

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

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Word Count: 3727

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 ≥ 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

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

66 *Conclusions*

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

PROVISIONAL

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 1-17 years, younger adults as 18-64 years, and older adults as aged ≥ 65 years (≥ 60 for RSV). Studies reporting age

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

115 **Outcomes**

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

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

124 **Statistical Analysis**

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

130 **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% (95% 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 One 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

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

Influenza

Pregnancy

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

Adults aged ≥ 65 years

Two US SCCS found no increased risk of GBS among adults aged ≥ 65 years (**Table 3c**).^{91,117} An SCCS including people on Medicare found no increased risk of ischemic or hemorrhagic stroke following various influenza vaccines (**Table 3c**), but identified a statistically significant increased risk of a composite of ischemic stroke or TIA occurring 22-42 days after high-dose influenza vaccination (e.g., Medicare Advantage population, IRR 1.11, 95% CI, 1.01 to 1.22).¹¹⁷ Conversely, a Canadian cohort study found influenza vaccine within 30 days was *associated 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 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} Some 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, RSVPreF1 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.

FUNDING

The Center for Infectious Disease Research and Policy's Vaccine Integrity Project provided logistical support through an unrestricted grant from the Alumbra Innovations Foundation. Authors otherwise worked through donated time. The funder had no role in study design, data collection, analysis, interpretation, or manuscript preparation.

ACKNOWLEDGEMENTS

The authors express their gratitude to Angela Botticella and Sherri Berger for their operational support, Kevin Griffis for his communications work, Linh Le for her early abstract screening efforts, and Michael Osterholm—along with the entire CIDRAP team—for support, mentorship, and sponsorship.

PROVISIONAL

422 **Table 1. Summary results of vaccine effectiveness to prevent hospitalization *during varying follow-up* within 6 months**
423 **(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	58 (28 to 75)
				Pérez Marc 2025 ²⁷	71 (53 to 82)
				Gentile 2025 ²⁶	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 ^{1,32} 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 Frutos 2024 ⁴⁹ , VISION ^{s,u} Tenforde 2024 ^{n,53} , Frutos 2024 ⁴⁹ , NVSN ^{s,t} Frutos 2025 ⁷¹ , NVSN ^t Gharpure 2025, Chile Shinjoh 2025 ^{o,q,52} Pérez-Gimeno 2024 ^{o,51} Frutos 2025 ⁷¹ , VISION ^u Gharpure 2025 ⁵⁰ , 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)
				Pooled estimate (6 studies)	67 (58 to 75)
Adult	Any	Case-control	5	Tenforde 2024 ⁵³ , 50-64y Lewis 2025 ⁸⁰ , 50-64y Tenforde 2024 ⁵³ , 18-49y Lewis 2025 ⁸⁰ , 18-49y	40 (32 to 48) 47 (31 to 60) 51 (42 to 60) 53 (34 to 67)
				Rose 2025 ⁷³ , Scotland Rose 2025 ⁷³ , Denmark Frutos 2025 ⁷¹ , IVY Frutos 2025 ⁷¹ , VISION Rose 2025 ⁷³ , EU Maurel 2024 ^{o,72} , Rose 2025 ⁷³ , England Rose 2025 ⁷³ , North Ireland	28 (13 to 40) 44 (28 to 57) 48 (28 to 63) 51 (41 to 59) 52 (16 to 74) 53 (31 to 68) 53 (46 to 59) 72 (39 to 87)
				Pooled estimate (3 studies)	48 (39 to 55)
Adult/Older Adult	Any	Case-control	1	Domnich 2024¹⁵³, Flu A,^o Domnich 2024¹⁵³, Flu A(H1N1)	40 (-5 to 66) 35 (-17 to 63)
			2	Frutos 2024 ⁴⁹ , VISION Frutos 2024 ⁴⁹ , IVY Erdwiens 2025 ⁶⁶ , 60+y	41 (34 to 47) 44 (32 to 54) 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.

^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 SX). 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.

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.

^aKey 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.

^bStudies 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).

^cIn 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.

