

mRNA Vaccines: A Turning Point for Global Health?

Discussion paper

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EXECUTIVE SUMMARY

Vaccines are the most effective public health intervention, offering the highest social and economic return. The COVID-19 pandemic once again demonstrated their strategic value and brought mRNA technology to the forefront. These vaccines represent a technological leap with transformative potential: they allow for rapid, flexible, and adaptable design in response to emerging or evolving pathogens, can be produced at large scale without relying on biological systems, and have applications beyond infectious diseases, including cancer and other pathologies.

However, their consolidation as a transformative technology will depend on overcoming a series of challenges. On the scientific front, it is crucial to improve their stability and ability to generate long-lasting immunity. On the industrial side, solutions are needed to scale up production and optimize logistics, including the cold chain. Economically, high costs and intellectual property barriers pose risks to equity. Politically, it is essential to promote global mechanisms for universal access, technology transfer, and cooperation. Finally, strengthening public trust in the face of disinformation is more urgent than ever.

In summary, mRNA vaccines represent a turning point in immunisation. Their real impact on global health will depend on our collective ability to overcome these challenges.

INTRODUCTION

“The COVID-19 pandemic has been a powerful reminder of the enormous social value of vaccines, extending beyond health alone.”

Vaccines are the only way to protect ourselves safely and durably against infections caused by potentially lethal pathogens. Their history began in 1796, when Edward Jenner observed that milkmaids who had contracted cowpox (a mild disease) seemed to be immune to smallpox, which was deadly. To test his hypothesis, he inoculated an eight-year-old boy, James Phipps, with pus from a cowpox lesion and later exposed him to smallpox. The boy did not fall ill. Thus, the first vaccine was born—one that, nearly two centuries later, led to the eradication of the smallpox virus.

Today, we have approved vaccines against 25 infectious agents (see Table 1), and more than 15 others are in clinical development.

Table 1. Currently approved vaccines against infectious agents [WHO].

Cholera	Influenza (flu)	Pneumococcal disease	Tuberculosis (BCG)
COVID-19 (adults)	Japanese encephalitis	Polio	Varicella (chickenpox)
Dengue	Malaria	Rabies	Yellow fever
Diphtheria	Measles	Rotavirus	RSV [Respiratory syncytial virus]
Hepatitis (A, B and E)	Meningococcal meningitis	Rubella (German measles)	Herpes zoster (shingles)
Haemophilus influenzae type b (Hib)	Mumps	Tetanus	
Human papillomavirus (HPV)	Pertussis (whooping cough)	Tick-borne encephalitis	

Those currently recommended by the WHO as part of the Expanded Programme on Immunization

There are also two vaccines against chikungunya recently approved in the US and Europe, but not yet recommended by the WHO.

Adapted from: <https://www.who.int/teams/immunization-vaccines-and-biologicals/diseases>.

The COVID-19 pandemic has been a powerful reminder of the enormous social value of vaccines, extending beyond health alone. Vaccines constitute an ecosystem of their own, with scientific, industrial, political, and narrative implications of great relevance for society as a whole—possibly more than any other health tool.

The Health, Social, and Economic Impact of Immunisation

Immunisation is, without doubt, the public health intervention with the greatest impact. But developing safe and effective vaccines is not enough: it is crucial to ensure they reach the entire population. In this regard, the launch of the Expanded

Programme on Immunization (EPI) in 1974 **marked a turning point** in the history of vaccines. The program was launched by the World Health Organization (WHO) to guarantee universal access to life-saving vaccines. Since its creation, the EPI is estimated to have prevented *154 million deaths*, most of them in children under five years of age—equivalent to **saving six lives every minute**. Measles vaccine alone has prevented more than 90 million deaths. Beyond their health impact, vaccines also have a major social impact: for every life saved, an average of **66 years of healthy and productive life** are gained. Following the success of the EPI, the *Decade of Vaccines*, was launched in 2010 with the goal of extending the benefits of immunisation to all people and communities, including the introduction of vaccines not originally covered by the EPI, such as those against rotavirus or Japanese encephalitis.

