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COVID-19 vaccination. Putting messenger RNA vaccines into context: there should be no doubt that they are beneficial

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Abstract

Only a few years have passed since the onset of the pandemic caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which has significantly lower activity and incidence. To address this current favorable epidemiological situation, the rapid development and widespread administration of COVID-19 vaccines—particularly messenger ribonucleic acid (mRNA) vaccines—has played an undeniable role. Numerous studies have convincingly shown that the benefits achieved with these types of mRNA immunization in controlling infection and disease far outweigh the potential risks associated with the administered vaccines. Alongside this success during the pandemic, widespread misinformation has emerged and still persists today, reaching a broad segment of the general population. This misinformation, which is focused on the safety profile of these vaccines and amplified through various social media and digital platforms, generates unnecessary skepticism, reluctance, and a sense of uncertainty—even among healthcare professionals. The aim of this review is advocacy-oriented, providing accurate information about the reality of mRNA technology in preventing infection by the SARS-CoV-2 virus, which is here to stay, as well as its potential benefits in other infections and as a therapeutic approach for certain diseases. Despite these positive results, research continues to overcome certain limitations and achieve its full potential by improving factors such as increasing immunogenicity, prolonging the duration of humoral immunity, and inducing nasal mucosal immunity, all while ensuring the lowest possible reactogenicity. Transparent verification and communication regarding cited side effects and their rarity are also crucial to maintaining confidence in them. Strengthening medical and social trust in the face of inevitable misleading or false information about these vaccines—information not based on scientific data or evidence—is essential, as it can seriously harm individuals who rely on it when making decisions about their health.

Keywords: SARS-CoV-2 virus, pandemic, mRNA vaccines, mRNA technology, spike proteins, misinformation of vaccines, effectiveness of mRNA vaccines, skepticism about COVID-19 vaccines, strengthening the credibility of COVID-19 vaccines

Background

In today's globalized and connected world, where both information and misinformation circulate rapidly through mass media and digital networks, concerns about the actual effectiveness and safety of vaccines have become prominent, potentially undermining efforts to protect communities from preventable diseases. During and after the last pandemic, there was a perceived greater appreciation that the uncertainty created (especially fostered on social media) regarding COVID-19 vaccines particularly messenger RNA (mRNA) vaccines ones among the population, and even spilling over to some healthcare personnel, negatively affected both potential recipients and the healthcare system that should recommend them. At that time, it was essential to promote and ensure that the benefits and scope of these vaccines and the risks of the diseases they prevent were well understood with positive information that could be impartially transmitted to the susceptible population. Currently, the landscape has changed because the SARS-CoV-2 virus responsible for the pandemic has mutated, is

now less virulent and prominent, and a large part of the population has acquired a certain level of immune protection from contracting the infection or being vaccinated. Therefore, the risk of developing severe COVID-19 is much lower, so the general interest in vaccination will no longer be the same as it was few years ago, especially if there is already some public uncertainty or fear regarding available vaccines. However despite the current lower aggressiveness of the infection than it did in the early years of the pandemic, available evidence suggest that COVID-19 vaccination provides additional protection against severe cases, hospitalization, and death, especially in individuals over 70 years of age and those belonging to at-risk groups. For these reasons, it is necessary to advocate for the benefit of vaccination and the value of recommended vaccines.

Vaccines are arguably the most powerful weapon with which people can combat infectious diseases caused by bacteria or viruses [1] Traditional vaccines have often been developed from live attenuated or inactivated microorganisms, or subunit antigens derived from pathogens [2]. The development and large-scale production of these traditional vaccines can be time-consuming, which may not be useful for sudden outbreaks of infectious diseases, such as the pandemic caused by the SARS-CoV-2 virus [1, 2]

Currently, antiviral vaccine designs are generally and simply categorized into two types: protein-based and genetic-based. The former carry and release the antigen that stimulates the immune system once administered. This class includes, for example, vaccines for poliomyelitis and influenza that are made from inactivated or killed whole virus antigens, and vaccines for hepatitis B and human papillomavirus (HPV), which use subunit antigens from specific virus particles or virus-like particles. In gene-based vaccines, live attenuated viruses such as those for measles, rubella, and mumps add their genetic instructions to generate viral copies that elicit the desired immune response in the host. More recent vaccines, DNA and mRNA viral vectors, are synthesized in the laboratory, and genetic instructions are inserted from the pathogen of interest so that they can induce immune responses once the vaccine is administered [3]. In the specific case of the SARS-CoV-2 virus, the intended antigen is the spike protein, which the virus uses to bind to and fuse with the cells of the people it invades (4). The virus's mRNA, which carries the instructions for this, can be rapidly designed and synthesized, and its sequence can be modified as needed to control emerging viral variants [5]. These vaccines are essentially chemically catalyzed components designed to accelerate their growth and, theoretically, enable larger-scale development, although they have never been mass-produced before as they are now.