^dAll 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 Le Vu 2024 ⁹⁴ , 0-21 days after dose 3, all	aOR 1.6 (0.61 to 4.2) 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 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 2, 184-213 day dosing interval Le Vu 2024 ⁹⁴ , 0-7 days after dose 2, >213 day dosing interval Le Vu 2024 ⁹⁴ , 0-21 days after dose 3, all	aOR 2.0 (1.0 to 4.0) aOR 1.5 (0.93 to 2.4) aOR 22 (16 to 30) aOR 34 (17 to 67) aOR 29 (16 to 54) aOR 19 (7.7 to 50) aOR 13 (7.7 to 23) aOR 7.3 (5.7 to 9.4) aOR 4.6 (2.8 to 7.4) aOR 6.4 (2.7 to 15) aOR 3.5 (1.7 to 7.1) aOR 3.8 (1.2 to 12) aOR 9.0 (2.2 to 38) 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 Ip 2024 ⁹³ , 0-7 days after dose 2, ischemic stroke Ip 2024 ⁹³ , 0-7 days after dose 2, SAH & hemorrhagic stroke Ip 2024 ⁹³ , 0-7 days after dose 3 ^c , ischemic stroke Ip 2024 ⁹³ , 0-7 days after dose 3 ^c , SAH & hemorrhagic stroke Xiang 2024 ¹⁰⁰ 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	aHR 0.74 (0.69 to 0.79) aHR 0.70 (0.57 to 0.86) aHR 0.77 (0.73 to 0.81) aHR 0.72 (0.62 to 0.84) aHR 0.18 (0.13-0.25) aRI 0.96 (0.79 to 1.17) aHR 0.91 (0.86 to 0.97) aHR 0.88 (0.82 to 0.93) aHR 0.75 (0.68 to 0.82)
		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 Chemaitelly 2024 ⁹⁸ Choi 2024 ⁹⁹ , within 21 days Ip 2024 ⁹³ , 0-7 days after dose 1, ischemic stroke Ip 2024 ⁹³ , 0-28 days after dose 1, SAH & hemorrhagic stroke Ip 2024 ⁹³ , 0-7 days after dose 2, ischemic stroke Ip 2024 ⁹³ , 0-28 days after dose 2, SAH & hemorrhagic stroke Ip 2024 ⁹³ , 0-7 days after dose 3 ^c , ischemic stroke Ip 2024 ⁹³ , 0-7 days after dose 3 ^c , SAH & hemorrhagic stroke	aOR 0.45 (0.30 to 0.67) aOR 0.86 (0.67 to 1.11) aIRR 1.17 (0.35 to 3.85) aHR 0.94 (0.42 to 2.10) aHR 0.83 (0.34 to 2.03) aHR 0.39 (0.08 to 1.89) aHR 0.25 (0.04 to 1.63) aHR 0.71 (0.61 to 0.82) 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	aIRR 0.68 (0.53 to 0.89)
				Chen 2024 ¹⁰⁵ , Ischemic stroke, 0-28 days, dose 2	aIRR 0.84 (0.67 to 1.05)
				Chen 2024 ¹⁰⁵ , Ischemic stroke, 0-28 days, dose 3	aIRR 0.75 (0.61 to 0.93)
				Chen 2024 ¹⁰⁵ , Hemorrhagic stroke, 0-28 days, dose 1	aIRR 0.22 (0.07 to 0.70)
				Chen 2024 ¹⁰⁵ , Hemorrhagic stroke, 0-28 days, dose 2	aIRR 0.39 (0.15 to 1.00)
				Chen 2024 ¹⁰⁵ , Hemorrhagic stroke, 0-28 days, dose 3	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 Lloyd 2025 ¹¹⁷ , Medicare FFS ^d Shi 2024 ¹⁵⁹	aIRR 0.72 (0.34 to 1.51) aIRR 1.10 (0.74 to 1.63) aIRR 0.90 (0.56 to 1.42)
		High-dose influenza vaccine	2	Lloyd 2025 ¹¹⁷ , Medicare Advantage Lloyd 2025 ¹¹⁷ , Medicare FFS Shi 2024 ¹⁵⁹	aIRR 0.71 (0.27 to 1.86) aIRR 1.22 (0.69 to 2.16) aIRR 0.89 (0.49 to 1.64)
		Adjuvanted influenza vaccines	2	Lloyd 2025 ¹¹⁷ , Medicare Advantage Lloyd 2025 ¹¹⁷ , Medicare FFS Shi 2024 ¹⁵⁹	aIRR 0.55 (0.10 to 3.09) aIRR 0.99 (0.55 to 1.77) 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 Lloyd 2025 ¹¹⁷ , Hemorrhagic stroke, Medicare Advantage, 22-42 days Lloyd 2025 ¹¹⁷ , Hemorrhagic stroke, Medicare FFS, 1-21 days Lloyd 2025 ¹¹⁷ , Hemorrhagic stroke, Medicare FFS, 22-42 days	aIRR 1.10 (0.96 to 1.26) aIRR 1.04 (0.91 to 1.19) aIRR 0.97 (0.89 to 1.05) 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)
		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)

528

529 IRR: incidence rate ratio, HR: hazard ratio, OR: odds ratio, RR: rate ratio, RI: relative incidence

530 GBS: Guillain-Barré syndrome, MI: myocardial infarction, CVST: cerebral venous sinus thrombosis, ITP: immune thrombocytopenic
531 purpura, FFS: Fee-for-service

532

533 ^aTime periods in the "Study Label" column refer to days since vaccination.

534 ^bEffect estimates prefixed with "a" indicate an adjusted effect estimate

535 ^cAfter any primary series

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