64y	40 (32 to 48)
				Lewis 2025[80], 50-64y	47 (31 to 60)
				Tenforde 2024[53], 18-49y	51 (42 to 60)
				Lewis 2025[80], 18-49y	53 (34 to 67)
				Rose 2025[73], Scotland	28 (13 to 40)
				Rose 2025[73], Denmark	44 (28 to 57)
				Frutos 2025[71], IVY	48 (28 to 63)
				Frutos 2025[71], VISION	51 (41 to 59)
				Rose 2025[73], EU	52 (16 to 74)
				Maurel 2024[o,72,]	53 (31 to 68)
				Rose 2025[73], England	53 (46 to 59)
				Rose 2025[73], North Ireland	72 (39 to 87)
				Pooled estimate (3 studies)	**48 (39 to 55)**
Adult/Older Adult	**Any**	**Case-control**	**1**	**Domnich 2024[153], Flu A,[o]**	**40 (-5 to 66)**
				Domnich 2024[153], Flu A(H1N1)	**35 (-17 to 63)**
			2	Frutos 2024[49], VISION	41 (34 to 47)
				Frutos 2024[49], IVY	44 (32 to 54)
				Erdwiens 2025[66], 60+y	76 (27 to 92)
				Pooled estimate (2 studies)	42 (37 to 48)

Population	Vaccine	Study design	# Studies	Study label	VE% (95% CI)[c]
Adult/Older Adult	Any	Cohort	2	Acuti Martellucci 2025[154], 60+y Ruzafa Martinez 2024[155]	47 (24 to 63) 78 (24 to 94)
Adult/Older Adult	Adjuvanted	Cohort	1	Acuti Martellucci 2025[154], 60+y	47 (40 to 54)
Adult/Older Adult	Non-adjuvanted HD	Cohort	1	Acuti Martellucci 2025[154], 60+y	38 (23 to 50)
Older Adult	Any	Case-control	10	Gharpure 2025[50], Brazil[47] Martínez-Baz 2025[81] Rose 2025[73], Scotland Lewis 2025[80] Maurel 2024[m,72] Emborg 2025 Tenforde 2024[53] Frutos 2025[71], Ivy Silva-Afonso 2025[34] Gharpure 2025[50], Chile Frutos 2024[49],VISION Frutos 2024[49], IVY Rose 2025[73], England Rose 2025[73], EU Rose 2025[73], Northern Ireland Rose 2025[73], Denmark Frutos 2025[71], VISION Gharpure 2025[50], Australia Gharpure 2025[71], New Zealand **Pooled estimate (10 studies)**	14 (-19 to 39) 28 (6 to 45) 29 (23 to 36) 31 (16 to 43) 36 (22 to 47) 36 (23 to 47) 36 (31 to 41) 38 (19 to 52) 39 (15 to 56) 40 (12 to 59) 42 (34 to 50) 42 (23 to 56) 48 (42 to 53) 49 (34 to 61) 52 (20 to 72) 55 (47 to 62) 57 (52 to 61) 59 (45 to 70) 72 (35 to 88) 42 (36 to 47)
Older Adult	Adjuvanted	Case-control	1	Emborg 2025[79], 70+y	47 (41 to 53)
Older Adult	Non-adjuvanted HD	Case-control	1	Emborg 2025[79], 65+y	53 (35 to 66)
Immuno-	Any	Case-control	1	Lewis 2025[80]	32 (7 to 50)

Population	Vaccine	Study design	# Studies	Study label	VE% (95% CI)[c]
compromised					

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

[*]Unadjusted estimate.

[a]Pooled 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.

[b]Data 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.

[c]Unadjusted 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.

[d]All 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.

[e]Study includes data from JN.1-predominant period only.

[f]Data provided only for mRNA and protein-based vaccines combined

[g]Includes studies of BNT162b2_XBB1.5 alone, mRNA1273_XBB1.5 alone, or combined mRNA XBB1.5 formulations.

[h]This 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).

[i]Includes mRNA KP.2 formulations, and protein-based JN.1 formulation.

[j]The 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 SX). All studies included in the pooled estimates for this outcome represent ages 0 to 12 months.