The successful outcomes achieved in the development of mRNA-based vaccines against SARS-CoV-2 have not only been decisive in combating the pandemic but have also promoted advances in this technology for other types of viral infections [6, 7]. Parallel to the deployment of this beneficial technology due to the pandemic, erroneous or misleading information about these types of vaccines has emerged and gained attraction in the media and social networks, alongside truthful information. These accounts, accessible to public opinion, could have generated unnecessary fear and uncertainty. This misinformation has largely focused on side effects, despite evidence highlighting that, apart from a few cases of serious health events following vaccination, the safety profile of mRNA vaccines remains favorable [7].

How do these vaccines work?

Let us recall that of the two known types of nucleic acids in the cell nucleus, DNA stores and encodes the entirety of the organism's genetic information and cannot leave the nucleus. However, through other nucleic acids, RNA, and its "messenger" with the desired instructions can be transmitted outside the nucleus, similar to a coded operator. This genetic contribution of mRNA as a notable messenger in our cells, already known and studied for years by researchers, was the starting point for new therapeutic targets. One of these advantages is the successful development of vaccines, as exemplified in vaccines against the SARS-CoV-2 virus [6]. These formulations, which transport the desired genetic information can be engulfed and efficiently translated into antigen-presenting cells when injected in vivo. In particular, mast cells, macrophages, and dendritic cells are fundamental for activating an adaptive immune response. It is an incredibly efficient process, and most cells that encounter trap it and produce the proteins. To maintain their viability for necessary time to perform their function, mRNA strands are wrapped in lipid molecules to form small spherical particles, which also protect them against degradation by the body's enzymes and facilitate the release of intact mRNA into the cells [2, 5, 8]. Furthermore, these nanoparticle components adapt as adjuvants to enhance the immune system's response to the vaccine, resulting in a more robust humoral and T cell response [9]. Once in the cytoplasm, the mRNA is captured and read as a template by ribosomes, the machinery responsible for producing copies of the specific viral spike protein [1, 2, 8, 9] (Figure). The immune system recognizes these foreign protein antigens as invaders, generates an adaptive humoral response by producing antibodies, and induces a strong cellular immune response from highly specific T-cells, establishing immunological memory [2, 9]. Thus, the organism is preparing its army against potential and possible attacks by recognizing the real virus and initiating the mechanisms generated and desired by the vaccine to defend against infection and disease [4]. To fulfill this function of immunizing and reducing its reactogenicity, the formulation to be administered requires that it be sufficiently stable; thus researchers have incorporated a modification of the mRNA used when synthesizing both vaccines, and added N1-methylpseudouridine molecules to eliminate undesirable uridines [9].

