Transparent and unbiased discussion about the medium-term effectiveness and safety of the anti-COVID-19 vaccination campaign is urgently needed

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, 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 [1-4]. WHO recognizes that "Accumulated evidence indicates that existing vaccines provide only modest and relatively limited duration of protection against infection". 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 [5-9].

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, 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 [10].

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 (reviewed in [11,12]).

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 [13-18]. 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 respectfully and yet with great conviction request the opening of a discussion table about the medium-term effectiveness and safety of the current anti-COVID-19 vaccination campaign, with health professionals and researchers **without conflict of interests**.

The present "opinion" paper has been sent as an open letter to Dr. Tedros Adhanom Ghebreyesus, Director General of the World Health Organization in Geneva.

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Note: CMSi (*Commissione Medico-Scientifica Indipendente* - independent medical scientific commission) is a collaborative multidisciplinary group of health experts systematically following the evolution of the current Covid-19 pandemic and related response and policies. The CMSi members and the commission as a whole have **no conflicts of interest** and entirely base their observations and deductions on the **evidence emerging from the analysis of national and international literature and institutional data**.

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