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Review Paper

mRNA-Based Therapeutics Beyond Vaccines: Emerging Applications, Challenges, and Future Perspectives

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ABSTRACT

Messenger RNA (mRNA) therapeutics have emerged as a transformative platform in modern biomedicine, moving rapidly beyond their initial success in infectious disease vaccines. Their ability to encode almost any protein of interest, combined with transient expression, rapid design, and scalable manufacturing, makes them highly attractive for the treatment of cancer, genetic disorders, protein deficiencies, regenerative conditions, and diseases requiring precise immune modulation. In recent years, significant progress has been made in mRNA engineering, delivery systems, chemical modification, and formulation strategies, enabling improved protein expression and clinical feasibility. Despite these advances, several barriers continue to limit broad therapeutic translation, including poor intrinsic stability, inefficient targeted delivery, innate immune activation, short duration of expression, and manufacturing complexity. This review summarizes the structural and functional basis of mRNA therapeutics, delivery technologies, and emerging non-vaccine applications, while also discussing current clinical progress, the role of artificial intelligence, and future directions such as self-amplifying RNA, circular RNA, and organ-specific delivery. Collectively, mRNA therapeutics represent a versatile platform with strong potential to reshape precision medicine across multiple disease areas.

INTRODUCTION

Messenger RNA has progressed from a basic biological messenger into one of the most adaptable therapeutic platforms in

modern medicine. In its native role, mRNA transmits genetic information from DNA to ribosomes, where proteins are synthesized; in

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therapeutic applications, that same process is repurposed by delivering engineered mRNA so cells can produce a clinically useful protein or functional biomolecule (1-2). This shift has changed the logic of drug development, because the treatment is no longer necessarily the protein itself, but the programmable instruction for making it inside the patient's own cells (2). The global success of mRNA vaccines during the COVID-19 pandemic marked a decisive turning point for the field. It showed that synthetic mRNA could be manufactured rapidly at scale, packaged into effective delivery systems, and produce strong biological responses with acceptable safety in humans (3-4). That achievement validated decades of RNA research and opened the door for non-vaccine uses in oncology, rare and inherited disorders, protein replacement, cardiovascular disease, autoimmune disease, and degenerative medicine (5-6). One of the greatest strengths of mRNA therapeutics is their versatility. The same platform can be adapted by changing the encoded sequence, refining untranslated regions, introducing nucleoside modifications, or selecting a different carrier system, making it suitable for highly individualized interventions (7-2). This flexibility is especially important for precision medicine, where the ideal therapy may depend on a patient's tumor profile, mutation type, tissue target, or immune state (8-5). At the same time, the field still faces major translational barriers. mRNA is inherently unstable, can provoke unwanted immune sensing, and remains difficult to deliver efficiently to specific tissues while maintaining durable expression (9-5). These limitations have driven intense work in LNP engineering, sequence optimization, and next-generation RNA formats such as self-amplifying RNA and circular RNA. Taken together, the strengths and limitations of mRNA make it one of the most dynamic areas in drug discovery and a

central platform for future therapeutic innovation (10-11).

Figure 1.} Structure of mRNA therapeutics:

1. Biology of mRNA:

mRNA is the intermediary molecule that links genomic information with protein synthesis. In its therapeutic form, mRNA is synthetically produced and optimized to behave as an efficient template for translation while avoiding excessive innate immune activation. A therapeutic mRNA molecule typically contains five major elements: a 5' cap, a 5' untranslated region, a coding sequence, a 3' untranslated region, and a poly(A) tail. Each component contributes to stability, translational efficiency, and overall biological performance (5,6,12). The 5' cap is critical for ribosome recognition and transcript protection. The untranslated regions influence translation initiation, mRNA stability, and intracellular handling. The coding sequence determines the therapeutic protein to be produced, while the poly(A) tail helps prolong transcript persistence and boost translation. In many therapeutic constructs, nucleoside modifications are introduced to improve stability and reduce immune sensing. These design features are central to the success of modern mRNA medicines (7,2,5). Compared with DNA-based approaches, mRNA offers an important safety advantage because it does not need to enter the nucleus and does not integrate into the genome. This makes it particularly attractive for applications where transient protein expression is sufficient or even preferred. For example, temporary expression is ideal in cancer immunotherapy and gene editing, where prolonged activity could increase toxicity or off-target effects (1,2,6).

