

LETTER TO THE EDITOR

Rational harm-benefit assessments by age group are required for continued COVID-19 vaccination

To the editor,

We read with interest the letter by Dr. Gül and Dr. Öztürk,¹ which comments about the previous letter by Dr. Polykretis.² The letter by Dr. Polykretis aimed to underline the differences between the genetic vaccines against COVID-19 and vaccines based on inactivated or attenuated viruses in terms of immunization mechanism. Moreover, and most importantly, it sought to emphasize the necessity of biodistribution studies in front of the numerous publications reporting on a variety of serious adverse events among vaccinees.² Considering that some pharmaceutical companies, such as Pfizer/BioNTech, had 'to move at the speed of science, to really understand what is taking place in the market' to release the vaccines (as declared later on by Janine Small, President of International Developed Markets, to the European Parliament on Monday, October 10th, 2022), there is nothing of scientifically despicable or misleading in seeking for the collection of more accurate data about biodistribution.

Dr. Gül and Dr. Öztürk accuse the letter by Dr. Polykretis of being 'misinforming' and of containing some 'basic errors', arguing on the definitions of genetic vaccines and autoimmunity. We would like to address on both cases. Regarding the definition of genetic vaccines, the letter by Dr. Polykretis is not misleading, as scientific literature reports that: 'gene vaccines are a new approach to immunization and immunotherapy in which, rather than a live or inactivated organism (or a subunit thereof), one or more genes that encode proteins of the pathogen are delivered'.³ As concerns the term autoimmunity, the Merriam-Webster medical dictionary it defines it as: 'a condition in which the body produces an immune response against its own tissue constituents'. Therefore, it is not misinforming or erroneous to define autoimmune reaction the response of the immune system against human cells that intake the lipid nanoparticles (LNPs) and translate the spike protein (in case of the mRNA vaccines), or that get infected by the adenovirus and express and translate the spike protein (in case of the adenovirus-based vaccines). Regarding the fact that even the 'traditional vaccines' cause the immune system

to respond by attacking self-cells during the immunization process, there are some fundamental aspects that should be underlined: (i) The vaccines based on inactivated or killed viruses involve principally presentation to antigen presenting cells (APCs) including macrophages, monocytes, B cells and dendritic cells that phagocytose the virus particles and present the viral antigens to CD4⁺ T-cells. The aforementioned classes of cells carry out this specific role within the organism, making them somewhat expendable, as there is a continuous turnover of such cells. (ii) The attenuated viruses have a reduced virulence and thus, the resulting infection involves a minor number of human cells. Instead, several sources of histopathological evidence demonstrate that the genetic vaccines exhibit an off-target distribution in tissues, which are terminally differentiated and subject to symptomatic injury. These include the heart and brain, which may sustain a massive production of spike protein which elicits a strong autoimmunological inflammatory response.^{4,5} The above mentioned histopathological findings confirm exactly the mechanism previously theorized by Dr. Polykretis: "For instance, if the mRNA contained in the LNPs would get internalized by cardiac myocytes, and such cells would produce the spike protein, the resulting inflammation would likely lead to the necrosis of the myocardium, with an extent proportional to the number of involved cells".²

An independent secondary analysis of serious adverse events reported in phase III clinical trials of Pfizer and Moderna, found that the mRNA vaccines combined were associated with an excess risk of serious adverse events of 1 per 800 vaccinated individuals.⁶ Nevertheless, indiscriminate COVID-19 vaccination has been expanded to include age groups and naturally immune with minimal chance of suffering major complications due to COVID-19. In these groups COVID-19 vaccination is not clinically indicated nor medically necessary. According to a large-scale risk-benefit analysis, between 31 207 and 42 836 young adults aged 18-29 years would need to receive a third mRNA vaccine dose to prevent one COVID-19 hospitalization over a course of six months.⁷

--- Baseline — 2020 — 2021 — 2022

0-14 years

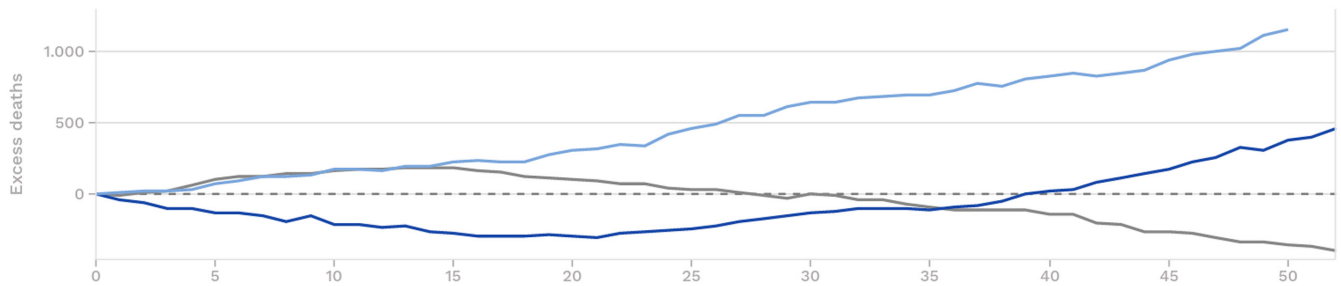


FIGURE 1 Graph showing the excess mortality in the age group 0–14 until week 2022–51, generated with data from 27 participating European countries (EuroMOMO 2022).