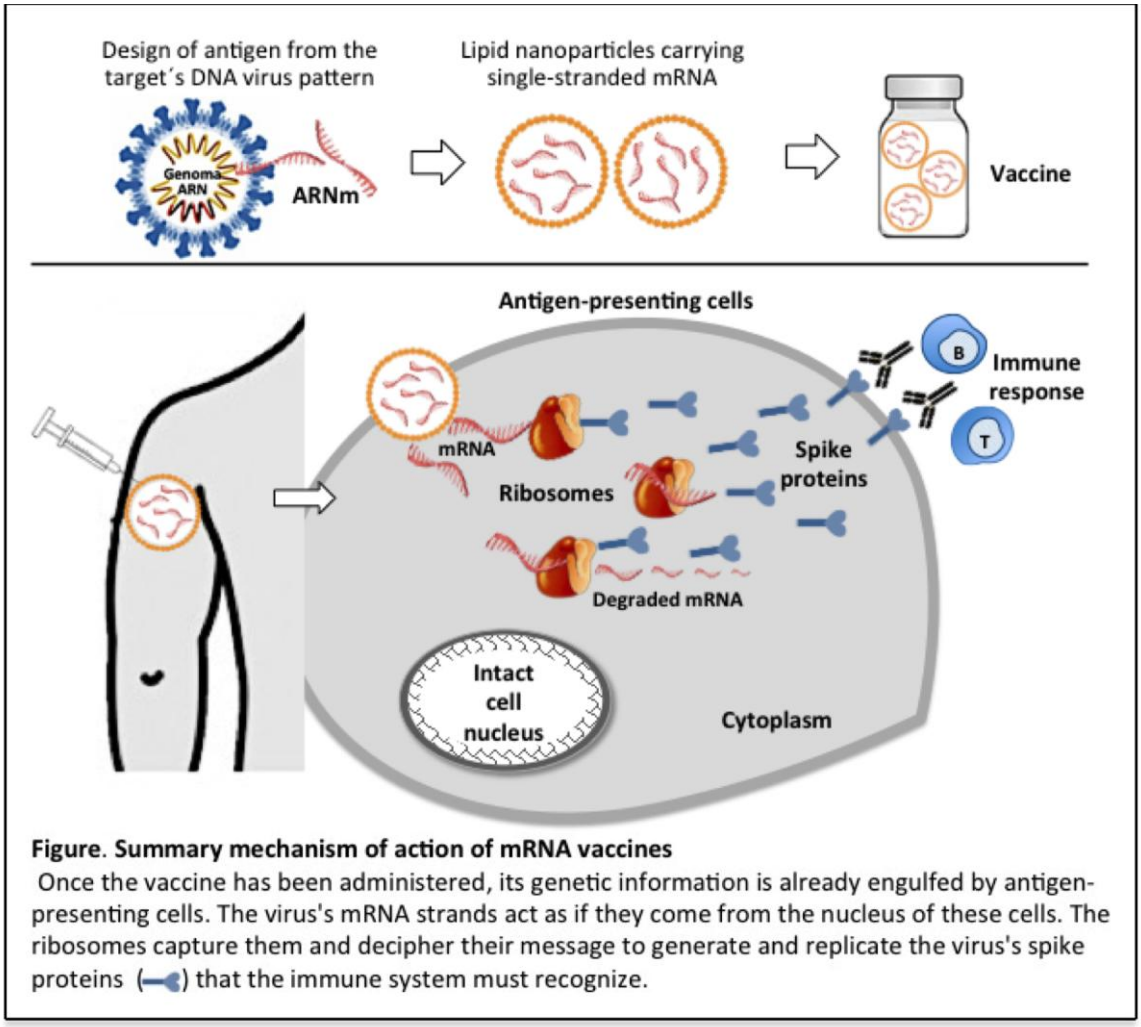

Figure. Summary mechanism of action of mRNA vaccines

Once the vaccine has been administered, its genetic information is already engulfed by antigen-presenting cells. The virus's mRNA strands act as if they come from the nucleus of these cells. The ribosomes capture them and decipher their message to generate and replicate the virus's spike proteins (—◂) that the immune system must recognize.

Furthermore, owing to the inherent thermal instability of mRNA molecules, vaccines require cold chain storage at extremely low temperatures that vary depending on the manufacturer (such as those produced by Pfizer and Moderna). This strategy had to be implemented during the COVID-19 pandemic, which at the time limited access to better immunization in low-resource countries and was also the reason for the cancellation of several vaccines already in development. It is essential to guarantee the preservation of physical, chemical, microbiological and biological properties during the storage period as well as across the entire lifecycle until the end of use [8, 10].

Effectiveness of mRNA Vaccines

Although effectiveness estimates are not 90% or greater because they were at the beginning of the pandemic against the original virus, these vaccines have generally proven to be safe and effective in real-world settings, particularly in preventing severe illness, with a substantial reduction in hospitalizations and deaths associated with this infection during the pandemic [6, 11-13]. Despite the emergence of viral variants that partially evade the immune responses induced by immunization, since vaccines are promptly updated by matching the mRNA sequence encoding the spike protein with that of circulating viruses [6], the results of a large preliminary study highlighted that the number of hospitalizations and deaths from COVID-19 have been persistently greater among the unvaccinated individuals that among vaccinated individuals (14). In Europe alone, across 34 countries, according to another study by the WHO (World Health Organization) European Respiratory Surveillance Network, direct immunization with vaccines against this virus has significantly altered the course of the pandemic, with an estimated 1.6 million lives saved [15]. This assessment is likely an underestimate, as the study does not consider the additional effects of herd immunity achieved through widespread vaccination. This is important because the decrease in transmission at the population level indirectly reduces exposure and, consequently, illness and deaths among unvaccinated individuals.

A lower incidence of persistent COVID was also observed after an acute infection in people previously immunized with these vaccines [16]. Some studies indicate that vaccination may be associated with a lower risk of persistent COVID in children [13]. Despite the marked effectiveness of current mRNA vaccines against symptomatic and especially severe disease, they are clearly less effective at preventing infection per se, as they do not offer robust protection. This immune deficiency occurs because these vaccines do not promote

adequate mucosal antibody (IgA) immunity in the upper respiratory tract (URT), compared with that achieved after having suffered a SARS-CoV-2 infection [4, 6]. The respiratory tract, as we recall, is the entry point and dissemination site for respiratory virus infections. It is an important immune enclave for fighting these microorganisms early on. [4, 17]. On the other hand, the characteristic evolutionary behavior of SARS-CoV-2, a decline in humoral immunity acquired over time, plus some immune escape from certain circulating variants and subvariants of the highly mutating virus, are reasons for the development of new infections, which are fortunately currently milder [7]. The also well-known and accepted reduction in antibody levels promoted by mRNA vaccines over time has been attributed to the high peak in antibody production initially induced, and not to these vaccines being truly incapable of generating lasting immunity. This decline is known to often involve drops of 10 to 20 times in antibody titers within 6 months of immunization [6, 7]. Fortunately, the defensive "arsenal" created after immunization is complemented by the cellular immune response and is more durable with cytotoxic T lymphocytes (CD8+) sufficiently prepared to activate forcefully after reinfections and most importantly, protects against progression to severe COVID-19 when the level of antibodies is not sufficient to neutralize the virus [5, 6]. These vaccine-generated T lymphocytes recognize antigens differently than antibodies, so they are less likely to be fooled and overcome by mutations in the viral sequence (strain variants) than antibodies [18]. The recommended booster doses of the vaccine aim to restore the humoral immunity provided by the vaccine, which wanes over time and is necessary against severe infections. Research and development continues to mitigate this decline, and an interesting challenge is updating mRNA vaccine formulations to safely induce strong mucosal immune responses in the respiratory tract via intranasal or oral administration. This could contribute to reducing the frequency of asymptomatic SARS-CoV-2 positive patients [17]. Antigens are also selected and designed without delay according to circulating strains, thus ensuring their effectiveness and ability to maintain acquired immunity for a longer period [6, 7].

