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A review of modern mRNA vaccines and their applications

Abstract

This review article explores the utilization of mRNA in vaccine development to treat a plethora of diseases once thought incurable. Thus, revolutionizing the vaccine industry and patient care. This cutting-edge technology surpasses traditional vaccines due to its unprecedented developmental timelines, patient safety and drug efficacy. Being synthetic, one pot in vitro transcription mediated mRNA results in generating quality mRNA free from viral vectors or animal growth conditions such as chicken embryos. This allows for reduced processing while enhancing product safety compared to traditional vaccine production and processing. The delivery mechanism of the therapeutic mRNA is facilitated by the lipid nanoparticle which encapsulates the therapeutic mRNA payload. In addition, it prevents exonuclease degradation and successful delivery via fusing with the host cell membrane and utilizes the host's own endosomal pathway. Customizability of the LNP with targeting moieties such as antibodies or sugars allows for targeted drug delivery (tLNP) which enables the platform to be utilized for treating diseases such as cancers. The mRNA being transient in nature ensures that the dosing could be tailored to meet the requirements of the patient and be adjusted as necessary compared to permanent gene editing methods such as CRISPR and its off-targeting genome wide effects. The therapeutic mRNA utilizes the host's cellular machinery to produce a foreign epitope or protein of concern which elicits rapid innate and adaptive immune responses upon first dose administration. Multiple payload capability in the same LNP is a promising future for combination therapies. Furthermore, it opens doors for customized patient therapies. The COVID-19 pandemic serves as a testament to the platform's capability which saved billions of lives with vaccines created in under a span of a year. Therefore, the mRNA platform is rapidly adapted by companies worldwide for designing novel therapeutics.

Keywords: mRNA, vaccines, applications, mRNA vaccines

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Abbreviations: mRNA, messenger ribonucleic acid; RNA, ribose nucleic acid; ORF, open reading frame; UTR, untranslated regions; LNP, lipid nanoparticle; TLNP, targeted lipid nanoparticle; CRISPR, clustered regulatory interspaced short palindromic repeats; MHC, major histocompatibility complex; VEGF, vascular endothelial growth factor; HPV, human papilloma virus; endoplasmic reticulum (ER), CTL, cytotoxic T lymphocyte; Rnase, ribonuclease; SARS-COV-2, severe acute respiratory syndrome coronavirus 2; COVID-19, coronavirus disease 2019; PBMC, peripheral blood mononuclear cell; TB, tuberculosis; IFN, interferon; FDA, food and drug administration; DC, dendritic cell; DNA, deoxyribonucleic acid; CD4+, cluster of differentiation 4 positive; APC, antigen presenting cell; GMP, good manufacturing practices; CD8+, Cluster of differentiation 8 positive

Introduction

Adaptation of mRNA vaccines has revolutionized vaccinology due to unprecedented vaccine development speed, safety and efficacy curing diseases once thought incurable.[1] The therapeutic agent, the messenger ribonucleic acid (mRNA), encodes a pathogenic protein of interest eliciting an immune response once translated upon entering the host cells via host endosomal pathway.[2] Since the mRNA is manufactured via in vitro transcription, eliminates the need for viral inactivation or attenuation compared to traditional viral vector vaccines.[3] The figure 1 depicts the most recent COVID-19 pandemic vaccine development timelines where vaccines were developed in under a year, a testament to the unparalleled speed and efficacy of the mRNA platform.

Therapeutic mRNA

The in-vitro transcribed mRNA contains the 5 prime 7 methyl guanosine cap, 3 prime poly A tail, the untranslated regions that enclose the open reading frame (Figure 1). These components enhance stability, increase translation efficiency and prevent enzymatic RNase and any other exonuclease degradation.[4] The synthetically produced therapeutic mRNA components are depicted in Figure 2.

