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Scientific evidence shows no link between COVID19 vaccines and child deaths

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Introduction

On September 12, 2025, reports appeared in the media announcing that "Trump health officials plan to link coronavirus vaccines to the deaths of 25 children as they consider limiting which Americans should get the shots." This announcement came on the heels of significant backlash from the public to the restrictions the Trump administration had already placed on COVID19 vaccine access in the absence of scientific evidence. The nature of the allegations about COVID19 vaccines and pediatric deaths by members of the Trump administration, including Health and Human Services Secretary (HHS) Robert F. Kennedy, Jr. and Food and Drug Administration (FDA) Commissioner Dr. Martin Makary, reveals their intent to try to justify the restrictions they have already placed on COVID19 vaccine access in the absence of scientific support, and to do so by misrepresenting factual information about the COVID19 vaccine and to stoke fears that have no basis in fact, all at the expense of the health of the people of the United States.

News articles indicated that the data used to allegedly tie COVID19 vaccines to pediatric deaths were derived from the Vaccine Adverse Event Reporting System (VAERS). This announcement was met with immediate and justified opposition by the medical and scientific community, because **the weight of the evidence clearly shows that COVID19 vaccines are safe and effective for adults and children alike**. Further, VAERS documents initial indications of possible adverse events that *may or may not be related to vaccination*. The reports contained within VAERS start as uninvestigated claims, because any type of concern can be reported to VAERS by anyone at all. Rigorous follow up often finds that these concerns are not, in fact, caused by vaccination. In this report we examine how VAERS is structured and what types of information it provides, as well as detailing why VAERS alone cannot be used to state that vaccines cause a particular condition.

The numerous high quality studies and ongoing vaccine safety monitoring systems that have been in place from day one for COVID vaccines have shown repeatedly that the rate of pediatric deaths after COVID19 vaccination is not higher among the vaccinated than in the general population. Though Dr. Makary claimed in a recent CNN interview that the FDA is only now doing a "proper investigation" of pediatric deaths following

COVID19 vaccination, including speaking to family members and reviewing autopsy reports, as a former FDA official has stated, ***these investigations have already been done, and there is no link between COVID19 vaccines and pediatric deaths***.

Further, in April 2025, well before Dr. Makary made his statement, the former head of the Food and Drug Administration's vaccine program shared with the Associated Press that "government scientists spend hours adjudicating each report of serious injury or death, often by tracking down death certificates and interviewing health providers. It's not unusual for investigators to find reports of deaths that were caused by something totally unrelated to a vaccine, like a car crash, or that a death occurred months after vaccination in someone with a serious illness." In other words, what Dr. Makary suggests is a new and "proper investigation" ***has in reality been routinely conducted*** by experts at the FDA and Centers for Disease Control and Prevention (CDC) since COVID19 vaccines were first available to the public.

It must be made crystal clear that the only way to accurately investigate whether there is a causal link between pediatric COVID19 vaccination and deaths is to ask: **Is the rate of pediatric deaths after vaccination higher, lower, or the same as in the general population? As we show in this report, the clear answer to this question from thorough and rigorous scientific studies done by experts with years of experience is that the rate of pediatric deaths following COVID19 vaccination is *lower.* This tells us the COVID19 vaccine is not causing pediatric deaths.** We discuss this work in detail in this report.

The data used to make the claim that COVID19 vaccines have caused the deaths of 25 children have not yet been released to the public, nor has the protocol with methodology explaining the data source or how the data were analyzed. Therefore, it is not yet possible to critique the report itself. However, Defend Public Health is dedicated to providing accurate information about scientific research and healthcare to counter the misinformation and propaganda that are regularly created and amplified by Mr. Kennedy and others in the Trump administration.

In this report, we provide evidence-based information about how we know that COVID19 vaccines are not associated with pediatric deaths; what is known about the safety and effectiveness of COVID19 vaccines, particularly in the pediatric population; what is known about adverse events; the numerous strategies by which vaccines are monitored for safety both before and after they are marketed in the United States, and why the use of the VAERS database alone to make allegations about adverse effects of vaccines without appropriate statistical comparisons would constitute egregious scientific misconduct.

From the numerous, rigorous vaccine safety surveillance mechanisms routinely used by the FDA, CDC, and other organizations, we know that **tens of millions of children have received the COVID19 vaccine, and their experiences continue to show there is no credible link between COVID19 vaccination and pediatric deaths**.

