COVID-19 Treatment and Vaccine Decisions from a Pediatric Perspective:

Evaluating the risks and benefits for your child or adolescent beyond CDC, FDA or WHO proclamations

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Children's Health Defense

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Executive Summary

- The vast majority of children who experience COVID illness have mild symptoms and uneventful outcomes. The estimated survival rate for children under age 17 is 99.998%.
- Effective COVID treatments for kids are available, including inexpensive therapies like vitamins C and D, zinc, ivermectin and hydroxychloroquine.
- It is crucial for parents to understand children's very low SARS-CoV-2 risk when they evaluate the risks of COVID-19 vaccines not subjected to long-term safety studies. In the Pfizer clinical trial with 12–15-year-olds, harms outweighed potential benefits.
- The mRNA vaccine clinical trials showed less than a 1% decrease in the absolute risk of getting COVID, also showing that between 88 and 142 kids would need to be vaccinated to theoretically prevent one case of COVID.
- Health officials are ignoring many measures to strengthen children's innate immune system—the non-specific immunity that makes kids able to cope with a wide variety of health challenges.
- The fallout from lockdowns and other restrictive measures has taken a far greater toll on children's physical and mental health than COVID. Negative impacts include increased reliance on processed foods, decreased exercise and time outdoors, loss of interactive play, social isolation, overuse of carcinogenic sanitizers, developmentally inappropriate online education, increased mental health problems (including an uptick in young suicides) and social and emotional stunting from mask-wearing.

- Vaccine makers' assumption that cells will make just enough spike protein for vaccine recipients to develop adequate antibodies but not enough to cause harm is not borne out by the evidence. The synthetic spike proteins triggered into production by COVID vaccines may "prime the immune system toward development of both auto-inflammatory and autoimmune disease," both in the short- and long-term.
- Rat studies show that the lipid nanoparticles in the mRNA injections penetrate the blood-brain barrier within 15 minutes; vaccine spike protein circulates in blood for at least two weeks, accumulating in the spleen, bone marrow, liver, adrenals and ovaries.
- Experts have grave concerns about potential fertility problems that might not be evident for years. Already, a CDC study showed that 82% of pregnant women who received COVID injections in the first or second trimesters experienced miscarriages.
- Healthy adolescents receiving COVID vaccines have experienced blood clots, uncontrolled bleeding, paralysis, abnormal menses, extreme fatigue and death. Outcomes such as myocarditis are changing the trajectory of some young people's lives.
- It is unethical for companies and officials to ask children and adolescents to incur health risks to "protect the elderly and infirm," especially with unknown long-term risks. Even a small risk is not worth taking if the potential consequences include serious or fatal short-term outcomes or life-long health and financial consequences.
- Children and adolescents, with vanishingly small risks of death or disability from COVID-19, should be allowed to go to school, socialize with peers, play in the dirt and contribute to herd immunity through natural infection. Childhood exposure to coronaviruses is likely to induce strong and long-lasting immunity that, in turn, is likely to protect children from serious problems from COVID-19.

I. Introduction

First, do no harm

"First, do no harm." This most basic tenet of medicine was first articulated more than 2,000 years ago and has never been more important than today. At a time when we have thousands of medications, dozens of vaccines and multiple surgical options, it is more important than ever to use those options wisely for the benefit of the patient.

During the COVID-19 pandemic, 24/7 media coverage subjected the population around the world to messages emphasizing death and stoking fear. However, according to the current best estimate from the Centers for Disease Control and Prevention (CDC), the risk of dying from COVID for someone age 17 or less is 0.002%.[1] Despite the media alarmism that continues to prevail, it is crucial for parents of children and adolescents to understand children's very low SARS-CoV-2 risk when they evaluate the risks and benefits of COVID-19 vaccines.[2]

The U.S. Food and Drug Administration (FDA) authorized messenger RNA (mRNA) and adenovectored COVID vaccines under a provision of the Federal Food, Drug, and Cosmetic Act called Emergency Use Authorization (EUA).[3] With billions of dollars being spent on marketing campaigns to convince the population to get vaccinated, it is easy to lose sight of the fact that EUA is quite different from formal licensure. At the time of their widespread rollout, these vaccines were not FDA-approved in the classic sense.

To get EUA status, there must be a pandemic, and no other viable treatment options can be available.

According to the current best estimate from the Centers for Disease Control and Prevention (CDC), the risk of dying from COVID for someone age 17 or less is 0.002%.

In reality, effective, inexpensive alternatives *are* available, but their value has been censored or suppressed.[4] Instead, populations have been asked to take novel one-size-fits-all vaccines—developed at Warp Speed—that have not been subjected to long-term safety and efficacy studies. The FDA's behind-closed-doors decision on August 23 to grant full approval to the Pfizer-BioNTech Comirnaty COVID injection does not change the fact that there are no long-term safety data.[5]

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II. Prevention and Early Treatment

Ages and stages

In pediatrics, illnesses tend to present differently depending on the age of the child. In fact, some illnesses (like rotavirus and respiratory syncytial viruses) are more likely in infants, and others are more likely in teens (such as mononucleosis and chlamydia).

With COVID-19, the younger you are when you get it, the less likely you are to be very symptomatic. Many young children have been declared "infected" without their parents even noticing any symptoms.

In the early stages of COVID, when the virus is replicating, helpful treatment strategies interfere with the virus being able to get into your child's cells and hijack their cellular machinery to make more viral particles. In later stages of COVID, there is a risk of respiratory distress and inflammatory overreactions. This is what leads to hospitalizations in a small percentage of people.

Chronic illness management

SARS-CoV-2 is rarely fatal in children and teens unless there are underlying chronic medical conditions. So, if your child has asthma or heart problems, make sure his or her medications are current and being taken regularly, if needed. It is especially important to use anti-inflammatory supplements or medications, since pre-existing inflammatory states are risk factors for worse outcomes if your child does develop COVID-19.

We came across what seems like an important study in the U.S. National Library of Medicine. The description of the Human Epidemiology and Response to SARS-CoV-2

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(HEROS) trial states that investigators enrolled 5,599 participants to determine the prevalence of SARS-CoV-2 carrier status over time in children and parents, assess antibody development over time and compare carrier status and antibody development in children who did and did not have asthma or atopic conditions like allergic rhinitis.[6] Although the study started on May 1, 2020 and was completed on January 24, 2021, months later, no results have been posted. Government employees deserve kudos for getting the trial up and running so quickly, but it is disappointing that potentially important data—including information about children with chronic illness—have not been released.

Prevention—nutrition, sleep, play and nurturing relationships

During the lockdowns, it was disappointing to hear so many public health messages about masks, social distancing and staying home—and so little about basic measures to stay healthy, including good nutrition, adequate exercise, high-quality sleep and meaningful social contact. If another health crisis emerges, hopefully we will not repeat the mistakes made during the management of COVID-19.

For example, a diet that emphasizes fresh, organic, nutrient-dense foods is one of the best ways to enhance resistance and nurture the non-specific immunity that protects children from a multitude of diseases. (Grandmothers are right: kids need to eat their vegetables.) In food that comes from nature and is as organic as possible, phytonutrients and polyphenols act synergistically to support overall health and immune function. Some foods,

like coconuts, brussels sprouts and cabbage are specifically antiviral and could be particularly good additions in the age of COVID-19. Furthermore, those foods do not have dangerous and unknown side effects, as do experimental vaccines.

The value of other basics like deep sleep, unstructured play and nurturing relationships for children's health cannot be underestimated. Sleep, for example, is crucial for detoxification and growth. Growth hormone is released during sleep. When you are asleep, your brain cells shrink a bit so that glymphatic fluids can wash over the brain, taking out the toxins that accumulated during the day.[7]

The anxiety and depression created by the official response to the so-called pandemic disrupted the sleep of many children and parents. According to sleep specialists, "Studies have clearly demonstrated that sleep deprivation imposes major adverse effects on host defense mechanisms and on the magnitude and characteristics of the inflammatory response."[8] Other researchers have described how "Insufficient sleep induces innate immune

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responses as evidenced by increased expression of pro-inflammatory mediators in the brain and periphery," while conversely, immune challenges can "upregulate immunomodulator expression," altering processes and behaviors mediated by the central nervous system, including sleep.[9]

The advice of public health officials also curtailed close contact with extended family and friends, ignoring the hundreds of articles in the medical literature demonstrating that human relationships nurture healthy immunity. Touch, in particular, has measurable health and immune benefits, including decreased blood pressure, lower heart rate, lower cortisol levels and higher levels of oxytocin (the bonding hormone).[10] Touch and massage increase natural killer cell functioning and decrease depression.

Effective COVID treatments for kids—available but ignored

"Stay home, wait for the vaccine and don't go for medical treatment unless you have trouble breathing." Did this message from public health officials ring true to you? Pediatricians, who have classically been quite concerned with preventive care, were actively discouraged from trying low-cost, easily available home therapies. Even worse, those of us who wondered whether tried-and-true therapies used for other viruses or in other cases of cytokine activation gone haywire might be valuable treatments were ostracized by our peers.

As early as mid-March 2020, data coming out of China pointed to vitamin C infusions as a promising option. Vitamin C is known to be an excellent antiviral and a magnificent antioxidant. It is water-soluble, with a known profile of low side effects, the most common of which is diarrhea. It subsequently became a crucial part of the MATH+ hospital treatment protocol, designed by intensive care physicians who had success treating hospitalized patients with inexpensive, immune-enhancing therapies like vitamins C and D, zinc and ivermectin.[11]

Also, early on in the pandemic, vitamin D emerged as a stratifying factor for COVID-19 mortality. In other words, if your vitamin D levels were low, you were more likely to die. As vitamin D levels rose, there was a linear relationship correlating with less mortality.[12] More than a year and a half into the pandemic, however, nurses at many local hospitals tell us that it is still not routine to check vitamin D levels in COVID-19 patients or to use vitamin D therapeutically.

The I-MASK+ and I-RECOVER protocols

Clinical research by the Front Line COVID-19 Critical Care (FLCCC) Alliance has identified a handful of inexpensive and widely available tools for global use against COVID-19. Their ongoing clinical research informs up-to-date recommendations about prevention, early treatment, and clinical strategies for hospitalized patients. In June 2021, they added treatment guidelines for clinicians trying to help patients with "long haul COVID" (the I-RECOVER protocol).[13] (Copious information, including references from the peer-reviewed medical literature, can be found at covid19criticalcare.com.)

The FLCCC group created the I-MASK+ prevention protocol—ivermectin, a thermometer,

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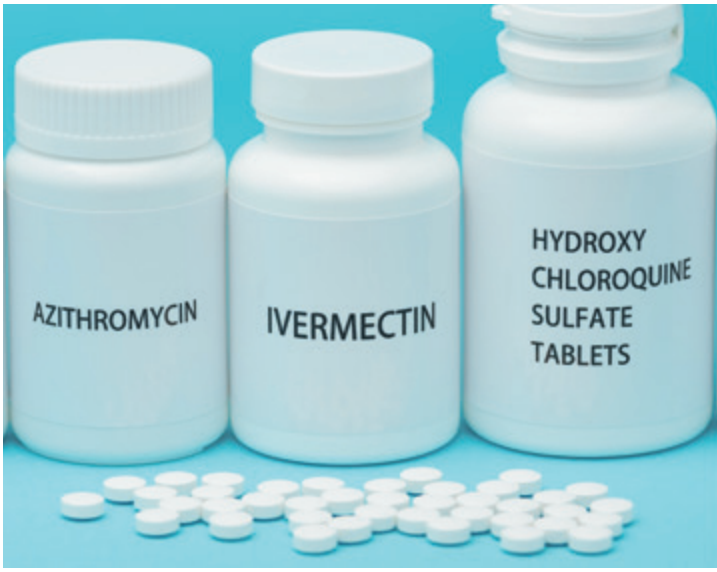
multivitamins and vitamin D—with the aim of facilitating generalized distribution during regional outbreaks and in low-resource countries.[14] The protocol also includes inexpensive over-the-counter measures like gargling twice a day with a mouthwash containing cetylpyridinium (a widely used, broad-spectrum antiseptic). Frontline clinicians—taking care of real patients—have also contributed to the development of treatment protocols to be instituted at home in the early stages of COVID-19. In August 2021, the group's medical team updated its I-MASK+ prevention and early treatment protocol to strengthen patients' ability to respond to variants.[15] For "maximal impact as well as ease of deployment with the lowest burden of required elements," the I-MASK+ treatment approach centers on a few high-impact elements such as ivermectin.

Ivermectin

Ivermectin is a cheap, widely available medication with a long history of use and an exquisitely safe side-effect profile. It has antiviral and anti-inflammatory properties and is commonly used as an anti-parasitic. The FLCCC Alliance reminds the public that ivermectin is on the World Health Organization's (WHO's) list of essential medicines, "has been given 3.7 billion times around the globe, and has won the Nobel prize in 2015 for its global and historic impacts in eradicating endemic parasitic infections in many parts of the world."[16]

Countries that deployed ivermectin saw dramatic decreases in the burden of COVID disease. Why, then, did U.S. public health authorities denigrate and suppress its use?[17] Could it be because pharmaceutical companies would not have been able to obtain Emergency Use Authorization for their vaccines if safe alternative treatments were available?



Maverick doctors like Pierre Kory, Paul Marik and JJ Rajter have reported good clinical results from treating COVID outpatients with ivermectin.[18] In January 2021, Dr. Rajter and colleagues published results in the journal *Chest* that added valuable clinical information derived from bedside care of patients in Florida.[19] The study reviewed the charts of 280 patients; 173 were treated with ivermectin and 107 were not, and "[m]ost patients in both groups also received hydroxychloroquine, azithromycin, or both." In adjusted multivariate analyses, the researchers found significantly lower mortality in the ivermectin group, notably in patients with severe lung involvement.

Theresa Lawrie, an internationally recognized authority on analyzing medical research, is the founder of Evidence-based Medical Consultancy in the United Kingdom. After analyzing multiple studies on ivermectin for SARS-COV-2, Dr. Lawrie and her colleagues concluded that the data are clear: ivermectin markedly reduces COVID-19 death rates.[20] Using a meta-analysis approach to assess 15 trials involving ivermectin, Lawrie's group found with "moderate certainty" that "large reductions in COVID-19 deaths are possible using ivermectin" and that using

ivermectin early on "may reduce numbers progressing to severe disease." The analysis also called attention to the apparent safety and low cost of ivermectin, stating that these factors put ivermectin in a position "to have a significant impact on the SARS-CoV-2 pandemic globally."

With the cumulative research on ivermectin, we now know that the drug works well as both a preventive and early treatment agent against SARS-COV-2, with efficacy around 90%. That is as good as the vaccines' relative efficacy—and without the known and unknown side effects emerging from novel vaccine technologies!

