Scientists Call for Global Moratorium on mRNA Vaccines, Immediate Removal From Childhood Schedule

A review paper published last week in the journal Cureus is the first peer-reviewed paper to call for a global moratorium on the COVID-19 mRNA vaccines. The authors say that reanalyzed data from the vaccine makers' trials and high rates of serious post-injection injuries indicate the mRNA gene therapy vaccines should not have been authorized for use.

By Brenda Baletti, Ph.D.

Governments should endorse a global moratorium on mRNA vaccines until all questions about their safety have been thoroughly investigated, according to the authors of a new, peer-reviewed article on the COVID-19 vaccine trials and the global vaccination campaign published last week in Cureus, Journal of Medical Science.

Cureus is a web-based peer-reviewed open-access general medical journal using prepublication peer review.

The authors surveyed published research on the pharmaceutical companies' vaccine trials and related adverse events. They also called for the COVID-19 vaccines to be removed immediately from the childhood immunization schedule.

After the first reports from vaccine trials claimed they were 95% effective in preventing COVID-19, serious problems with method, execution and reporting in the trials became public, which the paper reviewed in detail.

Evidence also shows the products never underwent adequate safety and toxicological testing, and since the vaccine rollout, researchers have identified a significant number of adverse events (AEs) and serious adverse events (SAEs).

Authors M. Nathaniel Mead, Stephanie Seneff, Ph.D., Russ Wolfinger, Ph.D., Jessica Rose, Ph.D., Kris Denhaerynck, Ph.D., Steve Kirsch and Dr. Peter McCullough detailed the vaccines' potential serious harms to humans, vaccine control and processing issues, the mechanisms behind AEs, the immunological reasons for vaccine inefficacy and the mortality data from the registrational trials.

They concluded, "Federal agency approval of the COVID-19 mRNA injectable products on a blanket-coverage population-wide basis had no support from an honest assessment of all relevant registrational data and commensurate consideration of risks versus benefits."

They also called for the vaccines to be immediately removed from the childhood immunization schedule and for the suspension of the boosters.

"It is unethical and unconscionable to administer an experimental vaccine to a child who has a near-zero risk of dying from COVID-19 (IFR, 0.0003%) but a well-established 2.2% risk of permanent heart damage based on the best prospective data available," they wrote.

Finally, the authors called for a full investigation into misconduct by the pharmaceutical companies and the regulatory agencies.

It is the first peer-reviewed study to call for a moratorium on the COVID-19 mRNA products, Rose told The Defender.

"Once a proper assessment of the safety and efficacy claims was made herein — upon which the emergency use authorization (EUA)'s and ultimate final authorizations were granted — it was found that the COVID-19 injectable products were neither safe nor effective," she added.

According to McCollough, "mRNA should never have been authorized for human use."

Lead author Mead told The Defender, "Our view is that any risk-benefit analysis must consider how much the presumed benefit in terms of reduced COVID-19 related mortality is offset by the potential increase in vaccine-induced mortality."

Here are six takeaways from the review:

1. The COVID-19 'vaccines' are reclassified gene therapies that were rushed through the regulatory process in a historically unprecedented manner

Before the seven-month authorization process for the mRNA vaccines, no vaccine had ever gone to market without undergoing testing of at least four years, with typical timelines averaging 10 years.

To speed the process, the companies skipped preclinical studies of potential toxicity from multiple doses and cut the typical 6-12 month observation period for identifying longer-term adverse effects and the established 10-15-year period for monitoring for long-term effects such as cancer and autoimmune disorders, the authors wrote.

The trials prioritized documenting effective symptom reduction over SAE and mortality. This was particularly concerning, the authors argued, because mRNA products are gene therapy products reclassified as vaccines and then given EUA for the first time ever for use against a viral disease.

However, the gene therapies' components have not been thoroughly evaluated for safety for use as vaccines.

There is an uninvestigated and major concern that the mRNA could transform body cells into viral protein factories — with no off-switch — that produce the spike protein for a prolonged period causing chronic systemic inflammation and immune dysfunction.

The spike protein in the vaccine, the authors said, is associated with more severe immunopathology and other AEs than the spike protein in the virus itself.