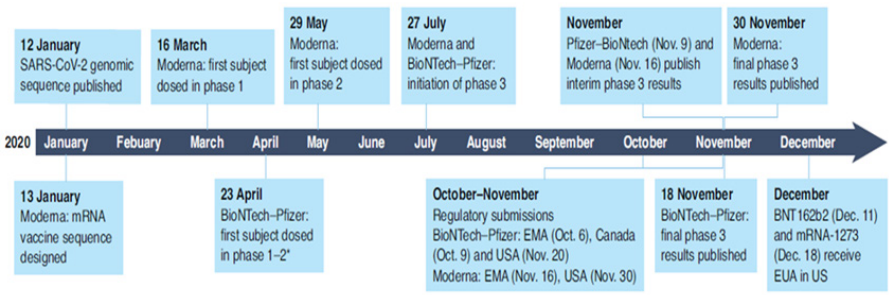

Figure 1 Timelapse of COVID-19 vaccine creation process from design to emergency authorization.[41]

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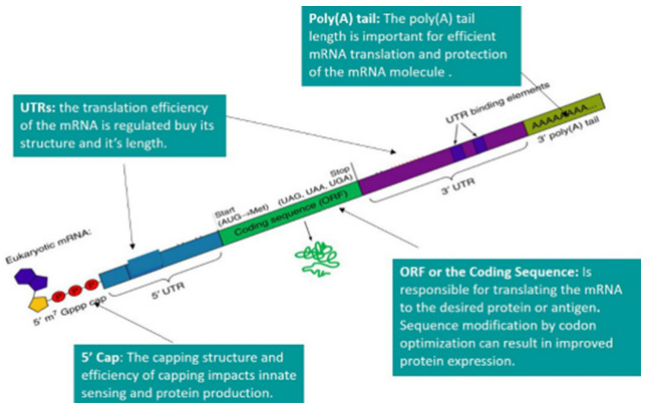

Figure 2 The components of the therapeutic mRNA in the vaccine. The labeled components are modified to enhance the vaccines safety and efficacy.[1]

The mRNA vaccines provide unparalleled flexibility, where changing the therapeutic mRNA sequence enables to treat new variants or create custom vaccines such as cancer vaccines. Thus, opening doors for disease specific treatments to complement or replace therapies such as chemotherapy which are very taxing on patients.[5]

Lipid nanoparticle (LNP)

The delivery of the therapeutic mRNA is performed by encapsulating within a lipid nanoparticle that acts as the vehicle delivering the therapeutic payload to the cell by fusing with the cell membrane and transport via the host endosomal pathway.[6] The lipid nanoparticle could be customized to fuse with specific cells creating targeted lipid nanoparticles (tLNP) which maximizes payload delivery and vaccine efficiency by targeting specific cells such as T Cells. Enabling in vivo chimeric antigen receptor T cell therapy allows a wide range of disease treatments and applications.[7] Components of the lipid nanoparticle are depicted in Figure 3.

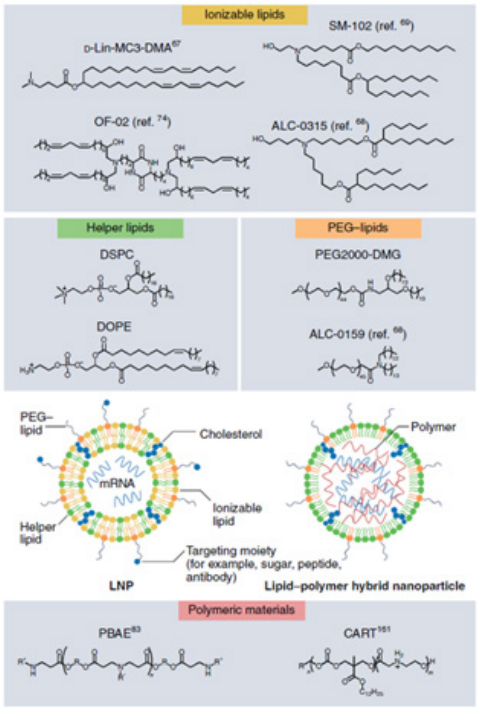

Figure 3 Components of the lipid nanoparticle (LNP) of the mRNA vaccine.[41]

The evolution of mRNA vaccines in Global Health and personalized medicine

The efficiency, storage and stability of the mRNA vaccines have increased significantly due to cutting edge manufacturing and production facility advancements as well as vaccine component optimization studies.[8] The recent pandemic is a testament to the robustness and flexibility of this vaccine platform as a cure was created at an unprecedented rate and made available globally in no time. Thus, providing the ability to create boosters for novel variants by merely changing the therapeutic mRNA to match the novel variants.[9]

This platform is adopted by industry to create cancer vaccines and allows the ability to create neoantigen or custom-made therapies designed to target specific cancers in patients. A faster, safer and effective rate than conventional means revolutionizing the field of personalized medicine.[10] Being transient in nature, and not permanently editing genes such as CRISPR, this platform though promising will require priming of the immune system at proper intervals to prevent waning immunity or low antibody titer levels to ensure proper protection from the disease of concern.[11]

