



The Approval of the First mRNA-Based Influenza Vaccine for Older Adults in Iran

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Messenger RNA (mRNA) technology has transformed modern vaccinology by enabling the rapid development of safe and effective vaccines, as demonstrated during the COVID-19 pandemic (1). Building on this success, the same platform is now being applied to seasonal influenza prevention (1, 2). Recently, the U.S. Food and Drug Administration (FDA) approved Moderna's mRNA-based influenza vaccine, mFlusiva, marking the first influenza vaccine developed using mRNA technology (3). This milestone represents an important advance in vaccine innovation, offering a faster and more adaptable approach to combating rapidly evolving influenza viruses while expanding the clinical applications of mRNA platforms beyond COVID-19 (1, 2).

Although the concept of mRNA-based vaccination dates back more than 3 decades, its translation into clinical practice required years of scientific and technological progress (1). Advances in mRNA engineering, nucleoside modification, manufacturing, and delivery systems have gradually overcome many early limitations of this platform (1). The successful development and large-scale deployment of nucleoside-modified mRNA vaccines against COVID-19 provided compelling evidence of the feasibility, scalability, and favorable safety profile of this approach (1). Moreover, the relative simplicity and flexibility of antigen design have facilitated investigation of mRNA vaccines against a broad spectrum of viral, bacterial, and parasitic pathogens (1). Nevertheless, important challenges remain. Further elucidation of the mechanisms underlying mRNA-induced immune responses, together with advances in rational antigen design, delivery technologies, and vaccination strategies, will be essential for developing the next generation of

mRNA vaccines with improved potency, durability, and safety (1).

The FDA has approved mFlusiva, the first influenza vaccine developed using the same mRNA technology that played a major role during the COVID-19 pandemic (3). The vaccine is indicated for adults aged 50 years and older, providing a new option for influenza prevention, particularly among older adults who remain at increased risk of severe disease and influenza-related complications (3). Despite the availability of several influenza vaccines, including formulations specifically recommended for older adults, influenza continues to contribute substantially to morbidity and mortality each year (3).

A major advantage of the mRNA vaccine platform is its adaptability (1). Because seasonal influenza vaccines must be reformulated annually to correspond to circulating viral strains, the relatively rapid design and manufacturing process of mRNA vaccines may offer an important advantage when circulating strains change unexpectedly or when rapid vaccine updating is required (1, 2).

FDA approval in middle-aged adults was supported by a large clinical trial involving approximately 40,000 participants, in which the mRNA vaccine reduced influenza cases by approximately 27% compared with a routinely used influenza vaccine (4). In the older population, accelerated approval was based on immunogenicity data demonstrating a robust immune response compared with an existing high-dose influenza vaccine, while additional postmarketing evaluation is ongoing (3). Available safety data revealed no major safety concerns, although transient adverse reactions, including injection-site pain, fever, headache, fatigue, and myalgia,

were reported somewhat more frequently than with conventional influenza vaccines (4).

For Iran, approval of the first mRNA-based influenza vaccine represents more than a scientific milestone; it highlights an opportunity to strengthen national preparedness against seasonal respiratory infections. With the country's growing older population and the anticipated co-circulation of influenza viruses and SARS-CoV-2 during the autumn and winter seasons, protecting high-risk groups, including older adults, individuals with chronic diseases, immunocompromised patients, and healthcare workers, should remain a public health priority. The increasing proportion of older adults in Iran is particularly relevant because this population is more susceptible to severe influenza, complications, and hospitalization. During seasonal influenza peaks, the resulting increase in healthcare utilization can place substantial pressure on hospitals and outpatient services. Therefore, access to effective mRNA-based influenza vaccines, particularly for older and high-risk populations, could potentially reduce severe disease, influenza-related hospitalizations, and the associated burden on the healthcare system.

Moreover, preventing influenza may have broader implications for antimicrobial stewardship. Respiratory viral infections frequently lead to antibiotic prescribing, including unnecessary antibiotic use when bacterial infection is absent (5). By preventing influenza and reducing influenza-associated healthcare encounters and secondary bacterial complications, effective vaccination strategies may contribute to reducing unnecessary antibiotic consumption and, consequently, the selective pressure that drives antimicrobial resistance (5). Reduced healthcare utilization and hospitalization could also translate into lower healthcare expenditures, an important consideration for health systems facing increasing demands from an aging population.

As additional evidence on the effectiveness and cost-effectiveness of mRNA influenza vaccines becomes available, Iranian health authorities should consider evaluating their incorporation into national influenza vaccination strategies, with particular attention to older adults and other high-risk populations. Given the

approaching influenza seasons and the predictable annual pressure of respiratory infections on healthcare services, timely access to effective and adaptable vaccine platforms could provide both clinical and public health benefits. At the same time, investment in domestic mRNA vaccine research and manufacturing capacity could improve preparedness for future epidemics, increase national self-sufficiency in vaccine development and production, and ultimately strengthen the country's long-term health security.

Footnotes

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