Once again, however, our FDA has failed us by releasing a statement "not for or against" ivermectin's use for COVID-19, which most people understandably interpret as meaning there are not enough data to support recommending ivermectin. The media mischaracterize ivermectin as a "horse paste deworming agent" and ignore per kilogram prescription dosing and its role as an anti-inflammatory. In various parts of the world, doctors have even been threatened with losing their medical licenses or going to jail if they prescribe ivermectin to their patients for the purpose of preventing or treating COVID-19.

Quercetin

Quercetin is a supplement with a long history of safe use as an antiviral and mast cell stabilizer. It is one of the tools in the I-MASK and MATH+ protocols developed by clinicians actually taking care of COVID patients. These protocols were released in spring 2020 but not widely used by doctors in outpatient practice, due to public health officials' statements that such treatments did not work.

Quercetin, found in foods, is a flavonoid—protecting cells from oxidative stress and protecting blood vessels from leakage. In fact, quercetin is the most abundant flavonoid found in vegetables and fruits. Quercetin acts to suppress inflammasomes, which generate active forms of cytokines (think "cytokine storms"). Because quercetin has known antioxidant, analgesic and anti-inflammatory properties, it, too, has value as part of prevention and treatment strategies for COVID-19.[21]

Melatonin

Melatonin is best known for its role in inducing sleep, but it has many other beneficial qualities, including functioning as an excellent antioxidant and anti-inflammatory. It is part of the I-MASK and MATH+ protocols for COVID prevention and early treatment. Melatonin inhibits the SARS-CoV-2 main protease (an enzyme that breaks down protein).

The effectiveness of melatonin has not yet been broadly studied in a randomized clinical trial. Because it is inexpensive, widely available and safe, there is less likelihood that funding will be available for such a trial. A prudent clinician, however, might recommend it for COVID patients as part of a more comprehensive immune enhancement strategy. The critical care physicians at Eastern Virginia Medical School recommend doses starting at 0.3 milligrams and

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going up to 2 milligrams at night; some people may do well with even higher doses.

Vitamin D

Low levels of vitamin D correlate with high mortality in COVID patients, whereas adequate levels are very protective. Yet, more than a year into the pandemic, nurses at many local hospitals tell us that vitamin D testing in hospitalized patients with positive COVID tests is not routinely done. Why is there so much resistance to something so basic and important for human health?

In an open letter circulated in February 2021, more than 200 physicians and scientists called for immediate widespread increased vitamin D intakes as a way to curtail COVID-19 infections, hospitalizations and deaths.[22] They pointed out:

- "Higher vitamin D blood levels are associated with lower rates of SARS-CoV-2 infection.
- Higher D levels are associated with lower risk of a severe case (hospitalization, ICU, or death).
- Intervention studies (including RCTs [randomized controlled trials]) indicate that vitamin D can be a very effective treatment.
- Many papers reveal several biological mechanisms by which vitamin D influences COVID-19.
- Causal inference modelling, Hill's criteria, the intervention studies & the biological mechanisms indicate that **vitamin D's influence on COVID-19 is very likely causal,** not just correlation" *[emphasis in original]*.

In their letter in which they begged for immediate action, these physicians and scientists shared crucial information that rates of true vitamin D deficiency (<20 ng/ml) are present in more than 33% of the world's population; vitamin D insufficiency (<30 ng/ml) exceeds 50% of the global population, with higher rates in some countries. The letter's authors also pointed out that rates of vitamin D deficiency are highest in winter, in overweight patients and in care-home residents. Those with dark skin are most vulnerable to vitamin D deficiency, and indeed have suffered disproportionately from SARS-CoV-2 infections.

Vitamin D is inexpensive, has an extremely good safety profile and should have been a crucial part of the COVID pandemic response. Young people with adequate vitamin D levels (perhaps in the range of 60-80 ng/ml) would likely be at extremely low risk for bad outcomes if infected with SARS-CoV-2.

More than 100 studies demonstrating the benefits of adequate vitamin D levels in preventing morbidity (disease) and mortality (death) from SARS-CoV-2 are available.[23] For children and adolescents, the huge benefits and virtually non-existent risk from maintaining vitamin D levels in the optimal range beat the uncertainties of the new vaccines in protecting them from COVID disease.

Hydroxychloroquine

Early on, frontline doctors desperate for ways to help the patients in their care rallied to figure out what pre-existing treatments might have value in treating COVID-19 and zeroed in on hydroxychloroquine. Like ivermectin, hydroxychloroquine is an old drug. Why do we like old

drugs? Because their side effects are well characterized after years of use. Hydroxychloroquine is also cheap. The U.S. had a large stockpile that could have been deployed early in the pandemic. An additional feature of hydroxychloroquine is that it is one of relatively few drugs that has been demonstrated to be extremely safe in pregnant women. It is widely used for other indications like lupus and malaria. There are literally hundreds of published studies about its safety profile and indications.

In the spring of 2020, however, something terrible happened that derailed treating clinicians from using hydroxychloroquine for COVID-19. A paper appeared in the *Lancet*, a highly respected medical journal on a par with the *New England Journal of Medicine,* that allegedly proved that both men and women treated with hydroxychloroquine (or chloroquine) for COVID were more likely to die.[24] Mehra and colleagues reported results on over 96,000 hospitalized patients who tested positive for SARS-CoV-2, reportedly using registry data from a company called Surgisphere (from 671 hospitals in six continents) and reportedly controlling for many confounding variables. A few weeks later, however, the authors requested that the study be retracted, with the following explanation: "Our independent peer reviewers informed us that Surgisphere would not transfer the full dataset, client contracts, and the full ISO audit report to their servers for analysis as such transfer would violate client agreements and confidentiality requirements. As such, our reviewers were not able to conduct an independent and private peer review and therefore notified us of their withdrawal from the peer-review process."[25]

Unfortunately, the publication of this paper, even post-retraction, had a chilling effect on anyone who wanted to give hydroxychloroquine to outpatients. The FDA and the American Medical Association (AMA) even published statements that hydroxychloroquine should not be used for either inpatients or outpatients. Pharmacy regulators told pharmacists not to fill prescriptions from physicians who wanted to give it to patients in early stages of illness.

Bear in mind that the government agency doctors who made these decisions were not the ones actually treating COVID-19 patients. Most were bureaucrats, whose jobs consisted of reviewing grant proposals, allocating research funding and attending policy meetings. In other disciplines, most people would not dream of advising others about legal matters, the stock market, agriculture or topics about which they have no knowledge, training or expertise. Yet pronouncements by people at the CDC, FDA, National Institutes of Health (NIH) and National Institute of Allergy and Infectious Diseases (NIAID) constrained experienced clinicians from doing their jobs. Suddenly, giving health-promoting advice, considering the patient as an individual and trying to help patients with proven clinical strategies had no value. People were told to do nothing therapeutic in those critical days at the beginning of viral infections when good clinicians knew much more could be done.

In the fall of 2020, researchers pushed back against the damaging influence of the retracted *Lancet* paper. In September, for example, a meta-analysis of five randomized controlled trials of hydroxychloroquine and COVID-19 (appearing in a preprint) estimated that use

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of hydroxychloroquine in the five study populations had prevented at least 24% of COVID-related infections, hospitalizations or deaths.[26] The analysis included over 5,500 patients. If patients reported any hydroxychloroquine side effects, the latter were mostly gastrointestinal, and there were no serious adverse cardiac events reported.

In November, two Illinois clinicians described their search of "PubMed, Cochrane, Embase, Google Scholar and Google for all reports on [hydroxychloroquine] as a treatment for COVID-19 patients," including preprints and other preliminary reports of research findings.[27] This search again showed that hydroxychloroquine was safe and "consistently effective against COVID-19 when provided early in the outpatient setting" as well as "overall effective" in inpatients, with no worsening of disease, no serious adverse events and no increased mortality risks.

The Hippocratic Oath

In August 2020, a morbidly obese patient with autism developed COVID-19 following his grandfather's funeral. His pediatrician, who had taken the Hippocratic oath, felt a deep sense of responsibility for this patient and could not parrot the advice to "keep him home and hope he does not have to go to the hospital." The doctor treated him with hydroxychloroquine after asking the parents to sign a disclaimer about how the FDA did not approve of the treatment. The mother now swears her son's symptoms dramatically improved within 24 hours. This type of "anecdotal" report is not considered of value in the current politicized medical climate, even though the treatment decision was based on the clinical observations of other physicians, published information about hydroxychloroquine for COVID-19 and a deep understanding that isolation in a hospital would be disastrous for that young patient with autism.

III. Vaccinating Our Way Out of a Pandemic: Preservation of Big Pharma and Big Government at the Expense of Your Child?

A controlled narrative

Documented communications from NIAID's Dr. Anthony Fauci and other government officials suggest major efforts to control messages to the public as opposed to truly following the science. Early on, many governments made the decision that the way out of the pandemic was worldwide vaccination. We now know that active campaigns to discredit cheap and widely available treatments like ivermectin and hydroxychloroquine—and the doctors who had success with those treatments—put the kibosh on promising treatments.

Think of all the precedents in medicine for early detection and treatment. Cancer screenings come to mind. And with other infectious illnesses like community-acquired bacterial pneumonia, skin infections or influenza, we know that people do better when they get treatment early. If pediatricians see a child who is gaining weight rapidly, eating high-carb processed foods and with a strong history of diabetes, do they wait until he goes into diabetic keto-acidosis before making any recommendations? Of course not.

We at Children's Health Defense were shocked and saddened as the pandemic progressed and public health officials doubled down on prolonging lockdowns. Isolation is terrible for immune function. We were also flabbergasted that no federal agency ever talked about the value of

Isolation is terrible for immune function.

strengthening innate immunity—the non-specific immunity that makes one able to cope with a wide variety of infectious agents. There are many inexpensive and effective interventions that can bolster the innate immune system. Instead, however, the powers in charge seemed hell-bent on vaccinating our way out of the pandemic, even though vaccines only address the specific, adaptive part of the immune system and thus may become less effective when a virus mutates, as indeed it has.

The message and assumption that nothing could be done to alter the course of illness after a positive COVID-19 test was dangerous and led to many deaths that could have been prevented with early treatment. Doctors either adopted "group think" (and looked to the ABC agencies for recommendations) or realized that such assumptions were in conflict with basic principles of healing.

Remember, too, that the vaccines' initial (and widely quoted) clinical trials were performed in extremely healthy populations, whereas the vaccines are now being rolled out to the population at large, including to many people who are unhealthy or have comorbidities. The clinical trials did not include people with multiple medical conditions, pregnant women or those who had already had COVID-19, yet all of those groups are now actively encouraged to get COVID vaccines.

According to the CDC's website, "The benefit of mRNA vaccines, like all vaccines, is those vaccinated gain protection without ever having to risk the serious consequences of getting sick with COVID-19."[28] This statement sounds good, doesn't it? However, it is disingenuous at best. Since we find ourselves in a

situation where public health officials and politicians have made the decision to vaccinate huge swaths of the global population, shouldn't we stop to think about what we don't know? As the recently deceased Donald Rumsfeld famously said, in addition to "known knowns" and "known unknowns," there are also "unknown unknowns—the ones we don't know we don't know."[29]

Clinical Trials with Limited Aims

It is crucial to know that the original clinical trials did *not* demonstrate that these "vaccines" would decrease transmission or prevent the recipient from getting COVID-19. Let us further clarify: The trials were not even *designed* to see if the novel vaccine would prevent transmission of the virus we had been taught to fear. The trials only showed—and were only designed to show—that vaccine recipients were not as symptomatic or sick for as long as those who were in the control group. Did you know that? Unless you read the manufacturers' submissions to the FDA for Emergency Use Authorization, probably not—because that information was not publicized on TV or the radio.

Eight months into the global rollout of COVID vaccines, we began seeing many reports of cases of "breakthrough" COVID-19 in the fully vaccinated. In Israel, where at least 70% of the population—more than anywhere else in the world—is fully vaccinated, at least half of new COVID cases are in the vaccinated. In a CDC study of recent COVID-19 cases on Cape Cod, 74% were among individuals who were fully vaccinated.

Sources:

ourworldindata.org/covid-vaccinations

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Irresponsible...or Malpractice?

In what seems to be irresponsible at best and malpractice at worst, COVID injections have been administered indiscriminately, with only cursory screening for previous allergies. Patients have reported that one nurse will ask about allergies at the very same time that another nurse is giving the injection.

Persons given injections in mass settings have sometimes fainted, had anaphylactic reactions or had car accidents while driving home. Yet when a 58-year-old African American woman in eastern Virginia reacted to the vaccine, was hospitalized and died several hours later, the initial shocking response from the commissioner of the Virginia Department of Health was to reassure the public that the vaccine did not seem to be to blame. No autopsy was performed.

Hank Aaron, the well-known baseball player, was recruited to get a COVID-19 injection publicly in order to encourage other African American citizens to line up for the jab. He died 17 days later. Public health officials again reassured the community that the vaccine did not seem to be at fault. The official position seems to be that he would have died anyway, since he was 86 years old. However, when Robert F. Kennedy, Jr. spoke directly to the coroner's office in Georgia, he was told that the Medical Examiner never saw Mr. Aaron's body and that no autopsy was ever done. Again, it seems disingenuous at best and fraudulent at worst to give such public reassurances in the absence of clinical or scientific data.

When the COVID vaccines first became available, physicians in some states developed plans to immunize their patients—even paying top dollar to get the special freezers—but then were told that they would not have access to the vaccine for several months. Meanwhile, firefighters in those same cities were trained over the course of three days to administer the injections in parking lots and convention centers. Does that make any sense to you?

Source:

Kennedy Jr. RF. National media pushes vaccine misinformation — coroner's office never saw Hank Aaron's body. *The Defender,* Feb. 12, 2021. childrenshealthdefense.org/defender/national-media-vaccine-misinformation-hank-aaron/

Initial response to the pandemic

In the winter of 2020, the world was caught by surprise. A serious virus seemed to be circulating around the world, and public health officials were sounding the alarm. These officials suggested that we should all "lock down" for short periods (initially two to three weeks) so that hospital systems could prepare for an onslaught of seriously ill patients.

The avalanche of expected patients did not immediately materialize, however, and some communities actually saw their hospitals become like ghost towns for several months. Meanwhile, lockdowns led to a dramatic escalation in mental health problems, and many people lost their jobs.

We learned in spring of 2020 that it was not the coronavirus infection itself that was hurting people. Rather, it was an overactive or poorly controlled immune response to the virus that was causing complications. In a subset of patients, what initially started with viral respiratory symptoms transitioned into an inflammatory state, and patients got much worse. Most kids, however, either did not develop symptoms or had mild symptoms like a bad cold.[30]

Risks would have shrunk if available prophylaxis (prevention) and the treatments discussed in the previous section (like vitamin D, vitamin C, zinc, quercetin, hydroxychloroquine and ivermectin) had been used more widely. Excellent work by frontline physicians who were actually taking care of patients with COVID clarified that there were clear stages of disease, and treatment strategies needed to be tailored to the patient's stage of illness.[31] Many of these doctors were uncomfortable with the advice given to patients to "stay home, stay socially distanced and don't come to the hospital unless you are having trouble breathing"—as well as the consistent message from NIAID director Fauci to wait for a vaccine. Unfortunately, when these clinicians applied their skills and expertise to treat the patients before them with already available medications, they often were subjected to ridicule, pushback or even threats.

