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Subject: Request for an open discussion about medium-term effectiveness and safety of the current anti-COVID-19 vaccination campaign

Sir,

We are an Italian multidisciplinary group of health experts collaborating as an independent medical scientific commission (*Commissione Medico-Scientifica Indipendente*) systematically following the evolution of the current Covid-19 pandemic and related response and policies. We have **no conflicts of interest** and entirely base our observations and deductions on the **evidence emerging from the analysis of national and international literature and institutional data.**

The World Health Organization repeatedly reaffirms the need to ensure the vaccination of at least 70% of the whole world population with anti-Covid-19 vaccines in order to contain the pandemic,¹ despite the evidence that even in countries that have achieved much higher vaccination coverage the epidemic has not be halted. The recommendation not only refers to fragile or especially vulnerable groups of population, but extends to children and youngsters whose risk to fall ill and eventually develop serious disease is very remote, with risk from the inoculation increasingly higher than the possible benefits deriving from the protection that the vaccination may provide.^{2,3,4,5}

WHO recognizes that “Accumulated evidence indicates that existing vaccines provide only modest and relatively limited duration of protection against infection”.⁶

Indeed, an attentive analysis of official data from a number of countries shows that since a few months after the last dose the protection from the inoculation is not only progressively reduced, but efficacy becomes negative, i.e. unvaccinated people receive less SARS-CoV-2 diagnoses than people of the same age group who were fully vaccinated or even received booster doses.^{7,8,9,10,11}

It must be noted that the original research and the results used for the emergency approval of the most widely used products (*Pfizer-BioNTech* and *Moderna COVID-19 Vaccines*) did not provide enough guarantees regarding their safety. Indeed, the number of

deaths for all causes among the placebo group were similar to (Moderna) or lower than (Pfizer-BioNTech) that in the group receiving the experimental vaccine. In addition, as you know the studies were later interrupted by vaccinating also members of the placebo group, so avoiding the possibility of a long-term follow-up, consequently invalidating the whole studies. Pfizer and Moderna mRNA COVID-19 vaccines were also associated with a higher risk of serious adverse events of special interest in vaccinated participants over placebo controls.¹²

For both mRNA and Viral vector vaccines one of the main assumptions regarding their safety was that the post-inoculation exposure to the spike protein produced by the cells of the recipient would be immediately destroyed in the site of the inoculation after having been exposed to the immune system of the recipient him/herself. Instead, several studies have shown that the Spike protein – known to be the most important pathogenic component of the coronavirus - can be found in many tissues of the inoculated person and could itself be the cause of adverse effects of the vaccination.^{13,14}

In the absence of active surveillance in most countries, the real incidence of adverse effects is greatly underestimated and the long-term consequences are not known. Passive surveillance results in a huge underestimation of vaccine adverse reactions, even severe ones.^{15,16,17,18,19,20}

Especially in children and young adults mRNA vaccines might be involved in the mortality excess seen in a number of European countries from week 22 of 2021 until all of 2022 [see Graphs and maps — EUROMOMO 0-14 and 15-44 years].

“*Primum non nocere*” is the Hippocratic principle that all health professionals as well as public health policies should respect. Therefore, we express our highest concern about WHO’s neglecting or minimizing the risks involved in the vaccination with the above mentioned vaccines and not adequately considering the emerging evidence of safety issues.

We would be very happy to have an open discussion about the exposed issue about the medium-term effectiveness and safety of the current anti-COVID-19 vaccination campaign, with health professionals and researchers **without conflict of interests**.

We look forward to your comments.

Kind regards,

Dr. Alberto Donzelli, Prof. Marco Cosentino , Prof. Vanni Frajese, Dr. Patrizia Gentilini,
Prof. Eduardo Missoni, Dr. Sandro Sanvenero, Dr. Eugenio Serravalle

- ¹ WHO press conference on monkeypox, COVID-19 and other global health issues – 25 August 2022
- ² BMJ, Vaccinating children against SARS-CoV-2 BMJ 2021;373:n1197 <http://dx.doi.org/10.1136/bmj.n1197>
- ³ Zimmermann P, Pittet LF, Finn A, et al Should children be vaccinated against COVID-19? *Archives of Disease in Childhood* 2022;107:e1-e8. <http://dx.doi.org/10.1136/archdischild-2021-323040>
- ⁴ Abi-Jaoude E, Doshi P, Michal-Teitelbaum C Covid-19 vaccines for children: hypothetical benefits to adults do not outweigh risks to children. *The BMJ Opinion*, 13 July 2021 <https://blogs.bmj.com/bmj/2021/07/13/covid-19-vaccines-for-children-hypothetical-benefits-to-adults-do-not-outweigh-risks-to-children/>
- ⁵ 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. *Journal of Medical Ethics* Published Online First: 05 December 2022. <http://dx.doi.org/10.1136/jme-2022-108449>
- ⁶ WHO, Global Covid-19 Vaccination Strategy in a Changing World, July 2022 update.
- ⁷ Woodbridge Y, Amit S, Huppert A, et al. Viral load dynamics of SARS-CoV-2 Delta and Omicron variants following multiple vaccine doses and previous infection. *Nat Commun* 2022; 13, 6706. <https://doi.org/10.1038/s41467-022-33096-0>
- ⁸ Chemaitelly H, Tang P, Hasan MR, et al Waning of BNT162b2 Vaccine Protection against SARS-CoV-2 Infection in Qatar. *N Engl J Med* 2021; 385:e83 <http://dx.doi.org/10.1056/NEJMoa2114114>
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- ¹¹ Shrestha NK, Burke PC, Nowacki AS, et al. Effectiveness of the Coronavirus Disease 2019 (COVID-19) Bivalent Vaccine. <https://www.medrxiv.org/content/10.1101/2022.12.17.22283625v1>
- ¹² 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, 40: 5798-5805, <https://doi.org/10.1016/j.vaccine.2022.08.036>.
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- ¹⁸ 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 Aug 19;7(8):196. <http://dx.doi.org/10.3390/tropicalmed7080196>
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- ²⁰ Supplement to: Ali K, Berman G, Zhou H, et al. Evaluation of mRNA-1273 SARS-CoV-2 vaccine in adolescents. *N Engl J Med*. <http://dx.doi.org/10.1056/NEJMoa2109522>