## COVID-19 child vaccination: irresponsible, unethical and unnecessary

June 9, 2021 (https://www.hartgroup.org/child-vaccination-irresponsible/)



We must not repeat mistakes from history

It is shocking that as of Friday 6 June the Medicines and Healthcare products Regulatory Agency (MHRA) approved the use of the Pfizer vaccine in children aged 12 to 15 years old.

The MHRA apparently carried out a "rigorous review" and found that "safety, quality and effectiveness have been met". Quite how they can be satisfied that the required safety standards have been met is unclear when this product is still at the research stage with only limited short-term safety data available and nothing yet known about any medium or long-term side effects.

The child clinical trials will continue to be monitored for long term protection and safety two years after vaccination. If serious, long-term health impacts emerge, it will be too late for those who are vaccinated now, who will have to live with the consequences. Already there seems to be a signal in the data from Israel revealing myocarditis (https://www.timesofisrael.com/israel-said-probing-link-between-pfizer-shot-and-heart-problem-in-men-under-30/) (inflammation of the heart muscle) described by the Israeli health authority as 1 in 44,000 16-30 year-olds, but with higher incidence in the youngest groups. This is not responsible medicine and is a reckless approach to children's health.

On 17 May, HART member Dr Ros Jones sent a letter (https://www.hartgroup.org/open-letter-child-vaccination/) — signed by dozens of doctors and academics — to the MHRA to express their grave concerns. Two hours after the MHRA announced they had given temporary emergency use approval (https://www.bbc.co.uk/news/health-57358446) for the vaccine, they sent this reply to that letter (https://www.hartgroup.org/wp-content/uploads/2021/06/MHRA-reply-04-06.pdf). In it, they claim that no new adverse events were identified and they link to this recent New England Journal of Medicine paper (https://www.nejm.org/doi/full/10.1056/NEJMoa2107456). But it is only if you take the time to read the supplementary appendix

(https://www.nejm.org/doi/suppl/10.1056/NEJMoa2107456/suppl\_file/nejmoa2107456\_appendix.pdf) that you discover that there were seven unspecified severe "events" and one life-threatening "event" reported in the vaccinated arm of the trial. Without clarification of these events, a proper analysis of safety cannot be made. Only 1,134 children were given the vaccine on this trial, far too small a number to be able to rule out uncommon but severe or life-threatening side effects — what else do we just not know yet? These points were made on 6 June in a follow up letter to Dr June Raine (https://www.hartgroup.org/wp-content/uploads/2021/06/Further-letter-to-MHRA-08-06-21-2.pdf), CEO of the MHRA, sent by Dr Ros Jones and signed by many others.

There are also urgent questions to be answered about how the trials in children were approved in the first place, when there is a lack of potential benefit to the trial participants and unknown risks with the adult trials still ongoing. Why was an emergency use authorisation granted in the USA when there is no COVID-19 emergency among children? Children are at vanishingly small risk from COVID-19 and experimenting on them with novel technologies is a road no ethical scientist should walk down.

Indeed the Royal College of Paediatrics and Child Health (https://www.rcpch.ac.uk/) has not recommended (https://www.rcpch.ac.uk/resources/coronavirus-vaccination-programme-statement) COVID-19 vaccination for children and in Germany, the Standing Vaccination Commission (STIKO) has stated that only children and adolescents with certain pre-existing health conditions (https://www.iamexpat.de/expat-info/german-expat-news/stiko-recommends-covid-vaccine-only-minors-health-conditions) should be vaccinated. Worryingly, the German government has ignored this advice and is pressing ahead (https://www.thelocal.de/20210607/germany-opens-up-covid-vaccines-to-everyone-over-the-age-of-12/) with vaccines for children 12 and up regardless. According to the official government response (https://petition.parliament.uk/petitions/586017) to Dr Ros Jones' petition on this matter, "the JCVI currently advises that children under 16 years of age, even if they are clinically extremely vulnerable (CEV), are at low risk of serious morbidity and mortality and given the absence of safety and efficacy data on COVID-19 vaccines, are not currently recommended for routine COVID-19 vaccination."

HART have closely scrutinised the evidence from Pfizer in their Emergency Use Authorization Amendment document (https://www.fda.gov/media/148542/download), which recommends use of their COVID-19 vaccine in American children aged 12 and up. Published on the US Food and Drug Administration (FDA) website, we would draw attention to page 33 where it appears 3 participants on the trial reported a DVT (Deep vein thrombosis) clot in the leg — which then went to their lung (Pulmonary Emboli). However, the paper is far from clear and others have suggested that the three events in question actually happened in the trial of 16 to 55 year olds. Either way, Pfizer urgently needs to clarify these details and also address the unspecified and unexplained severe and life-threatening events mentioned above in the New England Journal of Medicine paper.

Children have had to endure school closures, being cut off from friends and relatives, cancelled medical and dental appointments, masks in the classroom and now, they face huge emotional pressure to have a vaccine they don't need. Over the last 14 months we have forced them to carry a burden that was never theirs to carry. No child should have to suffer in order to protect adults, especially the vast majority of adults who have had the vaccination themselves and are apparently protected from severe illness and death. Some have claimed that children need to be vaccinated in order to keep schools open. If this is the case, we are vaccinating against politics — not a virus.

The Joint Committee on Vaccination and Immunisation (JCVI) must now advise the government on whether 12 to 15 ^ year olds should be vaccinated. HART urges them to **reject the calls to vaccinate children against COVID-19** and **exercise extreme caution**. We must not repeat past tragedies which have occurred when vaccines are rushed to market.



 $\begin{tabular}{l} $\P$ Child vaccination — implications for fully informed consent (https://www.hartgroup.org/child-vaccination/) \\ \end{tabular}$ 

 $Tony\ Blair\ calls\ for\ medical\ apartheid\ \rair\ (https://www.hartgroup.org/tony-blair-medical-apartheid/)$ 













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