Drumming Up Fear

Fear has well-documented effects on our ability to think clearly and make rational decisions. Fear is processed in the limbic system—the reptilian part of our brain that is prioritized for survival. Activating fear around the world, 2020's media coverage played sensationalized stories under the mantra, "if it bleeds, it reads." While the corporate media showed us freezers and body bags in hospital parking lots, New Yorkers clapping for frontline hospital workers and daily death tolls, there was no emphasis on the fact that the vast majority of people who got COVID-19 survived.

The general public may not know that deaths were attributed to COVID-19 in ways that deviated from previous medical guidelines for filling out death certificates.[32] Clinicians were instructed to put COVID-19 on the top line of the death certificate, even if the only manifestation of COVID illness was a positive test (or even if COVID was only "suspected").[33] As discussed in the next section, the PCR tests that are used—intended for laboratory research, not clinical use—have high false positive rates.

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IV. Coronaviruses: Some Scientific Background

Viruses—friends, foes or both?

There are two main branches of our immune system, which is incredibly complex with lots of redundant protective mechanisms. In childhood, exposure to germs helps develop both the innate immune system, which is a non-specific early response defense, and adaptive immunity, which is more specific and associated with long-term immunity. With their laser focus on vaccinating our way out of the pandemic, health officials overlooked many measures to strengthen the innate immune system.

Viruses have helped shape our genome for millennia. Viruses are ubiquitous, meaning that they are everywhere in our environment. In children, exposure to viruses is crucial to modulate a healthy immune system. Assuming we or our children can avoid viruses is a fool's errand.

In fact, evolutionary biology teaches us that we have a mutualistic, symbiotic relationship with viruses, meaning we actually depend on living with viruses. In many cases, viruses do good things for us.

Helpful Viruses

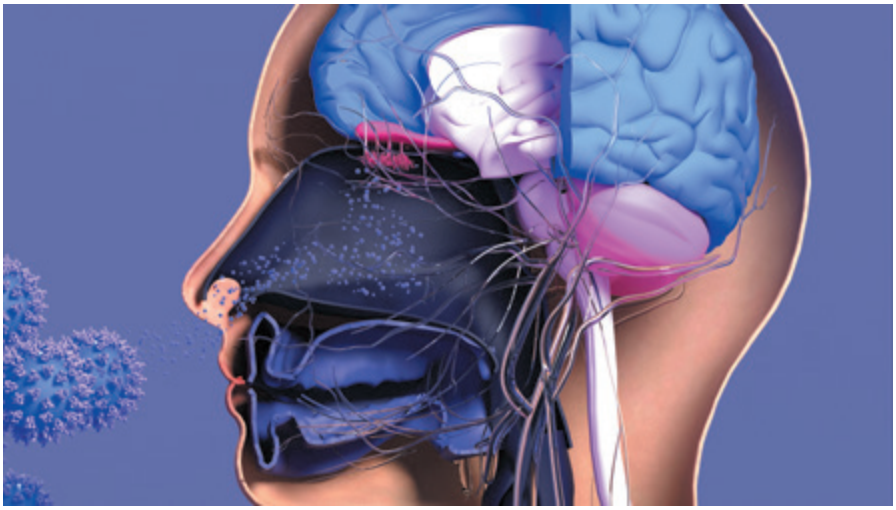
A 2011 article published in *Nature Reviews Microbiology* outlined some of the benefits of viruses for humans and other mammals:

- Endogenous retroviruses are abundant in many genomes of higher eukaryotes (organisms with a clearly defined nucleus); in placental mammals, viruses have been involved in the evolution of their hosts.
- Some mammalian viruses can protect their hosts from infection by related viruses or from disease caused by completely unrelated pathogens.
- Viruses can also protect their hosts by killing off competitors, as is seen with the killer viruses in yeasts.

Source:

Roossinck MJ. The good viruses: viral mutualistic symbioses. *Nat Rev Microbiol.* 2011;9(2):99-108. web.gps.caltech.edu/classes/ge246/roossinck_natrev2011_goodvi.pdf

The queen of aces—ACE2 receptors made simple



Early on in the pandemic, we discovered that the main target of COVID was the ACE2 (angiotensin-converting enzyme 2) receptor. ACE2 receptors are widely expressed in blood vessels, heart, lung, kidney, brain, gut and testis. ACEs play a huge role in regulating blood pressure by controlling the volume of fluids in the body.

ACE receptors facilitate three strains of coronavirus entering into the cell: the original SARS coronavirus from 2003; NL63 (a species of coronavirus identified in 2004); and SARS-CoV-2 from 2019.

The fact that ACE2 receptors are widely distributed in multiple tissues in our body leaves many organ systems vulnerable to SARS-CoV-2's destructive effects. When in the nose, ACE2 receptors can be thought of as points of entry for the virus; when in the lungs, they are part of the inflammatory process and—when in the brain, kidney or heart—they are part of the clotting pathology.

Italian researchers pointed out in June 2020 that having enough healthy ACE2 receptors limits detrimental effects such as blood clots, chronic inflammation or restricted oxygen flow to the heart or brain, but SARS-CoV-2 infection down-regulates (decreases the availability of) ACE2 receptors.[34] This explains why COVID patients are more likely to have inflammation (especially in the lungs) and abnormal clotting. Moreover, people who are at most risk of complications from COVID-19—those with diabetes, obesity or heart disease—may be low in ACE2 receptors to begin with.

Knowledge of this physiology was what led the doctors who ultimately formed the FLCCC Alliance to develop successful multifaceted treatment approaches, including protocols for use in high-risk patients. The group's protocols emphasize anti-inflammatories and blood thinners.[35] Their research was available as early as May and June of 2020, but there was significant institutional pushback against their recommendations.

What is really interesting and important about ACE2 receptors in kids is their relatively low rate of infection, perhaps related to the lower number of ACE2 receptors in children's noses. As the pandemic was unfolding in spring 2020, a very clever group of researchers decided to repurpose some nasal epithelial samples they had collected from an earlier asthma study from 2015-2018. Because the nose is one of the first sites of SARS-CoV-2 infection and because ACE2 receptors were known to be a point of entry for the virus, these investigators reasoned that it might make sense to examine their leftover nasal epithelial tissue for expression of ACE2.[36] Such actions restore our faith in science and make us wish these researchers were the ones on the evening news. This is what they found: Older people had more nasal expression of ACE2

than young children in the 4-9 age group. Furthermore, ACE2 expression was higher with each successive age group. Could this be part of the reason kids seem less likely to "catch" COVID-19?

What is a cytokine storm?

Many people have heard stories about patients who had minor COVID-19 symptoms for five to seven days and then crashed and had to be admitted to the hospital. If their condition deteriorated so much that they had to be intubated, their prognosis was very poor. These were the tragic stories that made the evening news. However, though there have been children who got very sick and died, the vast majority of those children were already chronically ill with conditions like leukemia or chronic kidney disease. Most children do not suffer such dire consequences.

Individuals who get very sick with COVID usually have several core problems: low oxygen, high inflammation and increased blood clotting. Successful treatments typically include combination medications that may function synergistically, meaning the drugs work better together than one would expect by merely adding up the anticipated benefits of each individual medication.

Cytokines are chemical messengers from the immune system. They have names like "tumor necrosis factor alpha," "interleukin 10" and "interferon gamma," to name just a few of at least 11 cytokines active in COVID-19. This phenomenon, called a "cytokine storm," means that lots of pro-inflammatory messengers become active in ways that cause problems for the patient. A thoughtful analysis published in June 2020 stated, "Early control of the cytokine storm through therapies, such as immunomodulators and cytokine antagonists, is essential to improve the survival rate of patients with COVID-19."[37]

For pediatric patients, the good news is that we have lots of ways to prevent cytokine storms and hyperinflammation. From our perspective, these interventions should start early since prevention is the hallmark of pediatric practice at its best.

PCR 101

The polymerase chain reaction (PCR) method was invented in 1983 by American biochemist Kary Mullis. PCR technology takes an infinitesimally small amount of biological material and multiplies it so that it can be studied.

According to Mullis, the PCR method was never intended to be used for diagnosing illness. And we now know that the vast majority of people who tested "positive" for COVID by PCR test had a false-positive test. So, did we really have a pandemic or did we have an epidemic of false-positive tests—with drastic consequences?

To put it simply, since PCR amplifies genetic matter from a virus, the fewer cycles required to demonstrate a viral footprint, the higher the viral load. Patients with large amounts of virus are likely more infectious than patients with small viral loads. For a given patient, doctors would find it useful to know how many replications (called the "cycle threshold") it took to make the patient's test turn positive; if just a few cycles, the patient is likely to be more infectious, and more aggressive management and containment strategies

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might be indicated. But if a test turns positive after 40-45 cycles, it is likely picking up viral debris of no clinical consequence.

A review by the *New York Times* looked at three sets of testing data that included cycle thresholds and concluded that up to 90% of people who tested positive "carried barely any virus."[38] If we were forensic scientists looking for evidence that the virus was at the scene of a crime, we might want an ultrasensitive test that would not miss any fragments of the virus, living or dead. But as clinicians, we want a test that gives some indication of how much virus the patient is carrying—and despite being over a year into this lunacy, we still cannot get that information.

Several months into the pandemic, a pediatrician attended a virtual webinar with the local health department director and other community doctors. She asked what cycle thresholds were being used in the local community testing centers. The health department director could not tell her. A pathologist on the call said he thought we might never know, as the information might be considered proprietary. In spring of 2021, a national lab emailed a notice that they had the "best, most accurate" PCR testing. "Aha," that doctor thought, "I can find out what cycle thresholds they are using." After waiting through a phone tree to get to the office of the company's medical director, she was told that they could not tell her. She made the case that, as a clinician, it was important to know if a patient's test was positive at 15-17 cycles (likely a high viral load) or not until 40-45 cycles (likely not truly infected and not a threat to the community). Her pleas fell on deaf ears.

Many people who tested positive at high cycle numbers—including children—probably had only dead fragments or protein sequences identified and were not a threat to their communities. Nevertheless, the outpatient protocols for handling PCR-positive tests often derailed children from being able to attend school. They also kept adults who felt well from working, which complied with quarantine guidelines but may have put some people at risk for being fired.

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V. Impact of COVID Restrictions on Children

Unscientific recommendations

It is understandable that, early in 2020, it was difficult to know what to recommend or what citizens should do. However, scientific evidence has now accumulated. At this juncture, it is reasonable to evaluate our COVID pandemic response and expect more from our public health officials. For over a year, unfortunately, public health recommendations have lagged far behind the published science. Messages from the CDC have changed frequently, sometimes been internally contradictory and confused many citizens.

Lockdown impacts on diet and exercise

Processed foods are pro-inflammatory and should have been avoided during the pandemic. Unfortunately, because the entire population was being fed a steady media diet of fear, people turned to "comfort foods" to cope. Locking down also led many families to rely more on cheap and processed foods. Even one fast-food meal is associated with significant elevations in pro-inflammatory cytokines.[39] Because SARS-COV-2 is marked by the potential for abnormal cytokine responses, it would make sense not to stoke the fires of inflammation with pro-inflammatory foods. Fast food also impairs the adaptive immune system, lowering host defenses against viruses.[40]

In kids, the combination of 24/7 access to processed foods, decreased exercise and lack of peer relationships was associated with significant weight gain. Documenting increased consumption of soft drinks, simple carbohydrates and sweet and salty snacks, German researchers found that body weight had increased

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significantly in 10- to 12-year-olds, with 24% of boys affected and 13% of girls.[41] The health benefits of exercise were also curtailed as children were kept inside by anxious parents during the height of the COVID pandemic. The German researchers found that physical activity declined in 38% of all children and in 60% of children aged 10 years and older.

Loss of interactive play

The essence of early childhood development is unstructured play. On the playground, children learn how to negotiate their role in the group and nurture their imaginations. The question that many have been asking since early 2020 is whether the trade-off of sacrificing interactive play in the name of avoiding a respiratory virus is worth it.

If kids were a major source of infection to others, one might argue that the sacrifices of staying inside for a year and being told "not to share" were worth it to protect vulnerable groups like the elderly or the chronically ill. But the data we will examine in more detail show that kids have largely not been responsible for transmitting COVID infections.

The risk of transmitting COVID outside also turns out to be miniscule.[42] Unfortunately, many parents took social distancing very seriously and limited kids from playing outside in parks and playgrounds unless they could maintain six feet of separation.

Germ overkill

Kids were indoctrinated during COVID to wash their hands frequently to get rid of "bad germs." The "Happy Birthday" song was even repurposed as a timer for effective hand washing. Well-meaning parents deployed hand sanitizers widely to protect their children from what was perceived as a deadly virus.

Summarized as the "hygiene hypothesis," decades of evidence have demonstrated that children who play in the dirt and are exposed to animal licking are healthier than kids who grow up in overly sterilized environments.[43] The value of exposure to nature and animals for modulating a healthy immune system in childhood has been confirmed by evidence from multiple cultures.

Exposure to dirt and animals plays a particularly important role in preventing autoimmune disorders, which have risen dramatically in the past several decades. In fact, pathogenic viruses, bacteria and parasites have strong protective effects for autoimmune diseases like type 1 diabetes, Hashimoto's thyroiditis and celiac disease.[44]

Responding to this body of evidence, pediatricians are beginning to use probiotics to help children develop good gut flora, especially if the child has been treated with lots of antibiotics or was delivered by C-section and, therefore, was not exposed to the mother's beneficial vaginal flora during childbirth.

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Educational fallout

As schools closed their doors to in-person learning, online approaches were employed for age groups developmentally unable to master the technologies being utilized. Elementary-school-aged children do not have the developmental skills to thrive with computerized distance learning. Most teachers now report that their virtual students have learned less than half of the expected academic content compared to in-class learning.

The results of a study that polled teachers, students, parents and policy-makers from multiple countries revealed numerous adverse effects of lockdowns on education, including learning disruptions, decreased access to education and increased student debt.[45] Poor infrastructure (such as limited network access, poor digital skills and power outages) also hampered the switch from in-person learning to online classes.

Mental health consequences

Lack of personal contact with peers can have a devastating mental health impact on adolescents. Suicide attempts began rising as early as February 2020 and, by March, were double the same month of the previous year. Comparing spring 2020 to spring 2019, obsessive-compulsive disorder (OCD) in adolescents also nearly doubled, and depression or anxiety increased fourfold.[46] Suicide attempts in youth stayed elevated through the summer.[47]

Younger children—with their limited ability to understand infectious diseases and medical complications—dealt with a wide variety of fears directly related to the coronavirus. Children have such vivid imaginations that they often envision scenarios that are worse than the reality. At the same time, children had to cope with difficult real-world situations such as being unable to visit grandparents who were sick in the hospital. And for children who lost loved ones, the bereavement experience was often very different from typical cultural grieving practices.