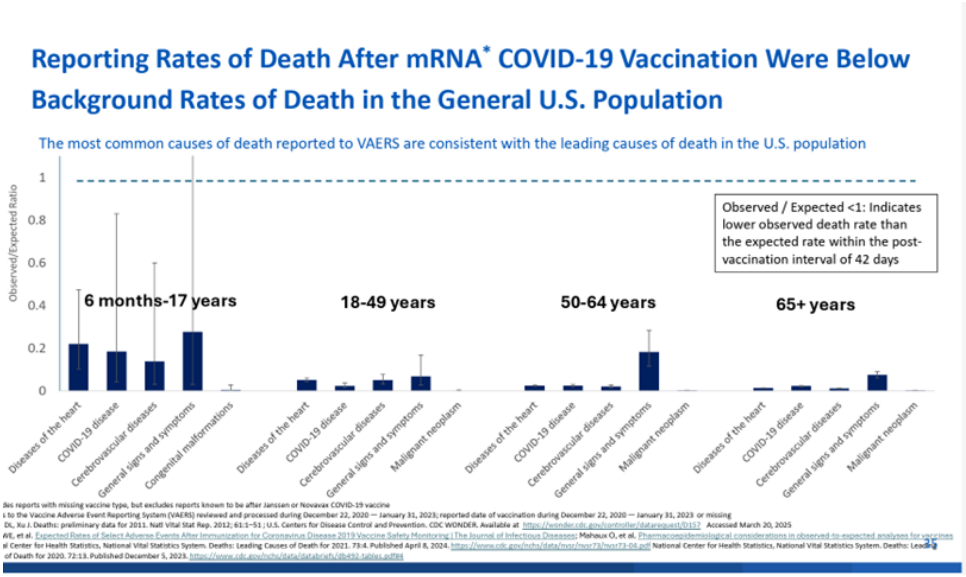
Is there a credible association between COVID19 vaccines and pediatric deaths?

The answer to this, based on rigorous, well-conducted studies done by experts, is a resounding NO. Several streams of reliable, rigorous,and thorough data collected and analyzed by experts demonstrate that COVID19 vaccines are not associated with pediatric deaths.

First, to examine the possibility of these associations, the Centers for Disease Control and Prevention (CDC) uses multiple vaccine safety surveillance systems that are described in detail later in this report. Expert CDC scientists continue to routinely conduct thorough analyses of adverse events after COVID19 vaccination using rigorous post-marketing surveillance data. **None of these analyses have to date indicated any relationship between COVID19 vaccines and pediatric deaths.**

The two figures presented below show the results of continued monitoring of COVID19 vaccine safety by the CDC and partner organizations, and were presented by Dr. Sarah Meyer at the Advisory Committee on Immunization Practices (ACIP) meeting on June 25, 2025.

For this work, trained CDC experts considered whether reports of deaths to VAERS are higher, lower, or the same as deaths in the general population of the United States.



Meyer, S. Meeting of the Advisory Committee on Immunization Practices, Centers for Disease Control and Prevention, 06/25/2025.

