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## Potential dangers associated with COVID-19 injectable products

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The *Pfizer/BioNTech* COVID-19 vaccine has NOT been approved or licensed by the U.S. Food and Drug Administration (FDA), having been authorized instead for emergency use by FDA under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 16 years of age and older. [1,2,3]

The precautionary principle promotes transparency and the adoption of preventative measures to address these adverse events (AEs) as risks to the public. It is vital that individuals are informed of potential risks before agreeing to participate in any medically-involved treatment program such as the roll-out of the *Pfizer/BioNTech* products into the adult population of Israel that began in January 2021, continuing into the juvenile population of Israel beginning in May 2021.<sup>1</sup>

### 1. Adverse event reports made in the context of COVID-19 products are atypically high

Adverse event reports are currently at 146,622 (U.S. VAERS) and this number is increasing at an exponential rate. There are already TWICE AS MANY total reports as of April 30<sup>th</sup>, 2021 (Figure 1, right) than for the ENTIRETY of the VAERS reports collected from last year.

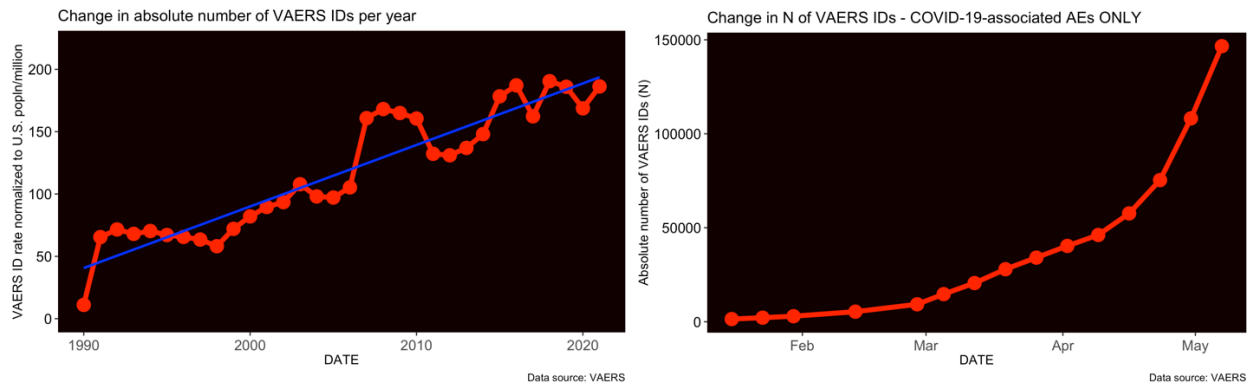


Figure 1: Time series plots showing VAERS reporting rate normalized to U.S. population by year with trendline in blue (left) and showing VAERS reports by absolute number of VAERS IDs associated with the COVID-19 products for the year 2021 (right). Data contains VAERS reports processed as of 4/30/2021.

#### 1.1 The number of deaths far out-numbers previous years

VAERS death reports from vaccinations are much higher than for the previous past two years. Figure 2 shows a comparison between the cumulative number of VAERS reported deaths reported throughout the year for 2019, 2020 and 2021. There were a total of 183 and 166 deaths reported in 2019 and 2020, respectively, and up to and including April 30<sup>th</sup> of this year, 2021, there are a total of 3731 deaths.

<sup>1</sup> The National Childhood Vaccine Injury Act of 1986 (NCVIA) requires health care providers and vaccine manufacturers to report to the DHHS specific adverse events following the administration of those vaccines outlined in the Act.[1]

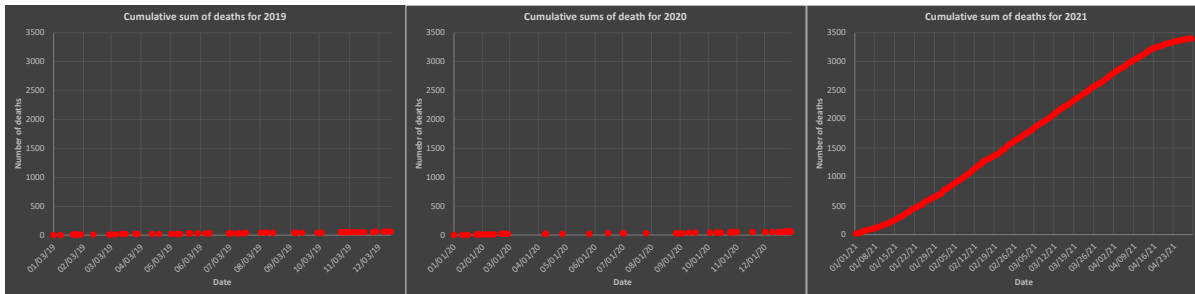


Figure 2: Scatterplots showing the cumulative number of VAERS reported deaths for 2019 (left), 2020, (middle) and 2021 (right). Data contains VAERS reports processed as of 4/30/2021.

