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CHILDREN'S HEALTH DEFENSE NEWS & VIEWS

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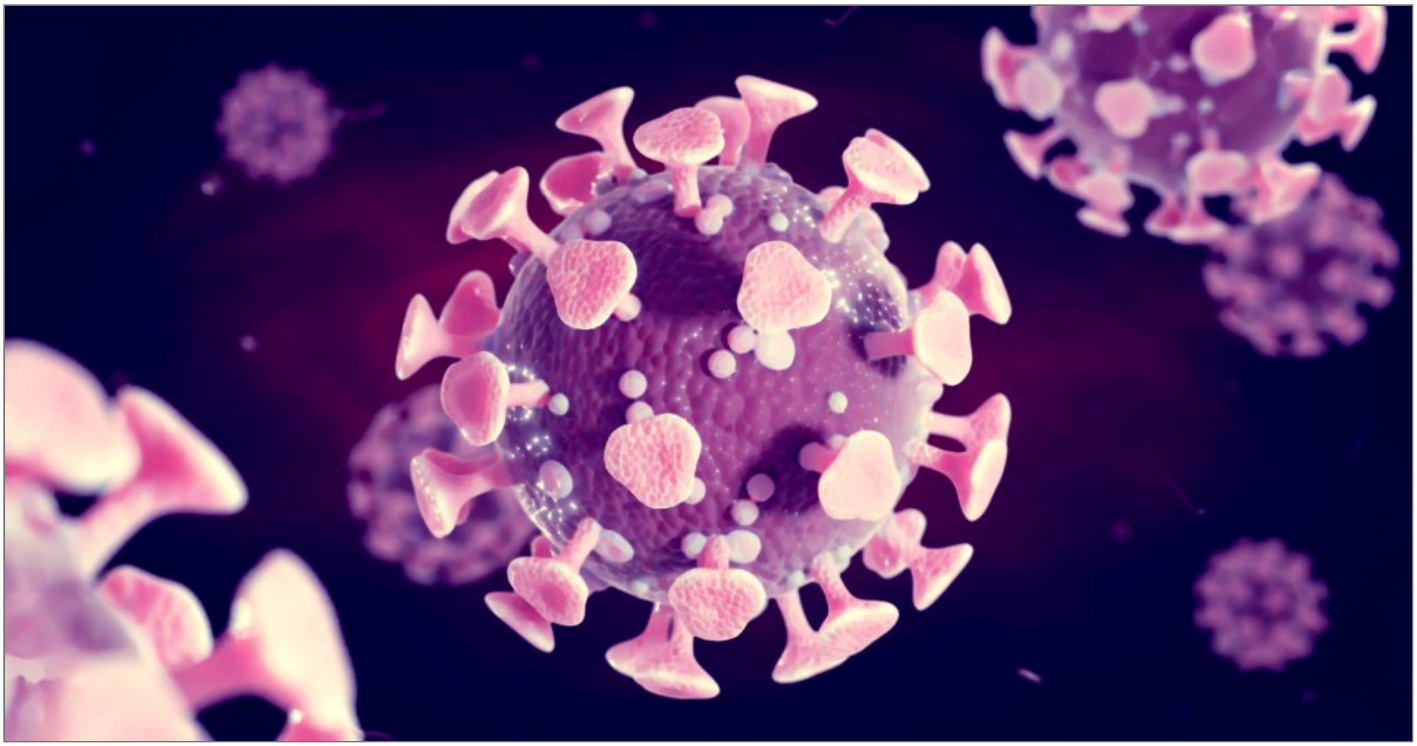
# Could Spike Protein in Moderna, Pfizer Vaccines Cause Blood Clots, Brain Inflammation and Heart Attacks?

*Dr. J. Patrick Whelan, a pediatric rheumatologist, warned the FDA in December that mRNA vaccines could cause microvascular injury to the brain, heart, liver and kidneys in ways not assessed in safety trials.*

**By Lyn Redwood, RN, MSN**





submission was in response to the agency's request for comments regarding vaccines against SARS-CoV-2 in advance of the Dec. 10 meeting when the committee would review the Pfizer/BioNTech (BNT162b2) SARS-CoV-2 vaccine for emergency use authorization (EUA).

Whelan's training (at Harvard, Texas Children's Hospital and Baylor College of Medicine) includes degrees in biochemistry, medicine and rheumatology. For 20 years, he worked as a pediatric rheumatologist. He currently specializes in treating children with multisystem inflammatory syndrome (MIS-C), which has been associated with coronavirus infections.

In his public submission, Whelan sought to alert the FDA about the potential for vaccines designed to create immunity to the SARS-CoV-2 spike protein to instead cause injuries.



Specifically, Whelan was concerned that the new mRNA vaccine technology utilized by Pfizer and Moderna has "the potential to cause microvascular injury (inflammation and small blood clots called microthrombi) to the brain, heart, liver and kidneys in ways that were not assessed in the safety trials."