Vaccination also provides the **best return on investment** in public health. Every dollar invested in immunization yields an *estimated return* of 20 dollars if only avoided medical costs are considered, and up to 52 dollars if social benefits are included. Between 2021 and 2023, immunisation against 10 pathogens prevented an economic burden of 828 billion dollars in 94 low- and middle-income countries.

Finally, thanks to vaccines, two diseases—smallpox and a cattle disease known as rinderpest—have been **eradicated**, freeing up human and financial resources previously devoted to their control.

COVID-19 Vaccines: An Unprecedented Milestone

Compared with previous pandemics, COVID-19 marked a turning point in the speed at which diagnostics, treatments, and above all, vaccines were developed. In just 11 months, safe and effective vaccines against a previously unknown pathogen were designed, tested, produced, and distributed. Until then, the fastest vaccine ever developed had been the mumps vaccine in the 1960s, which took four years from development to rollout.

This unprecedented achievement was made possible thanks to a combination of factors, including:

- **Scientific advances**, backed by more than 20 years of basic research in virology, immunology, and biochemistry, which laid the foundations for the accelerated development of new vaccines, particularly mRNA vaccines.
- **Political will and financial commitment**, with massive—and unprecedented—investments in the development, production, and procurement of vaccines.
- **Cooperation** between the pharmaceutical industry, the academic community, and regulatory authorities to speed up clinical trials without compromising safety.

Among all these advances, **mRNA vaccines** played a central role, demonstrating their enormous potential and obtaining, for the first time, approval for human use. This raises a key question: **do mRNA vaccines represent a new turning point in the history of vaccination?** The answer is: yes, but... Their true impact on society will depend on the ability to overcome a series of scientific, industrial, economic, and political challenges.

This paper aims to analyse precisely this dual question: to what extent mRNA vaccines represent a paradigm shift, and what factors will shape their medium- and long-term impact. To do so, we will begin by examining the origin and evolution of this technology, the challenges it faces in consolidating itself as a vaccine platform, and its political, economic, and social implications.

SECTION 1.

The Science Behind mRNA Vaccines

“mRNA vaccines stand out for a number of advantages, although their consolidation does not imply replacing more traditional platforms.”

The development of COVID-19 vaccines brought a new generation of vaccine platforms into the spotlight of the scientific and media debate. These technologies, at various stages of maturity, have opened up exciting possibilities for immunisation. In this context, mRNA vaccines stand out for a number of advantages, although their consolidation does not imply replacing more traditional platforms.

A New Generation of Vaccines

Unlike traditional vaccines, which contain the whole pathogen—attenuated or inactivated—or protein fragments, most vaccines developed during the COVID-19 pandemic use a different approach: they provide the genetic instructions for our own cells to produce the relevant protein(s). These instructions can be delivered via a viral vector or enclosed in tiny lipid particles, as is the case with mRNA vaccines. Each of these technologies has its own advantages and limitations in terms of the magnitude and duration of the immune response, safety, ease of production and administration, and cost.

Table 2. Traditional and New Vaccine Technologies.

