

Concern about Pediatric COVID-19 Inoculation in Puerto Rico

The paper entitled *The Use of Therapy Dogs in the Pediatric COVID-19 Vaccination at the University of Puerto Rico Medical Sciences Campus* article published in the PRHSJ vol 43(1) 2023 by Medical Sciences Campus, University of Puerto faculty presents a model for implementing and facilitating medical interventions in the pediatric population by having a prominent display of elements that are attractive to children such as the use of service dogs, medical students dressed as movie characters, cartoon posters and balloons (1). Have this model been used to educate children about safe, rational, science-based lifestyle choices to support and promote health such as nutrition, supplementation, exercise, and proper rest, we would have supported such an initiative. However, the model was presented to support a program for the experimental Covid-19 inoculation in children. Our group has published numerous articles to discuss the SARS-Cov2, the immune system, the new mRNA-based inoculations, its limitations, and risks of this new technology, the nature of inoculation injuries and its management (2,3,4,5,6,7,8,9,10).

The low risk of acute COVID-19 in children, its mild manifestation, and the lack of clarity on the relative side effects of the inoculation, indicate that the risk-benefit ratio of Covid19 inoculation in children is unclear. Two distinct syndromes, myocarditis and pericarditis, has been observed after COVID-19 inoculation especially in this age group. Myocarditis and pericarditis developed rapidly in younger patients, mostly after the second inoculation (11,12). The preliminary findings suggest that post-inoculation myocarditis may be explained by a direct spike mediated toxicity (13). There are at least 6 studies raising concern about vaccine safety, efficacy, and effectiveness (14,15,16,17,18,19). Current available research is limited and insufficient to evaluate possible long-term adverse effects. Also, maternal immune activation resulting from genic inoculation may impact a child's neurodevelopment and is another concern (20). Therefore, the innovative model should be reserved for high benefit, safety tested interventions.

In addition, there are other emerging concerns such as the potential for permanent incorporation of Spike protein gene into human DNA by reverse transcriptase enzymes in the human cells (21).

Finally, as an obvious but tragically ignored suggestion, the government and Public Health Agencies should be encouraging the population to take safe and affordable steps to properly optimize their immune systems naturally, such as getting out in the sunlight to raise vitamin D levels, exercise and eating mainly organic whole foods rather than chemical-laden, synthetic processed foods. Also, eating foods that are good sources of vitamin A, vitamin C should be encouraged. In fact, this approach has been documented to be protective from COVID. A meta-analysis with 4 million individuals confirms that a quality diet reduces the risk of COVID infection by 28% and hospitalization by 62% (22). In addition, based on nationally representative data in 26,282

adults in US, a high prevalence of inadequacy in four out of five key immune nutrients suggest that supplementation is important to address deficiencies and insufficiencies in vitamins and other micronutrients are linked to adverse outcomes from COVID-19 infection (23,24,25). In fact, some studies have shown that low levels of vitamin A, vitamin C, vitamin D, magnesium, selenium, and zinc have a significant clinical influence on COVID-19 patient's outcomes such as prolonged hospital stay, increase the mortality rate and raise the complications rate (26).

In conclusion, given this health relevant information, children directed models like these which present attractive environment that use cartoons, characters and service animals should be used to implement safe, well documented, empowering and proven health promoting strategies. Children should not be inoculated with the Covid 19 experimental injection mistakenly called "vaccine".

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REPLY

Dear Editor:

We are writing in response to a Letter to the Editor from Dr. Jorge R Miranda-Massari and colleagues regarding our article titled The Use of Therapy Dogs in the Pediatric COVID-19 Vaccination at the University of Puerto Rico Medical Sciences Campus (1).

We acknowledge your concerns about Pediatric COVID-19 Inoculation in PR and here is our response according to the issues raised in the letter:

1. *"Have this model been used to educate children about safe, rational, science-based lifestyle choices to support and promote health such as nutrition, supplementation, exercise, and proper rest, we would have supported such an initiative..."*

Thanks for supporting our initiative for other uses, such as the education of children and promoting health-related practices such as nutrition, exercise, and proper rest. We clarify that our publication is a report on the experiences at a COVID-19 vaccination center during the implementation of mass vaccinations after emergency use authorization of vaccines for use in children. As part of the strategies to make the center a children's friendly place, therapy dogs were

available, and they seemed to decrease anxiety and stress during the immunization experiences.