2. Components of mRNA Therapeutics:



The therapeutic behavior of mRNA is determined not only by the encoded protein, but also by the molecular architecture of the transcript. The 5' cap promotes efficient translation and protects against degradation.

The 5' and 3' untranslated regions are powerful regulators of expression. These regions can be borrowed from naturally stable transcripts or engineered synthetically to enhance ribosome loading and increase mRNA half-life. The coding sequence itself is often optimized for codon usage, reduced secondary structure, and improved protein output. In addition, the poly(A) tail contributes to translation efficiency and transcript stability (5,12,6). Nucleoside modifications represent one of the most important advances in mRNA engineering. Early synthetic mRNA platforms triggered strong innate immune responses that limited their utility. By incorporating modified nucleotides, researchers can reduce activation of immune sensors while improving translation. This strategy has played a major role in transforming mRNA from an experimental tool into a clinically viable platform (7,2,9).

Delivery Systems:

Delivery remains the central bottleneck in mRNA therapeutics. Free mRNA is rapidly degraded by nucleases and poorly crosses cell membranes, so it must be protected by a carrier that enables delivery to the right tissue and supports endosomal escape after uptake (5,9,13). TABLE:1 } Delivery systems for mRNA therapeutics:

Lipid nanoparticles:

Lipid nanoparticles are currently the most advanced and widely used delivery platform for mRNA. They encapsulate and protect the transcript, improve cellular uptake, and facilitate release into the cytoplasm. Their composition can

be tuned with ionizable lipids, cholesterol, phospholipids, and PEG-lipids to optimize stability and reduce toxicity. Because of their success in mRNA

vaccines, LNPs have become the leading platform for therapeutic development beyond vaccines as well (5,13,14). *Figure:2-} Lipid nanoparticle-mediated delivery mechanism:*

Polymer nanoparticles:

Polymer-based systems are attractive because they can be chemically tailored and may support controlled release. However, their broader clinical use has been limited by cytotoxicity, variable transfection efficiency, and formulation challenges. They remain valuable in preclinical research and in applications where specialized control over release is needed (9,15).

Liposomes:

Liposomes are biocompatible, flexible carriers that have long been used in drug delivery. They can encapsulate mRNA effectively and may be useful for localized delivery or combination therapy. Their clinical translation, however, has been overshadowed in recent years by the success of optimized LNPs (5,6).

Peptide-based carriers:

Peptides can be designed to enhance cell entry or target specific receptors. These systems are promising for precision delivery, but they often require significant optimization to balance efficiency, specificity, and safety (5,15).

Viral versus non-viral delivery:

Viral vectors remain highly efficient, but they are associated with concerns about immunogenicity, manufacturing complexity, payload limitations,



and repeat dosing. Non-viral systems, particularly LNPs, are increasingly preferred because they are more flexible and safer for repeated administration. As a result, most next-generation mRNA therapeutics are being developed with non-viral carriers (5,13).

3. Therapeutic Applications Beyond Vaccines:

Cancer immunotherapy:

Cancer is one of the most promising areas for mRNA therapeutics. mRNA can encode tumor-associated antigens, personalized neoantigens, cytokines, immune-modulating proteins, or receptors used to engineer immune cells. Personalized cancer vaccines are especially important because they allow treatment to be tailored to the molecular profile of an individual tumor. This may improve specificity and reduce off-target toxicity. mRNA is also useful in ex vivo cell engineering, such as CAR-T cell production or immune cell reprogramming. In these cases, transient expression can be beneficial because it supports functional modification without permanent genetic alteration. Combination approaches with checkpoint inhibitors, chemotherapy, or targeted therapy may further enhance effectiveness (6,8,16).