[k]Studies 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.

[l]At-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).

[m]Population 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.

[n]Outcome is acute respiratory illness-associated hospitalizations >24h duration.

[o]Outcome is hospitalization with influenza A.

[p]Outcome is hospitalization with influenza B.

[q]Outcome is fever plus hospitalization.

[s]Frutos 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.

[t]Outcome is for all flu subtypes, ARI in inpatient setting from NVSN.

[u]Outcome is for all flu subtypes, ARI in inpatient setting from VISION.

485 **Table 2. Summary results of studies regarding key vaccine safety outcomes[a] in pregnancy**

Safety outcome	Vaccine	# Studies w/ comparison group[b]	Study label	Effect estimate (95% CI)
a. Covid-19				
Miscarriage	BNT162b2	1	Sheth 2025[83]	aOR 0.97 (0.57 to 1.66)
	mRNA-1273	1	Sheth 2025[83]	aOR 0.59 (0.29 to 1.19)
Stillbirth	BNT162b2	3	Denoble 2024[84] Mensah 2024[85] Suseeladevi 2024[86]	aOR 1.00 (0.69 to 1.43) aOR 0.85 (0.69 to 1.05) aHR 0.72 (0.52 to 1.00)
	mRNA-1273	2	Denoble 2024[84] Mensah 2024[85]	aOR 1.00 (0.62 to 1.62) aOR 0.97 (0.71 to 1.32)
Congenital anomalies	BNT162b2	2	Jorgensen 2024[87] Kim 2025[88]	aPR 0.91 (0.80 to 1.04) OR 0.98 (0.88 to 1.09)
	mRNA-1273	2	Jorgensen 2024[87] Kim 2025[88]	aPR 0.88 (0.65 to 1.21) OR 0.90 (0.74 to 1.10)
Preterm birth	BNT162b2	4	Hall 2025[89] Kim 2025[88] Mensah 2024[85] Suseeladevi 2024[86], 24-<32 weeks Suseeladevi 2024[86], 32-36 weeks	aHR 1.12 (0.88 to 1.42) OR 0.72 (0.63 to 0.82) aOR 0.86 (0.83 to 0.90) aHR 0.79 (0.65 to 0.97) aHR: 0.93 (0.87 to 0.99)
	mRNA-1273	3	Hall 2025[89] Kim 2025[88] Mensah 2024[85]	aHR 0.84 (0.60 to 1.16) OR 0.82 (0.66 to 1.03) aOR 0.86 (0.81 to 0.93)
b. RSV				
Gestational hypertension,	RSVPreF	2	Jin Hsieh 2025[106]	aRR 0.97 (0.91 to 1.04)

Safety outcome	Vaccine	# Studies w/ comparison group[b]	Study label	Effect estimate (95% CI)
pre-eclampsia, or eclampsia			Simões 2025[29]	OR 1.12 (0.70 to 1.79)
Stillbirth	RSVPreF	1	Simões 2025[29]	OR 1.11 (0.45 to 2.73)
Congenital anomalies	RSVPreF	1	Simões 2025[29]	OR 0.82 (0.68 to 1.00)
Preterm birth[c]	RSVPreF	3	Jin Hsieh 2025[106] Madhi 2025[109] Blauvelt 2025[108]	aRR: 1.01 (0.89 to 1.15) RR: 1.20 (0.98 to 1.46) aOR: 1.03 (0.55 to 1.93)
c. **Influenza**[d]				
Miscarriage	Seasonal	2	Regan 2023[115] Regan 2024[114]	aHR 0.83 (0.47 to 1.47) aHR 0.61 (0.50 to 0.74)
Gestational hypertension, pre-eclampsia, or eclampsia	Seasonal	3	Getahun 2024[112] Lee 2025[113] Regan 2024[114]	aRR 1.10 (0.99 to 1.21) aRR 0.76 (0.72 to 0.80) OR 1.08 (1.03 to 1.13)
Stillbirth	Seasonal	1	Regan 2024[114]	aHR 0.99 (0.76 to 1.30)
Congenital anomalies	Seasonal	2	Lee 2025[113] Malange 2025[116], Spina bifida Malange 2025[116], Cleft lip +/- palate Malange 2025[116], Gastroschisis	aRR 1.19 (0.96 to 1.48) aOR 0.9 (0.4 to 2.0) aOR 0.6 (0.4 to 0.9) aOR 0.4 (0.2 to 0.7)
Preterm birth	Seasonal	2	Getahun 2024[112] Fell 2024[111]	aRR 0.83 (0.78 to 0.89) OR 0.92 (0.80 to 1.06)