2. *"[T]he model was presented to support a program for the experimental Covid-19 inoculation in children."*

Regarding the misperception about approved vaccines as experimental, we want to clarify that they are not experimental. To approve a vaccine, even as an emergency authorization, both the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP-CDC) review extensive data on clinical trials on the products (2-3)

Clinical trials are research activities in which products (in this case, vaccine candidates) are studied in diverse populations with strict ethical standards that include informed consent, close monitoring of implementation and study procedures and guidelines, monitoring and classification of adverse events, verification of production standards and description of pre-clinical animal data that includes dose, toxicity, teratogenicity and other

issues, inclusion of community advisory boards that provide input on community education and understanding of the trials, trial design, recruitment strategies, dissemination of results and other issues. The trials usually have at least two experimental groups: placebo and intervention (vaccine). The participants know that the assignment to groups is random, and they accept to receive either placebo or products. Most volunteers participate in vaccine trials due to a sense of altruism and a desire to benefit public health, not just their own.

Data from the clinical trials or experiments is then reviewed and analyzed to move with emergency authorization. For these decisions, the committees also have ethical reviews and analyses of the impact on populations regarding the potential benefits and risks.

Therefore, the vaccines administered to populations even under emergency authorization are **not experimental**. Nevertheless, like all FDA-approved products, there is post-approval monitoring of outcomes and side effects. Some of these systems rely on clinicians' reporting, for example, the FDA Adverse Event Reporting System (FAERS) <https://www.fda.gov/drugs/drug-approvals-and-databases/fda-adverse-event-reporting-system-faers> and some rely on patients' own reporting (Vaccine Adverse Event Reporting System (VAERS)). <https://vaers.hhs.gov/>.

The impact of COVID-19 vaccines has been analyzed in several ways, including averted cases, deaths, and costs. Their efficacy has also been reported in meta-analysis of reported clinical trials (4). Vilches et al. estimated that COVID-19 immunizations averted more than 14 million cases, 241 thousand deaths and 1.1 million hospitalizations in the US by late June 2021 (5).

3. As per the statement "*The low risk of acute COVID-19 in children, its mild manifestation, and the lack of clarity on the relative side effects of the inoculation, indicate that the risk-benefit ratio of COVID-19 inoculation in children is unclear*", we want to refer the authors to several publications on the benefits of pediatric immunizations. In the article titled: "The Burden of COVID-19 in Children and Its Prevention by Vaccination: A Joint Statement of the Israeli Pediatric Association and the Israeli Society for Pediatric Infectious Diseases (6), Stein and colleagues described COVID-19 cases in Israel of which 512,613 were in children and adolescents (33% of all COVID-19 cases), and which the 5-11 year age group accounted for 43% (223,850) of them. The authors reviewed Israeli and international epidemiological data on COVID-19 morbidity and its sequelae in children. They also reviewed vaccine efficacy in reducing morbidity, transmission, and vaccine safety data, and performed a risk-benefit analysis regarding the vaccination of children and adolescents. They concluded that vaccines are safe and effective and are recommended for all children aged 5 to 11 years to protect them from COVID-19 and its complications and to reduce community transmissions (6).

Additional publications report that the impact among children is not only on COVID-19 incidence, severity, and the potential development of Long-COVID but also on the adverse emotional, social, and educational impact related to individual and family isolation due to symptoms, school closures, absenteeism, and need for alternative care and educational strategies (7-8).

Fitzpatrick et al. reported that as of October 30, 2022, COVID-19 caused more than 163,000 hospitalizations and 1,800 deaths in children up to age 17 (9). They also reported that school closures in response to the pandemic in 2020 affected more than 90 percent of the world's students. These closures and hybrid educational systems affected the test scores in many students. In the same publication, the authors estimated that a booster campaign would avert 36 million pediatric isolation days and more than 22 million days of school absenteeism.

Furthermore, Gupta and colleagues estimated that by May 9, 2021, the US vaccination campaign was associated with a reduction of 139,393 COVID-19 deaths and that by May 9, 2021, these reductions in mortality accounted for a value of statistical life benefit ranging between \$625 billion and \$1.4 trillion (10).

In summary, the UPR Medical Sciences Campus established a COVID-19 vaccine center as part of the response to the epidemic, following laws and regulations and executive orders for immunizations. We successfully implemented a model for pediatric immunizations using therapy dogs as adjuncts and motivators for a better experience among children and their parents.

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