Generation	Platform		Advantages	Disadvantages	Examples	
1st gen	Whole virus	Live attenuated	<ul style="list-style-type: none"> Highly immunogenic Preserves native antigens Long-lasting immunity 	<ul style="list-style-type: none"> Risk of residual virulence Not safe for immunocompromised people Requires strict biocontainment 	Oral polio, yellow fever, rubella	
		Inactivated	<ul style="list-style-type: none"> High immunogenicity Safer than live attenuated 	<ul style="list-style-type: none"> Inactivation may alter antigens Requires strict biocontainment Often needs booster doses 	Injectable polio, rabies, cholera, typhoid	
2nd gen	Proteins	Protein subunit	<ul style="list-style-type: none"> Safe and well-tolerated Flexible Stable at 4 °C 	<ul style="list-style-type: none"> Requires adjuvants to enhance immunogenicity 	Pertussis, influenza, Hib	
		Virus-like particles (VLPs)	<ul style="list-style-type: none"> High immunogenicity Safe and well-tolerated Flexible Stable at 4 °C 	<ul style="list-style-type: none"> Production is slower and more complex 	Hepatitis B, HPV	
3rd gen	Viral vectors		<ul style="list-style-type: none"> High immunogenicity Relatively fast production Can be designed to target specific cells Stable at 4 °C 	<ul style="list-style-type: none"> Pre-existing immunity to the vector may reduce efficacy Large-scale vector production required Potential risk of genome integration Rare adverse events (e.g., thrombosis in some COVID-19 vaccines) 	Ebola Zaire [rVSV-ZEBOV, Ad26.ZEBOV], COVID-19 [ChAdOx1-S]	
		Nucleic acids	DNA	<ul style="list-style-type: none"> Highly adaptable Rapid production, no biological material needed Stable at room temperature 	<ul style="list-style-type: none"> Very low immunogenicity Potential risk of genome integration 	In development, some clinical trials
			mRNA	<ul style="list-style-type: none"> Highly adaptable Rapid production, no biological material needed No risk of DNA integration Can encode multiple antigens 	<ul style="list-style-type: none"> Moderate immunogenicity (may need adjuvants) Requires ultra-cold storage and distribution 	COVID-19 [Comirnaty, Spikevax], RSV [mRESVIA]

Adapted from: <https://doi.org/10.3390/vaccines13010056> and <https://www.frontiersin.org/journals/public-health/articles/10.3389/fpubh.2024.1429265/full>.

Balanced Development

It is worth emphasising that several vaccines recently approved or in late-stage clinical trials for diseases with high global impact still rely on more traditional technologies. For example, the recently approved malaria vaccine R21/Matrix M, is protein- and adjuvant-based, while the candidate **PfSPZ** vaccine, which contains attenuated parasite sporozoites, is in advanced clinical stages. Other notable examples include the **Qdenga** dengue vaccine, which uses an attenuated virus, and **Vimkungunya** against chikungunya, which employs virus-like protein particles (VLPs) and has recently been recommended for commercialisation by the European Medicines Agency (EMA). Maintaining a balanced development across different vaccine platforms is key to ensuring options suited to diverse epidemiological, logistical, and contextual needs.

mRNA Vaccines: A Technological Leap

The concept of mRNA vaccines was first proposed in 1990, but it took decades of research to turn it into reality. These vaccines have two essential components: the mRNA molecule, which carries the instructions for our cells to produce the target antigen, and a lipid capsule that protects the mRNA from degradation and facilitates its entry into the cell. Both components (mRNA and lipids) influence the quality and magnitude of the immune response.

Two breakthroughs made the success of COVID-19 mRNA vaccines possible: modifying the building blocks of mRNA (nucleosides) to reduce inflammatory reactions and increase stability; and developing lipid nanoparticles that not only protect the mRNA and help it enter cells, but also act as adjuvants, boosting the immune response.

Advantages of mRNA Vaccines

An “ideal” vaccine should be safe, effective, and easy to manufacture. In this regard, mRNA vaccines offer several advantages:

- i. Speed and flexibility in design:** The mRNA sequence can be quickly modified to adapt to changes in a pathogen or to new pathogens.
- ii. Ease of production:** Synthesising mRNA does not require cells or other biological materials, simplifying the manufacturing process.
- iii. Efficient large-scale production:** Perfect for pandemic situations or for vaccines that need annual updates, such as influenza vaccines.
- iv. Versatility:** mRNA molecules can be designed to encode multiple antigens from the same pathogen or even from different pathogens simultaneously. This is especially relevant to the WHO’s strategy, which calls for the development of combination vaccines against multiple pathogens to simplify their deployment.
- v. Safety:** Unlike DNA vaccines or those using viral vectors, mRNA remains in the cytoplasm, greatly reducing the risk of integrating the genome and causing mutations.

Future Applications of mRNA Vaccines

The COVID-19 pandemic marked the beginning of the mRNA vaccine era. Currently, around 50 mRNA vaccines are in preclinical (animal testing) and clinical (human trials) stages, not only for infectious diseases but also for cancer and other non-communicable diseases.