During times of economic instability, and especially when parents have lost their jobs, rates of domestic violence and child abuse increase.[48] The economic fallout from COVID-19 lockdown measures has been no exception. When parents are under severe stress, it is hard to parent effectively and consistently. Removing children from imaginative play with their peers and from the normalizing experience of interacting at school with teachers and classmates also exacerbated children's stress and diminished their coping mechanisms.

Unnecessary School Closures

When COVID-19 emerged in the winter of 2019-2020, schools were rapidly closed in mainland China and Hong Kong. However, an analysis of data from China, Hong Kong and Singapore concluded, "school closures did not contribute to the control of the epidemic." At best, these investigators continued, "Recent modelling studies of COVID-19 predict that school closures alone would prevent only 2–4% of deaths."

Source:

Viner RM, Russell SJ, Croker H, et al. School closure and management practices during coronavirus outbreaks including COVID-19: a rapid systematic review. *Lancet Child Adolesc Health*. 2020;4(5):397-404.

The downside of masks in childhood

Children's Health Defense has reviewed the scientific literature about the effectiveness of masks in preventing transmission of SARS-CoV-2; we conclude there is no consistent, unbiased and credible

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evidence that masks work to prevent transmission in community settings. As advocates for children's health and well-being, we are concerned that mandating masks in school or community settings has adverse impacts on children's social and emotional development.

During the COVID crisis, educators and psychiatrists have raised concerns that "covering the lower half of the face reduces the ability to communicate, interpret, and mimic the expressions of those with whom we interact," noting that "Positive emotions become less recognizable, and negative emotions are amplified."[49] These experts also point out that masking reduces "emotional mimicry, contagion, and emotionality," affecting "bonding between teachers and learners, group cohesion, and learning." The mask-related amplification of negative emotions comes on top of the 24/7 cycle of bad news that has ramped up children's fears and activated the amygdala. When children are afraid, they are even more prone to misinterpret benign events as threatening, making it more likely they will flee or fight.

A whole series of social-emotional milestones are an integral part of childhood development. In infancy and early childhood, being able to recognize and interpret the facial expressions of others is one of the most crucial developmental tasks. Pediatricians watch for the development of a social smile between six and 10 weeks of age as an early marker of normal bonding and social interaction.

Two decades ago, a study of 120 school-aged children (ages 5-10 years) sought to determine how

visual spatial parameters of facial expression develop in relationship to pathways of emotional language.[50] The researchers concluded that "Emotion cognition is a variegated domain" and is complex. We do not know the extent to which covering the lower half of the face is confusing for preschool and elementary school-age children.

A large body of research has confirmed that children are able to match expressions of joy, sadness, surprise and anger with varying degrees of accuracy. However, child development experts have discovered that children match happy expressions with fewer errors than when they attempt to match surprised or angry faces, suggesting that a "levels-of-processing effect is...operating in young children's discrimination and categorization of facial expressions."[51] Again, we do not know the extent to which exposure to less visual and auditory input from masked faces will affect children's ability to "read" faces and decipher or remember emotional content.

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VI. Putting Pediatric SARS-CoV-2 in Perspective

One-size-fits-all rarely works

It is ironic that at a time when we are able to customize chemotherapy to the genome of particular tumors, and functional and integrative medicine are gaining traction in their strategies to evaluate patients individually, the world is being asked to accept one-size-fits-all COVID injections that were initially studied only in extremely healthy adults. In fact, people with comorbid conditions, patients with autoimmune disease and pregnant and breastfeeding women were specifically excluded from the initial clinical trials.

One-size-fits-all public health measures are both illogical and harmful. Most pediatric patients have robust innate immune systems, meaning that they have strong defenses to a variety of viruses. In contrast, many older people experience immunosenescence as they age, meaning they are more vulnerable to a variety of viral, bacterial and fungal infections.[52]

COVID in kids is different from COVID in the elderly

Within a few months of COVID-19 hitting our shores, we knew that risks were stratified according to age and underlying risk factors. Healthy people under age 50 were likely to experience COVID-19 in the same way as other coronaviruses—like a bad head cold or a flu that caused symptoms for less than a week. The elderly, in contrast—especially if they had underlying health problems like obesity, diabetes or chronic problems with their lungs, heart or kidneys—were more likely to get very sick or die. Even so, survival rates in the elderly remain 97% or better through age 79, falling to about 92% only for those age 80 and above.[53]

One-size-fits-all public health measures are both illogical and harmful.

Since the beginning of the pandemic, children and adolescents, in the absence of underlying obesity, diabetes or serious chronic illness, have faced risks that are vanishingly small.[54] As mentioned, the chance of a child less than 17 years of age dying from COVID-19 is 0.002% according to the CDC's most recent estimate.[55]

A seven-country analysis (France, Germany, Italy, South Korea, Spain, United Kingdom and the United States) found that the COVID death rate in children was 1.7 per million; across the seven countries, as of February 2021, COVID-19 deaths in children comprised 0.48% of total mortality from all causes in a normal year.[56] Those cold, hard numbers may help parents put in perspective the true risks facing children and adolescents as they make COVID vaccine decisions.

Take risks to protect others?

Pediatricians are used to giving vaccines, and most have the mindset that if a vaccine has been developed, they should give it if it seems safe. In this instance, however, pharmaceutical companies and public health officials are claiming it is crucial to immunize kids against COVID-19 not primarily for children's own protection but to achieve "herd immunity" and protect the vulnerable.

There is a fundamental ethical argument against asking children and adolescents to take health risks to protect others.[57] Not only do all vaccines have potential adverse outcomes, but with COVID vaccines that utilize new technology—vaccines that have been studied for months, not years—the long-term risks are totally unknown. If these vaccines can trigger myocarditis, infertility or autoimmune diseases—as injury reports and published papers already suggest—they have the potential to change the trajectory of young people's lives, all in the unproven hope of "protecting the elderly and infirm."[58-60]

With other viral illnesses like influenza and measles, children are often viewed as major spreaders of infection. That does ***not*** seem to be the case with SARS-CoV-2, with multiple strands of data suggesting that "children are not significant drivers of the COVID-19 pandemic."[58] As early as June 2020, the evidence that children were unlikely to be "major transmitters" had already accumulated; during contact tracing in China, for example, the WHO identified zero episodes where COVID transmission went from child to adult.[59] In a subsequent multicountry analysis of studies that described "household transmission clusters," only three cases were identified in which the child was the index case, and in all three cases, the child had symptoms.[60] Another detailed analysis of 107 pediatric index cases and their household contacts showed definitive evidence of only one instance of onward transmission from a teenager.[61]

In January 2021, two University of Vermont physicians thoughtfully looked back at COVID-19 household contact studies involving children, considering symptoms, infection rates and transmission dynamics.[62] (Only 33 of the households they analyzed included children, so the small sample size merits caution in drawing conclusions.) They found that having a parent sick with COVID was a clear risk factor for the child, but not the other way around. The overwhelming majority of children who got sick exhibited mild symptoms.

"Unlikely to Be Caused by SARS-CoV-2"

A study published in July 2021 retrospectively examined nine months of records for 117 pediatric patients (< age 18) hospitalized "with COVID" (that is, young patients with a positive PCR test result). The researchers assessed severity of illness (asymptomatic, mild to moderate, severe or critical) and also whether the hospitalization was likely or unlikely to have been caused by SARS-CoV-2. They found that nearly four in 10 (39.3%) children had no COVID-19 symptoms, and they categorized nearly half (45%) of the admissions as "unlikely to be caused by SARS-CoV-2." The investigators delicately concluded that diagnostic records based purely on positive PCR test results may overestimate pediatric SARS-CoV-2 hospitalizations.

Sources:

Kushner LE, Schroeder AR, Kim J, et al. "For COVID" or "with COVID": classification of SARS-CoV-2 hospitalizations in children. *Hosp Pediatr*. 2021;11(8):e151-e156.

Several recent meta-analyses suggest that children overall are less susceptible to infection than adults, especially if they are under 10-12 years of age. The odds ratio for infection in children aged 5-12 versus adolescents aged 13-18 is 0.36, meaning that teens are three times more likely to get infected than elementary school children.[63] These data suggest that approaches should be tailored based on age.

Children's return to child care, school and summer camps has generated data that continue to point to a very low prevalence of outbreaks in such settings. This has been confirmed in studies in Australia,[64] France,[65] Germany,[66] Ireland,[67] Singapore,[68] and Rhode Island in the U.S.[69] In communities with widespread transmission of the COVID virus, adults are nearly always responsible for the spread in child care settings.

There are two take-home messages from this body of research. First, current data in the aggregate show that children have reduced susceptibility and infectivity compared to adults. Second, younger children and older teens have different profiles with regard to susceptibility and infectivity and should be treated differently when deciding about mitigation strategies.[70]

Protective mechanisms

There are a number of possible mechanisms that may be protecting our young children from infection with SARS-CoV-2. First, coronaviruses are already responsible for 15% to 30% of seasonal upper respiratory infections. Several lines of research suggest that the frequent exposure to similar coronaviruses may induce some effective immunity in children (and perhaps pediatricians and elementary school teachers). In one study, researchers found SARS-CoV-2 reactive antibodies, predominantly IgG, in patients who did not have COVID-19, and more so in children and adolescents than in adults; the antibodies targeted the S2 subunit of the spike protein.[71]

T-cell responses are exquisitely orchestrated immune responses that are part of the adaptive immune system and, therefore, important in the development of long-term immunity. Do T cells

play a big role in protective immunity against SARS-CoV-2? Again, several lines of research suggest yes. Germany-based researchers found S-reactive CD4 T cells in 83% of COVID-19 patients but also in 35% of healthy blood donors who were SARS-CoV-2-unexposed.[72] In another important paper published in *Nature*, researchers in Singapore studied T cell responses to the nucleocapsid protein (NP) and other regions of SARS-CoV-2 in patients with COVID-19.[73] In 23 patients who had previously recovered from severe acute respiratory virus (SARS), the Singapore research

group showed that 17 years after the 2003 SARS outbreak, SARS-recovered patients "still possess[ed] long-lasting memory T cells reactive to SARS-NP, which displayed robust cross-reactivity to SARS-CoV-2 NP."[74]

Let that sink in for a minute—if you were one of those 23 patients who had SARS back in 2003, you still have robust immunity today. Furthermore, you have memory T cells that cross-react to the current SARS-CoV-2 virus! The take-home message is that childhood exposure to certain coronaviruses is likely to induce strong and long-lasting immunity to the nucleocapsid protein that, in turn, is likely to protect your child from serious problems from COVID-19. We wish every official tasked with making COVID vaccine recommendations for young children—and parents trying to make vaccine decisions for or with their kids—knew about the results of this research.

VII. COVID Vaccine Risks

Novel vaccine technology plays out in real life

Traditional vaccines inject a small portion of a dead bacterium or an attenuated (meaning reduced in force) virus into a healthy child or adolescent to prompt the body to mount an immune response. The concept is this: When your child encounters that infectious agent in the future, he or she will have antibodies to fight the infection and will not get very sick.

The current "vaccines" for SARS-CoV-2 work very differently (see Figure 1). In the injections that use synthetic (meaning made by a chemical process to imitate a natural substance) mRNA (messenger ribonucleic acid involved in the code of life), the mRNA directs our cells to make a protein. In this case, cells are told to make the spike protein that is on the outer membrane of SARS-CoV-2. The theory is that our bodies will recognize the spike protein, make an effective immune response and keep us from getting very sick. In the COVID injections that use a common cold "viral vector" called an adenovirus instead of mRNA, the adenovirus transports genetic instructions into the cells and again, tells the cells to make the SARS-CoV-2 spike protein.

Figure 1. How the mRNA COVID Vaccines Work

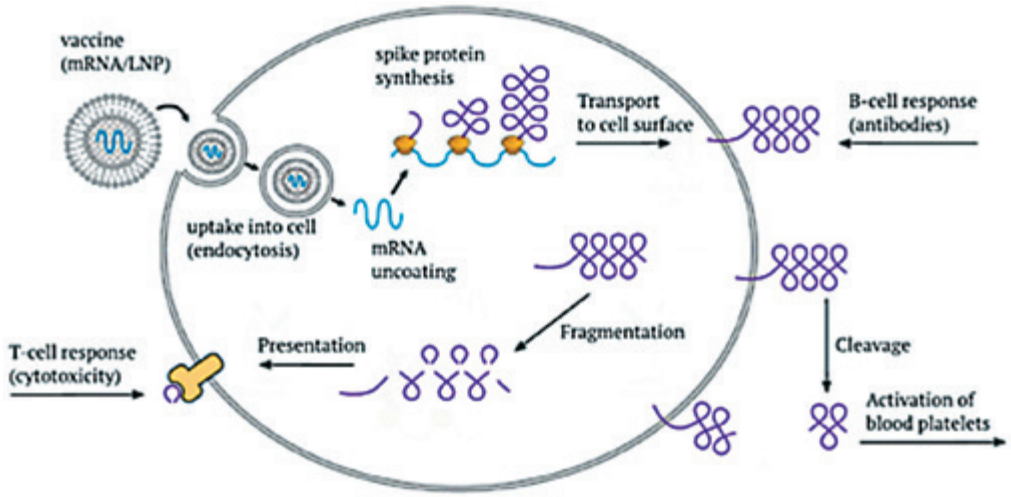

Image courtesy Michael Palmer, MD

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The new mRNA vaccines introduce several layers of complexity into the process of mounting an immune response. A delightful PhD pharmacologist from the United Kingdom, Dr. Mike Yeadon, who used to be a vice president at Pfizer, has explained this complexity using an "Apollo rocket" analogy. Describing the multiple steps involved, Dr. Yeadon states that first, the synthetic mRNA (wrapped in a synthetic fatty layer) must get into human cells. Second, it must direct the cell to make copies of the spike protein. Then, the immune system has to make a measured and appropriate response.

What could possibly go wrong? As Yeadon explains it, "Each step along the way is subject to individual variation" in the way the person responds. Some people will not respond with adequate immunity; some may make just enough spike

Small COVID Risk, Big Vaccine Consequences: A Real-Life Example

If a teenage basketball player has a vanishingly small risk of dying from COVID but is pressured to take a COVID shot so that he can play in a basketball tournament in another state, the adults in charge of vaccine policy need to make very sure that the risks are worth it. "Rare" side effects can change the trajectory of young people's lives.

Everest Romney was a 6-foot 9-inch basketball player, 17 years old, who did not want to get a COVID shot. He felt sure he must have had COVID already, even though he had no symptoms, because so many of his friends had had the illness when he was around them. However, it appeared that he would need proof of COVID vaccination to play in summer tournaments. His parents considered the options and encouraged him to "get the shot over with," a decision that now fills them with remorse and guilt.