CI: confidence interval, aOR: adjusted odds ratio, aHR: adjusted hazard ratio, aPR: adjusted prevalence ratio, aRR: adjusted Risk Ratio. Results are reported to two significant digits when at least that many were reported in a study.

[a]Key vaccine safety outcomes included: miscarriage, stillbirth, congenital anomalies, preterm birth, and gestational hypertension/pre-eclampsia/eclampsia (prioritizing the most severe of those when reported). Additional vaccine safety outcomes in pregnancy, including small for gestational age, placental abruption, Guillain-Barre Syndrome, and cardiovascular disease are presented in Appendix Table S6; no concerning safety signals were identified for these outcomes.

[b]Studies were included in the main body of the table if they report data that allows for comparison between a vaccinated group and an unvaccinated group (studies with an active comparator [e.g., other vaccine product] are not included in footnotes).
[C]In the MATISSE trial (Madhi 2025), participants received RSVPreF at 24-36 weeks gestation. Post-marketing surveillance data as reflected in Jin Hsieh 2025 and Blauvelt 2025 were collected after guidelines recommended administration later in pregnancy, at 32-36 weeks.
[d]All seasonal influenza vaccines during the time period of the study.

526 **Table 3. Summary results of studies regarding vaccine safety not specific to pregnancy. Studies reporting safety outcomes**
527 **without comparator groups permitting a risk estimate are excluded and provided in the Supplement.**

Safety outcome	Population	Vaccine	# Studies with comparator group	Study Label[a]	Effect estimate (95% CI)[b]
a. Covid-19					
GBS	Child	BNT162b2	1	Copland 2024[90], 1-42 days after vaccine	<10 events, no effect estimate
		mRNA-1273	1	Copland 2024[90], 1-42 days after vaccine	0 events, no effect estimate
	Adult/Older Adult	BNT162b2 XBB1.5	1	Pan 2025[95]	aIRR 0.25 (0.02 to 4.02)
		mRNA-1273 XBB1.5	1	Pan 2025[95]	aIRR 0.42 (0.02 to 2.44)
	Child/Adult/ Older Adult	BNT162b2	3	Le Vu 2023[103], dose 1 Le Vu 2023 [103], dose 2 Le Vu 2023[103], dose 3 Nasreen 2025[102], dose 1 Jung 2024[104]	aIRR 1.1 (0.91 to 1.4) aIRR 1.0 (0.83 to 1.3) aIRR 0.92 (0.70 to 1.2) IRR 0.39 (0.23 to 0.65) aHR 1.91 (1.35 to 2.70)
		mRNA-1273	3	Le Vu 2023[103], dose 1 Le Vu 2023[103], dose 2 Le Vu 2023[103], dose 3 Nasreen 2025[102], dose 1 Jung 2024[104]	aIRR 1.2 (0.68 to 2.1) aIRR 1.3 (0.84 to 2.0) aIRR 0.98 (0.64 to 1.5) aIRR 0.71 (0.41 to 1.24) aHR 1.08 (0.64 to 1.81)
Myocarditis	Child	BNT162b2	1	Copland 2024[90], dose 1 Copland 2024[90], dose 2	IRR 1.92 (1.08 to 3.43) IRR 2.96 (1.65 to 5.32)
	Adult/Older Adult	BNT162b2	1	Ip 2024[93], 0-7 days after dose 1 Ip 2024[93], 0-14 days after dose 1 Ip 2024[93], 21-28 days after dose 1 Ip 2024[93], 0-7 days after dose 2 Ip 2024[93], 0-14 days after dose 2 Ip 2024[93], 21-28 days after dose 2 Ip 2024[93], 0-7 days after booster Ip 2024[93], 0-14 days after booster	aHR 2.05 (1.28 to 3.29) aHR 1.41 (0.81 to 2.48) aHR 1.07 (0.67 to 1.70) aHR 3.14 (2.04 to 4.85) aHR 1.63 (0.94 to 2.82) aHR 0.98 (0.59 to 1.63) aHR 1.65 (1.07 to 2.57) aHR 1.06 (0.62 to 1.82)