The authors suggested that massive government investment in mRNA technology, including hundreds of millions before the pandemic and tens of billions once it began, meant, "U.S. federal agencies were strongly biased toward successful outcomes for the registrational trials."

The financial incentives along with political pressures to deliver a rapid solution likely influenced a series of flawed decisions that compromised the integrity of the trials and downplayed serious scientific concerns about risks with the technology, they added.

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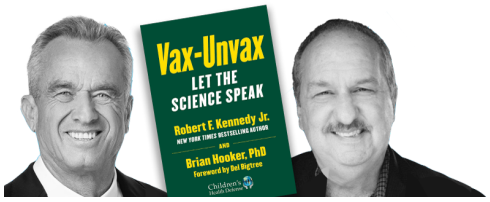

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2. Steps were taken in trials to overestimate vaccine efficacy

Because the trials were designed to assess whether the mRNA vaccine reduced symptoms, they did not measure whether the vaccines prevented severe disease and death. Yet the vaccine makers repeatedly claimed that they do.

"No large randomized double-blind placebo-controlled trials have ever demonstrated reductions in SARS-CoV-2 transmission, hospitalization, or death," the authors wrote.

Additionally, the number of people who contracted clinical COVID-19 in both the placebo and intervention groups was "too small to draw meaningful, pragmatic, or broad-sweeping conclusions with regard to COVID-19 morbidity and mortality."

Pfizer's 95 % efficacy claims were based on 162 of 22,000 placebo recipients contracting PCR-confirmed COVID-19 compared to eight of 22,000 in the vaccine group. None of the placebo recipients died from COVID-19. In the Moderna trials, only one placebo death was attributed to COVID-19.

There was also a much larger percentage of "suspected COVID-19 cases" in both groups, with participants showing COVID-19 symptoms but a negative PCR test. When factoring in those cases, measures of vaccine efficacy drop to about 19%.

The trial subject pool was comprised of largely young and healthy individuals, excluding key groups — children, pregnant women, elderly and immunocompromised people — which can also obscure the vaccine's actual efficacy and safety.

Findings from reanalyses of data from the Pfizer trials can be interpreted as showing the vaccines made "no significant difference" in reducing all-cause mortality in the vaccinated versus unvaccinated groups at 20 weeks into the trial, the authors wrote.

Even the six-month post-marketing data Pfizer presented to the U.S. Food and Drug Administration (FDA) showed no reduction in all-cause mortality from the vaccine.

The authors reanalyzed that data, adjusting the analysis of deaths to better account for the fact that when Pfizer unblinded the study people from the placebo group took the vaccine, and found the vaccine group had a higher mortality rate (0.105%) than the unvaccinated group (0.0799%), which they said was a conservative estimate.

One of the most glaring issues with the registrational trials, they noted, was that they exclusively focused on measuring risk reduction — the ratio of COVID-19 symptom rates in the vaccine group versus the placebo group — rather than measuring absolute risk reduction,

which is the likelihood someone will show COVID-19 symptoms relative to people in the population at large.

According to FDA guidelines, accounting for both approaches is crucial to avoid the misguided use of pharmaceutical products — but the data were omitted, leading to an overestimation of an intervention's clinical utility.

While both vaccines touted an approximately 95% risk reduction figure as their efficacy figure, the absolute risk reductions for Pfizer and Moderna's vaccines were 0.7% and 1.1% respectively.

"A substantial number of individuals would need to be injected in order to prevent a single mild-to-moderate case of COVID-19," the authors wrote.

As an example, using a conservative estimate that 119 people would need to be vaccinated to prevent infection, and assuming that COVID-19 had a 0.23% infection fatality rate, they wrote that approximately 52,000 vaccinations would be necessary to prevent a single COVID-19-related death.

However, "Given trial misconduct and data integrity problems … the true benefit is likely to be much lower," they wrote.

And, they added, one would need to assess that benefit along with harms, which they estimate to be 27 deaths per 100,000 doses of Pfizer. That means, using the most conservative estimates, "for every life saved, there were 14 times more deaths caused by the modified mRNA injections."