The authors estimate that at least 18.5 serious adverse events could occur for every COVID-19 hospitalization prevented. From January 2021 to the time of writing, 1598 athletes suffered cardiac arrest, 1101 of which with deadly outcome.⁸ Notably, in a 38-years timespan (1966–2004), 1101 athletes under the age of 35 died (~29/years) due to various heart-related conditions, 50% of whom had congenital anatomical heart disease and cardiomyopathies and 10% had atherosclerotic heart disease with early onset.⁹ According to a study done on 301 teenagers between the ages of 13 and 18 who had received two doses of the Pfizer/BioNTech vaccine, 29.24% of participants experienced cardiovascular complications such as tachycardia, palpitations and 2.33% suffered myopericarditis.¹⁰ It is noteworthy, that no statistically significant increase in the incidence of myocarditis or pericarditis was observed in un-vaccinated subjects after SARS-CoV-2 infection, in a large population study.¹¹ Since the end of 2021 and throughout 2022, young age excess mortality has substantially increased in many European countries (Figure 1), in concert with the vaccine program.¹²

In conclusion we thank our colleagues for advancing the discourse on the extremely concerning safety data after COVID-19 vaccination, which prompt us to emphasize again and more firmly the need of biodistribution studies as well as of rational harm-benefit assessments by age group.

CONFLICT OF INTEREST

The author declares that he has no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

Panagis Polykretis¹
Peter A. McCullough²

¹Independent Researcher, Florence, Italy

²Chief Medical Advisor, Truth For Health Foundation, Arizona, Tucson, USA

Correspondence

Panagis Polykretis, Independent Researcher, 50124 Firenze, Italy.

Email: panagis.polykretis@gmail.com

REFERENCES

- Gül A, Öztürk R. Immune response against viral infections and nucleic acid-based vaccines. *Scand J Immunol.* 2022;96(6):e13221.
- Polykretis P. Role of the antigen presentation process in the immunization mechanism of the genetic vaccines against COVID-19 and the need for biodistribution evaluations. *Scand J Immunol.* 2022;96(2):e13160.
- Srivastava IK, Liu MA. Gene vaccines. *Ann Intern Med.* 2003;138:550–559.
- Baumeier C, Aleshcheva G, Harms D, et al. Intramyocardial inflammation after COVID-19 vaccination: an endomyocardial biopsy-proven case series. *Int J Mol Sci.* 2022;23:6940.
- Mörz M. A case report: multifocal necrotizing encephalitis and myocarditis after BNT162b2 mRNA vaccination against COVID-19. *Vaccine.* 2022;10:1651.
- Fraiman J, Erviti J, Jones M, et al. Serious adverse events of special interest following mRNA COVID-19 vaccination in randomized trials in adults. *Vaccine.* 2022;31:5798–5805. doi:10.1016/j.vaccine.2022.08.036
- Bardosh K, Krug A, Jamrozik E, et al. Covid-19 vaccine boosters for young adults: a risk-benefit assessment and ethical analysis of mandate policies at universities. *J Med Ethics.* 2022. doi:10.1136/jme-2022-108449. Epub ahead of print.
- 1598 athlete cardiac arrests, serious issues, 1101 of them dead, since COVID injection – real science; 2021. <https://goodsciencing.com/covid/athletes-suffer-cardiac-arrest-die-after-covid-shot/>. Accessed December 24, 2022.

9. Bille K, Figueiras D, Schamasch P, et al. Sudden cardiac death in athletes: the Lausanne recommendations. *Eur J Cardiovasc Prev Rehabil.* 2006;13:859-875.
10. Mansanguan S, Charunwatthana P, Piyaphanee W, Dechkhajorn W, Poolcharoen A, Mansanguan C. Cardiovascular manifestation of the BNT162b2 mRNA COVID-19 vaccine in adolescents. *Trop Med Infect Dis.* 2022;7:196.
11. Tuvali O, Tshori S, Derazne E, et al. The incidence of myocarditis and pericarditis in post COVID-19 unvaccinated patients – a large population-based study. *J Clin Med.* 2022;11:2219.
12. EuroMOMO euromomo.eu 2022: graphs and maps from EUROMOMO. *EUROMOMO.* <https://euromomo.eu/dev-404-page/>. Accessed December 24, 2022.