

KEY FINDINGS

Population	Comparator	Evidence Rating
Adults 18–65 (Excluding Men Ages 18–24)	No Vaccine	C+
Adults 65+		B+
Males 12–24		P/I (promising but inconclusive)
Children 5–18 (Excluding Boys 12–18)		C+
Children 2–5		C+
Children 1–2		C++
Children 6–12 Months		B+
Vaccination During Pregnancy		B+
People With Comorbidities Under Age 65		C++
People Living in the US in 2026	Any of 4 vaccines	I (inconclusive)

“The current confusion in the US around vaccine policy is challenging for both health care professionals and the American public. Policymakers, especially public health leaders, need reliable and unbiased assessments of how well therapies work for patients. For 20 years, ICER has delivered that through our evidence-based analyses and public meetings. This public meeting highlighted what we know about the current evidence on Covid-19 vaccines, and where there are opportunities to gain an even better understanding of how these vaccinations impact different subpopulations. Ultimately, ICER’s transparent and public process sheds light on the broader context that policymakers should consider when making recommendations about Covid-19 vaccines.”

– ICER’s President and CEO, Sarah K. Emond, MPP

THEMES AND RECOMMENDATIONS

- Action is required in multiple spheres and by multiple parties to increase the likelihood that access to vaccines for Covid-19 will be equitable moving forward:
 - It is incumbent upon private payers to continue their public commitment to cover Covid-19 vaccines with zero cost sharing.
 - Manufacturers should continue to price vaccines in alignment with their value.
 - To maximize vaccination rates, providers must know, at the time they are interacting with a patient, that they will be paid for the vaccine and its administration
- Research is needed in specific areas where we currently have inadequate information on the benefits, harms, and burdens of Covid-19 vaccination.
- Research is needed on how best to counter misinformation and support individuals and groups in making informed decisions:
 - Even before the pandemic, there was growing skepticism in the US around vaccines and vaccination. It is imperative to approach this as a question amenable to research and understanding rather than as a political or social movement leading to anger and shaming.

Clinical Analyses

KEY CLINICAL BENEFITS STUDIED IN CLINICAL TRIALS

In Wuhan, China, in December 2019, patients began to present with atypical pneumonia. Over the next several months, the disease that would be called Covid-19 and was caused by the virus SARS-CoV-2 spread around the world as a pandemic, disrupting life in nearly every country. More than 1.2 million people died of Covid-19 in the United States (US).

On April 30, 2020, the first Trump Administration launched Operation Warp Speed to quickly produce a vaccine for Covid-19. In mid-November 2020, vaccines using messenger RNA (mRNA) technology developed by Pfizer and BioNTech and by Moderna were found to be approximately 95% effective. These and other vaccines were rolled out in early 2021 and by June 2021, more than 300 million vaccine doses were administered in the US. These vaccines dramatically affected the course of the pandemic. Booster vaccines to address waning immunity and vaccine modifications to address viral variants were developed, and over time the vast majority of people in the US received vaccines, had experienced prior infection(s) with SARS-CoV-2, or both, creating a population that was no longer immunologically naïve. In this setting, early data from randomized trials of mRNA and other vaccines, including the FDA-approved Novavax spike protein vaccine provide only limited information about the current effects of immunization in the US population.

Four vaccines for Covid-19 are currently available in the US: Spikevax® (Moderna); mNEXSPIKE® (Moderna); COMIRNATY® (Pfizer, BioNTech); and Nuvaxovid® (Sanofi, an updated version of the prior Novavax vaccine). Recent recommendations from the Advisory Committee on Immunization Practices (ACIP) as of September 2025 generally follow revised FDA labels that approved vaccination for people age 65 and older and for those 6 months or older but younger

than 65 with at least one underlying condition that puts them at risk for severe Covid-19. A US District Court order on March 16, 2026, issued a preliminary ruling that stayed all votes taken by the ACIP since June 11, 2025. Some professional associations and state public health departments have promulgated guidance that is more aligned with prior ACIP guidance that recommended Covid-19 vaccination for all persons ages six months or older.

Updated vaccines are expected to be available again in the fall of 2026. In this report, we examine the best available evidence on the likely comparative effectiveness and cost effectiveness of vaccination for Covid-19 in the 2026–2027 season, with a focus on subgroups at varying risk from Covid-19 when examining comparative effectiveness.

We performed a systematic review of the evidence that identified the original randomized trials and large amounts of observational data since 2020; this is discussed in the main report and in the supplement. In the absence of recent trials, we had a strong preference for the most recent data available; older data were felt to necessarily be low quality evidence for most outcomes due to the degree of indirectness to the current population living in the US that has been repeatedly exposed to Covid-19 antigens and seen continued decreases in rates of severe illness. As such, we chose to focus primarily on three well-conducted observational studies examining vaccine effectiveness in the 2024-2025 season. These included two studies using a “test-negative” design, a type of case-control study that can provide relative vaccine effectiveness, that we refer to as “The Adult CDC Study” and “The Childhood CDC Study” in this report. The third study, central to anchoring our results, we refer to as “The VA Study”. This is a cohort study that, unlike the case-control studies,

Clinical Analyses

can provide data on absolute effectiveness as well as relative effectiveness and that we felt was at very low risk for bias or confounding. However, the population was predominantly male with a mean age of 71 and so was necessarily indirect evidence for estimating effects in many other groups, which leads to uncertainties.