They also noted that post-rollout evidence confirmed the efficacy claims were overstated. For example, two large cohort Cleveland clinic studies showed the vaccine could not confer protection against COVID-19 — instead, in those trials, more vaccinated people were more likely to contract COVID-19.

One study showed the risk of "breakthrough" infection was significantly higher among people who were boosted and that more vaccinations resulted in a greater risk of COVID-19.

A second study showed adults who were not "up-to-date" with their shots had a 23% lower incidence of COVID-19 than their "up-to-date" colleagues.

3. The trials underestimated the adverse events, including death, despite evidence in the data.

Harms were also underreported and underestimated for a number of reasons, according to the authors, a practice that tends to be common in randomized industry-sponsored vaccine trials in general and "exceptionally evident" here.

First, because Pfizer unblinded the trial within just a few weeks of the emergency use authorization and allowed people in the placebo group to take the vaccine, there was not sufficient time to identify late-occurring harms because there was no longer a control group.

"Was this necessary, given that none of the deaths in the Pfizer trial were attributed to COVID-19 as the primary cause, and given the very low IFR [infection fatality rate] for a relatively healthy population?" they asked.

Also, trial coordinators were "haphazard" in their approach to monitoring AEs. They prioritized documenting events thought to be related to COVID-19 rather than to the vaccines for the first seven days and only recorded "unsolicited" AEs for 30-60 days. After that period, even very SAEs, like death, were not recorded. Even for the AEs recorded in the first seven days, they only solicited data from 20% of the population.

None of the trial data was independently verified. "Such secrecy may have enabled the industry to more easily present an inflated and distorted estimate of the genetic injections' benefits, along with a gross underestimation of potential harms," they wrote.

Subsequent analysis by Michels et al. revealed that deaths and other SAEs — like life-threatening conditions, inpatient hospitalization or extension of hospitalization, persistent or significant disability/incapacity, a congenital anomaly, or a medically significant event — did occur after the cutoff period and before the FDA advisory meeting where emergency authorization was recommended.

During the first 33 weeks of the Pfizer trials, 38 subjects died, according to Pfizer's own data, although independent research by Michels et al. estimated that that number is only approximately 17% of the actual projected number due to missing data.

And after that, the rate of deaths continued to increase. Michaels et al. found Pfizer failed to report a substantial increase in the number of deaths due to cardiovascular events. They also found a consistent pattern of reporting delays on the date of the death on subjects' case reports.

Overall, the review authors reported that there were "twice as many cardiac deaths proportionately among vaccinated compared to unvaccinated subjects in the Pfizer trials."

In their discussion, the authors wrote "Based on the extended Pfizer trial findings, our person-years estimate yielded a 31% increase in overall mortality among vaccine recipients, a clear trend in the wrong direction."

This raises serious red flags about how the registrational trials were conducted, Mead said. "Assessments of the safety profile of the COVID-19 modified mRNA injections warrant an objective precautionary perspective, any substantial upward trend in all cause mortality within the intervention arm of the trial population reflects badly on the intervention."

4. Numbers of SAEs in the trials and post-rollout reporting are well-documented, despite claims to the contrary.

Both Pfizer and Moderna found about 125 SAEs per 100,000 vaccine recipients, or one SAE for every 800 vaccines. However, because the trials excluded more vulnerable people, the authors note, even higher proportions of SAEs would be expected in the general population.

The Fraiman et al. reanalysis of the Pfizer trial data found a significant 36% higher risk of SAEs, which included deaths and many life-threatening conditions in the vaccinated participants.

Official SAEs for other vaccines average around only 1-2 per million. Fraiman et alestimated 1,250 SEAs per million vaccines, exceeding that benchmark by "at least 600-fold."

After the vaccine rollout, analyses of two large drug safety reporting systems in the U.S. and Europe identified signals for myocardial infarction, pulmonary embolism, cardio-respiratory arrest, cerebral infarction, and cerebral hemorrhage associated with both mRNA vaccines, along with ischemic stroke.

And millions of AEs have been reported to those systems.

