# The COVID-19 Spike Protein and the Still Uncertain Side Effects of the mRNA Vaccines

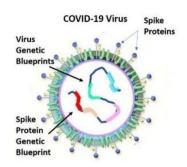
#### Introduction

The U.S. Centers for Disease Control and Prevention (CDC) states that the COVID-19 mRNA vaccines are safe and effective and developed "under the most intense safety monitoring in United States history". It recommends that all adults receive the vaccine as soon as possible, and there is a discussion that children be vaccinated, even though they have a very low risk for a serious COVID infection.

Unfortunately, **the statement above is misleading**. The U.S. lacks an effective active surveillance program to detect vaccine injuries and deaths. Instead, the CDC and the Food & Drug Administration (FDA) are relying on an antiquated 32-year-old passive data system to determine if the experimental mRNA vaccines are causing serious harm.

Furthermore, as of 1 May 2021, the CDC has taken steps to minimize the accurate reporting of vaccine effectiveness. It will now only investigate vaccination failures in patients who are hospitalized or die. This flawed data collecting strategy will miss 90% of the vaccine failures and thus confuse the issue of the effectiveness of the mRNA vaccines.

#### The COVID-19 Virus



The COVID-19 virus is a small assembly of proteins, certain fats, and sugar molecules surrounding a long-compacted string of RNA molecules. This RNA contains the individual "blueprints" or "genes" that carry the instructions that allow the COVID virus to replicate to create new daughter viruses. Individual viruses are extremely tiny in size and only visible under a powerful electron microscope, with only a few exceptions.

It is important to remember that the COVID virus is not "alive." Until it penetrates and enters into one of the living cells of its host, a virus remains an inert collection of tightly bound chemicals

The COVID virus needs a special "key" to pass through the outer membrane of a host cell. This "key" is in the form of the Spike Proteins that protrude outward from the virus. Conversely, the host cell has a "lock" on its outer membrane. This "lock" is in the form of a protein called ACE-2. When the Spike Protein "key" of the virus attaches to the cell's ACE-2 protein "lock," the virus can attach itself and enter the cell to cause infection.

Once inside a suitable cell, the COVID virus turns into the ultimate parasite of nature as it hijacks the cell's metabolism and forces it to perform a series of virus-driven biochemical reactions. These reactions lead to the self-assembly of hundreds of new "daughter" viruses at a time.

A single infectious virus particle inside a cell may produce some 100,000 daughter viruses within the first 10-hours. Within a few days, the number of viral particles inside an infected animal or human may be as high as 10,000,000,000,000 new viruses.

Some of these new daughter viruses are released into the environment by coughing or sneezing droplets of virus-laden mucous or as an invisible aerosol of oral fluids generated by talking. These replicated, escaped viruses are now free to infect other humans under the right conditions.

#### How Do the mRNA Vaccines Function?

The mRNA vaccines represent an experimental technology used to create a faster immune response in its recipient, should they be exposed to the COVID

virus. For simplicity, this discussion will focus on the Moderna and Pfizer/BioNTech mRNA vaccines, which despite receiving an FDA Emergency Use Authorization, remain highly experimental and are not FDA approved.

As mentioned, the Spike Protein allows the COVID virus to enter and infect human cells. Vaccine manufacturers chose this protein to train the immune system to recognize the virus when it enters the body. To accomplish this goal, they chemically synthesized the protein's genetic blueprint in the form of a long messenger RNA molecule (mRNA). This synthetic mRNA contains the chemical code that will force an infected cell to make a modified version of this protein (Figure One).