Safety outcome	Population	Vaccine	# Studies with comparator group	Study Label[a]	Effect estimate (95% CI)[b]
				Ip 2024[93], 21-28 days after booster	aHR 1.11 (0.73 to 1.69)
		BNT162b2 XBB.1.5	1	Pan 2025[95], 0-28 days	aIRR 0.45 (0.13 to 1.16)
		mRNA-1273	1	Ip 2024[93], 0-7 days after dose 1 Ip 2024[93], 0-14 days after dose 1 Ip 2024[93], 21-28 days after dose 1 Ip 2024[93], 0-28 days after dose 2 Ip 2024[93], 0-28 days after booster	aHR 4.64 (1.40 to 15.31) aHR 1.52 (0.21 to 10.99) aHR 0.87 (0.12 to 6.45) aHR 10.80 (3.79 to 30.83) aHR 0.86 (0.49 to 1.51)
		mRNA-1273 XBB.1.5	1	Pan 2025[95], 0-28 days	aIRR 0.39 (0.06 to 1.44)
	Child/Adult/ Older Adult	BNT162b2	1	Le Vu 2024[94], 0-7 days after dose 1 Le Vu 2024[94], 0-21 days after dose 1 Le Vu 2024[94], 0-7 days after dose 2, all Le Vu 2024[94], 0-7 days after dose 2, <22 day dosing interval Le Vu 2024[94], 0-7 days after dose 2, 22-28 day dosing interval Le Vu 2024[94], 0-7 days after dose 2, 29-35 day dosing interval Le Vu 2024[94], 0-7 days after dose 2, >35 day dosing interval Le Vu 2024[94], 0-21 days after dose 2, all Le Vu 2024[94], 0-7 days after dose 3, all Le Vu 2024[94], 0-7 days after dose 3, <153 day dosing interval Le Vu 2024[94], 0-7 days after dose 3, 153-183 day dosing interval Le Vu 2024[94], 0-7 days after dose 3, 184-213 day dosing interval	aOR 2.0 (1.5 to 2.6) aOR 1.5 (1.3 to 1.8) aOR 7.1 (6.0 to 8.5) aOR 15 (11 to 20) aOR 7.8 (5.7 to 11) aOR 5.6 (3.2 to 9.8) aOR 3.5 (2.5 to 4.8) aOR 3.1 (2.7 to 3.6) aOR 4.2 (3.2 to 5.5) aOR 6.5 (3.8 to 11) aOR 4.7 (3.3 to 6.8) aOR 3.4 (2.0 to 5.7)