The day of his COVID shot, Everest did not feel well. He developed a headache and swollen neck glands, and by day five, had a fever and could not move his head. By day eight, with no relief from his severe headache, he went to the emergency room. A CT scan showed blood clots in his brain, known to be associated with the COVID vaccines and predicted by independent scientists even before the vaccines' rollout. He spent three days in the intensive care unit and five more days in the hospital.

Everest faces a long recovery. He has orthostatic hypotension, meaning that his blood pressure drops when he stands up; he falls down multiple times a day. He also has blurry vision, so he cannot see the basketball hoop well. He has to take blood thinners and sleep with his head elevated 30 degrees. He is banned from contact sports. His childhood dream of playing college basketball, for which he trained four to six hours a day, six to seven days a week for years, is in great peril, particularly since this is his junior year of high school, when college scouts look for promising new players. He will likely be on the bench.

If you think this story could not get any worse, you would be wrong. It turns out that Everest *had* already had COVID, as he suspected. Hospital lab tests showed that Everest had nucleocapsid antibodies and an IgM immune response to SARS-CoV-2, meaning that he had an asymptomatic COVID infection in the weeks before his COVID shot. It was not necessary for him to take the vaccine. Our best evidence to date indicates that he likely would have had long-lasting natural immunity. We know that survivors of the 1918 flu epidemic have robust immunity even nine decades later. We also know that survivors of the first SARS virus (from 2003) have robust immunity 17 years later, with this immunity expected to persist for some unknown number of years into the future.

Everest was a healthy athlete when he got COVID. His complex immune response, honed over years of evolution (or created by a higher power, depending on your perspective), would have beaten an immune response generated by Pfizer's mRNA jab every time.

Sources:

Redshaw M. Teen hospitalized with blood clots in brain after first dose of Pfizer vaccine. *The Defender,* May 10, 2021. https://childrenshealthdefense.org/defender/teen-hospitalized-brain-blood-clots-after-pfizer-vaccine/

Children's Health Defense. Before COVID vaccine, her son was a healthy athlete — now he can "barely walk," mom says. *The Defender,* May 26, 2021. https://childrenshealthdefense.org/defender/rfk-jr-the-defender-podcast-cherie-romney-17-year-old-pfizer-vaccine-blood-clots/

protein and just enough of an adequate immune response; and some people predictably will express high amounts of spike protein.

In biology, many phenomena occur in the shape of a Bell curve—meaning that most cluster in the middle—but there are always "outliers" on both ends of the curve. There are many examples of this. Growth curves, where most kids are in the middle but a few are fat or skinny, are one example. Another is medications, when most people get better but a few have a bad side effect and some do not respond as predicted. With the novel COVID vaccine technologies that have come into use on an experimental basis, Yeadon cautions, there will be outliers on each side of the expected response.

When it comes to the health and safety of our children, even a small risk may not be worth taking if the potential consequences include serious or fatal short-term outcomes or life-long health and financial consequences. A small risk may also not be worth taking if it is more than the risk of the disease itself.

We cannot find any evidence that pharmaceutical products can outperform Mother Nature in complexity, redundancy and efficacy of immune responses. Yet never before has natural immunity been so completely denigrated in favor of "vaccine-induced" immunity. Have you heard Dr. Fauci say that people who had COVID (the disease) should get the shots anyway? Have you seen the CDC website recommend that everyone get the shot, even if they have recovered from COVID? Have you seen the story about the nurses at Houston Methodist Hospital in Texas who got fired because they did not want to take the vaccine after they had recovered from COVID?

Binding and fusing: like space ship docking stations

Let's review the basics about viruses, SARS-CoV-2 and the COVID vaccines. Viruses are microscopic infectious particles consisting of RNA or DNA. They cannot survive independently. To reproduce, they must inject their genetic material into the cells of living creatures and effectively "hijack" the host cell for their own survival purposes.

When it comes to the "SARS-CoV-2" virus and its spike protein, we have all seen the pictures—a round ball with spikes all over—intended to strike fear into our hearts about an unseen enemy. Merriam-Webster defines a spike protein as a "glycoprotein [sugar protein] that protrudes from the envelope of some viruses (such as a coronavirus)." Spike proteins are now known to be major pathologic drivers of bad outcomes in COVID.[75]

To understand how SARS-CoV-2 and its spike protein interact with humans, think of a spaceship's docking station. The spike proteins fuse into the receptors on the membranes of host cells, allowing the virus to gain entry to the innards of the cell to use cellular metabolism to replicate. As explained by Dr. Stephanie Seneff, a Massachusetts Institute of Technology (MIT) scientist, the "spike protein, which facilitates both viral binding to a receptor (in the case of SARS-CoV-2 this is the ACE2 receptor) and virus fusion with the host cell membrane. The SARS-CoV-2 spike protein is the primary target for neutralizing antibodies."[76] Neutralizing antibodies are antibodies that are responsible for defending cells from pathogens.

We know that spike proteins have the ability to bind to receptors on

We cannot find any evidence that pharmaceutical products can outperform Mother Nature in complexity, redundancy and efficacy of immune responses. Yet never before has natural immunity been so completely denigrated in favor of "vaccine-induced" immunity.

multiple types of cells. We also know that there is extensive immune cross-reactivity between SARS-CoV-2 antibodies and many different groups of antigens (the molecules that stimulate an immune response). U.S. researchers reported in early 2021, "We found that SARS-CoV-2 antibodies had reactions with 28 out of 55 tissue antigens, representing a diversity of tissue groups that included barrier proteins, gastrointestinal, thyroid and neural tissues, and more."[77] These researchers showed similarities between spike (and other SARS-CoV-2 proteins) and more than half of the human tissue antigens tested—concluding that the "extensive immune cross-reactivity between SARS-CoV-2 antibodies and different antigen groups may play a role in the multi-system disease process of COVID-19, influence the severity of the disease, precipitate the onset of autoimmunity in susceptible subgroups, and potentially exacerbate autoimmunity in subjects that have pre-existing autoimmune diseases."[78]

What could possibly go wrong? The Goldilocks dilemma

mRNA injections work by incorporating the genetic blueprint for the key spike protein on the virus surface to instruct our cells to make that spike protein. In theory, the body will then make antibodies against the spike protein to protect against SARS-CoV-2 infection. To trick human cells into making the spike proteins, the synthetic mRNA is wrapped in a fatty layer of lipid nanoparticles. In what seems like a leap of faith, vaccine developers seem to be assuming that the cell will make just enough spike protein for vaccine recipients to develop adequate antibodies but not enough to cause harm.

Such an injection—one that is neither "too hot" (that is, not so much spike protein that it causes damage to the recipient) nor "too cold" (that is, not so weak that an immune response is not generated) but "just right" would need to be perfect enough to trick Mother Nature, who has undergone millennia of evolutionary progress resulting in complex, well-orchestrated biologic systems that we are only beginning to understand. What could possibly go wrong? Let us count the ways....

Bad news from Japan

Ideally, biodistribution studies would have been done in a variety of animals prior to unleashing the novel spike protein "vaccines" on healthy people on a global scale. Scientists in Japan showed that lipid particles from the "vaccines" penetrate the blood-brain barrier of rats within 15 minutes. A scientist in Canada, Dr. Byram Bridle, is on record explaining that biodistribution research obtained through the Japanese equivalent of a Freedom of Information Act (FOIA) request showed that the spike protein circulates in blood for at least two weeks and accumulates in the spleen, bone marrow, liver, adrenal glands and ovaries (see Figure 2).[79]

Figure 2. Transcytosis (Transport) of Lipoproteins from the Bloodstream into the Tissues

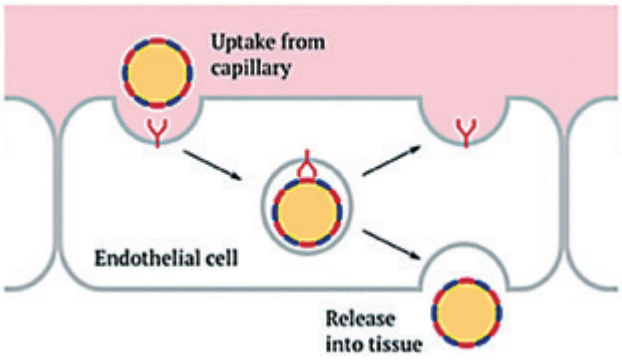


Image courtesy Michael Palmer, MD

What do we know about how antibodies generated in response to the novel COVID vaccines will behave? Thus far, not enough. However, the research on spike protein cross-reactivity with tissue antigens[80] suggests that vaccine spike proteins could cross-react with tissue proteins of the antibodies made in response to the spike protein, potentially leading to an increase in autoimmune disease (the hallmark of which is the body attacking its own tissues).

Short-term safety data, control group gone

Autoimmune diseases, already surging in prevalence in recent decades, take decades to present.[81] The initial clinical trials for COVID injections lasted only two months. Moreover, the comparison group for ongoing safety and efficacy studies has effectively been wiped out due to manufacturers' decision to offer the real mRNA injections to placebo recipients following FDA's emergency authorization. Nearly all Moderna (98%) and Pfizer (93%) placebo recipients elected to get the real jab. In one clinical trial site involving over 600 volunteers, all but "a couple" of placebo recipients "went ahead and got the actual vaccine" as soon as it was offered.[82] To clarify, this means we do not have a matched control group to compare outcomes for long-term unanticipated side effects.

Ordinarily, the body has molecular mechanisms to remove cellular debris. Vaccine makers and the CDC seem to be assuming that the cells will get rid of the broken-down genetic instructions carried in by the vaccine. But have adequate studies been done to show how that was achieved in the clinical trials or whether it is being achieved in the population at large now? No data have been made available to the public demonstrating the post-injection removal of cellular debris.

The synthetic mRNA in the injections gives instructions to our cells to make spike proteins, which have been shown to be toxic proteins responsible for most of the bad effects of SARS-CoV-2 infections. So, what happens to the spike proteins post-injection after we make the hoped-for antibody response? Evidence suggests that the spike protein antigen goes into the bloodstream and circulates throughout the body.[83] A group of scientists at Harvard published work in spring of 2021 showing that 11 of 13 recipients of Moderna's mRNA injections demonstrated spike antigen from the shots circulating in the blood within one day.[84] Spike proteins' propensity to bind to platelets and endothelial cells lining our blood vessels could explain the clotting and bleeding observed clinically and reported to the Vaccine Adverse Event Reporting System (VAERS) following COVID vaccination.[85]

Is the risk proportional to the threat in young people?

In a situation in which the disease itself poses very little risk to a healthy young person, the safety profile of any recommended vaccine should be exemplary. Instead, teens who receive the COVID jabs may be accumulating toxic proteins known to attach to critical ACE2 receptors—and known to be at the heart of COVID pathology—in their liver and spleen or, in the case of girls, accumulating lipid nanoparticles in the ovaries, or having a stroke from a blood clot or a cerebral hemorrhage.

How widespread are these outcomes in the population at large?

In a situation in which the disease itself poses very little risk to a healthy young person, the safety profile of any recommended vaccine should be exemplary. Instead, teens who receive the COVID jabs may be accumulating toxic proteins.

We do not know yet. In the coming months, we will find out whether the vaccines' supposedly "rare" side effects pose a threat greater than the infection itself. In the meantime, parents need to carefully evaluate risks versus benefits.

Fertility concerns

If you hope to have children or grandchildren, you need to know that many scientists and clinicians are worried about the potential effects on fertility of these experimental vaccines. Remember, the manufacturers did not study the injections in pregnant or breastfeeding women before rolling them out to the public—with accompanying bullying, bribery and bamboozling for everyone to "do their part" by taking the injection.

One reason that vaccine trials historically have taken a decade to conduct is to allow for assessment of the vaccines' effects on female and male fertility. Fertility outcomes simply cannot be assessed in trials that last merely months, as was the case for COVID vaccines before they were rolled out for public distribution. Children's Health Defense shares many experts' grave concerns about potential fertility problems that might not be evident for years, even as COVID injections are being recommended and mandated in younger and younger age groups.

Scientists with special expertise in lipid metabolism are particularly worried about the slow elimination from the mRNA injections of fatty molecules called cationic lipids. Cationic lipids are one of several lipids used to deliver the mRNA—and they are toxic. International doctors Sucharit Bhakdi, MD and Michael Palmer, MD, of the expert group Doctors for COVID Ethics, explain that in "persons repeatedly injected with mRNA vaccines containing these lipids—be they directed against COVID, or any other pathogen or disease—this would result in cumulative toxicity."[86] They add, "There is a real possibility that cationic lipids will accumulate in the ovaries," with an "implied grave risk to female fertility [that] demands the most urgent attention of the public and of the health authorities." Children's Health Defense urges readers to examine the numerous referenced documents posted on the Doctors for COVID Ethics website.[87]

Pregnancy loss

The mRNA vaccine trials specifically excluded pregnant and breastfeeding women, yet both mRNA vaccines are now recommended for pregnant and breastfeeding women.

Both the VAERS database in the U.S. and the European Union drug adverse events registry (called EudraVigilance) have received reports of menstrual abnormalities and spontaneous miscarriages after COVID injections, as well as fatalities in breastfed newborns shortly after their mothers received COVID injections. Unfortunately, a widely publicized CDC study that appeared in the *New England Journal of Medicine* on June 17, 2021 shows that medical journals are willing to publish highly misleading conclusions.[88]

To "characterize the initial safety" of the mRNA vaccines, the study (conducted from mid-December 2020 through February 2021) examined data from VAERS but also scrutinized data from 827 pregnant women enrolled in the CDC's smartphone-based v-safe COVID-19 Vaccine Pregnancy Registry.[89] The

majority of these women (n=700 or 84.6%) received their first dose of vaccine in the third trimester of pregnancy. If you were a busy doctor who only had time to read the study's abstract, the article's conclusion—that "Preliminary findings did not show obvious safety signals"—might have seemed reassuring. However, anyone who went on to read the fine print would have found, hidden in plain view, a strong signal of concern for pregnancy loss.

In the paper's Table 4 (titled "Pregnancy Loss and Neonatal Outcomes in Published Studies and V-safe Pregnancy Registry Participants," adapted and reproduced on this page), the authors report that 104 women experienced spontaneous abortions (miscarriages) at less than 20 weeks of pregnancy (that is, before the third trimester), with 96 of these occurring before 13 weeks of gestation. However, the authors' denominator of 827 includes the 700 pregnant women who received their first dose of COVID vaccine in the *third* trimester—women who could not possibly have had a miscarriage in their first 20 weeks of pregnancy.

This third-trimester group should have been subtracted from the denominator to calculate "spontaneous abortion <20 weeks." And if we consider pregnancy loss at less than 20 weeks for the appropriate group—the 127 pregnant women who were not in their third trimester—the numbers and warning signs are quite different. From the study's misleading reported rate of 12.6% (104/827), *the true spontaneous miscarriage rate becomes 82%* (104/127), which is significantly higher than the background rate of 10% to 26% for ordinary pregnancies.