Since its rapid adaptation, there are many studies and research conducted on understanding the mRNA vaccines safety, efficacy, pharmacokinetics and dynamics in order to develop better and safer vaccines with time.[12] The antigen produced by the vaccine elicits an immune response by activating both the adaptive and innate immune responses of the host.[13] Therefore, creating both immediate and long-term immunity for the disease the vaccine is administered for. The ability to elicit an immune response rapidly even upon the first dose has caused mRNA vaccine platforms to be adopted globally to treat highly pathogenic diseases such as COVID-19.[14] The Figure 4 provides a visualization of the process of administration and the immune cells and response activated by the vaccine.

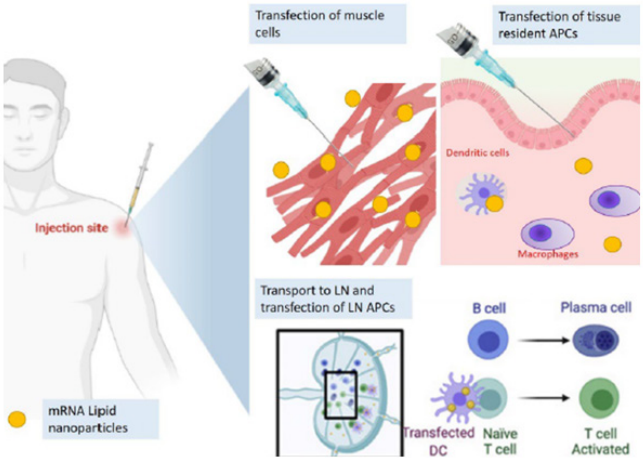

Figure 4 Visualization of the process of administration and the immune cells and response activated by the vaccine.[1]

Mechanism of action

These vaccines prime the immune system's own T cells to target cancers via in vivo CAR T cell therapy, showing promising results to combat tumor growth and reoccurrence.[15] Thus, enabling us to fight specific cancers of concern effectively. The Figure 5 depicts the mechanism of entry into the host cell and immune response generated by the therapeutic mRNA upon vaccination.

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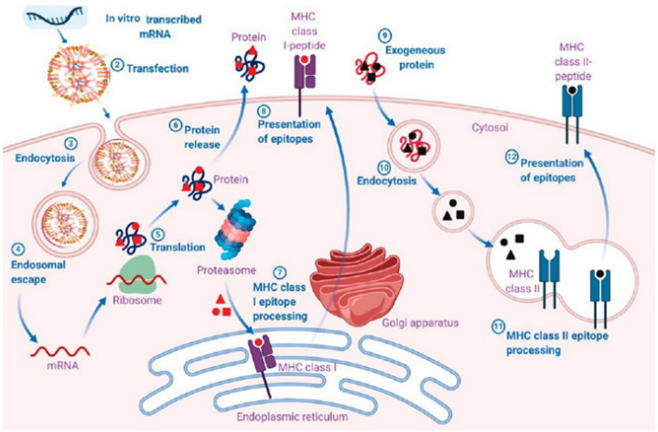

Figure 5 The mechanism of entry into the host cell and immune response generated by the therapeutic mRNA upon vaccination.[1]

The animal model studies such as mouse studies are constantly conducted to optimize and determine the efficacy and safety of these vaccines.[16] This research is critical for providing the medical field with safer vaccines to fight newly emerging and virulent strains such as the Omicron variant of the COVID-19.[16] Rapid vaccine turnaround facilitated by this platform is essential for combating highly pathogenic and rapidly evolving diseases that are viral in origin. The mRNA vaccines are unmatched by any other conventional vaccine production platforms while maintaining safety and efficacy thus providing hope for better addressing pandemics in the future.[17] Pathogenic diseases mediated by other vectors such as bacteria or fungus are also addressable via this platform by tailoring the payload to match the antigen of concern, thus showing the extreme flexibility of this platform.18 Although this technology remained dormant for decades, the recent pandemic was a testament to the versatility of this platform and decades of scientific research and development which is worthy of being recognized and appreciated.[19]

Vaccine production and optimization

The mRNA scientific community and their work have saved millions of lives in the recent COVID pandemic.[19] There are ongoing vaccine development efforts for the treatment of diseases such as human papilloma virus (HPV), which if untreated could result in complications such as cancers.[20] The immunity generated by this platform is so rapid, that the mere first dose of a vaccine such as COVID-19 has shown to be significantly effective against even the novel variants. The strong immune response developed without booster vaccinations shows the ability to fight highly virulent diseases easily with the aid of periodic booster administrations.[21]