Safety outcome	Population	Vaccine	# Studies with comparator group	Study Label[a]	Effect estimate (95% CI)[b]
				Le Vu 2024[94], 0-7 days after dose , >213 day dosing interval	aOR 1.6 (0.61 to 4.2)
				Le Vu 2024[94], 0-21 days after dose 3, all	aOR 2.3 (1.9 to 2.8)
		BNT162b2 XBB.1.5	1	Sun 2025[96], 0-21 days	aRI 1.50 (0.22 to 12.61)
		mRNA-1273	1	Le Vu 2024[94], 0-7 days after dose 1	aOR 2.0 (1.0 to 4.0)
				Le Vu 2024[94], 0-21 days after dose 1	aOR 1.5 (0.93 to 2.4)
				Le Vu 2024[94], 0-7 days after dose 2, all	aOR 22 (16 to 30)
				Le Vu 2024[94], 0-7 days after dose 2, <22 day dosing interval	aOR 34 (17 to 67)
				Le Vu 2024[94], 0-7 days after dose 2, 22-28 day dosing interval	aOR 29 (16 to 54)
				Le Vu 2024[94], 0-7 days after dose 2, 29-35 day dosing interval	aOR 19 (7.7 to 50)
				Le Vu 2024[94], 0-7 days after dose 2, >35 day dosing interval	aOR 13 (7.7 to 23)
				Le Vu 2024[94], 0-21 days after dose 2, all	aOR 7.3 (5.7 to 9.4)
				Le Vu 2024[94], 0-7 days after dose 3, all	aOR 4.6 (2.8 to 7.4)
				Le Vu 2024[94], 0-7 days after dose 3, <153 day dosing interval	aOR 6.4 (2.7 to 15)
				Le Vu 2024[94], 0-7 days after dose 3, 153-183 day dosing interval	aOR 3.5 (1.7 to 7.1)
				Le Vu 2024[94], 0-7 days after dose 2, 184-213 day dosing interval	aOR 3.8 (1.2 to 12)
				Le Vu 2024[94], 0-7 days after dose 2, >213 day dosing interval	aOR 9.0 (2.2 to 38)
				Le Vu 2024[94], 0-21 days after dose 3, all	aOR 2.2 (1.5 to 3.2)
	Immuno-compromised	BNT162b2	1	Fabbri 2025[156], dose 3 or 4	aOR 0.33 (0.01 to 8.28)

Safety outcome	Population	Vaccine	# Studies with comparator group	Study Label[a]	Effect estimate (95% CI)[b]
ITP	Child	BNT162b2	1	Copland 2024[90], ages 5-11 years, 1-42 days after any vaccine dose Copland 2024[90], ages 12-17 years, 1-42 days after dose 1 Copland 2024[90], ages 12-17 years, 1-42 days after dose 2 Copland 2024[90], ages 12-17 years, 1-42 days after dose 3	<15 events, no effect estimate IRR 0.76 (0.55-1.07) IRR 0.83 (0.57-1.21) IRR 0.72 (0.37-1.37)
		mRNA-1273	1	Copland 2024[90], ages 5-11 years, 1-42 days after vaccine Copland 2024[90], ages 12-17 years, 1-42 days after vaccine	0 events, no effect estimate <5 events, no effect estimate
	Immuno-compromised	BNT162b2	1	Chen 2024[105], 0-28 days after dose 1 Chen 2024[105], 0-28 days after dose 2 Chen 2024[105], 0-28 days after dose 3	aIRR 1.03 (0.63 to 1.71) aIRR 1.04 (0.66 to 1.66) aIRR 1.14 (0.72 to 1.82)
CVST	Adult/Older Adult	BNT162b2	1	Ip 2024[93], 0-7 days after dose 1 Ip 2024[93], 0-7 days after dose 2 Ip 2024[93], 0-7 days after booster	aHR 0.16 (0.02 to 1.14) aHR 0.51 (0.18 to 1.43) aHR 0.45 (0.11 to 1.89)
		mRNA-1273	1	Ip 2024[93], 0-28 days after dose 1 Ip 2024[93], 0-28 days after booster	aHR 1.50 (0.36 to 6.23) aHR 0.26 (0.04 to 1.79)
	Child/Adult/ Older Adult	BNT162b2	1	Salmaggi 2025[101], 0-28 days	aIRR 1.73 (0.85 to 3.53)
		mRNA-1273	1	Salmaggi 2025[94], 0-28 days	aIRR 4.84 (1.47 to 15.89)
Stroke	Adult/Older Adult	BNT162b2	8	Ab Rahman 2024[97], dose 1 Ab Rahman 2024[94], dose 2 Ab Rahman 2024[94], dose 3 Byoun 2024[94] Chemaitelly 2024[98] Choi 2024[99], within 21 days Ip 2024[93], 0-7 days after dose 1, ischemic stroke	IRR 0.91 (0.81 to 1.01) IRR 0.98 (0.89 to 1.09) IRR 0.92 (0.84 to 1.01) aOR 0.42 (0.31 to 0.59) aOR 0.87 (0.72 to 1.04) aIRR 0.74 (0.56 to 0.97) aHR 0.69 (0.65 to 0.74) aHR 0.64 (0.53 to 0.78)