Reporting AEs that occur in temporal proximity to injection of biological material into humans is critical and serves as an early warning system for adverse events not detected during pre-market testing of such products.[4] It is especially relevant in the context of technologically novel treatments in the experimental phase of development such as the *Pfizer/BioNTech* mRNA injectables. Analysis of adverse event data suggests that these products are likely the *cause* of reported deaths, **spontaneous abortions**, anaphylactic reactions and cardiovascular, neurological and **immunological** AEs.<sup>2</sup>

Immunologically-related AEs are among the highest reported to date<sup>3</sup> (Figure 3) and imply that pathogenic priming could be at play.[5] Pathogenic priming can happen due to similarity in proteins between humans and viruses (due to shared ancestry between human and viral proteins) and it can lead to autoimmunity. Autoimmunity refers to an immunological reaction to self-proteins and can manifest clinically in many ways, from Fatigue to Multiple Sclerosis. There are over 80 types of autoimmune conditions classified to date.<sup>4</sup> As part of a recent peer-reviewed study on pathogenic priming, it was found that one-third of the immunogenic proteins in SARS-CoV-2 have potentially problematic homology to proteins that are key to the human adaptive immune system.[5] Clinically, this may manifest as something akin to immune deficiency but more generally, would manifest as COVID-19 disease enhancement. The list of potential autoimmune conditions that could develop due to this priming is unknown and the proportion of the individuals who may succumb to the effects of pathogenic priming is also unknown. Natural infection may not do as much damage as the injection itself since in most cases, innate immunity will supercede the necessity for a potent humoral response that may lead to priming.

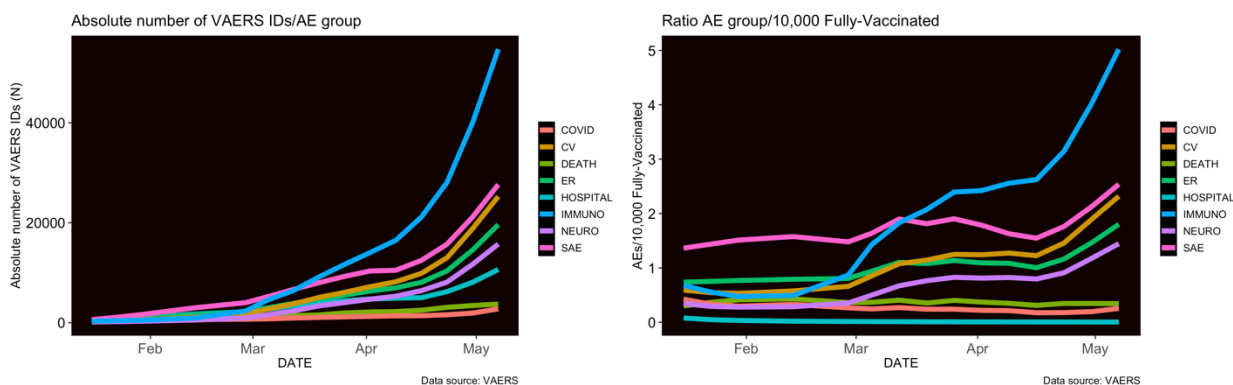


Figure 3: Time series plots showing absolute numbers of VAERS IDs as per AE group (left) and the percentage of AEs per group as per million fully-vaccinated in the U.S. (right).

<sup>2</sup> A study of the U.S. Vaccine Adverse Events Reporting System (VAERS) of the COVID-19 Messenger ribonucleic acid (mRNA) biologicals. Dr. Jessica Rose – in preprint

<sup>3</sup> A study of the U.S. Vaccine Adverse Events Reporting System (VAERS) of the COVID-19 Messenger ribonucleic acid (mRNA) biologicals. Dr. Jessica Rose – in preprint

<sup>4</sup> The Johns Hopkins University, The Johns Hopkins Hospital, and Johns Hopkins Health System.

What is clear, is that the absolute number of immunological AEs reports is growing exponentially (Figure 3 - left) and this is due to the injections. If pathogenic priming becomes a prevalent issue, it will simply be a numbers game. The more people who are exposed to these problems by being injected, the more people will succumb to them.

Safety is always a point of relevance with regards to new biological agents. Considering that no long-term studies were completed prior to the global-roll of these products, **and the exponential rise of AEs**, safety is certainly being called into question.

## 2. The potential disruption of the Renin-Angiotensin-Aldosterone System

Messenger RNA (mRNA) platforms are new in medical microbiology and have never before been implemented for use in human subjects on a global scale in the context of viruses. mRNA stands for messenger RNA and is the coding template for a protein. All living things use it for production of these building blocks of life. In the context of the *Pfizer/BioNTech* and *Moderna* products, the mRNA encoding the pre-fusion *spike* protein, which is the protein on the surface of the coronavirus that is used for binding and infection of host cells, is wrapped in a lipid-nanoparticle (LNP) shell to enable stable introduction to host cells via intramuscular injection. It is currently not known how long the mRNA remains for the purpose of production and presentation of spike proteins to specialized cells to induce a specific immune response against them. The protein on the surfaces of human cells that the spike protein binds to in order to infect the cell is called Angiotensin Converting Enzyme-2 (ACE-2). ACE-2 is an enzyme that acts to regulate the Renin-Angiotensin Aldosterone System (RAAS) to decrease blood pressure to normal levels and to maintain electrolyte levels at normal-functioning values, and can act in both membrane-bound and soluble forms. This protein is commonly expressed in many cell types distributed all over the body and is primarily associated with enterocytes which are specialized cells in the epithelium.<sup>5</sup> It is an essential component of the RAAS: an essential system in every human being. In the presence of SARS-nCoV-2 virions (viral particles), it is known that the binding sites of ACE-2 proteins are occupied by the SARS-nCoV-2 viral particle via the spike protein. This can result in dysregulation of the RAAS which would clinically manifest as hypertensive disorders, fibrosis or problems with any one of the organs involved with the system and/or the arteries.[56] These problems are matching the AEs that are being reported at record rates.