Cutting edge advancements in computational biology, bioinformatics databases and modeling have enabled scientists to study viruses such as influenza viruses with the aid of methods such as antigenic drift. This has resulted in vaccines that are capable of targeting the viral proteins inside hosts such as hemagglutinin enabling creation of influenza mRNA vaccines.[22] As a result of the recent COVID-19 pandemic, the mRNA industry has seen significant advancements with respect to manufacturing, logistics, safety, regulations and efficacy.[23]

Similarly, the rapid advancements that took place since the pandemic have propelled this field. The recent success of this technology has enabled pharmaceutical vaccine companies to adopt this platform to create many other therapeutics from viruses to cancers thus advancing the immunology field significantly.[24] The delivery mechanisms such as the lipid nanoparticle have undergone significant improvements that enable better vaccine efficacy, stability and safety. This has resulted in a readily adoptable platform for vaccine development for time sensitive and highly infectious diseases.[25] Figure 6 conveys the platform mRNA production process from upstream to downstream respectively.

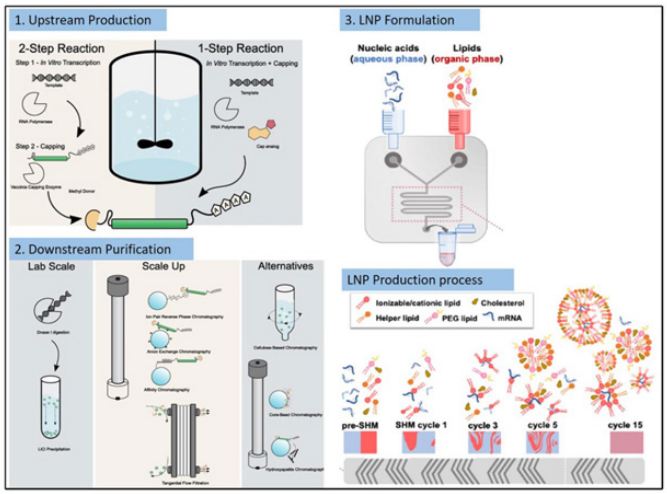

Figure 6 Platform mRNA production process from upstream to downstream.[1]

Discussion

Efforts are ongoing for creation of mRNA vaccines for treating tick borne diseases such as Lyme disease, and tick mediated encephalitis. Thus, proving the platform's versatility and promising better protection from a broad range of pathogens.[26] The constant advancements in the mRNA field and vaccine components such as the lipid nanoparticle has significantly boosted the vaccine potency. An example is the improved and efficient transfection that minimizes cellular and organ toxicity resulting from lipid nanoparticle constituents.[27]

As the payload and delivery optimizations are increasing the mRNA vaccine's overall efficiency and safety increases, resulting in many companies adopting the platform. Rapid adoptability results in a plethora of vaccines in biopharmaceutical company development pipelines. From autoimmune diseases to cancers, mRNA vaccines shed hope to improve the quality of lives of many patients.[28] Scope of the therapeutics that are being implemented utilizing the mRNA vaccine platform is depicted in Figure 7.

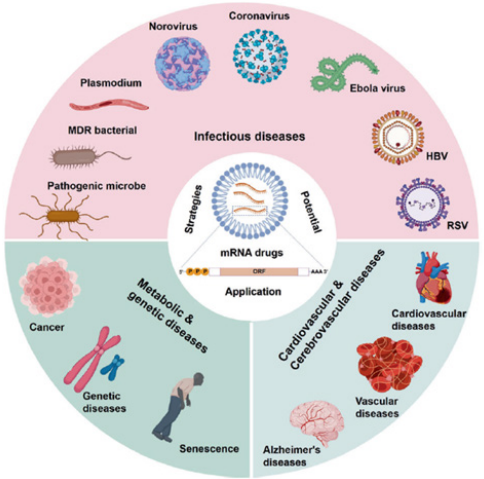

Figure 7 Scope of the therapeutics that are being implemented utilizing the mRNA vaccine platform.[42]