Protein replacement therapy:

Many inherited and acquired diseases result from insufficient production of a functional protein. mRNA offers a direct way to address this problem by enabling the patient's own cells to synthesize the missing protein. This has major implications for enzyme deficiencies, metabolic diseases, and disorders involving secreted or intracellular proteins. A key advantage of this strategy is that it bypasses some of the limitations of recombinant protein replacement, such as short half-life, repeated infusions, and high production costs. By using the body as the manufacturing site, mRNA

therapies may achieve more physiologic protein distribution (5,12).

Rare genetic diseases:

Rare diseases are particularly attractive targets because many are caused by single-gene defects. mRNA can be used to provide temporary replacement of a missing protein or, in some cases, to support gene-editing approaches. Since many rare diseases lack effective treatments, mRNA therapeutics may offer a valuable new option. However, these disorders often require delivery to specific organs such as the liver, lung, or central nervous system. This makes targeting a major challenge. Still, the platform's flexibility and rapid design capabilities make it well suited to orphan disease development (6,12).

Cardiovascular diseases:

In cardiovascular medicine, mRNA has been explored for angiogenesis, myocardial repair, and tissue regeneration after ischemic injury. For example, mRNA encoding vascular growth factors may support neovascularization in damaged tissue. Similarly, regenerative proteins could help limit cardiac damage after myocardial infarction. These applications are especially promising because cardiovascular injury often requires short-term signaling rather than permanent protein expression. Localized delivery may therefore be sufficient to trigger repair processes without prolonged exposure (5,17).

Autoimmune diseases:

Autoimmune diseases may benefit from mRNA-based immune modulation rather than simple suppression. Therapeutic mRNA could be used to induce tolerance, express immunoregulatory proteins, or alter immune cell behavior. This approach is conceptually attractive for diseases such as type 1 diabetes, multiple sclerosis, and



rheumatoid arthritis. The goal here is not necessarily high and sustained expression, but controlled expression in the right immune context. This makes mRNA a potentially powerful tool for immune reprogramming (6,18).

Neurological disorders:

Applications in neurology are more difficult because the blood-brain barrier limits delivery. Nevertheless, mRNA therapies may be useful for neuroprotective proteins, enzyme replacement, and disease-modifying factors in conditions such as Parkinson's,

Alzheimer's, and Huntington's diseases.

The most important barrier is tissue access. If effective CNS delivery can be achieved, mRNA could become useful for both replacement and repair-based strategies (14,5).

Regenerative medicine:

Regenerative medicine may be one of the most conceptually natural uses of mRNA because tissue repair often depends on transient expression of growth factors and regulatory proteins. mRNA can be used to promote wound healing, bone repair, cartilage regeneration, and stem cell programming. Because regeneration usually requires temporary signaling rather than permanent expression, mRNA is particularly well suited to this field. It may also work synergistically with biomaterials, scaffolds, and cell therapy approaches (12,17).

Gene editing:

mRNA is widely used to deliver CRISPR-Cas systems, base editors, and prime editors. In this context, mRNA encodes the editing protein while guide RNAs direct activity to the target sequence. The transient nature of mRNA expression is a

major benefit because it reduces the duration of nuclease activity and may lower off-target effects. This strategy is particularly important for ex vivo editing of cells and for in vivo correction of inherited disorders. Nonetheless, efficient and specific delivery remains a major barrier (19,20)

Table:2-} Clinical applications beyond vaccines:

4. Clinical Progress:

Clinical translation of mRNA therapeutics is advancing quickly, although the field remains unevenly distributed across indications.

Oncology currently leads in non-vaccine development, especially with personalized cancer vaccines and immune-cell engineering. Rare disease programs are also expanding, particularly in protein replacement and genome editing (5,6,16). The clinical success of mRNA vaccines established regulatory confidence in the platform, which has helped non-vaccine programs move forward. Several candidates are now in early- and mid-stage trials, and some personalized therapies are showing encouraging signals. Combination therapy is becoming a major strategy, especially in cancer, where mRNA-based agents are likely to be used

alongside checkpoint blockade or other immunotherapies (5,6,8,21).

