16 July 2023

Open Letter to Chief Executive and Chairman of all Participating Centres and NHS Trusts

CC: Dame June Raine, CEO MHRA

Chair of all Local Research Ethics Committees

Re: NextCOVE study

We wish to draw your attention to a Covid-19 vaccine trial in your hospital which has just started recruiting children aged 12-17 and which is in contravention of the Declaration of Helsinki[1] and other UK and international laws.

NextCOVE[2] trial was launched last month in Bradford, with several other centres across the UK due to start recruiting soon, including Leicester. The trial was announced by Yahoo[3] on the same date, 30th June 2023, that all routine Covid vaccines ended[4] for healthy children and young adults.

The information leaflet provided by Rotherham Doncaster and South Humber NHS Foundation Trust, opens with this emotionally loaded paragraph:

> *'The COVID-19 pandemic is like nothing we've seen in more than a century and it has altered each and every one of our lives. Now, you or your child could be a part of important research on an investigational COVID-19 vaccine. By enrolling in the NextCOVE Study, you or your child will be contributing to a potential solution to the evolving COVID-19 pandemic, which has affected the entire world.'*

Further on it states: '*By taking part in this trial, you or your child could make a difference for your family, your community and people everywhere.*'

The trial aims to compare two types of Moderna mRNA vaccines for use as boosters, the original vaccine produced against the Wuhan strain, compared against the latest bivalent vaccine which is a 50:50 mix of the original with a new omicron strain. There is no placebo control.

It is notable that the only group currently able to get a Covid vaccine[5] in the UK are high risk children aged 6 months to 4 years, all other vaccines having been suspended through the summer. Boosters are likely to be available again this autumn, only for specified high risk groups. Healthy young adults, let alone children, are not recommended to have boosters.

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[1] https://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/
[2] https://www.rdash.nhs.uk/wp-content/uploads/2023/06/mRNA-1283-P301_Recruitment_Brochure_UK_English_V2_21Mar2023_digital-GR-edit.pdf
[3] https://uk.news.yahoo.com/covid-19-vaccination-trial-begins-073007587.html
[4] https://www.gov.uk/government/news/people-urged-to-get-covid-jab-before-offer-ends
[5] https://www.nhs.uk/conditions/covid-19/covid-19-vaccination/about-covid-19-vaccination/

It is hard, therefore, to see how these boosters could significantly benefit the children entering the trial, which is an absolute requirement for research on children. The Declaration of Helsinki[1] states that *'All medical research involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the research in comparison with foreseeable benefits to them and to other individuals or groups affected by the condition under investigation'*.

The Medicines for Human Use (Clinical Trials) Regulations 2004[6] enacted the Declaration of Helsinki into UK law, and further provides that *'The rights, safety, and well-being of the trial subjects are the most important considerations and shall prevail over interests of science and society'*. The landmark international Universal Declaration on Bioethics and Human Rights(2005)[7] states that *'Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned'.* Article 7, referring to people without the capacity to consent, states, '*authorization for research and medical practice should be obtained in accordance with the best interest of the person concerned'* and that *'research should only be carried out for his or her direct health benefit'*.

The trial information leaflet does not mention any direct health benefit to the recipient, the aim of the study being *'to learn more about how it works in the body'.* The JCVI recently published a table of numbers needed to vaccinate[8] and for the age group 16-19, it requires 193,500 vaccinations to prevent one severe hospital admission. For healthy 20–29-year-olds the number is even larger at 418,100.

But if there is no tangible benefit, what of the potential harms? The Declaration of Helsinki clearly requires these to be given. The NextCOVE information leaflet states:

- *'The trial vaccine is investigational and has not yet been approved for use in adults or children. This means we are still researching the product and we do not know if it is effective and safe to use. We do not know if it will prevent SARS-CoV-2 infection or reduce the severity of COVID-19 illness.'*

This statement surely renders the trial illegal for children or any other groups who cannot give informed consent, and very questionable even for healthy adults.