There is increased activity of the RAAS in infancy and childhood.[6] The effects of both SARS-nCoV-2 and the spike protein as an injectable immune system stimulant, on the RAAS, are currently being investigated. It has been shown that the presence of SARS-nCoV-2 and the spike protein on its own induce ACE-2 expression downregulation and cause damage to vascular endothelial cells.[56] This means ACE-2 is less prominent on the surfaces of cells and subsequently, less prominent in soluble form. This downregulation of ACE-2 naturally means is that there are fewer binding sites to occupy with respect to ACE-2, both in membrane-bound and soluble forms of the protein. In the presence of a protein, like the spike protein, that binds ACE-2 with high affinity (very strongly), it is easy to envision competitive inhibition for binding sites arising. Thus, in the presence of high levels of spike proteins, even fewer ACE-2 binding sites would be available to exert their inherent purpose and subsequently, an overactive RAAS would ensue accompanied by fibrosis in many sites. In individuals who already have an overactive RAAS, such as many of our elderly with clinical manifestations of hypertension, the obese and pregnant women and children [6,57,58,59], this would result in an even more overactive RAAS due to the enhanced lack of readily-available ACE-2 to close the RAAS loop. The spike protein alone can also impair Nitric Oxide (NO) bioavailability and inhibit mitochondrial function.[56]

It is interesting that children are not suffering serious pathologies or death and this is likely due to robust and healthy innate immune responses as part of a balanced and fully-functioning immune system. This would result in a low viral burden and thus less ACE-2 binding due to infrequency of SARS-nCoV-2 spike protein and thus no serious clinical complications both in the context of the infection and in the context of the RAAS. The take home message on this point is that further studies are required prior to further experimentation in the human population. We simply do not know enough on this particular subject yet.

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<sup>5</sup> A thin, continuous, protective layer of cells that line the outer surfaces of organs and blood vessels throughout the body, as well as the inner surfaces of cavities in many internal organs. Wikipedia reference.

### 3. We inherently have effective natural host defenses!!

Effective antiviral responses against the SARS-nCoV-2 virus in the form of both cellular and humoral immune responses have been reported in peer-reviewed studies.[39-44] Because of the combination of a low Infection Fatality Rate (IFR) of 0.15% indicating effective and robust immune responses, it remains unclear why multiple experimental mRNA vaccines have been fast-tracked through conventional testing protocols and are currently being fast-tracked through production and administration into the public. What is even more unclear is why these products are being pushed into young demographics since these demographics do not suffer serious pathologies from COVID-19, as a general rule. The mortality rate from COVID-19 in children 17 and under is 0.06%, as per the CDC reports. With repurposed drugs like Chloroquine and Ivermectin showing extremely positive results in patients [20-30], it is also unclear why these drugs are not being more extensively promoted as effective tools in the fight against this virus. One looming possibility is that EUA is not permissible if FDA-recognized effective treatments exist. Newer to the market of COVID-19 treatments are Nitric Oxide products shown to be 100% effective at reducing viral burden.<sup>6</sup>[54, 55]

A healthy immune system is the best weapon we have against pathogenic organisms. It is vital that the public is made aware that the immune system cannot function optimally in the context of Vitamin D deficiency so it is recommended to check Vitamin D levels regularly, especially if you live in sun-deprived climate, and to supplement when necessary. A vitamin D level of 20 ng/mL or higher is considered to be a non-deficient level.[7]

Functioning and balanced systems are essential to health and this should be **highly promoted** by governing agencies, both as a rule of thumb, and especially in the context of a pathogen that we know uses the ACE-2 protein as receptor to bind and enter host cells to infect them. In the context of a balanced and functioning immune system and RAAS system, SARS-nCoV-2 does not impose a threat to the majority of humans. One way to ensure a disease state is to maintain a chronic imbalance in any one of these essential systems. One way to potentially induce an imbalance in the RAAS is by saturating it with a protein that binds one of its essential components. It is very concerning to me that millions of individuals have already had the coding material for the SARS-nCoV-2 spike protein injected into their bodies. The implications for the RAAS, even in individuals with functioning and balanced RAAS, are potentially serious and unknown at this point in time. It is imperative that further studies on the relationship between the spike protein and the RAAS are completed before any further roll-outs continue. The implications in the context of pathogenic priming are also serious and this also requires further study prior to advancement of any roll-out of these products.

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<sup>6</sup> See Bellerophon Therapeutics and Vero Biotech

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