Regarding the child population, a very recent study [19] highlighted that these vaccines not only protect against the coronavirus but have broader health benefits, for example, for those diagnosed with atopic dermatitis. Compared with unvaccinated children, immunized atopic children presented significantly lower rates of infections, such as otitis media, pneumonia, bronchiolitis, sinusitis, upper respiratory infections, impetigo, and molluscum contagiosum. These patients also had a lower risk of developing asthma, allergic reactions, contact dermatitis, and food-induced anaphylaxis. In a nationwide retrospective study in Taiwan involving children aged 6–11 years, primary immunization with two doses of the two available mRNA vaccines (BNT162b2 or mRNA-1273) was associated with substantial protection against moderate to severe COVID-19, as well as a lower risk of SARS-CoV-2 infection confirmed in emergency care services (20).

Fears and skepticism generated by vaccines against SARS-CoV-2, specifically mRNA vaccines

1. They were developed very quickly, without adequate time to verify their efficacy

The highly adaptable mRNA vaccine technology or platform is not new; it has been in development for years—the early years—and was already waiting back when COVID-19 arrived [2]. Three decades of scientific advances in mRNA design and delivery technologies have enabled vaccines encoding novel typed antigens to become powerful tools for combating infectious diseases [8]. Their development and use, driven by necessity, were rapidly accelerated from the start of the COVID-19 pandemic, placing this technology at the forefront of the race with other vaccines, and all the researchers had to do essentially determine which part of the virus they were going to put into the vaccine and then administer it. This system requires viral sequencing instead of the use of live attenuated or inactivated viruses and once the genetic sequence of specific microorganism is known, the corresponding mRNA is rapidly synthesized [21]. In vitro production of synthetic mRNA has proven to be a simple and cost-effective process and can take only two days, as it does not require a biological phase thus allowing access to clinical trials in a very short time [17]. This early development fostered a degree of skepticism. Unlike conventional vaccines, mRNA vaccines are not grown in eggs or cells, which is a costly and time-consuming process. For example, flu vaccines are typically produced from embryonated eggs and require 6 to 8 months [2].

Owing the invaluable effort and collaboration of scientific researchers, physicians, ethics approval committees, manufacturers, and regulatory agencies, all this control occurred. This goal was achieved by utilizing existing advances in vaccine technology and platforms developed after years of research by providing generous support from governments and other funding sources. Furthermore, large-scale production and to expansion were carried out in parallel with clinical trials.

2. Unfounded fears about the safety of these vaccines

The novelty of the technology behind these vaccines and the accelerated manufacturing timelines raised doubts about the safety of the administered mRNA after its introduction during the pandemic, generating significant misinformation, in addition to questions about its actual efficacy in studies. The rapid and widespread dissemination of information and news, often taken out of context, has contributed to the uncertainty surrounding these vaccines among the recipient population and even some healthcare professionals. Therefore, transparent review and communication regarding side effects and their rarity are crucial to maintaining confidence in them. This misinformation, part of the prevailing infodemic — fortunately now lessened as the virus and the consequences of the infection play a less prominent role-led at that time to the circulation of derogatory terms such as "vaccine potions," "toxic vaccines," "experimental gene therapies," or "famous injections against a supposed pangolin virus."

2.1 General reactogenicity

mRNA vaccines against COVID-19, which are delivered via lipid nanoparticles, are extremely safe, according to the available credible information. Since they are not based on live viruses, there is no risk of causing infection or illness in vaccinated individuals. After the spike protein is produced in cells the injected mRNA degrades rapidly in the body (within a few days), mitigating the risk of long-term side effects [4, 21]. The most frequent systemic reactions are similar to those already known for traditional vaccines: mild, transient, and self-limiting. These adverse events, which vary in severity, include fever, malaise, headaches, and body aches. Notably studies suggest that the high initial defensive activity of the mRNA-induced vaccines is closely related to several of these side effects [22]. Greater systemic reactogenicity, especially fatigue and headaches, may indicate more robust immune responses, as observed more frequently in younger populations than in older populations and more so after the second dose. This finding suggests the involvement not only of innate immune responses but also of the adaptive immune response [4, 16, 22]. Importantly, with these vaccines, reactogenicity and immunogenicity often have a very close relationship; therefore, maintaining an appropriate balance between these two opposing responses (efficacy and reactogenicity) is essential for developing an effective vaccine. On the other hand, the hypothetical or nonexistent long-term side effects discussed later should not be a cause for concern if the established immune memory is maintained. Doubts have been raised about the practice of immunizing people who have already been infected with these vaccines, as they might develop more of vaccine-related adverse effects due to existing immunity. A study of a large number of vaccinated individuals with a mean age of 67 years, some with comorbidities, after having had the infection, revealed no increase in adverse reactions compared with those vaccinated without prior infection, indicating that two doses of the mRNA vaccine were safe [23].

These mRNA vaccines have been shown to cause no fewer than 57 secondary disorders of different systems and organs, both mild and severe, as well as potential complications. The question is, is it possible to accept such a large number of side effects? [22]. Since the pandemic, there has been a certain legend or popular trend to suggest, ask, or report whether certain medical processes of different kinds that arise at any time in people should be attributed to side effects of the vaccines received against COVID-19, not only those of mRNA.