The leaflet then goes on to state:

- *All vaccines may have some side effects, and this is true for this investigational vaccine too.*
- *In other trials of individuals receiving investigational vaccines similar to mRNA-1283.222, the most common side effects were fever, headache, muscle aches or pain, joint aches or pain, tiredness, nausea/vomiting and chills. These side effects have been more commonly reported after the later injections of the investigational vaccine and typically last between 2 and 3 days.*

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[6] https://www.legislation.gov.uk/uksi/2004/1031/pdfs/uksi_20041031_en.pdf

[7] https://www.unesco.org/en/legal-affairs/universal-declaration-bioethics-and-human-rights

[8] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1131409/appendix-1-of-jcvi-statement-on-2023-covid-19-vaccination-programme-8-november-2022.pdf

There is no mention of myocarditis in the information leaflet, despite the fact that the highest age group for this serious complication is 16-17s according to information presented to the FDA[9] at 69.1 cases per million second doses in males. A further paper from the same group gave a rate of 105.9 per million doses[10]. These studies are using passive reporting systems but one study from Thailand, where boys were brought back for blood tests on day 3 and 7 after their second dose, found an extremely worrying 1 in 43[11] with clinical or subclinical myocarditis/pericarditis. Many reports only include the Pfizer vaccine which was the predominant mRNA vaccine in use, but a study from Canada shows the incidence of myocarditis after Moderna was significantly higher than after the Pfizer vaccine, especially in young adults aged 18-29[12].

There is also no mention that far from side effects *'typically lasting between 2 and 3 days'*, the effects of myocarditis may include permanent scarring to heart muscle with increased risk for sudden death. It has been suggested that post-vaccination myocarditis in children is mild and settles quickly, but this is not borne out by the facts. One small follow-up study[13] has been published in which 69% of the children studied still had significant abnormalities on cardiac MRI scans 3-8 months after their initial illness. The Late Gadolinium Enhancement (LGE) seen on the scans has previously been described as an indicator of risk for later deaths[14]. In a large follow-up study from the US[15], 519 children with myocarditis reported to the VAERS system, were followed 3-6 months later. 30% still had intermittent pain, 26% were still on medication. Of 151 who had a follow-up cardiac MRI scan, 54% were still abnormal. There has been sufficient concern that the FDA are now funding a large study of children with MACiV[16] (Myocarditis After COViD Vaccination).

An analysis of the results from the original Pfizer and Moderna mRNA vaccine trials found that 1 in 800 suffered a serious adverse event, as defined by the WHO endorsed Brighton Collaboration[17]. Thus on balance, the risks from these trial injections potentially outweigh the benefits by as much as 500:1. Indeed, the JCVI itself[18] concluded in July 2021 that the balance of benefit and risk was too close to recommend to healthy under 18s – that was long before omicron and when we knew a lot less about the poor efficacy and apparent immune imprinting of the vaccines.

[9] https://www.fda.gov/media/153514/download
[10] https://jamanetwork.com/journals/jama/fullarticle/2788346
[11] https://www.mdpi.com/2414-6366/7/8/196
[12] https://www.sciencedirect.com/science/article/pii/S0735109722068243
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[14] https://jcmr-online.biomedcentral.com/articles/10.1186/1532-429X-13-S1-M7
[15] https://www.thelancet.com/journals/lanchi/article/PIIS2352-4642(22)00244-9/fulltext
[16] https://www.nymc.edu/news-and-events/news-archives/us-fda-awards-dr-supriya-jain-19-million-to-support-research-on-covid-19-vaccine-associated-myocarditis.php
[17] https://www.sciencedirect.com/science/article/pii/S0264410X22010283
[18] https://www.gov.uk/government/publications/covid-19-vaccination-of-children-and-young-people-aged-12-to-17-years-jcvi-statement/jvci-statement-on-covid-19-vaccination-of-children-and-young-people-aged-12-to-17-years-15-july-2021

As outlined above, recruitment of children to the NextCOVE trial is in clear breach of the Declaration of Helsinki[19], the Medicines for Human Use (Clinical Trials) Regulations 2004[20] and the Universal Declaration on Bioethics and Human Rights(2005)[21].

Moreover, it has come to our notice that another trial centre is offering £1500 to children at completion of the study. This contravenes the Ethical Research Involving Children(ERIC) guidance[22], which specifically advises, '*Ensure that any payment is not used to unduly bribe, coerce or pressure children or parents to participate in research'.* Can you confirm whether or not similar financial inducements have been offered by your research team?

This trial must cease recruiting children, with immediate effect and before a healthy volunteer comes to harm.

Yours sincerely,

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[19] https://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/
[20] https://www.legislation.gov.uk/uksi/2004/1031/pdfs/uksi_20041031_en.pdf
[21] https://www.unesco.org/en/legal-affairs/universal-declaration-bioethics-and-human-rights
[22] https://childethics.com/payment-compensation/#1652396073278-952504c9-a815

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