Among the most advanced and promising are:

- **Respiratory syncytial virus (RSV):** In August 2024, the *European Medicines Agency (EMA) approved* Moderna’s mRNA vaccine against RSV, and several others

are in clinical development. This virus severely affects infants and older adults, placing considerable pressure on healthcare systems during winter months.

- **Influenza:** Seasonal flu causes high mortality among older adults and people with chronic conditions and has a strong impact on productivity and healthcare services. Companies such as Sanofi Pasteur, Moderna, Pfizer, and GSK are developing vaccines against seasonal flu, as well as combined COVID-19/flu vaccines. Moderna's *combined vaccine* has shown very promising results in advanced clinical trials.
- **Cytomegalovirus (CMV):** Moderna's CMV vaccine, targeting a common cause of congenital malformations, is being tested in women aged 16–40. It is estimated that one in every 200 babies is born with the infection, with a higher burden in low- and middle-income countries.
- **HIV-1:** HIV vaccines are particularly challenging due to the virus's genetic diversity and its ability to evade the immune system. Currently, three mRNA vaccines are in clinical trials, each with slightly different versions of the viral surface antigen. An effective vaccine could have a transformative impact, especially in sub-Saharan Africa, where more than half of the *1.3 million new infections* in 2023 occurred and access to antiretrovirals remains limited.
- **Zika:** In 2017, Zika was the first mRNA vaccine to show positive results in animal models. Several promising candidates are now in clinical trials. In the future, a “multicomponent” vaccine could potentially protect against Zika, dengue, and other flaviviruses that affect millions, mainly in tropical and subtropical regions.
- **Cancer:** Moderna and Merck are testing their mRNA-4157 vaccine to enhance the efficacy of immunotherapy for various cancers, including head and neck cancer and melanoma. This approach opens new avenues for personalised therapeutic vaccines, though it presents significant access challenges in low- and middle-income countries.

Beyond their innovative aspect, these examples illustrate **the potential of mRNA technology to address diseases with a high socio-economic burden.**

SECTION 2.

The Scientific Challenge: Potency, Duration, and Tolerability

“Much research is still needed to overcome certain limitations and unlock their full potential.”

mRNA vaccines were the most widely used in the Western world during the COVID-19 pandemic. Despite their success, much research is still needed to overcome certain limitations and unlock their full potential. The main challenges include:

Increasing immunogenicity: A common challenge for all vaccines is predicting the magnitude and quality of the immune response based on animal models. In the case of mRNA vaccines, including those against COVID-19, the response observed in humans has been lower than that seen in mice. The reasons for this are not yet fully understood, but one possible strategy to enhance the immune response is the use of self-amplifying mRNA (saRNA), which makes many copies of itself once inside the cell. This allows greater antigen production from much smaller doses of mRNA. Japan was the *first country to approve* a vaccine using this technology (ARCT-154 against COVID-19), and several others are in development.

Reducing adverse reactions: mRNA vaccines are relatively reactogenic, meaning they often trigger a strong immune response, especially in younger individuals, which can cause fever, headaches, and muscle pain. Although these side effects are generally transient, they can lead to vaccine hesitancy and lost workdays. To mitigate these effects, changes in lipid formulations and adjustments to mRNA doses are being tested.

Increasing the duration of immunity: The duration of protection provided by mRNA vaccines is still a matter of debate. While circulating antibody levels decline during the first six months, they eventually stabilize. To extend protection, new nanoparticle formulations and adjuvants are being investigated to elicit a more durable immune response.

Stimulating cellular and mucosal responses: In COVID-19 and many other viral infections, T cells play a crucial role in protecting against severe disease. To enhance this response, researchers are refining mRNA design, lipid composition, and co-expression of mediators that stimulate T-cell activity. For respiratory viruses like SARS-CoV-2, there is also a focus on inducing immunity in the nasal mucosa to reduce transmission. Alternative formulations to lipid nanoparticles are being studied to make intranasal delivery safer and more efficient.