2.2 Main adverse reactions that have been reported as serious or of great concern

As with other types of vaccines, serious side effects from mRNA vaccines are possible, but extremely rare.

Myocarditis and pericarditis are communicated risks especially after the second dose is given to adolescent and young adult males. In a systematic review, evidence of myocarditis associated with these vaccines occurred at rates of 1.3-3.1 per 100,000 doses in this age group, with a lower risk at longer dosing intervals [13]. In clinical studies on these vaccines, myocarditis and pericarditis were estimated at approximately 0.02% and 0.01% of recipients of the BNT162b2 vaccine and at 0.03% and 0.01% with the mRNA-1273 vaccine respectively, mainly during the first month after vaccination [24]. However, it is clear that the benefits of vaccination far outweigh this infrequent risk, which is mild since patients respond well to conservative treatment with rapid recovery [4]. These two processes occur more frequently as a complication of COVID-19 than after vaccination [9].

Ischemic stroke. There is some reference to this risk but without a clear definitive review of it according to the data collected [12].

Anaphylaxis. The incidence of this very rare, severe reaction has been estimated at 2-11cases per million doses of these vaccines [23] and has been attributed to a component, an excipient (e.g., polyethylene glycol, tromethamine), or a carrier (lipid nanoparticle) [2, 7]. The presence of polyethylene glycol in consumer products, such as toothpaste and shampoos, can lead to existing sensitization in some people with antibodies against pegylated lipids [2, 4]. Research continues into the potential components responsible for anaphylaxis and the associated mechanisms [22, 23]. Some evidence suggests that the most severe immediate allergic reactions reported after mRNA vaccines are probably not IgE-mediated and therefore have a low risk of recurrence after subsequent vaccine doses. However, consultation with specialists is always mandatory before revaccination [25].

Other diseases mentioned as worrying

In relation to all vaccines against SARS-CoV-2 administered during the pandemic, the emergence of certain processes that generated concern at that time has been cited. Regarding mRNA vaccines, events such as Guillain-Barré syndrome, Bell's palsy, thrombocytopenic thrombosis syndrome, or myocardial infarction have been reported, but the available evidence rejects a causal relationship with the vaccines [9]. With respect to other cited processes such as chronic inflammatory demyelinating polyneuropathy, transverse myelitis, chronic headache, postural orthostatic tachycardia syndrome, or immune thrombocytopenic purpura, the reviewed evidence is inadequate to accept or reject a causal relationship due to a scarcity of epidemiological and technical data [9].

However information on the significant adverse effects of mRNA vaccines against COVID-19 in the vulnerable individuals, such as children, is relatively limited. Specifically, in children under 12 years of age, there is a lack or less information due to the later authorization of these vaccines in this age group and the lower vaccination rates that in adults, which has led fewer studies of adverse events in children [9]. However, in initial studies of children under 5 years of

age, the safety profile was good in the three weeks following vaccination and during 9 months of surveillance with more than 245,000 doses of mRNA vaccines. Importantly, no cases of myocarditis or pericarditis occurred [26]. A very recent study, which extended the age range to 17 years, revealed that rare conditions such as myocarditis, pericarditis, thromboembolism, and thrombocytopenia occur more frequently after SARS-CoV-2 infection than after vaccination against the disease. This information provides quantitative evidence to support public health decisions regarding SARS-CoV-2 infection and vaccination in children and young people [27]. In elderly individuals, another vulnerable group, the safety profile remains favorable, and since most side effects are self-limiting and require minimal medical attention, older adults can continue to receive the vaccines [7].

Overall, although countless adverse reactions have been reported following vaccine administration, the extent of serious side effects, such as those mentioned and a few others, is minimal after hundreds of millions of doses are administered. These rare events require in-depth study and follow-up to identify unknown components of mRNA vaccines that may be responsible for these events [7]. Given the fear and uncertainty surrounding these potential risks for vaccine recipients, they can be reassured that the risk of having a serious car accident while traveling to work or to a medical appointment (risks that are always accepted as possible) is greater than a severe reaction to these vaccines.