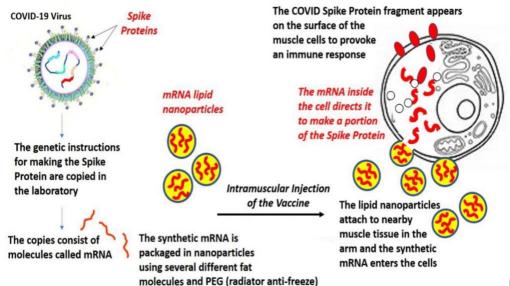


Figure One

#### Figure One how the mRNA vaccine works.

The vaccine developers claim that the mRNA vaccines only carry enough genetic information to make either a long or short fragment of the COVID virus Spike Protein (depending on the manufacturer). This mRNA is microencapsulated inside lipid nanoparticles which do not need the ACE-2 receptor to enter a cell. They theoretically can enter any cell in the body on direct contact but cannot bypass the Placenta of a pregnant woman or pass through the Blood-Brain Barrier to enter the brain.

When the nanoparticles attach to human cells, their mRNA is released into the cell to access its protein manufacturing system. There, the mRNA is translated into the proper sequence of amino acids needed to create a modified version of the COVID-19 Spike Protein. These newly manufactured proteins migrate to the cell surface, where they embed and project out to trigger an immune response. In the development phase of the vaccine and due to the corporate and political rush to market, several dangerous assumptions went unchallenged by the FDA.

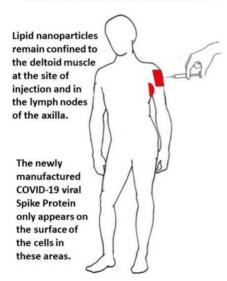
The first assumption was that the only function of the Spike Protein was to help the virus enter a human cell. However, we now know that the natural Spike Protein itself can cause harmful effects. As a result, some scientists are worried that the modified Spike Proteins generated by the mRNA vaccines may still participate in some degree of ACE 2 receptor binding and trigger blood vessel inflammation.

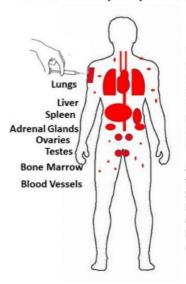
The second assumption was that the nanoparticles of encapsulated mRNA would behave like the "traditional" vaccines and remain mainly at the vaccination site in the shoulder and in the regional lymph nodes in the axilla. However, uncovered data suggests this assumption may also be wrong.

A group of scientists recently obtained a summary of Pfizer's bio-distribution study in animals. This type of study determines if a particular injected substance will concentrate in any organ or tissue. The study showed that after injection, the nanoparticles of encapsulated mRNA were accumulating in various animal organs in "high concentrations". <sup>1</sup> This included the ovaries. If these studies apply to humans, there is a disconnect between public messaging and reality.

#### What The Public Has Been Told

#### What Actually May Be Happening





The injected lipid nanoparticles are widely distributed throughout the body and are concentrated in the ovaries and other tissues.

After vaccination, the COVID-19 viral Spike Protein can be detected circulating in the blood stream for up to 29 days.

Another separate study measured sequential plasma samples collected from 13 recipients of the Moderna vaccine at intervals. Eleven individuals had detectable levels of the vaccine-modified Spike Protein in their bloodstream as early as one day after the first vaccine dose. These proteins could still be detected in the bloodstream an average of 15 days after the first injection. One patient still had Spike Protein detectable on day 29, one day after a second vaccine dose, which disappeared two days later. <sup>2</sup> The manufacturers claim the Spike Proteins exist in **exceedingly low concentration** and are rapidly cleared from the bloodstream coincident with the individuals' developing an immune response. However, the animal studies indicate that the Spike Proteins were concentrating in the ACE-2 rich tissues.

There are now accusations that Pfizer may have cut corners to rush its COVID-19 mRNA vaccine into production and that it failed to submit bio-distribution issues to the European Medicines Agency for review. <sup>3</sup> This includes not performing the full panel of industry-standard reproductive toxicity and genotoxicity studies.

The question remains, can the vaccine mRNA-generated Spike Proteins bind to the ACE-2 positive tissues to cause blood vessel inflammation or cause direct cell damage? To address this, we must examine the pathology the intact COVID virus can cause in an infected patient and what side effects are experienced by vaccine recipients.