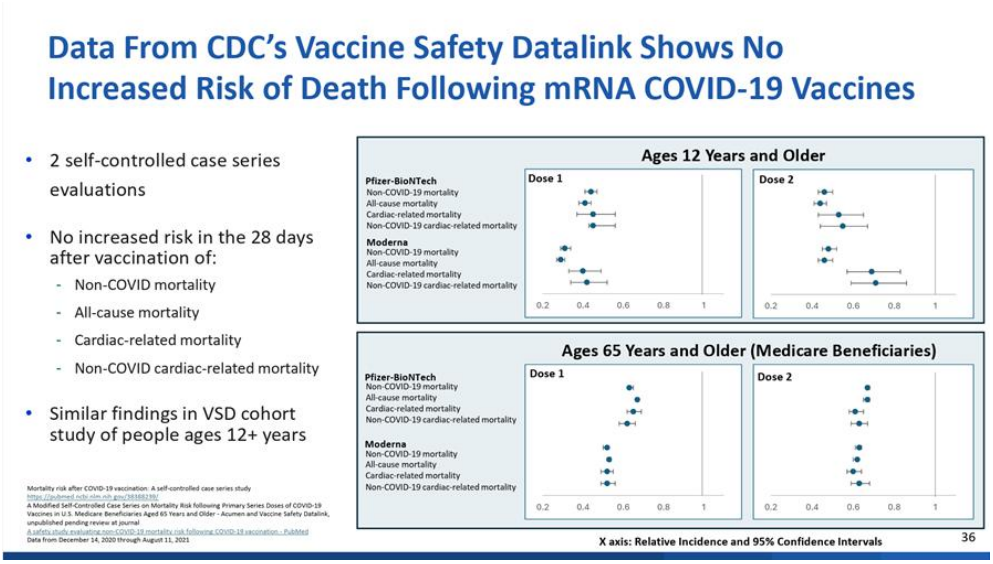
The first Figure presents analyses conducted to follow up on adverse events reported to VAERS. These analyses are done because VAERS alone cannot be used to assess causal relationships. Details on why this is so can be found in the section below about the VAERS database. In short, VAERS only includes vaccinated individuals, and therefore the rate of reported deaths generally cannot be compared to the rate which would be expected based on data for the entire population in this age group, including those who are unvaccinated.

CDC experts compared the rate of reports of deaths to VAERS (observed rate) with the known rate of deaths in the United States (expected rate) for each age group. In this graph the dashed line at 1 indicates where the expected and the observed rates would be equal; in other words, where the rate of reports of deaths in VAERS would be equal

to the rate of reports of deaths in the general population. All of the reported rates of deaths in VAERS after mRNA COVID19 vaccination are lower than 1, meaning that they are lower than the overall mortality rate for the US population for all age groups.

These results demonstrate that for children aged 6 months to 17 years, the death rate after mRNA COVID19 vaccination is *lower* than that of children of the same ages in the US population overall.

The second Figure presents data obtained from another surveillance system, the Vaccine Safety Datalink (VSD), which includes information from approximately 15.5 million people across the United States, and is described in further detail later in this report. These results show that in the 28 days or less following vaccination, **there is no increase in mortality after mRNA COVID19 vaccination for individuals aged 12 years and older**. The analyses show no increase in non-COVID19 mortality, all-cause mortality, cardiac-related mortality, or non-COVID19 cardiac-related mortality after vaccination.



Meyer, S. Meeting of the Advisory Committee on Immunization Practices, Centers for Disease Control and Prevention, 6/25/2025.

Taken together, these data show that there is no evidence from rigorous expert analyses using the CDC's extensive vaccine safety monitoring systems that indicates a relationship between mRNA COVID19 vaccination and pediatric deaths.

In addition to the extensive CDC analyses, epidemiological studies of COVID19 vaccines have revealed no association between vaccination and pediatric deaths. It must be noted that these studies are difficult to conduct because, fortunately, pediatric deaths are rare in the United States. Nonetheless, by combining data from multiple studies and via other data collection techniques, it is possible to obtain an answer.

First, a systematic review was conducted investigating the safety and efficacy of COVID19 vaccines by combining data from 26 randomized controlled trials (RCT) that included 60,000 children, with more than 10,000 of the children in three large RCTs of mRNA vaccines. **The results showed zero pediatric deaths in either the mRNA COVID19 vaccine or the placebo groups.**

In another study done with participants in the Centers for Disease Control and Prevention (CDC)'s COVID19 Vaccine Pregnancy Registry (C19VPR), parents were asked about their children's vaccination status at least 15 months after birth and, if

vaccinated against COVID19, whether there were any adverse events following vaccination. **Among 5564 children, no deaths were reported among children who were vaccinated.**

Overall, the evidence from rigorous, thorough research, done by experts either analyzing data from CDC vaccine safety monitoring systems or conducting epidemiological studies, shows no relationship between mRNA COVID19 vaccines and pediatric deaths.

How do COVID19 vaccines continue to be assessed for safety since they were approved?

Detailed descriptions of the vast infrastructure and rigorous data collection methods deployed to assess COVID19 vaccine safety after they were released can be found from several reliable sources. At the CDC, four different but complimentary data collection systems are used: The Vaccine Adverse Event Reporting System (VAERS), V-safe, the Vaccine Safety Datalink (VSD), and the Clinical Immunization Safety Assessment (CISA). **In the almost five years since COVID19 vaccines were licensed, none of these systems detected any indication that COVID19 vaccines might be associated with deaths in children, even though they have detected other rare events, such as myocarditis in certain subgroups.**

Why can't we use the Vaccine Adverse Event System Reporting System alone to determine whether vaccines cause harm?

