

mRNA Shot Shows Efficacy Against Influenza-Like Illness

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Seasonal influenza continues to pose a significant public health burden, necessitating ongoing advancements in vaccine technology to improve efficacy and broaden protection. Traditional egg-based and cell-based influenza vaccines often face limitations in manufacturing speed and strain matching. This new mRNA vaccine platform offers a potential alternative, demonstrating efficacy against influenza-like illness (ILI).

KEY TAKEAWAYS

- **The Pivot:** mRNA technology, previously validated for SARS-CoV-2, is now showing promise for influenza prevention.
- **The Data:** The mRNA vaccine demonstrated a significant reduction in the incidence of ILI.
- **The Action:** While not yet available, clinicians should monitor the development of mRNA influenza vaccines as they may offer improved protection and manufacturing agility.

Influenza viruses undergo constant antigenic drift, requiring annual vaccine reformulation and administration. Current influenza vaccines, while effective, exhibit variable efficacy influenced by the match between vaccine strains and circulating strains, as well as host factors.¹ The development of novel vaccine platforms, such as messenger RNA (mRNA) technology, aims to address these challenges by offering rapid manufacturing capabilities and the potential for broader, more durable immune responses.² The application of mRNA technology, successfully deployed against SARS-CoV-2, presents an opportunity to enhance influenza prevention strategies.

The Trial

A phase 3, randomised, observer-blinded, placebo-controlled clinical trial evaluated the efficacy of an investigational mRNA vaccine against influenza-like illness (ILI). The study enrolled 25,000 participants aged 18 years and older across multiple international sites. Participants were randomised in a 1:1 ratio to receive either a single intramuscular dose of the mRNA influenza vaccine or a placebo. The primary endpoint was the incidence of laboratory-confirmed influenza, defined by a positive reverse transcription polymerase chain reaction (RT-PCR) test for influenza virus in participants presenting with ILI. Secondary endpoints included vaccine efficacy against severe influenza, hospitalisation, and all-cause mortality.³

The investigational mRNA vaccine encoded for the haemagglutinin (HA) antigens of four influenza strains (two A strains, H1N1 and H3N2, and two B strains, Victoria and Yamagata lineages), mirroring the composition of quadrivalent inactivated influenza vaccines. Participants were monitored for the occurrence of ILI symptoms, defined as fever (oral temperature $\geq 38.0^{\circ}\text{C}$) plus at least one respiratory symptom (e.g., cough, sore throat, nasal congestion) and at least

one systemic symptom (e.g., headache, myalgia, fatigue). Nasopharyngeal swabs were collected from all participants reporting ILI for RT-PCR testing. Safety surveillance included solicited local and systemic adverse events for 7 days post-vaccination and unsolicited adverse events for 28 days post-vaccination. Serious adverse events were collected throughout the study period.³

Key Findings

The trial demonstrated that the mRNA influenza vaccine significantly reduced the incidence of laboratory-confirmed influenza-like illness. Among participants who received the mRNA vaccine, the incidence of laboratory-confirmed influenza was 1.2% (N=150), compared to 2.8% (N=350) in the placebo group. This translated to a vaccine efficacy of 57.1% (95% CI, 48.2% to 64.7%; $p < 0.001$) against laboratory-confirmed influenza. Efficacy was consistent across age groups and against different circulating influenza strains identified during the study period. Specifically, efficacy against influenza A/H3N2 was 52.3% (95% CI, 39.8% to 62.5%), and against influenza B was 61.8% (95% CI, 45.1% to 73.5%).⁴

Regarding secondary endpoints, the mRNA vaccine showed a reduction in severe influenza cases, defined as those requiring hospitalisation or resulting in complications such as pneumonia. There were 5 hospitalisations in the vaccine group compared to 18 hospitalisations in the placebo group, although this difference did not reach statistical significance ($P = .06$). No deaths related to influenza were reported in either group. The safety profile of the mRNA vaccine was generally consistent with other mRNA vaccines, with common adverse events including injection site pain (78%), fatigue (35%), and headache (28%). These events were typically mild to moderate in severity and resolved within 48 hours. Serious adverse events were rare and occurred at similar rates in both vaccine and placebo groups, with no events considered vaccine-related.⁴

Limitations of the study include its focus on ILI as a primary endpoint, which may not capture all asymptomatic or mild influenza infections. The study duration covered a single influenza season, limiting the assessment of long-term durability of protection. Furthermore, the trial population was primarily healthy adults, and efficacy in immunocompromised individuals or the elderly, who are at higher risk for severe outcomes, requires further investigation. Future research should explore the potential for multivalent mRNA vaccines targeting multiple respiratory pathogens and the long-term immunogenicity and effectiveness of this platform.⁵

CLINICAL IMPLICATIONS

The demonstrated efficacy of an mRNA vaccine against influenza-like illness marks a significant step, not just for influenza, but for the broader landscape of infectious disease prevention. For clinicians, this platform promises a more agile response to emerging strains, potentially reducing the annual guesswork involved in vaccine composition. The current reliance on egg-based production often leads to manufacturing delays and suboptimal strain matches, directly impacting vaccine effectiveness in the clinic. An mRNA approach could mean a more consistently effective vaccine, translating to fewer patient consultations for ILI and a reduced burden on primary care during peak seasons.

From an industry perspective, this development solidifies the mRNA platform's utility beyond SARS-CoV-2. Companies like Moderna and BioNTech, having invested heavily in this technology, now have a clear path to diversify their product pipelines. The ability to rapidly design and scale production for seasonal influenza

could disrupt the established market dominated by traditional vaccine manufacturers such as Sanofi and GSK. This competitive pressure may accelerate innovation across the entire vaccine sector, potentially leading to combination vaccines that target multiple respiratory viruses simultaneously, simplifying vaccination schedules for patients and practitioners alike.

For patients, the prospect of a more effective influenza vaccine is compelling. While current vaccines offer protection, the variability in efficacy can lead to vaccine hesitancy. A consistently effective mRNA vaccine could improve uptake rates, particularly among vulnerable populations. The safety profile, mirroring that of existing mRNA COVID-19 vaccines, should also reassure patients. Ultimately, this technology offers the potential for a future where annual respiratory virus threats are met with a more precise, rapid, and broadly protective immunological response, moving us closer to truly comprehensive seasonal respiratory disease control.

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