2.3 Very concerning effects (harmful?) have also been attributed to these vaccines

"*mRNA vaccines are experimental gene or genetic therapies*", with the risk of causing genetic alterations in the healthy population. A misleading, ignorant, and inappropriate notion is that they pose this danger when administered to prevent infections. Gene therapy, by definition, involves altering the expression of a gene or genes to prevent, treat, or cure certain diseases caused by alterations in a person's genome. This involves modifying the DNA of potential patients and replacing or deactivating a gene that is not functioning normally [28]. mRNA vaccines are not gene therapies because they do not interact with or alter the recipient's genetic material. It is designed in the laboratory where instructions for genes of the pathogen of interest are synthesized and inserted by transcription from DNA to mRNA, a molecule that will be administered to people for translation into the necessary proteins as antigens. The translation of mRNAs that take place in the cell cytoplasm is more efficient in the cellular introduction (transfection) of nucleic acids and has lower toxicity [7]. The mRNA does not enter the recipient's genome, thus avoiding potential long-term risk [1, 2, 4, 17, 29]. The misguided fear that the mRNA administered in the vaccine is unalterable is unfounded since it is inherently unstable, has a very limited half-life, and degrades rapidly within hours or days once the antigenic protein is generated, becoming undetectable four weeks after vaccination. The exception is the lymph nodes of vaccinated individuals, where mRNA persists for up to 60 days after the second dose, although the amount detected declines over time. These are specific and expected findings in the lymph nodes, which is precisely where antibody-producing cells develop their ability to recognize pathogens. Their central role in the immune system means that the limited persistence of vaccine mRNA and the spike protein is neither unexpected nor rare, suggesting that the potential long-term effects of the vaccine on the body can be minimized [4, 29-31]. The presence of the spike protein it encodes is also temporary, being eliminated over varying periods of time by the immune system [29, 31]. Concerns have also been raised that residual DNA could pose a risk and cause autoimmune diseases. Bacterial plasmid DNA, after the introduction of the desired spike protein DNA, is used to produce these COVID-19 vaccines. However, these vaccines undergo an elaborate purification process so that the very small and fragmented plasmid DNA residues in the mRNA of bacterial origin are degraded, posing no risk as they cannot reach the cell nucleus, unlike the residual DNA from animal cell cultures used in other vaccines [5, 29].

These vaccines against infectious diseases should not be labeled as gene therapy formulations per se since they do not modify the genetic makeup or DNA of vaccinated individuals

"*Since the widespread use of these vaccines, more deaths have been recorded than before the pandemic*".

Some information is shared on social media and other public communication channels. Unfounded claims that has been categorically denied. There is sufficient evidence that vaccines save far more lives than they cost. Making a vaccine dependent on such an adverse event requires a high level of evidence, including autopsy findings and medical records that rule out other causes of death and show whether the affected person was infected with the SARS-CoV-2 virus. Recent, large-scale, rigorous studies shown that postvaccination death rates are lower than death rates from other causes in the general population. In conclusion no increased risk of mortality, including sudden death, from causes unrelated to COVID-19 was found between recipients of these widely used vaccines and those who were not vaccinated, even in the long term and as the pandemic progressed [12, 32-34]. It is crucial to distinguish between causality and coincidence. Similarly, another report based on data from the Vaccine Adverse Event Reporting System (VAERS), which the Centers for Disease Control and Prevention (CDC) uses to monitor vaccine safety, reported that deaths occurring between 7 and 42 days after vaccination were lower than those expected from all other causes [9]. Available medical information critically evaluating the association of sudden death with COVID-19 immunizations is scarce and has many methodological limitations.

"*Do COVID-19 vaccines promote the development of cáncer*?"

It has also been highlighted in news media that mRNA vaccines against COVID-19 (specifically the second dose) cause changes in cells (T cell depletion) that could promote cancer growth. This is an exaggerated deduction, but numerous virologists and cancer experts note that there is no

medical evidence to support this claim, and epidemiological follow-up data have not shown a sudden increase in cancer cases following the use of COVID-19 vaccines [35]. This misinformation is incomprehensible and contrasts sharply with the current use of mRNA technology and novel vaccines as advances in cancer treatment, which are shown some surprising results due to their ability to trigger a potent T-cell response, their unique suitability for personalized design, and their well-tolerated nature [22]. A very recent study revealed that COVID-19 vaccination with mRNA significantly improved survival in patients with advanced lung cancer or skin melanoma who had started immunotherapy treatments within the last 100 days [36].

"*The spike proteins generated by vaccines cause side effects*."
There is information indicating that these antigenic proteins may be toxic even on its own when released and remain as a residue of a viral particle. References suggest that contact with these proteins damages or alters the function of endothelial cells lining the body's blood vessels, thus affecting well-vascularized organs [37-39]. Effects and disorders, such as difficulty concentrating, fluctuations in blood pressure, palpitations, dizziness, nausea, visual disturbances, persistent headaches, debilitating fatigue, paresthesia, and cognitive difficulties, have been reported in a small group of people who, after vaccination, experience persistent symptoms for at least three months. These are extremely rare reported reactions to all types of SARS-CoV-2 vaccines, with estimates of 0.73 cases/100,000 vaccinations or 0.2%-0.9% of vaccine recipients, although their precise prevalence is unclear [40, 41]. However, the scope of this toxicity reported after vaccination and attributed to the spike protein extends to at least 36 persistent medical conditions, including neurological, psychiatric, cardiovascular, autonomic and multisystemic syndromes and visual, auditory, gustatory, respiratory, dermatological, gastrointestinal, and muscular disorders [42]. Is the number of cited events excessive? All of these have recently been labeled "post-COVID-19 vaccination syndrome". Similar manifestations have already been observed in the infection itself, particularly in the most severe cases and in long COVID-19 cases, with the generated spike proteins also being implicated. In addition to the highly immunogenic nature of SARS-CoV-2 spike proteins, existing information regarding their potential or actual toxicity is prompting further research [43]. Discrepancies exist concerning the presence and persistence of these proteins in the blood and various organs among infected individuals, as well as their potential or purported toxicity in vaccinated individuals [42]. In infected people, this may depend on individual differences in viral clearance or the perpetuation of viral reservoirs or components [44], which are not expected in vaccinated individuals, and warrant further study. Concerns about this potential toxicity following mRNA vaccine injections may be less serious than they appear. For example, in a study conducted on groups of patients with long COVID-19, the prevalence and persistence of this protein (consistent with other studies) did not correlate with the established infection or postvaccination time points. No association was observed with the specific prolonged symptoms studied or with their severity, nor was there a link with markers of endothelial dysfunction, inflammation, or hypercoagulability [45].