#### 1. The Spike Protein of the COVID Virus Can Cause Small Blood Vessel Dysfunction

Studies show that the purified COVID-19 Spike Protein alone, when injected, can bind to the ACE-2 receptors on the cells lining the inside of the microscopic blood vessels (capillaries). Once bound, these cells become dysfunctional as a result of damage to their cellular mitochondria (energy-producing organelles), and fluid leaks out of the vasculature into the tissue spaces. 415

This occurrence is apparent in the central nervous system, where the brain cells, together with their supporting capillaries, form a tight "neurovascular unit." The injection of purified Spike Protein into the tail veins of hybrid mice causes widespread Spike Protein deposition in the brain capillaries with surrounding tissue swelling, occasional microscopic blood clots (microthrombi), and necrotic brain cell death. This protein deposition is concurrent with the mice developing neurological signs.

In a postmortem study of COVID-infected humans, the Spike Protein was detected in 26/26 brain tissues autopsied. Of the cells containing the Spike Protein, over 95% were in the cells that line the microscopic capillaries. <sup>6</sup>

## Are mRNA Vaccine Recipients Suffering Central Nervous System Damage?

This is unclear but accumulating data shows a 5-month total of 1,220 cases of serious paralysis events following COVID mRNA vaccination. This includes 1,099 cases of Bell's Palsy and 121 reports of the more serious and rarer Guillain-Barré Syndrome. These cases were occurring close to the time of vaccination. <sup>2</sup>

The CDC has stated that the appearance of Bell's Palsy and Guillain-Barré Syndrome after COVID vaccination is consistent with the normal background for the occurrence of these disorders in non-vaccinated individuals. Therefore, there is no talk of suspending the current COVID-19 vaccination program. Instead, there are plans to expand the vaccination program to include children

as young as age 12, who are naturally at extremely low risk of dying from COVID-19.

This is in contrast to the historical behavior of the CDC and FDA. In 1976, the outbreak of a "swine flu" influenza virus led to a frantic immunization program with a rushed vaccine quickly associated with 362 patients developing the serious Guillain-Barré Syndrome. The national vaccination program was immediately suspended.

#### 2. The Heart is a Major Target Organ in COVID-19 Virus Infection

When the heart is damaged, a muscle protein called *Troponin I* leaks out of the injured cells and can be detected in the bloodstream. § This is a very sensitive test and has been used to estimate that 10-30% of hospitalized COVID patients may develop a viral Myocarditis (*myo- meaning muscle*) (carditis- meaning heart inflammation). §

By the end of March 2020, doctors in Europe and China were observing that some hospitalized COVID-19 patients had only mild to moderate lung damage, but they were dying from extensive heart muscle damage, irregular heartbeats, and progressive cardiac failure. 10 | 11 | 12

The autopsy results from these cases revealed traces of the COVID virus's genetic material in the damaged heart muscle cells. Other studies showed the presence of the COVID Spike Protein. <sup>13</sup> | <sup>14</sup> Using a powerful electron microscope, the tiny (70–100 nanometer) COVID viral particles were found inside the autopsied heart muscles and in the inner chambers of the heart.15 Experiments show the COVID virus can destroy lab-grown cardiac muscle tissue causing identical damage to that observed in Covid-19 autopsies. <sup>16</sup> | <sup>17</sup>

These studies may explain why some recovered COVID patients remain short of breath for weeks with a possible risk for future heart failure. 18

#### Are mRNA Vaccine Recipients Suffering Heart Tissue Damage?

On 2 June 2021, Israel reported that it had identified 275 cases of myocarditis among its first five million vaccine recipients. A link was found between

receiving the second dose of the Pfizer mRNA vaccine and the onset of heart inflammation in men aged 16 to 30. The link was more pronounced in the 16 to 19 age group, and many patients required hospitalization. Some were critical, and deaths had occurred. 19

The U.S. noted multiple cases of myocarditis in young individuals after taking the COVID-19 vaccine. On 24 May 2021, 155 cases of myocarditis were reported to the *U.S. Vaccine Adverse Event Reporting System (VAERS)*, explained on the following pages.