While Whelan did not dispute the vaccines' potential to quickly arrest the spread of the virus (assuming that the vaccines prove to actually prevent transmission — also not assessed in the clinical trials), he cautioned that "it would be vastly worse if hundreds of millions of people were to suffer long-lasting or even permanent damage to their brain or heart microvasculature as a result of failing to appreciate in the short-term an unintended effect of full-length spike protein-based vaccines on other organs."

Unfortunately, Whelan's concerns were not acknowledged, and the agency instead relied on the limited clinical trial data. The VRBPAC endorsed the use of the Pfizer vaccine on Dec. 10. The following day, the FDA issued the first COVID-19 vaccine emergency use authorization allowing the Pfizer-BioNTech COVID-19 vaccine to be widely distributed in individuals 16 and older without calling for the additional studies that Whelan felt were critical to assure safety of the vaccine, especially in children.

Why was Whelan worried about the mRNA vaccines causing blood clots and inflammation?

One of the peculiar and often deadly findings with regard to SARS-CoV-2 infection is widespread damage occurring in numerous organs beyond the lungs. Clinicians around the world have seen evidence that suggests the virus may cause heart inflammation, acute kidney disease, neurological malfunction, blood clots, intestinal damage and liver problems. Unexpectedly, however, clinicians observe a very limited or non-existent presence of the virus in organs other than the lungs.

Here is what we currently know about the impact of the virus outside the lungs.

**Cardiovascular complications from COVID-19**

Though COVID-19 was originally thought to be a respiratory infection, it's since become clear the infection threatens the heart, too.

Dr. Aeshita Dwivedi, a cardiologist at Lenox Hill Hospital in New York City has stated: "As the COVID-19 pandemic has evolved, research has progressively demonstrated this virus's impact on multiple organs

In a prospective study that followed 100 patients who recovered from COVID-19, the investigators found involvement of the heart on MRI scans in 78% of patients, and ongoing myocardial inflammation in 60%. These findings were independent of the severity of the infection, overall course of the illness and time from the original diagnosis.

In October 2020, researchers took a more detailed look at the heart after death from COVID-19 and found "cardiac damage was common, but more from clotting than inflammation" and that "microthrombi (small blot clots) were frequent."

"We did not expect this," said study co-author Dr. Renu Virmani, of CVPath Institute in Gaithersburg, Maryland. "It seems to be unlikely that the direct viral invasion of the heart is playing a major role in making myocardial necrosis and microthrombi."

Dr. Hyung Chun, a Yale cardiologist, suggests that the endothelial cells lining the blood vessels potentially release inflammatory cytokines that further exacerbate the body's inflammatory response and lead to the formation of blood clots. Chun has stated: "The 'inflamed' endothelium likely contributes not only to worsening outcome in COVID-19, but also is considered to be an important factor contributing to risk of heart attacks and strokes."

A subsequent study published last month confirmed the findings of microthrombi resulting in myocyte necrosis, indicative of a recent myocardial infarction (heart attack), in 40 individuals who died from COVID-19 infection — the studies also identified microthrombi as a major cause of cardiac injury.

**Neurological complications of COVID**

Individuals with COVID-19 experience a vast number of neurological symptoms, such as headaches, ataxia, impaired consciousness, hallucinations, stroke and cerebral hemorrhage.

But autopsy studies have yet to find clear evidence of destructive viral invasion into patients' brains, pushing researchers to consider alternative explanations of how SARS-CoV-2 causes neurological symptoms.

In a study of 18 COVID-19 patients with neurological symptoms who died in hospitals last April, Mukerji and colleagues found very low levels of viral RNA — the source of which is a mystery — in only five of the patient brains. Because the low RNA concentration "seems out of proportion to the profound deficits that people are experiencing," Mukerji said, "I'd be extremely surprised [if] the majority of cases where people are having neurological symptoms are due to direct viral invasion."

In a more recent analysis published Feb. 4, 2021, in the New England Journal of Medicine, researchers from the National Institute of Neurological Disorders and Stroke documented microvascular injury but no evidence of virus in the brains of patients who died from COVID-19. They reported, "In a convenience sample of patients who had died from COVID-19, multifocal microvascular injury was observed in the brain and olfactory bulbs by means of magnetic resonance microscopy, histopathological evaluation and immunohistochemical analysis of corresponding sections, without evidence of viral infection."

If not viral infection, what else could be causing injury to distant organs associated with COVID-19?

The most likely culprit that has been identified is the COVID-19 spike protein released from the outer shell of the virus into circulation. Research cited below has documented that the viral spike protein is

What makes this finding so disturbing is that the COVID-19 mRNA vaccines manufactured by Moderna and Pfizer and currently being administered throughout the U.S. program our cells to manufacture this same coronavirus spike protein as a way to trigger our bodies to produce antibodies to the virus.

According to Whelan's letter to the FDA, the "Pfizer/BioNTech vaccine is composed of an mRNA that produces a membrane-anchored full-length spike protein."

A landmark study in Nature Neuroscience, published a few days after Whelan's letter, found that the commercially obtained COVID-19 spike protein (S1) injected into mice readily crossed the blood-brain barrier, was found in all 11 brain regions examined and entered the parenchymal brain space (the functional tissue in the brain).