Before describing the other databases used to assess vaccine safety, special attention must be paid to VAERS. This system was launched in 1990 as part of the National Childhood Vaccine Injury Act, and is run as a collaboration between the CDC and the FDA. It is known as a "passive" system, because it relies upon reports from healthcare providers, vaccine manufacturers and anyone in the general public. Reports about adverse events that occurred after vaccination are encouraged to be submitted **whether they are believed to be related to the vaccine or not.** VAERS serves as an excellent potential early warning system. ***However, as the CDC and FDA state repeatedly***, ***this system alone cannot be used to draw conclusions about whether or not a vaccine caused a reported event.***

There are several reasons that VAERS alone cannot be used to make conclusions about causality. First, because this database is open to submissions from any member of the public, it is vulnerable to false reports, as was intentionally demonstrated by James Laidler, a physician, in 2004. He submitted a report to VAERS claiming that the influenza vaccine had turned him into the Incredible Hulk, in order to highlight the vulnerability of VAERS to false reports.

Further, research has shown that media reports of possible vaccine-related adverse events, whether accurate or not, result in significantly increased numbers of reports from the public. One example occurred after Andrew Wakefield's paper falsely claimed that the Measles, Mumps and Rubella (MMR) vaccine caused autism in 1998. In the following weeks, researchers observed an increase of about 70 additional reports per week about adverse events after MMR vaccination.

VAERS data have been systematically abused by anti-vaccine activists. These groups employ scare tactics such as this headline from Robert F. Kennedy's Children's Health Defense which reads, "*45 Deaths, 5,000+ Adverse Events Following Updated Booster Shots Reported to VAERS, CDC Data Show."* This headline, designed to alarm the general public, is utterly disingenuous. It is dangerous because it takes a factual statement—that deaths have been reported after people have received vaccines—and implies that the vaccine caused these deaths, when there is absolutely no factual evidence that they did. *Articles like this one fail to ask the proper scientific question: Is the proportion of deaths and other events after vaccination higher, lower, or the same as for people who did not receive a vaccine?*

In fact, as discussed earlier in this report, this question has been asked and answered via numerous studies of COVID19 vaccines, which demonstrate that not only are deaths from COVID19 lower among the vaccinated compared to the general population, deaths from any cause are also lower among those who are vaccinated.

This example highlights the most critical problem with VAERS from an epidemiological standpoint of assessing causality. **VAERS includes no denominator or control group.** Every report is putatively about a person who has been vaccinated, and as such, several more steps must be taken to evaluate whether or not the number of adverse events among the vaccinated is similar or different to the number of adverse events seen among those who were not vaccinated. **This is the piece that anti-vaccination activists fail to share with the public.**

To illustrate this, imagine a study of whether caffeine causes headaches using a system set up to only receive reports of headaches after drinking coffee. Many reports of headaches after people drink coffee will be received. If the study is stopped there, one could claim that coffee causes headaches, but it would be false, because the system did not include the number of people who got headaches and didn't drink coffee. The correct question is whether people who drink coffee get ***more*** headaches than people who don't drink coffee. This question can't be answered with information only from coffee drinkers.

VAERS alone cannot be used to determine causality between vaccination and any reported condition. This is why VAERS is used for the potential detection of early warning signals only – in other words, as a sign that something may need further study. Its strength is that many reports come in since it is easy to use and anyone can use it. If scientists see a signal in VAERS from multiple reports of an event that occurs after a vaccine is received, they then follow it up using one of the more scientifically rigorous databases described next, as was demonstrated with the data from the CDC presented in the first section of this report.

What systems other than VAERS are used to assess COVID19 vaccine safety since they were approved?

Vaccine Safety Datalink (VSD)

The VSD is a significantly more robust system than VAERS. It was developed in1990 in a partnership with health systems across the United States to monitor vaccine safety, and includes data from Electronic Health Records (EHR) from approximately 15.5 million people. Data from this system are analyzed **every week** in a process called rapid cycle analysis. Baseline information about the occurrence of an extensive number of conditions are compared to weekly reports of potential adverse events after vaccination. If the rate of an adverse event is greater than would be expected from the baseline occurrence of the condition, then an immediate investigation into a possible relationship with the vaccine is launched by the CDC.