Improving stability: Another technical challenge is enhancing mRNA stability through optimised lipids and new excipients. This could preserve integrity without the need for extremely low freezing temperatures, which can be challenging even in high-resource countries. Vaccines stable at 4°C or even at room temperature would significantly increase the global impact of mRNA vaccines, enabling their distribution in rural and resource-limited areas.

Finally, artificial intelligence is emerging as a key tool to accelerate mRNA vaccine development, from selecting the most suitable antigen to improving clinical trial design.

SECTION 3.

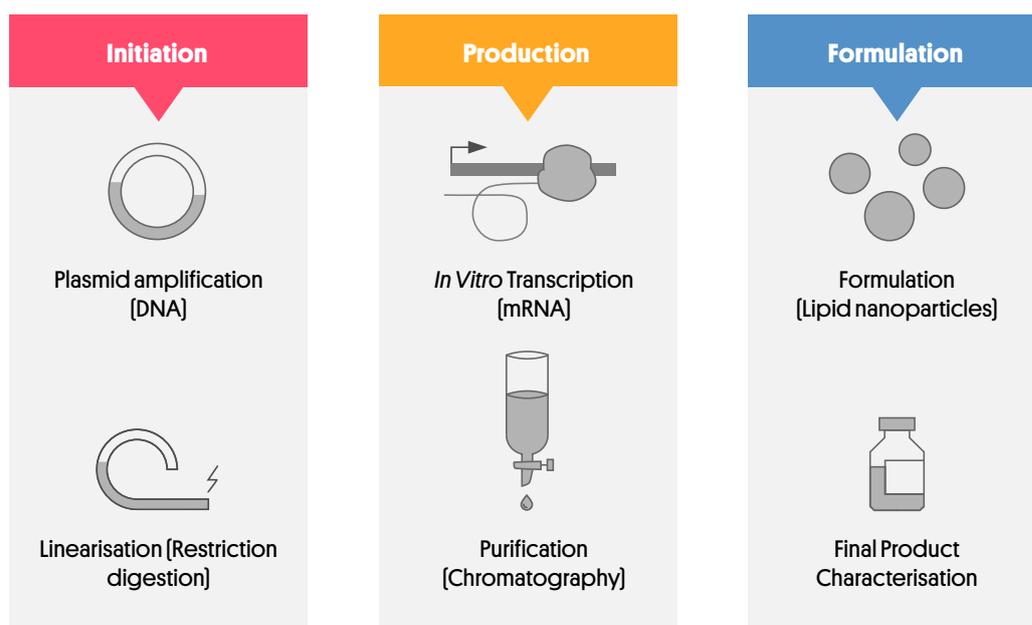
The Industrial Challenge: Speeding Up, Reducing Costs, and Expanding Production

“A globally distributed development and production network would strengthen epidemic preparedness.”

mRNA vaccines are transforming the vaccine industry in several key ways, but their full potential is limited by a number of industrial hurdles regarding production and distribution. These obstacles—including difficulties scaling production, high per-dose costs, and the need for strict cold chains—have uneven consequences across countries and populations.

Speed: Traditional vaccines require growing the pathogen using biological systems (eggs or cell cultures), a process that can take months. In contrast, mRNA vaccines can be produced synthetically once the pathogen’s genetic sequence is known, allowing very rapid development and updates. Thanks to this, *CEPI* (Coalition for Epidemic Preparedness Innovations) has set a goal to develop a vaccine against a new emerging threat—the next “*Disease X*”—in just *100 days* (the COVID-19 vaccine took slightly over 300 days). However, bottlenecks remain in the process. For instance, producing the DNA “template” used to generate mRNA can take up to a month. CEPI is addressing this problem by partnering with *DNA Script* to accelerate synthetic DNA production.

Figure 1. Stages of mRNA vaccine production.



Adapted from: <https://www.nature.com/articles/s41467-023-41354-y>.

Scalability: Traditional vaccines require specialised facilities and strict regulations due to the handling of biological material. mRNA vaccine production, in contrast, can be carried out more easily, safely, and with lower contamination risk. Still, challenges remain to improve scalability and ensure product quality, such as adapting reactors for producing mRNA from DNA—the most delicate and costly step in the production process.