The CDC did accurately report that the VAERS data showed an increase in cases of myocarditis in 16 to 24-year-olds. <sup>20</sup> However, the data from its *Vaccine Safety Datalink (V-Safe)* failed to show that these rates were above normal for unvaccinated individuals. The CDC never mentioned that by March 2021, the *V-Safe* system had enrolled only 6.4% of all COVID-vaccinated individuals in the U.S. This is an example of incomplete data the CDC is using to make important health decisions.

By 10 June 2021, the number of vaccine-linked myocarditis cases had risen to 226 cases in people aged 30 and under, and by 14 June, it was reporting 511 cases of possible myocarditis. The FDA is now considering putting a "warning" for myocarditis on the vaccine insert. Not exactly a major shift in policy.

## 3. The Spike Protein of the COVID Virus Can Initiate Abnormal Blood Clotting or Bleeding

Platelets are the tiny, microscopic, colorless, disk-shaped fragments found in large numbers in the circulating blood. They are produced when a larger cell in the bone marrow called the Megakaryocyte, fragments to produce platelets that are released into the general circulation. When the platelets became activated, their normal function is critical for controlled blood clot formation (thrombosis). The blood clotting mechanism (coagulation) is very tightly controlled because any dysregulation of this process can have drastic consequences.

Both the Megakaryocytes and the platelets have the special "ACE 2 receptor" proteins on their outer surface membrane, and the COVID virus Spike Protein

can recognize and attach itself to these receptors. It falsely activates the platelets causing them to release various clotting factors into the bloodstream. <sup>21</sup> Consequently, COVID-19 patients may enter a pro-thrombotic state with an increased risk of blood clots that can cause a stroke, heart attack, lung, kidney, liver, spleen injury, and or sudden death.

This risk is compounded by the fact that the COVID-19 virus can attack the cells that line the small microscopic blood vessels. <sup>22</sup> This creates a general state of microvascular inflammation which further pre-disposes a patient to abnormal blood clot formation. These "microthrombi" may occur in the lung, heart, and kidney blood vessels of COVID-19 patients and have been noted on autopsy, even in cases of mild COVID-19 viral pneumonia. <sup>23</sup>

Large-scale studies show that 18.8% to 36.2% of the COVID-19 patients admitted to the hospital have abnormally low platelet counts (Thrombocytopenia) when they arrive. This may be due to an inappropriate immune response or due to increased platelet consumption from tiny microscopic blood clots forming in the capillary beds of the major organs. <sup>23</sup> | <sup>24</sup>

## Do mRNA Vaccine Recipients Suffer From Abnormal Bleeding or Clotting?

Globally, there have been hundreds of reports of menstrual hemorrhage and blood clots following vaccination with the mRNA COVID-19 vaccines. While not well documented, a vaccine-induced Thrombocytopenia is proposed as an explanation for the heavy menstrual bleeding. <sup>25</sup> | <sup>26</sup> | <sup>27</sup>

Two other mRNA vaccines have been in the news; the Johnson & Johnson (J&J) and the AstraZeneca's vaccine. Both avoid using nanoparticles to deliver the mRNA for the Spike Protein into a cell. Instead, they use a neutered "common cold" virus as the carrier vehicle.

The J&J vaccine was paused soon after its introduction because six women in the U.S. developed a rare and serious disorder called *cerebral venous thrombosis*, which occurs when a large blood clot forms in the brain's venous sinuses. The vaccine is now back in use. <sup>28</sup>

An additional rare clotting abnormality that can develop is called *Thrombosis* with *Thrombocytopenia Syndrome (TTS)*. <sup>29</sup> Overall, TTP has been linked to 28 cases with a "suggestive plausible causal association" with the Johnson & Johnson vaccine. Nevertheless, a regulatory decision was made that using the vaccine outweighed the risk of contracting COVID-19.