Another study by Skidmore et al. estimated the total number of fatalities from the vaccines in 2021 alone was 289,789. Autopsy studies have also provided additional evidence of serious harms, including evidence that most COVID-19 mRNA vaccine-related deaths resulted from injury to the cardiovascular system.

In multiple autopsy studies, German pathologist Aren Burkhardt documented the presence of vaccine-mRNA-produced spike proteins in blood vessel walls and brain tissues. This research helps to explain documented vaccine-induced toxicities affecting the nervous, immune, reproductive and other systems.

The Pfizer data also showed an overwhelming number of adverse effects. According to a confidential document released in August 2022, Pfizer had documented approximately 1.6 million AEs affecting nearly every organ system, and one-third of them were classified as serious.

In Pfizer's trial, Michels and colleagues found a nearly 4-fold increase (OR 3.7, 95%CI 1.02-13.2, p = 0.03) in serious cardiac events (e.g., heart attack, acute coronary syndrome) in the vaccine group. Neither the original trial report nor Pfizer's Summary Clinical Safety report acknowledged or commented on this safety signal.

"The serious adverse events are all well documented," Mead said. "Yet it's surprising to see so many in the medical field continue to ignore or dismiss outright the latter half of the equation when considering all cause mortality trends."

5. The failure to appropriately test for safety and toxicity poses serious problems.

Researchers have raised concerns that the mRNA technology is inherently unstable and difficult to store, which leads to batch variability and contamination linked to different rates of AEs.

Recent findings by McKernan et al. that found Pfizers' mRNA vaccines are contaminated with plasmid DNA that shouldn't be present — and wasn't present in the vaccines used in the trials – raising serious safety issues.

That's because "Process 1," used in the trials to generate the vaccines involved in vitro transcription of synthetic DNA — essentially a "clean" process. However, that process isn't viable for mass production, so the manufacturers used "Process 2," which involves using E. coli bacteria to replicate the plasmids.

Removing plasmids E coli. can result in residual plasmids in the vaccines and the effects of their presence is unknown.

McKernan's work also revealed the presence of DNA from simian virus 40 (SV40), an oncogenic DNA virus originally isolated in 1960 from contaminated polio vaccines, induces lymphomas, brain tumors, and other malignancies in laboratory animals, raising other safety concerns.

Researchers from Cambridge published a paper in Nature in December 2023, where they found an inherent defect in the modified RNA instructions for the spike protein in COVID-19 immunizations that causes the machinery that translates the gene to the spike protein to "slip" about 10% of the time

This process creates "frameshifts" that cause cells to produce "off-target" proteins in addition to the spike. These proteins, which developers either failed to look for or did not report to regulators, cause undesirable immune responses whose long-term effects are unknown.

6. There are many different possible biological mechanisms that cause AEs and vaccine ineffectiveness.

The review points readers to a series of papyrus that explain a number of different theories to explain the high number of AEs from the COVID-19 mRNA vaccines.

"The mechanisms of molecular mimicry, antigen cross-reactivity, pathogenic priming, viral reactivation, immune exhaustion, and other factors related to immune dysfunction all reinforce the biological plausibility for vaccine-induced pathogenesis of malignant and autoimmune diseases," they wrote. And these mechanisms of immune activation are distinct from the body's response to a viral infection.

They also note the toxic effects of the primary adjuvant, PEG, and of the spike protein itself.

They close their analysis of the vaccines with a complex explanation for the different immunological basis for protection provided by the vaccines versus natural immunity through infection. They explain the mechanisms for vaccine failure and problems generated by the ability for the mRNA vaccines to perpetuate the emergence of new variants.

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Brenda Baletti, Ph.D.
Brenda Baletti Ph.D. is a reporter for The Defender. She wrote and taught about capitalism and politics for 10 years in the writing program at Duke University. She holds a Ph.D. in human geography from the University of North Carolina at Chapel Hill and a master's from the University of Texas at Austin.

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It's amazing how fast that the Covid jabs were approved for use, especially when you consider the amount of adverse events that occurred in the trials that were ignored or eliminated. Now that the information is out there that this jab is not only ineffective, but causes much more harm than good, lets see how long the major players keep touting the safe and effective mantra. They