Notably the spike proteins produced by virus-infected cells and those generated by cells in response to the vaccine are very similar, although not identical, and also that much information on the persistence of these proteins and their potential toxicity comes from studies in vaccinated mice, in which, incidentally, lower levels of spike proteins were detected than in infected mice [46]. Scientists and researchers have noted a key difference between the spike protein molecules induced by the SARS-CoV-2 virus and those generated by mRNA vaccines [43, 44, 47]. Importantly, both viral spike protein molecules and vaccine spike protein molecules have a fatty attachment region known as the transmembrane domain (TD) in the S1 subunit. Its purpose is to bind these molecules to the outer membranes of cells or to many other lipid-rich internal membranes. The TD of the intact viral spike protein, in addition to this binding, is active and essential in the infection process [48]. It promotes viral penetration into target cells through its affinity for angiotensin-converting-enzyme 2 (ACE2) receptors. Once inside the infected cell, the mRNA generates countless copies of spike proteins, which, in their evolutionary drift, are added to new virus particles. Thus, most manage to escape the cells where they are formed. They are free to invade other nearby tissues and/or enter the bloodstream. The spike protein molecules that do not escape remain trapped in the outer membrane of the infected cell, which the immune system recognizes to perform its defensive function [47]. However, the spike proteins encoded by the vaccines (those from mRNAs, adenovirus vectors, and recombinant proteins) behave differently. A double proline mutation was introduced into the structures of these proteins at specific positions (986 and 987). This mutation strengthens the spike protein in its prefusion state and anchors it to the cell surface, hindering its release and thus reducing its binding to ACE2 receptors on other cells throughout the body. Theoretically, this could cause less toxicity and fewer potential complications than expected with viral spike proteins lacking this mutation (42). On the other hand once inside antigen-presenting cells, the injected mRNA chains promote the production of only a large quantity of one element, the spike protein. Because other components or particles of the viral structure are not generated, the newly created proteins lack easy means of exiting the cell. Most remain floating, fragmented or intact and are transported and retained by the cell's outer membrane to be recognized by the immune system. In short, owing to the aforementioned TD factor and its double proline mutation, the spike proteins generated by the vaccine invariably tended to become trapped in the cells where they were generated. In addiction, their concentration there is much greater than the dispersion load into the circulation and other organs, as occurs with those resulting from infection [31, 47]. After vaccination, the expression of spike proteins has a spatiotemporal profile that is theoretically much more

localized and limited in time than in cases of infection (44).

Nevertheless, concerns about its potential toxicity persist, considering that in its defensive activity, activated CD8+ T lymphocytes can destroy cells that express and protect the spike protein as a perceived external threat. The resulting cellular debris could release these proteins into the bloodstream, a possibility that has not yet been sufficiently proven [42]. Free spike protein has been detected in the blood and tissues of both patients with symptoms of hypothetical post-COVID-19 vaccination syndrome and in those with long COVID-19, indicating that it does not always remain bound [44]. It can be detected in blood up to two weeks after injection at levels that are probably too low—in the pg/ml range—to trigger endothelial cell dysfunction, and it is barely detectable or not detectable after the second dose of vaccination [32, 39]. However, much higher levels, capable of causing such damage, have been recorded in severe cases of COVID-19 [39, 49].

The perception is that the spike proteins generated after mRNA vaccination could have a limited and transient impact on endothelial cells with recovery in a few days, contrary to the information transmitted about the side effects of this type (its absence of toxicity is not absolute, e.g., mild cases of myocarditis in adolescents in whom high levels of spike protein are detected) [39]. The different levels of circulating spike protein reported in the various studies may be due to age-related differences or the time elapsed, since as spike protein is eliminated over time, it leads to lower rates detected months after vaccination.

The potential risk of post-COVID-19 vaccination syndrome attributed to the spike protein with such a high quantity of long-lasting and heterogeneous symptoms – similar e.g to what has been reported with HPV vaccine – remains uncertain or presumptive. There are no defined clinical diagnostic criteria or specific biomarkers, and further research is needed. The detection of these circulating proteins in analyses does not guarantee harm, as the levels capable of causing harm and whether they are biologically active have not been established [42]. In short, this syndrome, which seems to primarily affect young and middle-aged individuals, is not yet officially recognized as a distinct medical condition and remains controversial [40, 42, 50].

Immunizing with these mRNA vaccines is still a good decision and they are much less likely to cause that damage than the spike proteins produced during SARS-CoV-2 infections that the vaccines prevent.