Safety outcome	Population	Vaccine	# Studies with comparator group	Study Label[a]	Effect estimate (95% CI)[b]
				Ip 2024[93], 0-7 days after dose 1, SAH & hemorrhagic stroke	aHR 0.74 (0.69 to 0.79)
				Ip 2024[93], 0-7 days after dose 2, ischemic stroke	aHR 0.70 (0.57 to 0.86)
				Ip 2024[93], 0-7 days after dose 2, SAH & hemorrhagic stroke	aHR 0.77 (0.73 to 0.81)
				Ip 2024[93], 0-7 days after dose 3[c], ischemic stroke	aHR 0.72 (0.62 to 0.84)
				Ip 2024[93], 0-7 days after dose 3[c], SAH & hemorrhagic stroke	aHR 0.18 (0.13-0.25)
				Xiang 2024[100]	aRI 0.96 (0.79 to 1.17)
				Xu 2024[157]	aHR 0.91 (0.86 to 0.97)
				Xu 2025[158], 0-28 days after dose 1	aHR 0.88 (0.82 to 0.93)
				Xu 2025[158], 0-28 days after dose 2	aHR 0.75 (0.68 to 0.82)
				Xu 2025[158], 0-28 days after dose 3	
		BNT162b2 XBB.1.5	1	Pan 2025[95], 0-28 days	IRR 0.41 (0.20 to 0.76)
		mRNA-1273	6	Byoun 2024[94]	aOR 0.45 (0.30 to 0.67)
				Chemaitelly 2024[98]	aOR 0.86 (0.67 to 1.11)
				Choi 2024[99], within 21 days	aIRR 1.17 (0.35 to 3.85)
				Ip 2024[93], 0-7 days after dose 1, ischemic stroke	aHR 0.94 (0.42 to 2.10)
				Ip 2024[93], 0-28 days after dose 1, SAH & hemorrhagic stroke	aHR 0.83 (0.34 to 2.03)
				Ip 2024[93], 0-7 days after dose 2, ischemic stroke	aHR 0.39 (0.08 to 1.89)
				Ip 2024[93], 0-28 days after dose 2, SAH & hemorrhagic stroke	aHR 0.25 (0.04 to 1.63)
				Ip 2024[93], 0-7 days after dose 3[c], ischemic stroke	aHR 0.71 (0.61 to 0.82)
				Ip 2024[93], 0-7 days after dose 3[c], SAH & hemorrhagic stroke	aHR 0.45 (0.28 to 0.73)

Safety outcome	Population	Vaccine	# Studies with comparator group	Study Label[a]	Effect estimate (95% CI)[b]
				Xu 2024[157] Xu 2025[158], 0-28 days after dose 1 Xu 2025[158], 0-28 days after dose 2 Xu 2025[158], 0-28 days after dose 3	aRI 0.94 (0.76 to 1.16) aHR 0.88 (0.76 to 1.01) aHR 0.78 (0.68 to 0.89) aHR 0.68 (0.61 to 0.76)
		mRNA-1273 XBB.1.5	1	Pan 2025[95], 0-28 days	IRR 0.90 (0.60 to 1.32)
		NVX-CoV2373	1	Byoun 2024[94]	aOR 0.41 (0.06 to 2.97)
	Child/Adult/ Older Adult	BNT162b2	1	Salmaggi 2025, Ischemic stroke, 0-28 days Salmaggi 2025, Hemorrhagic stroke, 0-28 days	aIRR 0.98 (0.91 to 1.06) aIRR 0.95 (0.83 to 1.08)
		BNT162b2 XBB.1.5	1	Sun 2025[96], Ischemic Stroke, 0-28 days Sun 2025[96], Hemorrhagic Stroke, within 28 days	RI 1.52 (0.44 to 5.94) RI 0.32 (0.04 to 1.66)
		mRNA-1273	1	Salmaggi 2025[101], Ischemic stroke, 0-28 days Salmaggi 2025[101], Hemorrhagic stroke, 0-28 days	aIRR 1.40 (1.23 to 1.60) aIRR 1.22 (0.96-1.55)
	Immuno-compromised	BNT162b2	1	Chen 2024[105], Ischemic stroke, 0-28 days, dose 1 Chen 2024[105], Ischemic stroke, 0-28 days, dose 2 Chen 2024[105], Ischemic stroke, 0-28 days, dose 3 Chen 2024[105], Hemorrhagic stroke, 0-28 days, dose 1 Chen 2024[105], Hemorrhagic stroke, 0-28 days, dose 2 Chen 2024[105], Hemorrhagic stroke, 0-28 days, dose 3	aIRR 0.68 (0.53 to 0.89) aIRR 0.84 (0.67 to 1.05) aIRR 0.75 (0.61 to 0.93) aIRR 0.22 (0.07 to 0.70) aIRR 0.39 (0.15 to 1.00) aIRR 0.90 (0.49 to 1.65)