The researchers acknowledged that such widespread entry into the brain could explain the diverse neurological effects of S1 such as encephalitis, respiratory difficulties and anosmia (the loss of smell). The injected spike protein was also found in the lung, spleen, kidney and liver of the mice.

A second study published in December, 2020, in Neurobiology of Disease reported that the SARS-CoV-2 spike proteins showed a direct negative impact on endothelial cells and provide "plausible explanations" for the neurological consequences observed in patients with COVID-19.

The researchers demonstrated that the angiotensin-converting enzyme 2 (ACE2), a known binding target for the SARS-CoV-2 spike protein, is "ubiquitously expressed throughout various vessel calibers in the frontal cortex."

In another investigation, researchers studying brain tissues from 13 fatal COVID-19 cases found pseudovirions (spike, envelope and membrane proteins without viral RNA) present in the endothelia of microvessels of all 13 brains. They concluded that ACE2+ endothelial damage is a central part of SARS-CoV-2 pathology and may be induced by the spike protein alone. Injection of the full-length S1 spike subunit in the tail vein of mice, as part of the same study, led to neurologic signs (increased thirst, stressed behavior).

An observed complication of SARS-CoV-2 infection in children is similar to the atypical Kawasaki disease shock syndrome characterized by multisystemic hyperinflammation, edema and vasculitis (MIS-C) that Whelan treats.

> "I am concerned about the possibility that the new vaccines aimed at creating immunity against the SARS-CoV-2 spike protein have the potential to cause microvascular injury to the brain, heart, liver and kidneys in a way that does not currently appear to be assessed in safety trials of these potential drugs."

Whelan was referring to the fact that mRNA vaccines work by incorporating the genetic blueprint for the key spike protein on the virus surface into a formula that — when injected into humans — instructs our own cells to make the spike protein.

In theory, the body then will make antibodies against the spike protein to protect against SARS-CoV-2 infection.

The problem with this scenario, as we saw above, is that the spike protein alone — which the mRNA vaccines instruct the body to make — has been implicated as a key cause of injury and death in COVID-19 infections.

Based on the research conducted to date, it is very likely that some recipients of the spike protein mRNA vaccines will experience the same symptoms and injuries associated with the virus.

Again according to Whelan, "the potential to cause microvascular injury (inflammation and small blood clots called microthrombi) to the brain, heart, liver and kidney … were not assessed in the safety trials."

Whelan also stated in his letter that "particular caution will be required with regard to the potential widespread vaccination of children before there are any real data on the safety or effectiveness of these vaccines…"

Sadly highlighting Whelan's concerns, a 17-year-old was recently hospitalized in the ICU in Israel complaining of severe pains in his chest a few days after receiving the second dose of the coronavirus vaccine.

Since the widespread introduction of these vaccines on Dec. 14, 2020, Children's Health Defense has been following the reports filed with the Vaccine Adverse Event Reporting System (VAERS), the media and emails from individuals and family members who have experienced adverse vaccine reactions.

As of Jan. 29, 11,249 adverse events had been reported to OpenVAERS related to the two mRNA COVID-19 vaccines. The reports included 501 deaths, 1066 hospitalizations, 2443 urgent care visits, 1447 office visits and 147 cases of anaphylaxis.

What is concerning is that these reports are just the tip of the iceberg. A 2010 Harvard-executed study commissioned by the Department of Health and Human Services (HHS) revealed that reported vaccine injuries to VAERS represent an estimated 1% of actual injuries.

Even vaccine manufacturers have calculated at least a " fifty-fold underreporting of adverse events."

On Dec. 18, 2020, Robert F. Kennedy, Jr., Children's Health Defense chairman and chief legal counsel, wrote to Dr. David Kessler, then-co-chair of Biden transition's coronavirus task force and now the chief scientific officer of President Biden's COVID-19 response, requesting that Kessler consider the long-overdue need for a comprehensive, high-integrity system to monitor adverse outcomes following vaccination.

amplified responsibility to monitor adverse events. To date, we have not received a response from Kessler.

Children's Health Defense shares the same concerns as Whelan and numerous other clinicians and scientists who have spoken out about lack of adequate safety and efficacy testing prior to widespread distribution of the vaccines, especially in children.

Ignoring these valid and scientifically supported warnings may result in hundreds of millions of people suffering potentially deadly injuries or permanent damage following vaccination. It will also further erode the dwindling confidence that our country has in our federal regulatory agencies to protect the health of all Americans.

We encourage everyone to be informed consumers when making decisions about their health, especially when it comes to vaccinations. We ask that if you, a family member or friend have suffered any kind of adverse side effect, from any vaccine, do all three of the following:

- For U.S. residents, first file your report with the Vaccine Adverse Event Reporting System (VAERS), the official site of the U.S. Department of Health and Human Services (HHS).
- Go to VaxxTracker.com to file a report. This is an outside independent source versus government agency that tracks vaccine injuries globally.
- Using this page on the CHD website, share your vaccine injury story, pictures or videos. CHD will be publishing these events anonymously on The Defender website.

*The views and opinions expressed in this article are those of the authors and do not necessarily reflect the views of Children's Health Defense.*



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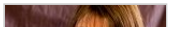

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