Cost: Although mRNA vaccine manufacturing is simpler, the cost per dose is *four times higher* than that of protein- or inactivated-virus-based vaccines. Roughly 80% of the expense comes from daily consumables (enzymes, nucleotides) needed to transcribe DNA into mRNA, while infrastructure and investment costs are comparatively lower. One potential strategy to reduce costs is the use of self-amplifying RNA (saRNA), which allows much smaller doses of mRNA per vaccine.

Manufacturing in low- and middle-income countries: Africa has around ten vaccine manufacturers, but most do not produce the active ingredients, instead focusing on the “fill and finish” of imported products. During the COVID-19 pandemic, efforts were made to transfer mRNA technology to these countries. Notable examples include partnerships between multinational companies and local manufacturers, as well as the WHO-backed *mRNA technology hub in South Africa*, led by Afrigen, Biovac, and the South African government. The hub aims to establish the technology and transfer it to companies in 15 countries across the Global South. Another potentially transformative initiative is BioNTech’s BioNtainers: scalable, transportable modules for mRNA production and formulation. The first BioNtainers facility in Africa opened in December 2023 in Kigali, Rwanda, with CEPI’s support. Once fully operational, it is expected to produce up to 50 million bulk doses for local partners to package. However, expanding mRNA vaccine production in low- and middle-income countries still faces obstacles, including technology transfer barriers, *intellectual property* restrictions, and capacity building.

Securing supply chains: During the COVID-19 pandemic, some countries restricted or banned the export of vaccines or production materials. Building more resilient production networks is therefore crucial to minimise the risk of disruptions in future pandemics. This is particularly relevant for influenza vaccines—a virus with high pandemic potential—which currently rely heavily on the availability of chicken eggs.

Clearly, a globally distributed development and production network would strengthen epidemic preparedness, reduce reliance on external suppliers, and allow low- and middle-income countries to produce vaccines tailored to their own needs. To ensure the long-term viability of local production, it is essential to maintain sustained demand for domestically manufactured vaccines, not only during crises. The growing industrial demand for these vaccines should help find solutions to these challenges.

SECTION 4.

The Economic Challenge: Investment, Patents, and Priorities

“Many vaccines in development are driven by commercial interests and do not necessarily address global health needs or priorities.”

From an economic and political economy perspective, the main challenges are as follows:

Pharmaceutical industry control and investment: High-income countries dominate the global vaccine market, accounting for 72% of its total value. In 2023, *7 billion doses* were produced, with two-thirds coming from just 10 producers, who capture 85% of the sector’s economic value. The global market for mRNA-based therapies—including vaccines—is projected to reach \$68 billion by 2030, *according to Statista*, representing an annual growth of nearly 9% compared with 2020. However, many vaccines in development are driven by commercial interests and do not necessarily address global health needs or priorities. While pharmaceutical companies focus on highly profitable products, organizations like CEPI aim to ensure the development of vaccines that serve the public good, particularly for neglected diseases or those with lower commercial appeal. Although many CEPI-supported vaccines are based on viral vectors or recombinant proteins, a few mRNA candidates are included *in its portfolio*. For example, CEPI is backing BioNTech’s mRNA vaccine against Mpox (in early clinical stages), as well as a couple of “universal” coronavirus vaccines developed by the international IVI consortium and the biotech company Gritstone. Collaboration between the public and private sectors is essential to balance innovation with equitable access to these emerging technologies, moving beyond an industrial policy focused solely on cost and efficiency.

