Applying brakes on ‘Warp Speed’ COVID-19 vaccinations for children

The long-term side effects are unknown

By Dr. Larry Kwak, Dr. Steven T. Rosen and Dr. Idit Shachar - - *Thursday, October 28, 2021*

OPINION:

As physician-researchers who have pioneered the invention of vaccines and other experimental drugs for over 30 years (against cancer), we feel compelled to highlight the need for caution and honest public debate about potential long-term consequences of the available COVID-19 vaccines. Operation Warp Speed successfully enabled rapid deployment of vaccines under emergency use authorization, but we believe there are urgent reasons to apply the brakes on mass vaccine mandates for children.

Disturbing short-term complications from COVID-19 vaccines in adults, including myocarditis, blood clots in the brain, and neurological disorders, warrant us to pause. But we must be transparent that the real threat to children is the unknown long-term complications.

One of the worst medical disasters was diethylstilbestrol (DES) which was commonly prescribed as an anti-miscarriage medication in the 1940s. It was recalled 30 years later after it was connected to a rare tumor that appeared in the next generation of daughters of women who had taken it. We rarely know everything about a new drug when it’s approved, and we must brace ourselves for side effects we may only learn of years later. The history of medicine documents time and time again tragic examples of new drugs causing unsuspected problems discovered after release.

The challenge for researchers to identify new COVID-19 viral target proteins and then to adapt existing manufacturing platforms already shown to be safe for vaccines against other pathogens is already a daunting endeavor. However, using a new, rapid, but previously untested manufacturing technology (mRNA or DNA) introduced a second variable. Herein lies the problem that every science student is taught to avoid: changing two variables simultaneously in a single experiment. This violates the classic scientific method. In this case, the vaccines generated were comprised of active (COVID-19 viral sequences) and inactive components (manufacturing ingredients, including any impurities), neither of which had a prior favorable safety track record in healthy adults or children.

But how likely is the risk of an epidemic of long-term medical complications worse than the pandemic itself, say five years from now?

RNA-based vaccines (Pfizer and Moderna) could trigger any number of autoimmune diseases, which can take years to manifest. This is because the resulting combination of viral and normal self-proteins expressed by any cell, which takes up mRNA, creates a brand-new target on normal cells, which the immune system potentially recognizes as foreign and attacks.
mRNA also activates danger sensors in the primal immune system, which in turn indirectly promotes the release of pro-inflammation factors, specifically interferons, which have been associated with autoimmunity. This issue is underscored by a clinical trial of an mRNA lung cancer vaccine in 2019, in which blood tests revealed elevated indicators for autoimmunity concerns in 20% of patients.

Immune responses directly against RNA molecules themselves cause autoimmune diseases, such as systemic lupus. In 2014 in the early days of the technology, an mRNA COVID-19 vaccine inventor published on this potential long-term concern of mRNA vaccines.
Finally, none of the mRNA vaccines has a built-in “off” switch to control where they travel in the body and how long they persist there.
Published animal safety studies showed traces of COVID-19 spike protein in the brain, heart, and other vital organs, and the European Medicines Agency’s assessment report acknowledged that low levels of mRNA itself were detected in most tissues. The potential consequences of vaccines crossing the natural blood-brain barrier in children’s developing brains are of the utmost concern to all future humanity.

One last theoretical concern is the Jannsen vaccine, which uses a virus stripped of its own genes to deliver payload DNA. Such virus vectors can cause cancer when they randomly insert their payload near a gene that causes cancer. This is more than a hypothetical concern, as this year, a clinical trial of gene therapy for sickle cell disease (admittedly, using a different virus) was suspended when two patients who received the therapy more than five years ago developed blood cancers.

Truthfully, even full FDA approval cannot guarantee safety. We are not opposed to vaccination for vulnerable subgroups. But for most children, who rarely become seriously ill from COVID-19, particularly those with immunity from prior infection, forging ahead with currently available vaccines makes minimal sense without longitudinal data to review.

Instead, we advocate for a more precise scientific approach. The decision to vaccinate is tailored to the individual, guided exclusively by consultation with the child's doctor, and based on their unique risk-benefit calculus. Requiring COVID-19 vaccines for school-age children, in the same way as traditional vaccines, is comparing "apples to oranges" because they don't have a long enough safety history with the untested aforementioned second variable. A recent scientific study of risk-benefit analysis in children showed conservatively that there is five times the number of deaths attributable to each inoculation vs. those attributable to contracting COVID-19 among the elderly.

What's the alternative? It is essential to underscore that there are various treatments on the horizon. Alternative COVID-19 vaccines based on protein or inactivated viruses, using traditionally safe technologies rather than mRNA or DNA, are already completing clinical trials and could be deployed soon.

Similarly, monoclonal antibodies, a technology with a 20+ year safety record, are being developed as a shot to prevent COVID-19 infection and are already available through trials. Finally, several early intervention treatments (including antiviral pills related to Tamiflu) are also completing trials, first in adults, then in children. So there is a robust pipeline of emerging tools against this pandemic.

There is still a lot that we don't know about the long-term safety of available COVID-19 vaccines. Bottom line, no health professional in good conscience can look a parent in the eye today and say that these vaccines are unequivocally safe. As medical students, we took the Hippocratic oath, a promise to practice "primum non nocere," meaning "first, do no

harm." Let us patiently wait for the completion of long-term safety studies before we rush ahead blindly with blanket public health solutions that may cause unintentional and irreparable harm.

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