5. Artificial Intelligence in mRNA Drug Development:

Artificial intelligence is becoming increasingly important in mRNA research and development. AI can improve sequence design by identifying optimal codons, untranslated regions, and structural motifs that enhance translation and reduce immune activation. It can also help predict which delivery systems are most likely to work for particular tissues or disease settings. In oncology,



AI can support neoantigen prediction and treatment personalization (22,23,5).

6. Advantages of mRNA Therapeutics:

mRNA therapeutics offer several major advantages. They can be designed rapidly once a disease target is known, making them well-suited for urgent or personalized applications. They do not integrate into the genome, which improves safety relative to many DNA-based approaches. (5,6,24). Another advantage is the transient nature of expression. This is useful when short-term protein production is enough to achieve a therapeutic effect, such as in cancer, gene editing, or acute tissue repair. Manufacturing is also relatively flexible, since the same platform can often be adapted to different sequences with limited changes in process design (1,5,6,12).

7. Challenges and Limitations:

Despite its promise, mRNA therapeutics face several unresolved challenges. One of the most important is instability, as mRNA is easily degraded by nucleases and requires careful handling. Delivery is another major obstacle because the molecule must be protected, internalized by the correct cells, and released into the cytoplasm efficiently (5,13,14). Immunogenicity remains a double-edged sword. Some immune activation can be desirable in vaccines and cancer immunotherapy, but it is often harmful in replacement therapy or gene editing (5,7,24). Manufacturing costs, cold-chain requirements, and stringent quality control also limit accessibility. Regulatory challenges are especially significant for personalized therapies, where each product may need to be manufactured individually (6,12). These barriers do not diminish the potential of the platform, but they do explain why broad clinical adoption will depend on

continued engineering improvements and translational innovation (16,6).

Table:3-} Advantages and limitations of different delivery platforms:

8. FUTURE PERSPECTIVES:

The future of mRNA therapeutics is expected to move well beyond the first wave of vaccine success and into a more mature era of precision, durability, and disease-specific design. As the field evolves, the central challenge will no longer be whether mRNA can work in humans, but how its performance can be optimized for different tissues, disease mechanisms, and clinical settings. This transition will likely be driven by innovations in RNA chemistry, delivery engineering, computational design, and manufacturing science. Self-amplifying mRNA represents one of the most promising next-generation formats. By encoding replication machinery along with the therapeutic sequence, saRNA can generate more copies of the target transcript inside cells, thereby reducing the dose required for biological activity. This lower-dose requirement may improve cost-effectiveness, reduce raw material demand, and potentially enhance immune or therapeutic responses. At the same time, the increased complexity of saRNA design and the need to control intracellular amplification will require careful safety evaluation, especially for repeated dosing and non-vaccine applications. Circular RNA is another important frontier. Unlike linear mRNA, circRNA lacks free ends, which can make it more resistant to exonuclease degradation and may extend intracellular persistence. This property is especially attractive for applications that require longer protein expression without continuous re-administration. CircRNA may therefore be useful in protein replacement therapy, regenerative medicine, and chronic disease management.