Patents and monopolies: Access to mRNA vaccines is heavily influenced by market control and intellectual property, posing not only an economic but also a political challenge. During the pandemic, a temporary waiver of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was proposed for COVID-19 vaccines and treatments, a measure later ratified by the World Trade Organization (WTO). However, its impact was limited. In many cases, pharmaceutical companies maintain strict control over patents, restricting the transfer of critical knowledge and technology. An inspiring example was the COVID-19 vaccine developed by the Center for Vaccine Development at the Texas Children’s Hospital, whose team offered the patent-free technology to the pharmaceutical company Biological E Limited in India for its development and production. While some aspects of mRNA technology are not patented, the lipids used to encapsulate the molecule are covered by patents that are difficult to circumvent. *The mRNA hub in South Africa* relies primarily on voluntary licensing agreements, which are not sufficient to ensure autonomous and sustainable production. Additional measures are needed, such as compulsory licensing, more inclusive technology transfer agreements, or regulatory frameworks that facilitate more equitable access to innovation. Unfortunately, the Pandemic Treaty recently adopted by WHO member states does not provide clear solutions to this challenge (*see Box 1*).

SECTION 5.

The Political Challenge: Equity, Solidarity, and Trust

“The Pandemic Agreement represents a historic opportunity to correct structural flaws and ensure a fairer response to future crises.”

The rapid development of vaccines during the pandemic, including mRNA vaccines, was a scientific success, but the inequitable distribution of these vaccines worldwide represented a political and moral failure. Despite these shortcomings, the pandemic has created an opportunity to rethink the narrative, redirect vaccine supply chains, and move from a model focused solely on cost efficiency toward one that is more equitable and sustainable.

Global governance: The *COVAX* mechanism was a commendable effort to distribute COVID-19 vaccines equitably between the Global North and South, delivering more than two billion doses. Yet it fell short of its initial goals. In any case, the pandemic highlighted the need to strengthen global governance mechanisms to prevent vaccines from being subject to political and economic interests. In this context, the Pandemic Agreement (*see Box 1*) represents a historic opportunity to correct structural flaws and ensure a fairer response to future crises. But equity is not only about access to pharmaceutical products (diagnostics, treatments, or vaccines) or to the technology and materials needed for local production. It also includes access to the genetic information of pathogens—a particularly relevant issue for mRNA vaccines. A positive step in this direction is the Centre for Epidemic Response and Innovation (*CERI*) in South Africa, which is doing excellent work strengthening genomic pathogen surveillance in Africa and reducing the dependence of low- and middle-income countries on major pharmaceutical companies.

The rise of isolationism: The resurgence of isolationist policies, such as those promoted by the Trump administration in the U.S., poses a serious threat to international health cooperation, particularly regarding vaccines. The recent decision to suspend funding to Gavi, the Vaccine Alliance, could result in *over a million preventable deaths*, according to the organization’s director. This, combined with the U.S. withdrawal from the WHO and cuts in development aid by several countries, significantly increases the vulnerability of low- and middle-income countries. Moreover, NIH funding cuts to universities and research centers threaten vaccine innovation; for example, *some HIV vaccine trials in Africa have been halted*.

Disinformation and vaccine hesitancy: The development and distribution of safe and effective vaccines loses much of its impact if people do not trust them. While vaccine hesitancy is not new, its reach and intensity have increased dramatically, fuelled in large part by the spread of false information, whether unintentionally (misinformation) or deliberately (disinformation), on social media and digital platforms. The consequences can be deadly: in the U.S., an estimated *320,000 COVID-19 deaths*

between January 2021 and May 2022 could have been avoided if all adults had received at least one vaccine dose. To counter this, healthcare workers play a vital role, listening to concerns and providing reliable guidance. According to the *Wellcome Global Monitor*, 73% of respondents across 140 countries trust their doctor or nurse for health information.

BOX 1. Global Governance in Vaccine Development and Access

WHO (World Health Organization): Sets technical guidelines and recommendations that guide the development and use of vaccines. It also manages the prequalification process, which certifies the quality, safety, and efficacy of vaccines. This is particularly useful for countries without robust regulatory authorities, enabling international agencies to purchase vaccines on their behalf.

CEPI (Coalition for Epidemic Preparedness Innovations): Funds and coordinates the research and development of vaccines against emerging diseases, especially those with pandemic potential. Its goal is to accelerate the development of safe and effective vaccines, ensuring they are available within the first 100 days of a health emergency.