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Apart from the lipid nanoparticle, the therapeutic mRNA itself is undergoing significant improvements to enhance stability and translational efficiency. Modification of the poly A tail, the untranslated regions as well as the 5' cap synergistically prevents the therapeutic mRNA strand from exonuclease degradation.[29] The lessons learned from the recent pandemic are used to proactively develop vaccines beforehand for infectious diseases that have a potential of escalating into pandemics to prevent and minimize the death tolls.[30]

Similarly, it is of utmost importance to innovate and optimize the payload and delivery mechanisms to ensure better and safer vaccines that are capable of fighting ever evolving and novel infectious diseases.[31] Utilization of the targeted lipid nanoparticle delivery vehicle has shown promising results in cancer vaccine development by enabling higher in vivo CAR-T cell therapy success resulting in effective tumor growth reduction and elimination.[32] Several mouse studies conducted have shown that the bivalent vaccines provide broader range of protection than monovalent vaccines, with respect to COVID-19 Wuhan and omicron variants used in the studies.[33] There is an ongoing effort to create mRNA vaccines for monkey pox disease, where the studies are showing promising results thus another instance depicting the power of the mRNA vaccine platform to combat infectious diseases.[34] The table represented in figure 8 depicts mRNA vaccines that are currently being developed by biopharmaceutical companies (Appendix).

Research conveys that the mRNA vaccines initiate less pro inflammatory cytokines as well as lower interferon responses compared to the traditional adenovirus mediated vaccines making them much safer compared to the viral vector mediated vaccines.[35] Cancer vaccines such as the glioblastoma vaccines undergoing clinical trials serve to prove the limitless potential of this platform helping to cure diseases which were once deemed incurable.[36] The mRNA vaccine's antigen expression can be significantly improved with the optimization of the signal sequences thus providing stronger and long-lasting immunity against infections.[37] There is an effort to utilize mRNA vaccines to address critical diseases such as tuberculosis where rapid and long-lasting immune response could mean the difference between life and death for affected patients.[38]

Conclusion and future considerations

Overall, the mRNA vaccine platform has shown promising results in addressing angiogenesis with respect to tumors, thus shedding light on stopping tumor growth and spreading in its tracks.[39] Furthermore, mRNA modified with the aid of nucleosides are successful in eliciting a strong immune response as they mimic rabies viral particles thus adding mRNA vaccines to the arsenal to fight rabies.[40] The platform's versatility has attracted several biopharma giants such as Moderna, Pfizer and Arcturus therapeutics to broaden the scope of vaccines in their pipeline depicted in table of Figure 8. Biotechnology startup Capstan Therapeutics adopted the platform to create novel CellSeeker Technology that utilizes the tLNP process to ensure targeted payload delivery. This proprietary platform ensures maximum drug efficacy and potency is obtained by delivering them to the cells of concern such as T immune cells facilitating in vivo CAR-T cell therapy.[41,42]

Similarly, biopharma companies are developing vaccines such as RSV, HIV, Zika Virus infection and influenza depicted in the table in Figure 8. Infectious diseases, oncology, genetic diseases, autoimmune diseases, metabolic disorders, cardiovascular diseases and fibrosis are some of the areas that are seeing mRNA mediated vaccine developments rapidly taking place as depicted in figure 8. Overall, the mRNA platform has shown rapid adaptability and the capacity to address a broad range of pathogens. All of these therapies could be produced at unprecedented speed, accuracy all while being safe thereby revolutionizing the field of immunology and vaccinology.

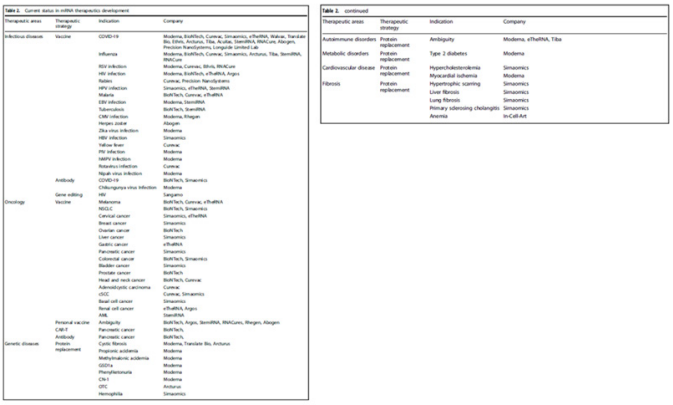

Figure 8 Table depicting mRNA vaccines that are currently being developed by biopharmaceutical companies.[42]

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Conflict of interest

Authors hereby declare that there is no conflict of interest.

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