Through this system, the higher occurrence of myocarditis in certain subgroups after mRNA COVID19 vaccination was detected, investigated, confirmed, and quickly reported to the public. VSD allows for near real-time monitoring of potential adverse events related to vaccines. ***It has never detected a signal for increased pediatric deaths following COVID19 vaccination.***

V-safe

V-safe is a new vaccine safety monitoring system that was launched to allow for rapid reporting and assessment of adverse events after COVID19 vaccination. This mobile technology allows vaccine recipients to report how they were feeling after receiving the vaccine. With more than 10 million people now enrolled in the program, V-safe is similar to VAERS in that it allows for rapid identification of conditions that may have arisen after vaccination, but **it cannot by itself determine causality**.

Clinical Immunization Safety Assessment (CISA)

CISA may be thought of as a deeper dive into individual case reports of adverse events following vaccination. If a healthcare provider or a health department has concerns about a case report of an individual with an unusual or complicated condition that arose after vaccination and which may raise concern about vaccine safety, they may request assistance from CISA. A consultant then investigates the details of the concern and provides data and support to the healthcare provider to assist in evaluating vaccine safety.

All of the systems described above are enhanced by partnerships with vaccine monitoring systems at other government agencies, including the FDA's Biologics Effectiveness and Safety System (BEST), which employs data from health insurance companies to study vaccine safety and includes data from 75 million people with private insurance. **While this system was among several that detected higher rates of myocarditis in certain subgroups after mRNA COVID19 vaccination, it has never reported any increase in pediatric deaths after COVID19 vaccination**.

Other large data systems that are used to evaluate vaccine safety but do not generally include data for children are the Centers for Medicare & Medicaid Services' Near Real-Time Surveillance, which includes data from 60 million individuals who use Medicare; the Department of Veterans Affairs Vaccine Rapid Cycle Analysis with data from 9 million military veterans; and the Defense Medical Surveillance System (DMSS), which includes data for more than 350,000 military beneficiaries.

In summary, contrary to misinformation propagated online, there is a rigorous infrastructure encompassing many federal agencies that use different but complementary methods to study vaccine safety after they are licensed. **These systems have demonstrated the ability to capture information about rare post-vaccination adverse events. None of them have ever shown an association between mRNA COVID19 vaccination and pediatric deaths.**

What else is known about the safety and effectiveness of COVID19 vaccines in children?

There has been extensive research into the safety and effectiveness of COVID19 vaccines overall as well as in the pediatric population specifically. The largest to date is a meta-analysis of 17 studies published in 2023 in a highly-regarded scientific journal, *JAMA Pediatrics*. With observational and randomized clinical trial data from 10,935,541 children who had been vaccinated and 2,635,251 who had not, the researchers found that COVID19 vaccination was associated with significant reductions in infection, symptomatic infection, severe illness, hospitalization, and multisystem inflammatory syndrome in children in children aged 5-11 years old.The research team also assessed numerous potential adverse events, including injection site pain, redness, or swelling; any systemic adverse events; fatigue, fever, headache, chills, myalgia, and myocarditis, and found that while COVID19 vaccination was statistically significantly associated with events like injection site pain, fatigue, and fever, *it was not significantly related to events that prevented normal daily activities*.

In terms of adverse events related to COVID19 vaccination, special attention must be given to myocarditis. Myocarditis is inflammation of the heart muscle, which may occur for many reasons, including after having COVID19 or other viral infections. An early warning sign of a potentially increased risk for myocarditis was first reported in April 2021, prior to the vaccines being approved for some children in the US in May 2021. This report was followed by another from Israel in June 2021. Contrary to rampant misinformation perpetuated on social media, these first signals were not concealed from the public; in fact, this information was widely disseminated. Myocarditis gained even more attention after a large study was published in the New England Journal of Medicine in August 2021; notably, the authors highlighted that risk for myocarditis was substantially higher after SARS-CoV-2 infection itself compared to after vaccination. **It is notable that each of the rigorous vaccine surveillance systems in place in the United States was able to very rapidly detect the signal for the rare occurrence of myocarditis in some subgroups after COVID19 vaccination, and they have never detected an increase in pediatric deaths.**

A meta-analysis found that myocarditis occurred at a rate of about 1.8 cases per million children vaccinated for those between the ages of 5-11 years. A separate meta-analysis found that risk for myocarditis after COVID19 infection was 7 times higher than after COVID19 vaccination. In addition, the form of myocarditis observed after COVID19 vaccination is not only rare, but has been described by experts as mild and self-limiting.