The use of AstraZeneca's vaccine had already been temporarily halted in several countries due to TTS with blood clots in the veins of the brain and abdomen (splanchnic vein thrombosis) and in the larger arteries. On 18 March 2021, the European Medicines Agency safety committee concluded that the benefits of using the AstraZeneca vaccine (Vaxzevria) continued to outweigh the risk of contracting COVID-19. 30

Both the Pfizer and Moderna mRNA vaccines have also been associated with Thrombocytopenia, but no real warning for these two vaccines has been prominently issued. 31

#### The VAERS (Vaccine Adverse Event Reporting System)

When the COVID pandemic started, the dysfunctional FDA was in the process of transitioning from a system used to track the side effects of the 2009 H1N1 vaccine. The new system, named the *Biologics Effectiveness and Safety System (BEST)*, was designed to be an active surveillance database. However, it is still under development; both the FDA and CDC are still months away from having this type of analytical capability.

For the rollout of the new mRNA vaccines, the FDA had to rely on an old, inaccurate patchwork of passive reporting systems called the **Vaccine Adverse Event Reporting System. (VAERS), the Vaccine Safety Datalink (V-Safe, a patient self-reporting system)**.

The VAERS is a 32-year-old federal data system managed jointly by the FDA and the CDC. It accepts reports of post-vaccination adverse events but has numerous limitations. These include <u>underreporting</u>, <u>misreporting</u>, <u>unverified</u> reports, inconsistent data quality, delays in reporting and analysis, and inadequate data about the number of people vaccinated. <sup>32</sup> | <sup>33</sup>

The VAERS is totally dependent upon the willingness of clinicians and individuals to report the vaccine's side effects accurately. Most Americans do not even know that the system exists or that they can file a vaccine side-effect report. VAERS has not been given any priority, and it is several months behind in its full reporting. 34

In 2009, a \$900,000 AHRQ-funded study by Harvard Pilgrim Healthcare found that less than 1% of post-vaccination side-effects were being reported to VAERS each year. <sup>35</sup> This study recommended the urgent upgrade to a proactive, spontaneous, automated system embedded within electronic medical records (EMRs) and other information systems for new vaccine effect quantification. Thirteen years later, the U.S. still lacks such a system.

When introducing any new mass vaccination program, it is essential to have an active surveillance system to monitor the vaccine's graded introduction into a population. This is especially critical for a highly experimental vaccine using unproven technology on a massive scale. Without such a system, neither the FDA nor the CDC has enough accurate data to make the correct vaccine efficacy and safety decisions.

At the moment, the FDA and CDC appear to be flying blind.

#### The Mortality Associated with the mRNA Vaccines

The VAERS data released on 23 April 2021 showed that an *estimated* 124 million Americans had been fully vaccinated against COVID-19. However, there were 3,544 COVID vaccine-associated deaths with 12,619 serious vaccine-related injuries between 14 December 2020 and 23 April 2021. Of the reported deaths, 24% occurred within 48 hours of vaccination, and 17% occurred within 24 hours. <sup>36</sup> By 3 May 2021, that figure had risen to 4,178 reports of deaths (0.0017% of all vaccine doses).

By comparison, on average, there are 20 to 30 deaths a year caused by the seasonal flu vaccine, which is administered to about 195 million Americans each year. Nevertheless, the CDC has stated that its review of available clinical information, death certificates, autopsy, and medical records, has

### failed to find any causal link between the COVID-19 mRNA vaccines and death.

It is difficult to believe that the CDC can properly review the clinical records and any associated autopsies of 3,544 deaths over six months, and I would like a name and the contact information for the individual at the CDC who made this outlandish statement. There needs to be accountability.

While the actual death toll from the existing COVID mRNA vaccines remains uncertain, the VAERS data is clearly abnormal by a considerable margin. *More individuals appear to be associated with dying after receiving the COVID vaccines than have died from all other types of vaccines combined from mid-1997 until the end of 2013 (15.5 years)*.