For their VAERS analyses, the authors also note that of 221

"Pregnancy Loss and Neonatal Outcomes in Published Studies and V-safe Pregnancy Registry Participants" (adapted from Table 4 in *New England Journal of Medicine* pregnancy study)

Participant-Reported Outcome	V-safe Pregnancy Registry number/total number
Pregnancy loss among participants with a completed pregnancy	
Spontaneous abortion: < 20 weeks	104/827 (12.6%)
Stillbirth: > 20 weeks	1/725 (0.1%)
Neonatal outcome among live-born infants	
Preterm birth: < 37 weeks	60/636 (9.4%)
Small size for gestational age	23/724 (3.2%)
Congenital anomalies	16/724 (2.2%)
Neonatal death	0/724

pregnancy-related adverse events captured by VAERS, 21% (n=46) were spontaneous abortions. Another noteworthy finding (made little of by the authors, who dismiss it as compatible with the published incidence of 8% to 15%) is that nearly one in ten women (9.4%) with completed pregnancies who were vaccinated before 37 weeks experienced preterm birth.

Animal data on reproductive toxicity lacking

Pfizer tested its "vaccine" on only one animal species (rats) and on only 21 rat litters for assessment of reproductive toxicity. Pre-implantation loss of embryos was 9.77% in the vaccine group, compared to 4.09% in the control group.[90] The manufacturer should have done further studies on larger populations and other species to clarify the statistical significance of those findings.

Children's Health Defense is grateful for the efforts of Doctors for COVID Ethics in shining a light on the shortcomings of global public health responses to SARS-CoV-2 and elucidating the nuances of the science. In the above-referenced analysis of the Pfizer mRNA injection's toxicity and pharmacokinetics, Drs. Palmer and

Bhakdi share the following disturbing observations: "The observed pre-implantation loss indicates toxicity at a very early stage of development, either to the embryo or the nascent placenta. It might be caused by a high level of spike protein expression, but also by toxic lipids; and it might occur already within the ovaries, but also affect the fertilized egg or subsequent developmental stages within the Fallopian tubes or the uterus. This also applies to malformations, although these would more likely be caused by damage later on in embryonic development, suggesting transfer of toxicity across the placenta."[91]

Can COVID vaccines cause harm to breastfeeding infants?

Deaths associated with bleeding have been reported in several breastfeeding infants within days of their mothers receiving COVID vaccines. In their dissection of the mRNA vaccine's pharmacokinetics and toxicity, Drs. Palmer and Bhakdi dive into the pathophysiology to explain what could be dangerous. They describe two possible pathways of breastfeeding mother-to-child toxicity (see Figure 3): "Uptake of the vaccine by mammary gland cells opens two possible pathways of toxicity to the breastfed child: firstly, the expression of spike protein and its secretion into the breast milk, and secondly, the wholesale transfer of the vaccine into the milk."[92]

Palmer and Bhakdi also correctly point out that mammary glands are apocrine, meaning that they can pinch off and release fragments of their own cytoplasm into breast milk. Targeted studies of breastfeeding infants of COVID-vaccinated mothers are urgently needed to discover if fragments of vaccines or the spike proteins they instruct cells to manufacture pose a risk to the babies.

Unheeded warnings

One of the highly credible scientists who raised timely concerns about unanticipated effects of the artificially manufactured spike proteins was J. Patrick Whelan, MD, PhD.[93] Whelan submitted a document to the FDA prior to the December 10, 2020 meeting at which an FDA committee reviewed the Pfizer/BioNTech mRNA vaccine for emergency use authorization.[94] Whelan's training (at Harvard, Texas Children's Hospital and Baylor College of Medicine) and his degrees in biochemistry, medicine and rheumatology made him well qualified to raise the concerns he articulated.

Specifically, Whelan sought to alert the FDA about the potential for vaccines designed to create immunity to the SARS-CoV-2 spike protein to cause injuries. Whelan also described biologically plausible mechanisms whereby such harms could occur. In his comment, Whelan expressed

Figure 3. Two Possible Pathways for Vaccine Toxicity to Breastfed Infants

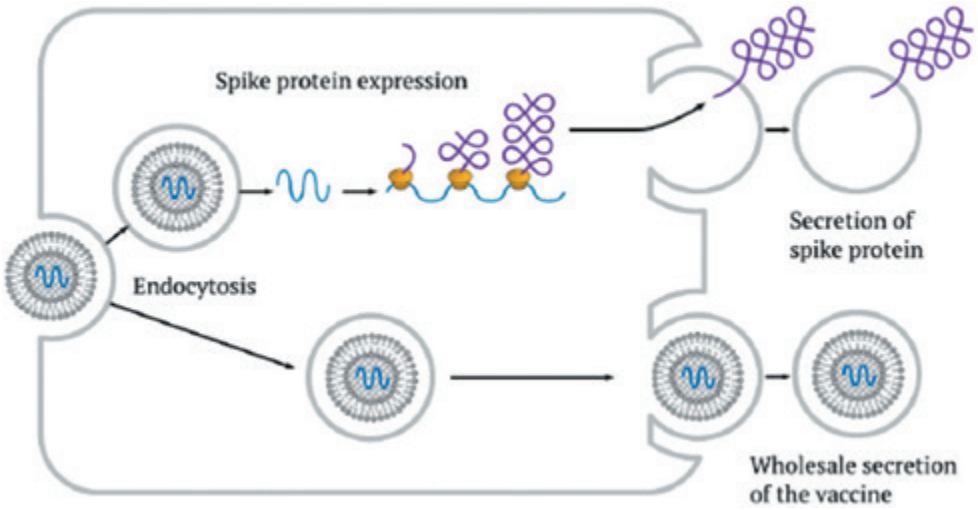


Image courtesy Michael Palmer, MD

concerns that the new mRNA vaccine technology used 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.[95] The point should have been well taken. Whelan also cautioned about the unforeseen consequences "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 these other organs." Unfortunately, the FDA relied on very limited clinical trial data collected in an unprecedented short time and went ahead and endorsed both the Pfizer and Moderna mRNA vaccines for emergency use in mid-December 2020.

Why was Whelan so 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 the widespread damage that sometimes occurs in organs beyond the lungs. Around the world, clinicians have seen evidence suggesting that the virus can cause heart inflammation, acute kidney disease, neurological malfunction, blood clots, intestinal damage and liver problems, and that the spike protein is the bad actor responsible for cardiovascular complications. In fact, COVID-19 is now widely accepted as being primarily a disease of the microvasculature with potentially systemic effects.

Spike protein production

A salient question is whether the virus is the main pathogen or whether it is the spike protein that causes the majority of the damage. If the spike protein is the major villain, have vaccine scientists now unleashed pathogenic proteins in cells without the means to adequately modulate their effects on human health? This question brings us full circle to what we have termed the "Goldilocks dilemma": Did vaccine makers—working at "Warp Speed" with billions of dollars on the line for the winners of the race—manage to create spike proteins that are neither "too hot" (reactive and damaging) nor "too cold" (unable to elicit an immune response) but "just right"? The odds seem stacked against outwitting Mother Nature and achieving this level of perfection.

Neurological clues from SARS-CoV-2

A discussion in *The Scientist* magazine in January 2021 noted that "Autopsy studies have yet to find clear evidence of destructive viral invasion into [COVID-19] patients' brains, pushing researchers to consider alternative explanations of how SARS-CoV-2 causes neurological symptoms."[96] When Boston researchers studied 18 COVID-19 patients with neurological symptoms who died in April 2020 while hospitalized,[97] they found "very low levels of viral RNA… in only five of eighteen patient brains"—a low RNA concentration that one of the researchers described as "out of proportion to the profound deficits that people are experiencing."[98] The researcher continued, "I'd be extremely surprised [if] the majority of cases where people are having neurological symptoms are due to direct viral invasion."[99]

In February 2021, researchers from the National Institute of Neurological Disorders and Stroke published a letter in the *New England Journal of Medicine* documenting microvascular injury but

No Additional Studies for Kids

The FDA allowed the Pfizer-BioNTech COVID-19 vaccine to be widely distributed to individuals age 16 and older without calling for the additional studies that Dr. J. Patrick Whelan felt were critical to assure safety, especially in children. Bearing in mind the low risk of long-term problems from COVID-19 to children and adolescents, Whelan was correct in insisting on a high safety bar for use of the new vaccine technology in the pediatric population. As this eBook goes to press, however, we anticipate the FDA will soon authorize the use of COVID vaccines in children even younger than age 12.

no evidence of virus in the brains of patients who died from COVID-19.[100] Using magnetic resonance microscopy, histopathological evaluation and immunohistochemical analysis, the researchers reported observing "multifocal microvascular injury…in the brain and olfactory bulbs …without evidence of viral infection."

If observed brain damage does not seem to be a direct effect of viral invasion, shouldn't we have lots of curiosity about the potential source(s) of such devastating pathology? The most likely culprit seems to be the COVID-19 spike protein released from the outer shell of the virus into circulation. Research has documented that the viral spike protein is able to initiate a cascade of events that triggers damage to distant organs in COVID-19 patients. Several studies have found that the spike proteins alone have the capacity to cause widespread injury throughout the body, without any evidence of virus.[101] What makes these scientific findings so disturbing is that the COVID-19 mRNA vaccines 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.

Crossing the blood-brain barrier

A few days after Whelan's warning letter to the FDA, *Nature Neuroscience* published a study showing that commercially obtained COVID-19 spike protein (particles called S1), when injected into mice, readily crossed the blood-brain barrier and were also found in the animals' lung, spleen, kidney and liver.[102] The researchers observed the S1 spike proteins in all 11 brain regions examined and in the parenchymal brain space (the brain's functional tissue). They acknowledged that such widespread entry into the brain could explain diverse neurological effects such as encephalitis, respiratory difficulties and the loss of the sense of smell. Can spike protein generated from COVID vaccines have similar effects? Reports of widespread adverse events are concerning.

Let's now return to the concerns voiced by Dr. Whelan in his prescient letter to the FDA: "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."[103] As Whelan pointed out to the FDA, the injections' potential to cause microvascular injury to the various organs *was not assessed* in the safety trials [emphasis added]. Moreover, participants who had various chronic conditions were *specifically excluded* from the trials (but then gleefully vaccinated following the EUA rollout).

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

More unintended consequences

In an important paper by Dr. Stephanie Seneff of MIT and coauthor Greg Nigh, the two authors point out that the SARS-CoV-2 spike protein is a type of protein called a "class I fusion glycoprotein"—proteins that mediate the fusion of host and viral

"May Be Induced by Spike Protein Alone"

A study published in December 2020 reported a direct negative impact of the SARS-CoV-2 spike proteins on endothelial cells, providing "a plausible explanation for the neurological consequences seen in COVID-19 patients." The researchers demonstrated that the spike protein binding target ACE2 is "ubiquitously expressed throughout various vessel calibers in the front cortex." In another investigation, researchers who examined brain tissues from 13 fatal COVID-19 cases concluded that ACE2 endothelial damage is a central part of SARS-CoV-2 pathology and may be induced *by spike protein alone* [emphasis added]. When, as part of the same study, the researchers injected full-length S1 spike subunit into the tail vein of mice, neurologic signs such as increased thirst and "stressed behavior" were the result.

Sources:

Buzhdygan TP, DeOre BJ, Baldwin-Leclair A, et al. The SARS-CoV-2 spike protein alters barrier function in 2D static and 3D microfluidic in-vitro models of the human blood-brain barrier. *Neurobiol Dis.* 2020;146:105131.

Nuovo GJ, Magro C, Shaffer T, et al. Endothelial cell damage is the central part of COVID-19 and a mouse model induced by injection of the S1 subunit of the spike protein. *Ann Diagn Pathol.* 2021;51:151682.

membranes—and is analogous to certain proteins produced by influenza and syncytial viruses and HIV.[104] A cautious scientist would pause to reflect on the lessons learned from influenza vaccination (such as the shots' low efficacy, year after year), disastrous attempts to develop syncytial vaccines (which resulted in infant deaths) and the four decades and counting in which vaccine scientists have failed to develop an effective HIV vaccine. Might some of these lessons apply to our current wrestling match with SARS-CoV-2?

Tweaking Mother Nature

Ordinarily, class I fusion proteins will rearrange from their pre-fusion native state into a post-fusion conformation. Seneff and Nigh note, however, that some COVID mRNA vaccine makers have "tweaked" the spike protein (changing certain amino acids) to encourage it to remain in a stable pre-fusion state. The two authors ask, "What might be the consequence of this? We don't know." They also point out that other COVID vaccine makers have changed other amino acid sequences with the aim of facilitating abundant spike protein production in the vaccinated. This may be a reasonable idea in theory, but again, what about unforeseen consequences? The old television commercial with the tagline "It's not nice to fool Mother Nature" comes to mind. Only time will tell whether these modifications to cellular machinery were brilliant innovations that worked well for most people or were instead the scientific equivalent of Icarus flying too close to the sun—with vaccine recipients being the ones to get burned.

Seneff's and Nigh's concerns about potential unintended consequences and side effects also extend to the evidence of "extensive sequence homology" (structural similarities) between the SARS-CoV-2 spike protein and various endogenous human proteins.[105] They state that these similarities "could prime the immune system toward development of both auto-inflammatory and autoimmune disease," diseases that "could present acutely and over relatively short time spans…or could potentially not manifest for months or years following exposure to the spike protein." That secondary exposure could come via natural exposure to SARS-CoV-2 or following booster doses of the vaccine.

Throwing Caution to the Wind?

Many thoughtful scientists—unencumbered by the bias of fortunes to be made—have grave concerns about the unintended consequences of making spike proteins that are homologous (similar in structure) with so many human tissues. Cautious scientists also worry about the unintended consequences of turning on cellular machinery in a novel way to make a protein that has been demonstrated to cause endothelial damage and widespread inflammation. Thus far, however, these men and women of integrity have not been able to reverse the momentum pushing populations to line up for "one-size-fits-all" gene manipulation vaccines.

Compare the scientific findings described in this eBook with the messages disseminated by the government and media in spring 2021. Dr. Anthony Fauci, for example, has repeatedly minimized safety concerns, stating that the risk of blood clots (now on the warning label for the Johnson & Johnson vaccine) is "less than one in a million," telling individuals who have recovered from COVID-19 that vaccine-induced immunity "is better than the response you get from natural infection" and stating that there should be more COVID vaccine mandates at the local level.

Have we thrown caution to the wind in a frenzy driven by fear, money and the leadership's desire for control? Have we permitted the creation of a Trojan horse—genetic instructions enclosed in a fatty, allergy-inducing vehicle—to make a dangerous spike protein that travels to people's most vulnerable organs? Have we forfeited our common sense and critical thinking skills in exchange for "permission" to hug our friends, fly on a plane or go to college? Have we planted the seeds of destruction in the majority who did not meet the criteria for study during COVID vaccine trials but are now being asked to roll up their sleeves for the "greater good"? It is certainly possible that Big Pharma has made a Big Mistake.