These facts are important to emphasize. For a parent considering the risk of their child developing myocarditis, it is important for them to know that getting an actual COVID19 infection is more likely to cause myocarditis, and cause a far more devastating degree of heart muscle inflammation, than what has been reported after receiving the COVID19 vaccine. For those worried about myocarditis, the choice of vaccination is clearly the choice that reduces the risk of harm.

The breadth of evidence demonstrating the safety and effectiveness of the COVID19 vaccine for children prompted organizations such as the American Academy of Pediatrics to recommend that all children aged 6-23 months receive COVID19 vaccinations, along with any child aged 2-18 years whose parent or guardian chooses to have them vaccinated for any reason.

How were COVID19 vaccines assessed for safety and effectiveness before they were approved?

COVID19 vaccines became a priority when the pandemic began, and were developed in a short period of time compared to prior vaccines due to the urgency of the situation. Through December 2020, before vaccines were available, it was estimated that there had been 480,000 hospitalizations and 350,000 deaths in the United States from COVID19. A conservative estimate is that COVID19 vaccines have saved 2.8 million lives and 14.8 million life-years globally. Despite rampant misinformation online, the speed with which these lifesaving vaccines were developed does not mean that corners were cut or that they were not thoroughly tested.

Several factors worked to allow for speedy development of these vaccines. First, neither coronaviruses nor mRNA technology were brand-new in 2020. For decades, scientists have studied coronaviruses and had a good idea of their properties. In addition to the SARS-CoV-1 outbreak of 2002-2003, there had also been ongoing infections of Middle East Respiratory Syndrome coronavirus (MERS-CoV) that had been studied extensively prior to the COVID19 pandemic. As for mRNA vaccine technology, it had been studied for 15 years by the time SARS-CoV-2 emerged, and it too helped scientists efficiently address the urgent need for a COVID19 vaccine.

Operation Warp Speed in the United States and similar global efforts provided the resources that were needed to quickly develop and test mRNA COVID19 vaccines. These processes can often take years due to the need to apply for often-limited funding to develop and study them and, in particular, to recruit and enroll participants into the trials demonstrating their safety for use. The COVID19 pandemic, with funding from Operation Warp Speed, became an “all hands on deck” situation, with unprecedented resources and personnel devoted to ensure COVID19 vaccine development could occur safely, on an accelerated timeline. mRNA vaccines for COVID19 went through all of the processes that have historically occurred for every vaccine marketed in the United States, and in fact were launched with additional safety monitoring systems put in place to further ensure their safety on an ongoing basis. Both of the major COVID19 mRNA vaccines used in the US—Moderna and Pfizer/BioNTech, went through all of the required rigorous testing steps required for FDA licensing of any vaccine, beginning with animal studies and ending with large, randomized, placebo-controlled Phase III Trials designed to assess both vaccine safety and efficacy. Moderna’s Phase III Trial enrolled 30,420 participants and showed significant protection from symptomatic and severe COVID19, with no identified safety concerns. For Pfizer/BioNTech, 43,548 participants were enrolled, with the vaccinated group experiencing significantly lower rates of symptomatic and severe COVID19 compared to the placebo group. No differences in severe adverse events between the vaccination and placebo groups were observed.

Concluding Remarks

We have described the rigorous methods used to determine vaccine adverse effects using large databases which ask whether a suspected event occurs more frequently, less frequently or at the same rate when comparing vaccinated people with unvaccinated individuals. We have shown that there is a vast, robust vaccine safety surveillance infrastructure in the United States consisting of several separate but complementary systems, and that these systems are quite capable of detecting rare adverse events, like myocarditis. **And finally, we have shown that none of these vaccine safety checks have ever detected an increase in pediatric deaths arising from mRNA COVID19 vaccines.**