The EudraVigilance system is the European version of the US VAERS system. It also shows many vaccine injury reports and vaccine-related deaths, with figures larger than the US VAERS data. However, this reporting is accompanied by numerous so-called "fact check" reports citing false websites and other confounders that attempt to increase the severity of mRNA vaccine side-effects, sowing further distrust and confusion over the actual situation.

The CDC maintains that the mRNA COVID vaccines are safe, effective, and "under the most intense safety monitoring in United States history". That statement, by itself, is incorrect for the reasons outlined above.

The COVID-19 mRNA vaccines appear to be dramatically more dangerous than the annual "flu" vaccines and, and unquestionably the related mortalities are being poorly monitored. The actual effectiveness of the mRNA vaccines remains uncertain. Nevertheless, there are serious recommendations being discussed in the U.S. for giving mRNA vaccines to children.

Unfortunately, accurate future statistics on vaccine efficacy will now be impossible due to a recent CDC policy change. From 1 May 2021 onward, the CDC will now only count COVID vaccination breakthroughs that result in patients being hospitalized or dying. This new policy causes an inexcusable gap in the data collection on vaccine effectiveness because it will discount almost 90% of cases of vaccine failure.

## This reckless behavior on the part of the CDC will only sow further vaccine distrust in the American population. This policy must be urgently challenged.

The widespread administration of highly experimental viral vaccines without an ongoing competent system to assess their side-effects and safety in the general population, is not only irresponsible, but it is, in itself, a potential threat to America's public health.

The scientific discovery of vaccines truly represents one of the significant quantum advances in public health. However, the highly experimental nature of the current mRNA vaccines, their rushed safety, and efficacy testing, together with the relentless propaganda and social campaign inflicted on the American population with demands for everyone to be vaccinated with a non-FDA approved preparation, raises serious concerns. This is compounded by the FDA's lack of an active, accurate vaccine monitoring system.

By law, an Emergency Use Authorization for the mRNA COVID vaccines can only be implemented and continued if there is no effective, safe drug treatment for COVID-19 patients. The decisions by the FDA to date ignored the overwhelming conclusive scientific evidence that demonstrates that Hydroxychloroquine is a safe drug for the treatment of early COVID-19 infection. 39

The number of Americans with serious vaccine side effects currently seems to be downplayed by the FDA, with the CDC calling these adverse events either coincidental or inconsequential. In reality, both the FDA and the CDC have no choice. After ludicrously banning Hydroxychloroquine for the outpatient treatment of COVID-19 infections, they have no alternate plan for pandemic management.

The CDC and the FDA were once well respected and trusted organizations, but for well over a decade now, they have failed every major public health challenge given to them (including the 2009 H1N1 Influenza scare, the ongoing opioid crisis, the 2014 U.S. Ebola response, and now their most massive failure, the COVID-19 response).

Both the CDC and the FDA are facing major internal scandals and funding issues that have destroyed all trust in their ability to respond to any future emerging disease outbreak. Both agencies have proven that they no longer can be trusted with public safety, which has become a national security issue. 40 | 41 | 42 | 43

Significant reorganization of both these institutions is long overdue.

#### What You Can Do

If you or someone you love has already received a COVID-19 vaccine and are experiencing side effects, REPORT IT preferably to all three of these locations;

- File a report on VAERS (U.S. residents only): <a href="https://vaers.hhs.gov/reportevent.html">https://vaers.hhs.gov/reportevent.html</a>
- File a report with <a href="https://VaxxTracker.com">https://VaxxTracker.com</a> (non-governmental adverse event tracker)
- File a report on the Children's Health Defence website.

All Americans need to know if the vaccines are working. Contact your elected representatives and demand that all COVID-19 infections contracted in fully vaccinated individuals be designated as a notifiable disease and the numbers recorded by the FDA and CDC to be published in real-time in an open database following HIPA regulations.

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