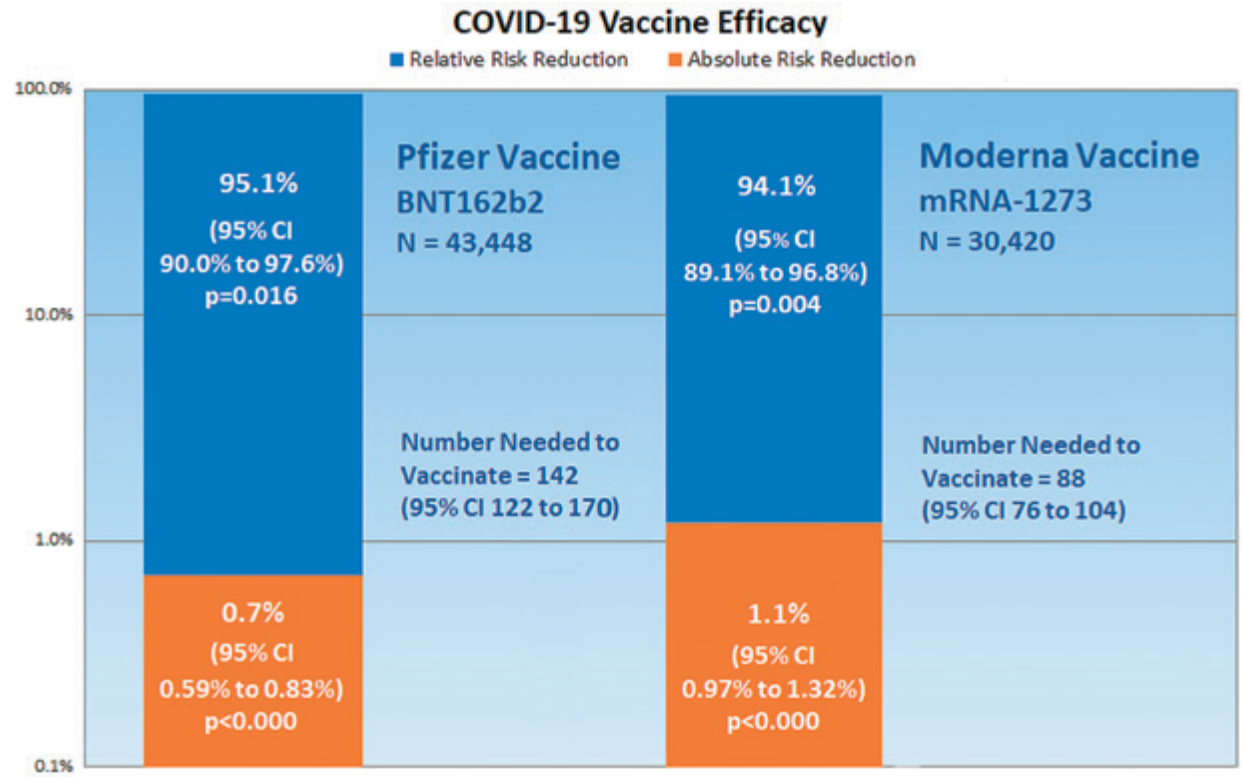
Big Pharma—tricking you with statistics

With experimental COVID "vaccines" already being aggressively marketed to 12- to 17-year-olds and rollout of the injections to even younger children on the horizon, parents must carefully analyze the risks of natural infection versus the risks of the new "vaccines." Among other factors, they should consider the crucial distinction between "absolute risk" (which is dependent on the background risk of infection in the population) and "relative risk" (which compares one group to another and is what the vaccine manufacturers are widely advertising). Relative risks "can exaggerate the perception of difference" between groups, especially, as in the case of COVID vaccines, "when the absolute risks are very small."[106]

Big Pharma recognizes that emphasizing relative risk sells drugs and vaccines, but absolute risk is the practical number that individuals who are weighing medical interventions are more likely to care about. Peter Doshi, an editor at *The BMJ* (formerly the *British Medical Journal*) and a researcher at the University of Maryland, put the efficacy numbers of Pfizer's mRNA injection into perspective in comments made to the FDA in June: "[T]he reported 100% efficacy in Pfizer's trial was based on 16 COVID cases in the placebo group versus none in the fully vaccinated group. But there were about 1,000 placebo recipients so just 2% got COVID. Put another way, 2% of the fully vaccinated avoided COVID, whereas 98% of the vaccinated wouldn't have gotten COVID anyway."[107]

Here is a chart (Figure 4) that explains the true risk reduction from mRNA vaccines. For a person who took the Pfizer vaccine in the clinical trial, they got the benefit of a 0.7% reduction in

Figure 4. Relative and Absolute Risk Reduction with mRNA COVID Vaccines



Source: Brown RB. Outcome reporting bias in COVID-19 mRNA vaccine clinical trials. Medicina. *2021;57(3):199. doi.org/10.3390/medicina57030199*

the overall risk of getting COVID compared to those who got the placebo.[108] Yes, you read that right—less than a 1% decrease in their absolute risk of getting COVID based on what was circulating at the time. Furthermore, the injection was shown to modestly decrease the severity of their symptoms if they did get COVID but was ***not*** shown to decrease the chance that they would transmit the disease to other people. So, the current spread of COVID illness by the vaccinated should not come as a shock—that truth was hiding in plain sight in the clinical trial data all the time.[109]

"Number needed to treat" is another concept worth explaining. Doctors make decisions about whether to prescribe medications based on the concept of how many patients they need to treat to meaningfully help one patient. In pediatrics, "number needed to treat" is important in making decisions about prescribing antibiotics in ear infections, for example. Most ear infections are caused by viruses, so antibiotics cannot kill the virus and are not indicated. In young children with lots of bad symptoms, however, it is more likely that a bacterium is the cause, so antibiotics can be helpful. But even in that situation, a pediatrician has to treat four children with antibiotics in order to really help one child.[110]

In the case of vaccines, we look at the "number needed to vaccinate" to prevent one case of the disease. For the Pfizer mRNA injection, the original clinical trial data show that the number needed to vaccinate to prevent one case of COVID is 142 (see Figure 4). For the Moderna shot, the number needed to vaccinate to prevent one case of COVID is 88. To put that number in context for children and adolescents, we would need to vaccinate between 88 and 142 kids to prevent one case of COVID. Given that the chance of surviving COVID in childhood is 99.998%, are the unknown risks of these novel injections worth taking for such statistically small advantages?

FDA approval process

On August 23, 2021, the FDA granted full approval to Pfizer's Comirnaty COVID-19 vaccine, but there is more than meets the eye to this approval.

Fist, despite the professed commitment to conduct ongoing clinical trials after the vaccine EUA rollout, Pfizer did not submit adequate follow-up data to FDA before the latter decided to award full approval. As Peter Doshi, PhD—senior editor at the journal *The BMJ*—pointed out in an extremely well-reasoned analysis published in *BMJ* the same day as the FDA's decision, "only half of trial participants (53%) made it to the four month mark, and mean follow-up is around 4.4 months."[111] Doshi continued, "By 13 March (data cut-off), 93% of trial participants…were unblinded, officially entering 'open-label followup.'" What this means, Doshi spells out, is that "only 7% of trial participants actually reached six months of blinded follow-up." In other words, there was inadequate follow-up to six months, and essentially no follow-up beyond six months. We commend Dr. Doshi for his advocacy for vaccine safety and his work with the Coalition Advocating for Adequately Licensed Medicines (CAALM), which formally (and vainly) petitioned FDA to refrain from fully approving any COVID-19 vaccine until adequate safety data become available from the two-year trials.

Pfizer also failed to respond to concerns about waning immunity that Children's Health Defense has been raising since summer

[In the Pfizer clinical trials,] there was inadequate follow-up to six months, and essentially no follow-up beyond six months.

2020. In Israel, where delta is now reported to be the dominant SARS-CoV-2 strain, the country's current vaccine woes are a cautionary tale that should be heeded, illustrating the pitfalls of making decisions without relevant data. In the context of delta, according Israel's Ministry of Health, the relative efficacy of Pfizer's COVID injection against infection and symptomatic disease had fallen to 39% by July 2021.[112] The FDA initially stated that it would require at least 50% efficacy for approval of any COVID vaccine.[113]

Such dramatic waning immunity and the growing talk of booster doses drastically changes the risk-to-benefit ratio for decisions about COVID vaccines, especially for children and adolescents. The long-term benefits of giving kids and teens a COVID vaccine every six months are simply not known.

As Robert F. Kennedy, Jr. and Meryl Nass, MD pointed out shortly after the approval: "While the media has trumpeted that the FDA has approved COVID vaccines, the FDA has not approved the Pfizer BioNTech vaccines, nor any COVID vaccines for the 12- to 15-year age group, nor any booster doses for anyone."[114] They add:

> *Here's what you need to know when somebody orders you to get the vaccine: Ask to see the vial. If it says "Comirnaty," it's a licensed product. If it says "Pfizer-BioNTech," it's an experimental product, and under 21 U.S. Code 360bbb, you have the right to refuse. If it comes from Moderna or Johnson & Johnson (marketed as Janssen), you have the right to refuse. The FDA is playing bait and switch with the American public — but we don't have to play along. If it doesn't say Comirnaty, you have not been offered an approved vaccine.*[115]

The World Health Organization's Short-Lived Caution

For less than 24 hours in late June, 2021, the following statement appeared on the World Health Organization website:

> ***Children should not be vaccinated for the moment.*** *There is not yet enough evidence on the use of vaccines against COVID-19 in children to make recommendations for children to be vaccinated against COVID-19. Children and adolescents tend to have milder disease compared to adults. However, children should continue to have the recommended childhood vaccines.*

Within one day, however, WHO replaced that statement with language that leaves the door wide open to vaccinate children and adolescents:

> *Children and adolescents tend to have milder disease compared to adults, so unless they are part of a group at higher risk of severe COVID-19, it is less urgent to vaccinate them than older people, those with chronic health conditions and health workers. ...WHO's Strategic Advisory Group of Experts (SAGE) has concluded that the Pfizer/BionTech [sic] vaccine is suitable for use by people aged 12 years and above.*

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VIII. COVID Vaccine Adverse Events

The tip of the iceberg

In the Pfizer clinical trial with adolescents, harms outweighed potential benefits in the 12–15 age group.[116] As described in the FDA's EUA memorandum (pp. 38–39), short-term side effects were common, including injection pain (90%), fatigue (77%), headache (75%), chills (49%), muscle pain (42%), fever (24%) and joint pain (9%).[117] In addition, in previously healthy adolescents who have gotten COVID vaccines authorized for emergency use, there have been reports of blood clots, uncontrolled bleeding, paralysis, abnormal menses, extreme fatigue and death.[118]

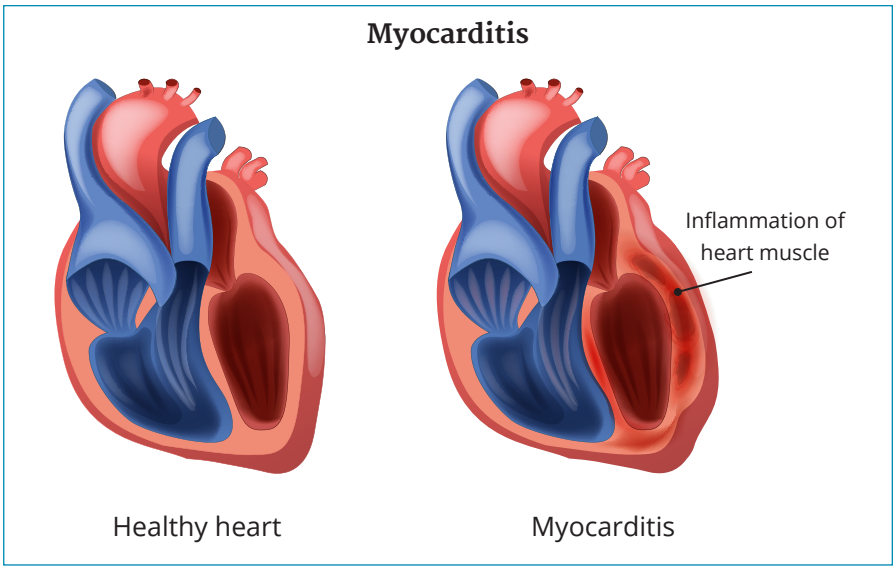
Clinicians wonder what the side effects are trying to tell us about the response of the body to the COVID vaccines. Does the extremely high rate of fatigue (three out of four youngsters) suggest impairment of mitochondrial function? Unfortunately, the mitochondria, responsible for generating energy, are sensitive to numerous environmental effects. Minor changes in salinity (salt concentration) and pH (how acidic the cell's environment is) can have an impact on mitochondrial function, as can viruses, bacteria, fungi and protozoa. Environmental toxins, like plastics and heavy metals, are also known to be toxic to mitochondria. We do not have evidence to reassure us that COVID vaccines are not mitochondrial stressors.

What about the extremely high rate of headache after COVID vaccination? Could that be telling us that the new COVID vaccines are breaching the blood-brain barrier and causing neurologic dysfunction? Do the chills mean that cytokines and other immune mediators are undergoing profound alterations that cause systemic effects? These are all excellent avenues for research.

Myocarditis

On June 23, 2021, the CDC's Advisory Committee on Immunization

Practices (ACIP) met to review reports of post-COVID-vaccination myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the sac around the heart) coming from VAERS and from pediatricians and intensive care physicians around the world.[119] (Note: It is widely recognized that VAERS captures only a small fraction of adverse events, perhaps less than 1%.) ACIP's slide presentation for that meeting is available on the CDC website, so readers can take a look at the information themselves.[120]



About 80 people at the CDC were apparently working on this issue as part of the COVID-19 Vaccines Safety Technical Work Group (VaST). However, during ACIP's ultimately disappointing discussion, most presenters talked in terms of "benefit-to-risk" ratios rather than the more customary "risk-to-benefit" ratio. Was this shift in language and emphasis intentionally chosen to suggest that benefits were paramount? The group also did not limit itself to reviewing vaccine-induced myocarditis but discussed other causes, including viruses, parasites, protozoa, bacteria, fungi, toxins, hypersensitivity reactions and immune-mediated problems.

From ACIP's discussion, we learned that gender seems to play an important role, with myocarditis being reported in males 76% of the time. Among the medical literature cited, the ACIP group discussed a case series in *Pediatrics* describing seven healthy males who developed myocarditis within four days of receiving their second mRNA COVID vaccine.[121] Four required intravenous immune globulin (IVIG) and steroids, while three improved with supportive treatment.

The group also discussed studies in adult patients—but the crucial point is that there are still no long-term data. According to the pediatric cardiologist presenting at the ACIP session, the risk of dying from "garden-variety" myocarditis was, before COVID, about 4% to 9%; several of those in attendance stated their impression that the post-vaccine myocarditis seemed "milder," voicing optimism that outcomes would be good. However, because ejection fractions and other objective markers of cardiac function were not presented—and because the patients were still in a phase of illness characterized by cardiac medications and severe limitations on activity, there were no data to confirm those positive impressions.