GAVI (Vaccine Alliance): Ensures equitable access to vaccines in low-income countries by managing their financing, procurement, and distribution. During the COVID-19 pandemic, it co-led the COVAX mechanism with the WHO and CEPI, with the aim to achieve fairer vaccine distribution.

IVI (International Vaccine Institute): Facilitates technology transfer between countries and promotes local vaccine production. Its work helps strengthen regional self-sufficiency and reduce dependence on producer countries.

Pandemic Treaty: After three years of negotiations, WHO member states (with the exception of the U.S.) reached a *legally binding agreement* to improve the global response to future health crises. The treaty provides for the rapid sharing of scientific and pathogen data, more equitable distribution of benefits (such as vaccines or treatments), and strengthened research across different regions of the world. It also proposes a global supply and logistics network and prioritises the reinforcement of health systems to better prepare for future emergencies. However, the agreed text does not establish binding mechanisms for the temporary suspension of intellectual property rights or for technology transfer.

BOX 2. The Future of mRNA Vaccines at Risk

The Trump administration has recently taken a series of decisions that could significantly undermine the development of mRNA vaccines, with repercussions worldwide:

- 1. Cancellation of funding for mRNA R&D.** Nearly €500 million previously allocated for the development of vaccines based on this technology has been withdrawn. The Biomedical Advanced Research and Development Authority (BARDA) cancelled 22 contracts with universities and private companies aimed at advancing new mRNA vaccines and therapies. This decision reduces the capacity of the United States – and the world – to respond to future bioterrorism threats or pandemics caused by emerging respiratory viruses.
- 2. Termination of the contract with Moderna.** The government annulled its agreement with the company for the advanced development of a human vaccine against avian influenza. This move is particularly concerning in a context where the virus has spread among livestock herds in the country, already causing more than 25 human infections.
- 3. Restructuring of the vaccine advisory committee.** The Advisory Committee on Immunization Practices (ACIP) at the CDC was disbanded and replaced with members with limited expertise in immunisation, many of whom are openly sceptical about vaccines, and mRNA technology in particular. This change has implications well beyond the United States, as many countries look to the committee's recommendations as a reference point.

SECTION 6.

Conclusion: A Historical Crossroads

“The greatest barriers to ensuring that mRNA technology benefits the entire population are not scientific but economic and political.”

mRNA vaccines have marked a qualitative leap in vaccine science, combining rapid development, scalability, and adaptability to confront emerging pathogens and highly mutating viruses. This technology has the potential not only to transform disease prevention, but also to accelerate responses to new threats and to democratise access to biomedical innovation. Their ultimate impact, however, will depend on the collective decisions we make today. While further research is needed to optimise their efficacy, the greatest barriers to ensuring that this technology benefits the entire population are not scientific but economic and political. Close collaboration between the public and private sectors is essential to develop vaccines that respond to real health needs, even when they are not commercially profitable, as well as to reduce production costs. The international community must put in place fair mechanisms for vaccine procurement and distribution in times of crisis, supported by legal frameworks that facilitate technology and knowledge transfer to producers in low- and middle-income countries, ensuring that these capacities remain sustainable in times of “peace”. Finally, combating disinformation and vaccine hesitancy must be a shared priority.

Only by addressing these challenges collectively can mRNA vaccines truly become a turning point in global health.

TO LEARN MORE

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GLOSSARY

Adjuvant: A substance added to some vaccines to enhance their effect and generate a stronger and longer-lasting immune response.

Antigen: A fragment of a pathogen capable of stimulating an immune response. Toxins, chemicals, or even harmless substances such as pollen can also act as antigens.

Antibody: A protein produced by the immune system in response to a pathogen or foreign substance. Antibodies attach to the pathogen and help eliminate it.

B lymphocytes (B cells): A type of immune cell that produces antibodies capable of recognizing specific antigens.

T lymphocytes (T cells): Another type of immune cell that plays a central role in regulating the immune response (CD4+ T cells) and in recognizing and destroying cells infected by a specific pathogen (CD8+ T cells).

Immunogenicity: The ability of a vaccine to activate the immune system and trigger a protective response, such as antibody production and T cell activation.

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