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English translation by Alice Ratti and Leyla El Moudden

Call for Moratorium on Anti-COVID-19 Children Vaccination

Introduction

This call has been written and signed by several Italian Medical Associations, by medical doctors and healthcare professionals operating within the Health System, primarily within academic research for the prevention and care of covid-19's patients. Following the joint letter of protest that has been signed by 93 Israeli doctors, this call aims to achieve the same outcome: to explain in detail why the anti-COVID-19 children vaccination is not necessary. The aim is to mention the available scientific evidence, discuss effective strategies against the disease and reject anti-vaccine manipulations.

Summary

Vaccines against COVID-19 are going to reduce serious illness cases and death rate. Where this disease may be dangerous and lethal, the vaccine administration is substantial to protect at-risk population.

For children, vaccination does not generate any significant advantages, considering the low relevance and moderate clinical signs on pediatric patients. Since children have an irrelevant role in the SARS-CoV-2 transmission, the vaccination wouldn't also produce benefits for the community.

Vaccines momentarily in use do not affect the transmission of infection; they have lowered duration and effectiveness on newly emerging variants. Currently, the requirement and regularity of the vaccination recall that preserve immunity (prospectively at least yearly) has to date not been established and the effect of a possible recurring immunisation is unknown.

In light of the minimal and negligible benefits, we shall present the case that exposing children to common and hostile risks (although probably reversible) and to long-term adverse events (not yet identified but possible) is placing them at unnecessary risk. The post-marketing surveillance on vaccinations has only just begun and essential data concerning rare and dangerous consequences could yet appear. Even active surveillance programmes could underline these data, but at the moment they prove to be absent or incomplete.

The current opinion within the scientific community is that the vaccine cannot lead to herd immunity, therefore there does not exist an "altruistic" or "ethical" justification for vaccinating children to protect the at-risk population, particularly one that has already been the subject of an intense vaccination campaign.

COVID-19 and Children

COVID-19 epidemic is less diffused among children [1] [2] [3] [4] [5] [6] [7] than adults. It is estimated that under 20 years old the disease hypersensitivity is half that of those aged over 20-year-old[8]. Cases of disease during childhood, in Europe, are between 1% and 5% of COVID-19 [9] total cases, while in Italy less than 1% of positive patients are under 18 years old [10].

The children's medical outcomes are more positive than adults[11] [12]. Children's covid is largely asymptomatic and 94,1% display tolerable or moderate clinical conditions. In the event of a unilateral or bilateral pneumonia, only 4% of cases required intensive care hospitalisation [13]. The most dangerous complication is the multi systemic inflammatory syndrome related to COVID-19 (MIS-C), an hyperinflammatory symptomatology that emerges 3-6 weeks after SARS-CoV-2 exposure. The nasopharyngeal swab with RT-PCR results negative but with positive serology.

The temporal connection and the low PCR positivity rate prove that the inflammatory condition with organ dysfunction is caused by a post-infectious mechanism instead of the sharp viral infection.

The morbidity between 0-15 years corresponds to 0,08% [14].

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The role of children and teenagers in the spread of infection is still under investigation, even though this isn't as significant as in case of seasonal influenza [15] [16] [17] [18]. Younger children (pre-school and primary school) spread SARS-CoV-2 less than teenagers. Children are not COVID-19 diffusers [19].
According to studies, infections inside the family unit are infrequent [20], with variable rates of transmission from pediatric index cases. On an International scale, a set of family groups underlined that children couldn't be the index case (zero patient), because they were responsible only for approximately the 10% of the groups [21].

Rare Adverse Reactions to Vaccinations

Vaccines against COVID-19 are still under trials. Current data about safety and efficacy are unsatisfactory and cannot be officially approved, therefore vaccines have received emergency use authorisation influenced by the European Medicine Agency. The application of reliable active surveillance systems (for example, surveillance applied during randomized controlled trials, RCT) prevents severe underestimations referring to the regularity and the import of short-term adverse reactions and it becomes possible to evaluate medium/long-term effects [22].
At the moment, we fear that an underestimation of adverse effects is now occurring. Anaphylactic reactions caused by the vaccination arise after minutes or hours and can be lethal if not promptly and effectively treated. There are also other unknown delayed serious consequences:: effects on platelets and blood pressure can be involved, because vaccines (in particular this virus) express the Spike protein and interfere with blood pressure regulation and pulmonary flow [23]. Vaccines that have been achieved through innovative techniques could produce different effects than those known up until now.
There is also the risk of antibody-dependent enhancement (ADE) [24], the increased vulnerability of the vaccinated to serious effects such as pulmonary disease when exposed to a new virus. The impact of multi systemic inflammatory syndrome, currently moderate, could increase as a result of vaccinations [25], in the same way as the VAED (Vaccine-Associated immune-mediated Enhanced Disease) or as the VAERD (Vaccine-Associated Enhanced Respiratory Disease). VAED is caused by the interaction between the antibodies induced by the Dengue vaccine and different strains of the wild virus. VAERD is a respiratory response that occurred in 1967 with the respiratory syncytial virus vaccine; this inoculation blocked the

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production of protective antibodies against the contamination of the wild virus. Following vaccinations, cases of cerebral venous sinus thrombosis with thrombocytopenia are emerging [26].