Safety outcome	Population	Vaccine	# Studies with comparator group	Study Label[a]	Effect estimate (95% CI)[b]
				Chen 2024[105], Stroke (any type)/TIA, 0-28 days, dose 1	aIRR 0.71 (0.55 to 0.91)
				Chen 2024[105], Stroke (any type)/TIA, 0-28 days, dose 2	aIRR 0.80 (0.64 to 1.00)
				Chen 2024[105], Stroke (any type)/TIA, 0-28 days, dose 3	aIRR 0.79 (0.65 to 0.96)
		mRNA-1273	1	Chen 2024[105], Stroke (any type)/TIA, 0-28 days, dose 3	aIRR 0.51 (0.20 to 1.30)
b. RSV					
MI	Older Adult	RSVPreF	1	Walsh 2025[110]	OR 1.11 (0.72 to 1.71)
GBS	Older Adult	RSVPreF	1	Fry 2025[47]	IRR 2.4 (1.5 to 4.0)
		RSVPreF3	1	Fry 2025[47]	IRR 1.5 (0.9 to 2.2)
c. Influenza					
GBS	Older Adult	Various influenza vaccines	2	Lloyd 2025[117], Medicare Advantage	aIRR 0.72 (0.34 to 1.51)
				Lloyd 2025[117], Medicare FFS[d]	aIRR 1.10 (0.74 to 1.63)
				Shi 2024[159]	aIRR 0.90 (0.56 to 1.42)
		High-dose influenza vaccine	2	Lloyd 2025[117], Medicare Advantage	aIRR 0.71 (0.27 to 1.86)
				Lloyd 2025[117], Medicare FFS	aIRR 1.22 (0.69 to 2.16)
				Shi 2024[159]	aIRR 0.89 (0.49 to 1.64)
		Adjuvanted influenza vaccines	2	Lloyd 2025[117], Medicare Advantage	aIRR 0.55 (0.10 to 3.09)
				Lloyd 2025[117], Medicare FFS	aIRR 0.99 (0.55 to 1.77)
				Shi 2024[159]	aIRR 0.79 (0.33 to 1.94)
Stroke	Older Adult	Any influenza vaccine	1	Lloyd 2025[117], Hemorrhagic stroke, Medicare Advantage, 1-21 days	aIRR 1.10 (0.96 to 1.26)
				Lloyd 2025[117], Hemorrhagic stroke, Medicare Advantage, 22-42 days	aIRR 1.04 (0.91 to 1.19)
				Lloyd 2025[117], Hemorrhagic stroke, Medicare FFS, 1-21 days	aIRR 0.97 (0.89 to 1.05)
				Lloyd 2025[117], Hemorrhagic stroke, Medicare FFS, 22-42 days	aIRR 0.94 (0.87 to 1.02)
					aIRR 1.01 (0.92 to 1.11)