One of the most controversial parts of the ACIP presentation came when a speaker presented a working document with a chart of recommendations for second doses of vaccine if the patient developed pericarditis or myocarditis after the first dose. For pericarditis beginning after the first shot, the working draft recommendations were to give the second dose of vaccine as long as the patient had recovered. For myocarditis beginning after the first shot, the language included a recommended discussion between patient and caregivers and

administration of the second dose as long as the patient had recovered.

For pediatricians and family doctors who are trying to provide the best care for the patients before them, it is difficult and counter-intuitive to order a second shot when the first was associated with a life-threatening heart condition. CDC officials (who do not provide direct patient care) have a different perspective from doctors who are directly responsible for patients. At the meeting, Dr. Pablo Sanchez expressed his personal reluctance to give a second dose of vaccine, pointing out appropriately that "whatever triggered myocarditis the first time could cause a problem with the second dose." He is also to be commended for emphasizing the need to inform patients and parents—*before* COVID vaccines are given—of the risk of myocarditis.

The committee did not mention death as a potential outcome, even though we knew of, at the time, at least two deaths in young people that seemed directly related to the COVID vaccines—one in a 13-year-old boy and one in a 19-year-old woman. According to VAERS data as of August 13, 2021 (excluding reports from outside the U.S.), there were 2,122 cases of myocarditis and pericarditis, with 1,335 cases attributed to Pfizer, 703 cases to Moderna and 78 cases to J&J's COVID vaccine.[122]

The ACIP discussions about benefits versus risks included data about background rates of hospitalization and death that seem fundamentally flawed. As already discussed, several studies have concluded that "COVID deaths" in pediatric patients include a significant percentage of patients who died of other proximate causes but with a positive COVID test. In many hospitals, patients are tested every day or two for infection control reasons. As also discussed, PCR testing reliability is highly dependent on the number of cycles run. During the past 18 months, most PCR tests were run at cycle numbers that generated a lot of false positives. In the numbers used by ACIP in its analysis, it is difficult to know how many of the cases generating concern were false positives.

Another factor muddying the waters is that safe, inexpensive and effective treatments that could have thwarted significant illness in pediatric COVID patients were not widely publicized or made available. Some pharmacists refused to fill prescriptions for ivermectin due to guidance from their regulatory bodies, despite a meta-analysis showing the drug's superb impact on diminishing serious illness and death.[123] As discussed in the section on ivermectin, this analysis determined with moderate certainty that use of ivermectin can achieve large reductions in COVID-19 deaths and that the drug's early use can limit progression to severe disease. Yet because the FDA did not recommend ivermectin's use, many clinicians felt constrained about prescribing it. If we optimized the health of as many pediatric patients as possible by promoting nutrient-dense foods, good sleep patterns, exercise, excellent vitamin D levels and nurturing relationships—using hydroxychloroquine or ivermectin as well as other supplements like zinc, vitamin C and quercetin as appropriate—children's baseline SARS-CoV-2 risk would diminish below the already low level of risk.

At the ACIP meeting, individuals making public comments delivered a lot of important information that should be highlighted. One speaker

At the ACIP meeting, Dr. Pablo Sanchez expressed his personal reluctance to give a second dose of vaccine, pointing out appropriately that "whatever triggered myocarditis the first time could cause a problem with the second dose."

pointed out the flawed premise for vaccinating young people against COVID, given a fatality rate on par with influenza and the seriousness of potential heart complications. He also mentioned the numerous treatment alternatives available and their suppression. Continuing, he stated that vaccine adverse event surveillance mechanisms are a "disaster" and voiced little confidence in the data being captured during the vaccine rollout in young people. Finally, he reminded the committee of the unsuitability of PCR testing in this clinical situation.

Dr. Tom Perry, a retired cardiologist, pointed out that natural immunity is good and durable, while objecting to wasting doses and risking side effects in pediatric patients who have already had COVID. He also pointed out the limitations of testing immunity with antibody titers, stating correctly that T cell immunity is more important.

A clinician trained in Chinese medicine reported her clinical experience with multiple patients presenting with a concerning constellation of symptoms after COVID injections, describing "frightening" changes in radial pulse characteristics and involvement of the heart in many patients—perhaps even more than are captured as myocarditis cases in our flawed surveillance.

Dr. Leslie Moore, a practicing physician, expressed incredulity that investigational COVID vaccines are being promoted to younger and younger children. She also noted that frontline physicians are being left to deal with the consequences of vaccine adverse events without emerging recommendations of what might be helpful. She correctly pointed out that the biodistribution studies from the Pfizer vaccine showed accumulation of the lipid nanoparticles in the ovaries, which should ring alarm bells for anyone making recommendations for pediatric patients with their fertile years ahead.

Another citizen reminded ACIP that Dr. Cody Meissner, an attending physician at Tufts, pointed out in a prior ACIP meeting that hospitalization rates of four per million in pediatric patients do not constitute an emergency and so logically there

should have been no call for emergency use vaccines. She stated that it was not ethical to ask children and adolescents to risk their health to protect other people. She asked why ACIP was ignoring natural immunity.

The most bizarre part of the ACIP meeting was the discussion of booster doses.[124] Dr. Sara Oliver explicitly acknowledged the problem of waning vaccine immunity and raised the specter of fear for variants. She did not concede, however, that children who have had COVID illness have durable immunity likely to surpass expectations for vaccine-induced immunity.

Blood clots and bleeding

We know that the spike proteins bind to platelets and can cause clotting or bleeding. Unusual bleeding and blood clots have occurred in people who received recombinant adenoviral vector vaccines for COVID (made by AstraZeneca and Janssen/Johnson & Johnson) and in patients who received Pfizer or Moderna mRNA vaccines. In one case series of 11 patients in Germany and Austria, researchers examined clinical and laboratory features in hopes of uncovering the mechanism of the vaccine injuries.[125] Beginning 5-16 days after vaccination, patients presented with thrombotic events, including fatal brain bleeding, cerebral venous thrombosis, splanchnic vein thrombosis, pulmonary embolism and other types of clots. The investigators concluded that thrombotic thrombocytopenia—mediated by platelet-activating antibodies against heparin-platelet factor 4 (PF4)—is a mechanism of vaccine injury for adenovector COVID vaccines. None of the patients had received heparin before the onset of their symptoms.

In a follow-up study of five patients who presented with thrombosis and thrombocytopenia 7-10 days after the first dose of an adenoviral vector COVID vaccine, all the patients (who were health care workers) had high levels of abnormal antibodies.[126] The authors referred to the patients' pathology as "vaccine-induced immune thrombotic thrombocytopenia."

Case reports of abnormal platelet counts, clotting and bleeding continued to appear throughout spring 2021. For example, a healthy 22-year-old male received the Pfizer COVID vaccine and developed widespread petechiae (spots on the skin from broken capillary blood vessels) three days post-injection.[127] In another case report, a 48-year-old White woman with an "unremarkable medical history" presented to the emergency department with mild anemia and severe thrombocytopenia, having received the Janssen/Johnson & Johnson vaccine 14 days previously.[128] The woman's platelet count was 13,000 per cubic millimeter (whereas the reference range is 150,000 to 400,000), and she also displayed "a marked elevation in the D-dimer level"—117.5 mg per liter where the reference value is less than 0.5—indicating a "disseminated intravascular coagulation-like state" post-vaccination.

As of August 13, 2021, VAERS showed 61 cases in 12- to 17-year-olds in which some varieties of the following clotting abnormalities were noted: cerebral venous sinus thrombosis, coagulopathy, deep vein thrombosis, disseminated intravascular coagulation, embolism, idiopathic thrombocytopenic purpura, immune thrombocytopenia, myocardial infarction, petechiae, pulmonary embolism or vasculitis.

Ordinarily, children and teens are at low risk of clotting abnormalities. Thrombocytopenia has also been reported as a side effect of other vaccines, most notably the measles-mumps-rubella (MMR) vaccine.[129] Unfortunately, abnormal platelet antibodies or abnormal bleeding profiles can continue for months or years after this adverse event occurs. Those making decisions about vaccinating children and adolescents need to carefully weigh the potential benefits of COVID vaccines in those age groups against the potential long-term effects of blood clots and bleeding problems.

Unusual bleeding and blood clots have occurred in people who received recombinant adenoviral vector vaccines for COVID (made by AstraZeneca and Janssen/Johnson & Johnson) and in patients who received Pfizer or Moderna mRNA vaccines.

Holes in vaccine safety studies

When parents hear the mantra "vaccines are safe and effective," they assume that vigorous safety testing was done during clinical trials. In fact, vaccines go through clinical trials primarily relying on clinical subjects self-reporting their observed symptoms. It is shocking that we cannot find results of basic lab tests like complete blood counts, platelet counts, D-dimer (tests used to assess blood clots), liver enzymes or clotting tests from COVID vaccine trials.

The CDC's v-safe smartphone monitoring system was designed to collect data about COVID vaccine side effects such as fevers, local inflammation and muscle aches in the weeks after vaccination.[130] At the ACIP meeting that gathered concerns about myocarditis and pericarditis after COVID vaccines, a participant who suggested adding symptoms of chest pain and shortness of breath to v-safe received the response that the app's questions had already been programmed, with no plans to add the cardiac symptoms. In other words, it will be up to patients, parents and physicians to detect myocarditis in vaccine recipients.

In places such as Tennessee and the District of Columbia, COVID vaccines are being offered to adolescents aged 12–17 without parental knowledge or consent.[131] [132] We envision situations in which a minor may not tell parents or even physicians that he or she has received the vaccine. Therefore, if the child develops symptoms, parents and clinicians will not know to include vaccine side effects in a differential diagnosis of what is wrong with the child. Children's Health Defense opposes the vaccination of minors without parental knowledge or consent.

IX. Herd Immunity

Morphing definitions

The Mayo Clinic in Rochester has a longstanding reputation as a shining citadel for medical research and clinical care. Mayo points out that there are two paths to herd immunity: natural infection and vaccination.[133]

As of June 2020, the WHO definition of herd immunity was consistent with this classic interpretation: "Herd immunity is the indirect protection from an infectious disease that happens when a population is immune *either through vaccination or immunity* developed through previous infection."[134] By October of 2020, however, the emphasis at WHO had morphed; the organization was instead stating,[135] "'Herd immunity', also known as 'population immunity', is a concept used for vaccination, in which a population can be protected from a certain virus if a threshold of vaccination is reached. Herd immunity is achieved by protecting people from a virus, not by exposing them to it." The site also explained that "Attempts to reach 'herd immunity' through exposing people to a virus are scientifically problematic and unethical. Letting COVID-19 spread through populations, of any age or health status will lead to unnecessary infections, suffering and death." Notice the caveat in the preceding statement—*of any age or health status*—which is at the crux of the strategies countries have adopted to cope with COVID-19.

Not at equal risk

When thinking about herd immunity, it is crucial to remember that individuals have varying degrees of susceptibility to an infectious agent. Many of the models for

projecting SARS-CoV-2 thresholds for herd immunity use oversimplified, linear models that assume a homogeneous population at equal risk of contracting the disease. This does not reflect the complexity of most populations.

Initially, the NIH assumed that one person would infect three others, leading to a calculation that 67% of people with acquired immunity would be needed to meet the SARS-CoV-2 herd immunity threshold.[136] However, some very smart people make a good case that the threshold for herd immunity is far lower than we have been conditioned to believe. In Stockholm, epidemiologists and statisticians documented a herd immunity threshold of 17%. Compare the Swedes' observed and published epidemiology to the constantly moving goal posts in the U.S.: 60% to 70% to 85% (depending on the political winds).

When the Swedes decided to avoid lockdowns (while the rest of the world was shutting down), they understood that transmission and infection depend on many social determinants. For example, the chance that an elderly person who lives alone, has groceries delivered and gardens as a hobby would infect many people is quite low. The chance for transmission would be higher for a nurse working without adequate personal protective equipment in a hospital COVID unit and who lives with eight other people in a 1000-square-foot home with poor ventilation.

Natural infections do not occur at random. Some populations are more easily infected than others, and some populations get more seriously ill than others. If you have a population group with a lot of exposure but who

do not get seriously ill (like kids), more of that group will become immune earlier, which lowers the herd immunity threshold. International researchers from the United Kingdom, Portugal, Brazil and Virginia Tech published calculations in a May 2020 preprint stating that "Naturally acquired immunity to SARS-CoV-2 may place populations over the herd immunity threshold once as few as 10-20% of its individuals are immune."[137] It seems to us that these insights went largely unnoticed as public health recommendations evolved.

We know that the vast majority of COVID infections in kids were probably not detected, since children usually are asymptomatic. We also know that the PCR tests, as used during the pandemic, have a high false-positive rate. Some kids who tested "positive" at high cycle thresholds had probably already handled the virus just fine and had small fragments of dead virus that triggered their positive test. At the same time, the CDC's own data show that 23% of 0- to 4-year-olds and 42% of 5- to 17-year-olds have already had COVID and have robust natural immunity.[138] Children's Health Defense thinks we should count those kids as highly valued members of the "herd" and spare them a novel injection that

No Need to Vaccinate Children

A deep dive into the medical literature raises logical and crucial questions about the perceived necessity of vaccinating kids to get to herd immunity. The evidence—the Swedish experience, academic publications from Virginia Tech, Stanford, Harvard and the Cleveland Clinic and other medical literature—indicates that the herd immunity threshold might well be reached if a population gets to 10%-20% natural infection. There is no need to vaccinate kids to get to an arbitrary and oversimplified herd immunity threshold of 70%. The evidence shows that COVID infections decline dramatically far below that threshold.

has concerning and still-emerging side effects and unknown long-term safety. Children's Health Defense also opposes efforts to vaccinate pediatric patients who have already had COVID on the grounds that any risk is too high when a medical intervention is forced on someone who does not need it.

One could argue that healthy children and adolescents, with vanishingly small risks of death or disability from COVID-19, should have been allowed to go to school, socialize with peers, play in the dirt and contribute to herd immunity through natural infection, while we developed better strategies to protect the elderly, chronically ill and immunocompromised.

The wisdom of frontline doctors who know your child

The COVID crisis has exposed the dangers of pronouncements on high from public health officials. Primary care pediatricians and conscientious family physicians report how infuriating it has been to read about COVID every day for more than year and yet be denigrated by public health officials who tell patients "There is nothing you can do" to prevent COVID. It is also discouraging to have local pharmacists refuse to fill prescriptions for ivermectin because regulatory agency guidelines tell them it is not indicated. Diligent frontline doctors have personalized therapeutic relationships with their patients and are motivated to do everything they know to help patients achieve better health. Patients may develop a new appreciation for the value of individualized care from someone they know when they see behind the curtain of the public health decisions that have been made in the past year.

Just because an injection using a novel technology was created does not mean everyone should receive it. Hippocrates was right in saying that "the greatest medicine of all is teaching people how not to need it."

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