The changing epidemiology of Covid-19 provides additional uncertainties. Table ES.1 in the Final Evidence Report shows annual hospitalization rates associated with Covid-19 in a range of age groups; however hospitalizations have been declining year over year. It is possible that rates of serious Covid-19 will decline further in the 2026–2027 season or that the emergence of new strains could lead to an increase in serious disease.

We estimated the benefits of vaccination assuming this same epidemiology for the 2026–2027 season and from the efficacy seen in the above studies, and present these results as numbers of people who need to be vaccinated to prevent one hospitalization or one death.

We feel that the evidence for these estimates is best for older adults as this most closely matches the group in The VA Study where we have high-quality evidence. Our estimates in other adults are primarily extrapolated from The VA Study, and this extrapolation is particularly uncertain in groups such as young adults and pregnant women. Results in children were extrapolated mainly from The Childhood CDC Study, and efficacy from vaccinating pregnant mothers for their infants younger than six months (numeric efficacy not estimated) was based on data from earlier in the pandemic and from biologic plausibility.

We did not consider reduction of transmission or prevention of prolonged symptoms after mild illness as a benefit of Covid-19 vaccination in the 2026–2027

season given the low quality evidence for such effects. We did not find adequate evidence on efficacy comparing the vaccines to each other.

We examined both trial and observational data for evidence of minor and serious harms from vaccination. Minor harms such as fever and malaise are relatively common and there is some evidence that they are more common with mRNA vaccines than with Nuvaxovid. Serious harms are extremely rare. Adolescent boys and young men were at increased risk for myocarditis after vaccination early in the pandemic but this risk has not been seen more recently. The reasons for this decrease are not clear and we considered that there were still some uncertainties around myocarditis when making evidence ratings for this population. We found no material evidence for other serious harms occurring at a frequency that would affect our evidence ratings.

Our evidence ratings are shown in on page 1 and the rationale for these ratings is described in the report. Uncertainties about rates of serious disease in the 2026–2027 season affect all these ratings. We intentionally made conservative choices about the relative effectiveness of Covid-19 in preventing events in deciding on these evidence ratings. While these evidence ratings represent our judgement of the evidence for the likely net benefit of Covid-19 vaccination for the 2026–2027 season, we note that these ratings are not recommendations or policy suggestions. Vaccination is a public health intervention and those who make such recommendations need to consider clarity and ease of implementation when designing policies.

Economic Analyses

LONG-TERM COST EFFECTIVENESS

We performed a cost-effectiveness analysis of Covid-19 vaccines for the 2026–2027 season. This analysis builds on the cost-effectiveness model by Prosser (2025) which informed ACIP deliberations during the 2023–2024 vaccination season. The replicated model incorporates updated vaccine effectiveness estimates based on more recent observational data. Key drivers of the cost-effectiveness estimates include

vaccine effectiveness against hospitalization and the probability of hospitalization from Covid-19. Weighted results (i.e., by age and risk) suggest that, at current prices, Covid-19 vaccination for the 2026–2027 season would meet commonly cited cost-effectiveness thresholds, driven primarily by reducing hospitalizations in people ages 50 and older.

POTENTIAL BUDGET IMPACT

Weighted results (i.e., by age and risk) suggest that, at current prices, Covid-19 vaccination for the 2026–2027 season would meet commonly cited cost-effectiveness thresholds, driven primarily by reducing hospitalizations in people ages 50 and older.

Because this potential budget impact analysis evaluates vaccines, we did not include such a threshold analysis, given that the threshold generally informs the use of a new therapy in the current candidate population of diagnosed patients. Because the candidate population for Covid-19 vaccines is any individual between the ages of 6 months and 64 years with at least one risk factor for severe disease, as well as all individuals age 65 and older, the budget impact threshold is less relevant. Furthermore, the Covid-19 vaccines have been available on the market for several years, so our typical analysis forecasting

how budgets may be impacted moving forward does not apply. Therefore, we focused this budget impact analysis on estimating the cumulative annual per patient blended budget impact of the Covid-19 vaccines compared to no vaccination, and we did not conduct a threshold analysis.

Public Meeting Deliberations

VOTING RESULTS

ICER's Public Meeting: Voting Results on Clinical Effectiveness and Benefits Beyond Health

ICER assessed, and the independent appraisal committee voted on the evidence for the net health benefit of Covid-19 vaccines.

The New England CEPAC panelists voted unanimously that vaccination demonstrated a net health benefit when compared to no vaccination for the following populations:

- Pregnant women
- Infants aged 6-12 months old
- Children aged 1-2 years old
- Adults 65+ years old
- People under age 65 with chronic comorbidities (such as cardiovascular disease, cerebrovascular disease, pulmonary disease, or chronic kidney disease)

ICER's Public Meeting: Voting Results on Long-Term Value for Money

- All panelists (13) found that at current pricing, Covid-19 vaccines represent “**intermediate**” (8) or “**high**” (5) long-term value for money.

At current vaccine prices, ranging from \$73 to \$177, Covid-19 vaccination for the 2026–2027 season would be cost effective for all US subpopulations.

About ICER

The Institute for Clinical and Economic Review ([ICER](https://www.icer.org)) is an independent, non-profit research institute that conducts evidence-based reviews of health care interventions, including prescription drugs, other treatments, and diagnostic tests. In collaboration with patients, clinical experts, and other key stakeholders, ICER analyzes the available evidence on the benefits and risks of these interventions to measure their value and suggest fair prices. ICER also regularly reports on the barriers to care for patients and recommends solutions to ensure fair access to prescription drugs. For more information about ICER, please visit www.icer.org.