Safety outcome	Population	Vaccine	# Studies with comparator group	Study Label[a]	Effect estimate (95% CI)[b]
				Lloyd 2025[117], Ischemic stroke, Medicare Advantage, 1-21 days	aIRR 1.07 (0.98 to 1.16)
				Lloyd 2025[117], Ischemic stroke, Medicare Advantage, 22-42 days	aIRR 1.00 (0.94 to 1.06)
				Lloyd 2025[117], Ischemic stroke, Medicare FFS, 1-21 days	aIRR 1.04 (0.99 to 1.10)
				Lloyd 2025[117], Ischemic stroke, Medicare FFS, 22-42 days	
		High-dose influenza vaccine	1	Lloyd 2025[117], Hemorrhagic stroke, Medicare Advantage, 1-21 days	aIRR 1.18 (0.98 to 1.41)
				Lloyd 2025[117], Hemorrhagic stroke, Medicare Advantage, 22-42 days	aIRR 1.11 (0.93 to 1.33)
				Lloyd 2025[117], Hemorrhagic stroke, Medicare FFS, 1-21 days	aIRR 1.04 (0.93 to 1.17)
				Lloyd 2025[117], Hemorrhagic stroke, Medicare FFS, 22-42 days	aIRR 0.99 (0.88 to 1.11)
				Lloyd 2025[117], Ischemic stroke, Medicare Advantage, 1-21 days	aIRR 1.00 (0.88 to 1.13)
				Lloyd 2025[117], Ischemic stroke, Medicare Advantage, 22-42 days	aIRR 1.06 (0.94 to 1.19)
				Lloyd 2025[117], Ischemic stroke, Medicare FFS, 1-21 days	aIRR 0.98 (0.91 to 1.07)
				Lloyd 2025[117], Ischemic stroke, Medicare FFS, 22-42 days	aIRR 1.06 (0.98 to 1.14)
		Adjuvanted influenza vaccines	1	Lloyd 2025[117], Hemorrhagic stroke, Medicare Advantage, 1-21 days	aIRR 1.11 (0.84 to 1.45)
				Lloyd 2025[117], Hemorrhagic stroke, Medicare Advantage, 22-42 days	aIRR 0.96 (0.74 to 1.26)
				Lloyd 2025[117], Hemorrhagic stroke, Medicare FFS, 1-21 days	aIRR 0.89 (0.77 to 1.02)
				Lloyd 2025[117], Hemorrhagic stroke, Medicare FFS, 22-42 days	aIRR 0.86 (0.75 to 0.98)

Safety outcome	Population	Vaccine	# Studies with comparator group	Study Label[a]	Effect estimate (95% CI)[b]
				Lloyd 2025[117], Ischemic stroke, Medicare Advantage, 1-21 days	aIRR 1.07 (0.91 to 1.26)
				Lloyd 2025[117], Ischemic stroke, Medicare Advantage, 22-42 days	aIRR 1.09 (0.93 to 1.28)
				Lloyd 2025[117], Ischemic stroke, Medicare FFS, 1-21 days	aIRR 1.01 (0.93 to 1.11)
				Lloyd 2025[117], Ischemic stroke, Medicare FFS, 22-42 days	aIRR 1.03 (0.94 to 1.12)
		Any adjuvanted or high-dose vaccine	1	Lu 2024[160], hemorrhagic stroke, 2016-17 Season	IRR 0.99 (0.88 to 1.12)
				Lu 2024[160], hemorrhagic stroke, 2017-18 Season	IRR 0.98 (0.89 to 1.08)
				Lu 2024[160], hemorrhagic stroke, 2018-19 Season	IRR 0.95 (0.85 to 1.07)
				Lu 2024[160], Non-hemorrhagic stroke, 2016-17 Season	IRR 1.02 (0.96 to 1.08)
				Lu 2024[160], Non-hemorrhagic stroke, 2017-18 Season	IRR 0.97 (0.92 to 1.02)
				Lu 2024[160], Non-hemorrhagic stroke, 2018-2019 Season	IRR 1.02 (0.97 to 1.08)
	Adult/Older Adult	Any influenza vaccine	1	Tanaka 2024[118], Stroke (any type), 0-30 days	aHR 0.66 (0.65 to 0.68)

IRR: incidence rate ratio, HR: hazard ratio, OR: odds ratio, RR: rate ratio, RI: relative incidence
GBS: Guillain-Barré syndrome, MI: myocardial infarction, CVST: cerebral venous sinus thrombosis, ITP: immune thrombocytopenic purpura, FFS: Fee-for-service

[a]Time periods in the "Study Label" column refer to days since vaccination.
[b]Effect estimates prefixed with "a" indicate an adjusted effect estimate
[c]After any primary series

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