At last, SARS-CoV-2 immunogenic epitopes (antigen parts) have similarity to human proteins and they might be responsible for auto immunological pathogenic priming [27].

It is clear that the evaluation between risks and benefits must be established with long-term analysis.

In the light of these uncertainties and of the particular life-expectations during childhood, the preventive principle requires resistance to experimentation on children. It's important to achieve enough knowledge about vaccine implications before exposing children to as yet unknown long and short term effects. .

Vaccines Protective Effectiveness

It appears that vaccinations are reducing hospitalisations and deaths related to COVID-19, without noticing climate changes or other modifications.

The real efficacy of the Pfizer and Moderna vaccines could be lower than reported by producers[28]. It would seem that m-RNA inside the vaccine has instability problems[29].

AstraZeneca vaccine has a documented average effectiveness of 76% for adults and 52% for over 65-year-old people[30], Janssen vaccine has the 67%[31]. If the estimations include asymptomatics, the RCT efficacy will be even lower. The duration of acquired immunity, when periodic recalls will be needed and additional risks and consequences are still unknown.

There's also the question of virus variants. Variants enable a better adjustment of the virus in the host environment, it's more transmissible[32], otherwise the most infective variants assert as much as the virus faces an hostile environment [33] [34]. Their rapid emergence is already reducing the antibody response to vaccines, by ~3[35] to 6 times, or more[36], to the point of irrelevance[37] [38], with plausible repercussions also on the efficacy and duration of protection.

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[37] https://www.sciencemag.org/news/2021/02/south-africa-suspends-use-astrazenecas-covid-19-vaccine-after-it-fails-clearly-stop

[38] Shabir A. Madhi, et al Efficacy of the ChAdOx1 nCoV-19 COVID-19 Vaccine against the B.1.351 Variant NEJM March 16, 2021 DOI: 10.1056/NEJMoa2102214

With the South African variant, the Pfizer vaccine had an antibody response 3 times lower[39], Moderna 6,4 times lower, and reports are even worse[40]. That could entail a lower effectiveness both in defence and in duration. It should be noted that the progress of a variant can be very fast: in Italy, the English variant was estimated by ISS (Italian National Institute of Health) at 54% on 18th February and at 91,6% on 15th April respectively. If vaccines efficiently contrast the English variant, it will be possible that other variants, which are less disturbed by vaccines, will replace the previous ones.

Vaccinations and Herd Immunity

The most effective vaccines Pfizer and Moderna seem to provide documentary evidence about the decrease of the infection at about 90%[41], even if with unbelievable exceptions[42]. People that have been vaccinated with AstraZeneca reported almost the same percentage compared to asymptomatic people who have received the full dose[43]; but with the split of the first dose of the vaccine, paradoxically, also the percentage of asymptomatic people vaccinated has decreased.

It is plausible a lower rate of transmission by vaccinated people, but asymptomatic people are more dangerous because of their reduction of preventative measures, even in case of soft symptoms.

Reaching herd immunity through mass vaccination is not reasonable for different reasons:

A. Vaccines warn the transmission of the virus among population only partially (excluding some variants that remain transmissible)[44].
B. Vaccination campaigns are proceeding at different rates in different countries and among the population in the same country.
C. Variants are emerging and are vaccine-resistant. These modifications rapidly spread through population movements. High immunisation rates may generate a selective influence that may benefit the other variants that vaccinated people should transmit.
D. The duration and the protection of the vaccine is still unknown.
E. Vaccinated subjects become less careful on preventative measures.
F. Several animal species could be the reserve of the virus.

It is expected that the virus will become endemic, manifesting itself in 'waves' of varying magnitude and frequency[45]. Hence, the collaboration between the vaccination of individuals at risk and the natural immunisation of individuals less endangered would take the advantage to reach previously herd immunity. This allows natural recalls to immune subjects, who reinforce the barrier against the virus and reduce the need of recurring vaccinations.[46] [47]

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The most crucial solutions to overcome the pandemic are the development of natural defenses inside the community, environmental improvements, lifestyle, socio-economic conditions, global health enhancement[48] [49] and the recognition of effective therapies.

Conclusion

Children respond to antigenic stimuli differently than adults, with clear differences based on the age range. The addition of new vaccinations on vaccination pediatric timetables would implicate a decrease on routine vaccinations coverage and provoke unknown interactions.

"Children aren't the most damaged by this pandemic, but they risk to be its most remarkable victims." [50]

The hippocratic imperative "*primum non nocere"* is fundamental for every Medical Doctor and thus should be also for every measure adepte by the public health administration.

The Number Needed to Treat (NNT) related to children could be very high to avoid COVID-19 cases. We are committed to promote healthy nutrition and sound lifestyle, which protect the physiological defense abilities of the organism to fight against infections, chronic and degenerative diseases.

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