Conclusions

The emergence of mRNA vaccine technology represents a significant advance in immunology and public health, providing a novel resource for combating infectious diseases and potentially other types of illnesses. One of the main advantages of mRNA-based therapies is their ability to target disease-causing proteins or genes while leaving unaffected cells healthy. The safety and efficacy of vaccines against the SARS-CoV-2 virus, demonstrated in clinical trials and subsequently resulting in high effectiveness in preventing severe illness and millions of deaths after mass vaccination (mostly with mRNA vaccines), has clearly shown their global impact [11, 15, 24, 51]. Taking this benefit as an example during the pandemic, it has been shown that mRNA vaccines, owing to their rapid research and development, large capacity and speed of production (using acellular, scalable, and cost-effective systems), good safety profile (not based on live microorganisms) [2, 10], and extraordinary advantage in antigen presentation and the generation of immune responses, possess great potential in the prevention and control of other infectious and noninfectious diseases [1, 4, 6, 22, 52]. In infection prevention, the stability, storage capacity, and cost of new vaccine developments are key and gain prominence, as long-term effects related to increased antibody persistence and cellular immunity are maintained. Notably, mRNA vaccines for COVID-19 have demonstrated a well-sustained cellular immune response despite a trend toward reduced humoral immunity. In this cellular response, CD8+ T cell activity is believed to protect against viral progression to severe COVID-19 in cases where the antibody response fails to neutralize the virus, which may occur with the new variants [6]. As vaccines are updated each year, the goal is to respond quickly and flexibly to new variants that may arise unexpectedly, while also having the capacity to scale up production when there is high demand for a particular vaccine. In this regard, a very recent study has pointed out that following the administration of updated (2024–25 COVID vaccines) monovalent booster doses tailored to circulating viral strains—comprising two mRNA vaccines and one protein subunit vaccine— they demonstrated continued protection against COVID-19 by reducing the likelihood of medical visits, emergency department encounters, hospitalizations, and severe complications related to the disease, compared to individuals who had not received the updated vaccine. This benefit was achieved over and above each individual's existing immunity, although protection appeared to wane over time (53). Although immunity conferred by the large number of infected individuals and systematic vaccination have reduced the rates of severe COVID-19 over time, the impact of COVID-19 on public health must still be considered. New variants of SARS-CoV-2 continue to emerge with mutations in the spike protein, leading to immune escape. For example, the BA.3.2 variant, which recently emerged in South Africa and has already been detected in at least 23 countries, has a greater predilection for childhood but evidence that it causes more severe disease is lacking [54].

Owing to their success in combating the pandemic and their broad reach, biotechnology companies have launched numerous mRNA vaccine developments for a range of infections, not only viral infections, several of which are currently in clinical trials [7]. Specifically, these vaccines target respiratory syncytial virus, influenza virus, human metapneumovirus, Epstein-Barr virus, cytomegalovirus, human immunodeficiency virus, Zika virus, Ebola virus, rabies virus, varicella-zoster virus, tuberculosis, malaria,

B. pertussis, and even provide protection against resistant microorganisms [2, 4]. mRNA-based vaccines and therapeutic antibodies against cancer have also been extensively studied and continue to be researched, and the technology is also being tested and used in cardiovascular, autoimmune, and rare genetic diseases [1, 21, 52]. In short, there are now multiple mRNA vaccines encoding novel personalized antigens that are promising. Furthermore, given the rapid development and application of these methods, quality control of these vaccines has necessarily become an important aspect and support for research [52].

Many side effects attributed to mRNA vaccines are similar to those of any other vaccine and are mild, transient, and self-limiting, requiring little medical attention. Therefore, more vulnerable individuals, such as elderly individuals, can continue to benefit from vaccination. Although many vaccines are miraculous and life saving, the capacity of mRNA vaccines to cause unforeseen and some serious idiosyncratic adverse effects remains a reality, but these are extremely rare and limited to a small group of people [55]. To date, safety has been rigorously investigated in millions of people for more than three years, with no evidence of widespread health problems or deaths, thus establishing their general confidence. They have a very good safety profile across all age groups, including children and people with underlying medical conditions, immunocompromised individuals, and pregnant women [56]. For international regulators, the overall benefits of these vaccines far outweigh their potential side effects. There are currently more than 41 mRNA vaccines in development for prevention of COVID-19 in clinical trials worldwide [2]. Very recently, on February 27 2026, the European Medicines Agency announced its recommendation to authorize the marketing of Moderna's combined mRNA vaccine against COVID-19 and influenza to protect older people. This decision was made following data from a trial in 8,000 older people, highlighting that the combined vaccine triggered a sufficient antibody response against both viruses with a good safety profile [57].

The inevitable dissemination of misleading and erroneous information about these vaccines, whether from the broadcast media or social networks, and not based on scientific data or evidence, can seriously harm people who need them when making decisions about their health. Sometimes, it can be difficult to distinguish truth from falsehood.

It is essential to convey confidence in vaccines since vaccine hesitancy or reluctance remains, according to the WHO, one of the ten threats to global health [58]

Abbreviatons

mRNA	Messenger RNA vaccines
HPV	Human papillomavirus
WHO	World Health Organization
URT	Upper respiratory tract
VAERS	Vaccine Adverse Event Reporting System
CDC	Centers for Disease Control and Prevention
ACE2	Angiotensin-converting-enzyme 2
TD	Transmembrane domain

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