However, the field still needs standardized methods for efficient circularization, purification, and translation enhancement before circRNA can become broadly clinically useful. Organ-targeted delivery will likely define the next major phase of translation. Current mRNA platforms are highly effective in the liver and certain immune contexts, but many clinically important diseases involve organs that remain difficult to reach, such as the lung, heart, brain, and skeletal muscle. Future delivery systems will need to combine tissue specificity with minimal toxicity and strong endosomal escape. In this setting, ligand-directed nanoparticles, local administration routes, biomaterial-assisted release systems, and organ-selective lipid formulations may all play a role. Improved targeting would not only increase therapeutic efficacy but also reduce off-target exposure and lower the risk of adverse effects. AI-assisted design is expected to become increasingly central to mRNA drug development. Computational tools can help optimize codon usage, untranslated regions, secondary structure, and immune-evasion features, while also predicting which delivery systems are most likely to succeed for a given indication. In oncology, AI may improve neoantigen selection and help generate individualized therapeutic constructs more efficiently. In rare diseases, it may support rapid matching of genotype to treatment design. More broadly, AI may shorten the design-test cycle, reduce development costs, and accelerate movement from concept to clinic. Precision medicine will remain a defining theme of future mRNA therapeutics. Because mRNA can be rapidly customized, it is especially suited to patient-specific treatment strategies in oncology, inherited metabolic disorders, and immune-mediated diseases. Global accessibility will also shape the future of the field. Although mRNA medicines have demonstrated remarkable

success, their broader use depends on solutions to cold-chain storage, manufacturing scalability, cost of goods, and regulatory standardization. If more thermostable formulations, lyophilized products, and decentralized manufacturing approaches become feasible, access could expand substantially across low- and middle-resource settings. This would be especially important for therapeutic applications outside oncology, where long-term treatment cost and infrastructure requirements can be major barriers. Overall, the next decade is likely to transform mRNA therapeutics from a highly promising platform into a more diversified and clinically integrated technology. The most successful programs will probably be those that combine molecular optimization, targeted delivery, and computational design with a clear understanding of disease biology. As these capabilities mature, mRNA may become a foundational component of future medicine, enabling safer, faster, and more personalized therapies across a wide range of conditions.

Table:4-3. Recent studies on mRNA therapeutics, 2022–2026:

CONCLUSION

mRNA therapeutics have rapidly evolved from a platform best known for vaccines into a broad and highly adaptable class of medicines with potential across oncology, rare and inherited diseases, protein replacement, regenerative medicine, autoimmune disorders, and gene editing. Their appeal lies in a rare combination of features: they can be designed quickly, modified with relative ease, and used to produce proteins transiently without altering the genome. This makes them especially well suited for precision medicine, where treatment can be matched to disease biology, patient mutation profiles, or individualized immune responses. A major reason for the growing enthusiasm around mRNA is its



platform nature. Unlike many traditional drugs that are limited to a single mechanism or target class, mRNA can be reprogrammed simply by changing the encoded sequence or optimizing the untranslated regions and delivery vehicle. This flexibility enables rapid adaptation across multiple indications and supports both standardized and personalized treatment strategies. In oncology, for example, mRNA can be used to stimulate anti-tumor immunity or engineer immune cells; in genetic disorders, it can restore missing protein function; and in regenerative medicine, it can provide short-lived biological signals that promote repair and healing. Despite this promise, several important barriers still limit widespread clinical deployment. Delivery remains one of the most difficult problems, especially for tissues such as the brain, heart, lung, and skeletal muscle. mRNA instability, susceptibility to degradation, and the need for specialized formulations continue to shape manufacturing and storage requirements. In addition, innate immune activation, variable expression duration, and the cost of production present major hurdles for long-term and global use. For personalized therapies, regulatory complexity and quality-control demands add another layer of difficulty. The next phase of progress will depend on how effectively the field solves these problems. Advances in lipid nanoparticle engineering, polymer and peptide carriers, organ-targeted systems, and local delivery approaches are expected to improve precision and reduce toxicity. At the same time, innovations in molecular design, including nucleoside modification, self-amplifying RNA, and circular RNA, may enhance stability and extend expression. AI-assisted optimization is also likely to accelerate sequence design, target selection, and delivery strategy development, making therapeutic development faster and more predictive. Overall, mRNA therapeutics are moving toward a future in which

they serve as a foundational tool in modern biomedicine rather than a niche technology. Their ability to bridge basic biology, precision medicine, and translational therapy gives them exceptional long-term potential. If ongoing scientific, manufacturing, and regulatory challenges can be addressed, mRNA medicines may become an increasingly routine part of clinical practice across a wide range of diseases.

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