

## **Open Letter: Safety and Ethical Concerns around use of Covid-19 Vaccines in Children**

We wish to notify you of our grave concerns regarding all proposals to administer Covid-19 vaccines to children. Recently leaked Government documents suggested that a Covid-19 vaccine rollout in children over 12 years old is already planned for September 2021, and the possibility of children as young as 5 years old being vaccinated in the summer in a worst-case scenario.<sup>i</sup>

We have been deeply disturbed to hear several Government and SAGE representatives calling in the media for the Covid-19 vaccine rollout to be “turning to children as fast as we can”.<sup>ii</sup> In addition, there has been disturbing language used by teaching union leaders, who have no medical or legal qualifications, implying that coercion of children to accept the Covid-19 vaccines through peer pressure in schools was to be encouraged, despite the fact that coercion to accept a medical treatment is against UK and International Laws and Declarations.<sup>iii</sup> Rhetoric such as this is irresponsible and unethical, and incites the public to demand the vaccination of minors with a product still in the experimental phase and about which no medium- or long-term effects are known, against a disease which presents no material risk to them. We set out our reasoning and evidence below.

### **Risks and benefits in medical treatments**

Vaccines, like any other medical treatment, come with varied risks and benefits. Therefore, we must consider each product, individually, on its merits, and importantly for which patients or sections of the population is the risk/benefit ratio acceptable. We are raising these concerns as part of the informed debate, which is a vital part of proper, scientific process, necessary to prevent tragedies occurring from the use of vaccines rushed to market, which has happened in the past. The swine flu vaccine hurriedly rolled out in the pandemic of 2010, caused over one thousand cases of narcolepsy, a devastating brain injury, in children and teenagers, before being withdrawn.<sup>iv v</sup> Dengvaxia, a new vaccine against Dengue, was also rolled out to children ahead of the full trial outcomes, and 19 children died of possible antibody-dependent enhancement (ADE).<sup>vi</sup> We must not risk a repeat of this with the Covid-19 vaccines, which would not only impact on the children and families affected, but would also have a hugely damaging effect on vaccination uptake in general.

No medical intervention should be introduced on a ‘one size fits all’ basis, but instead should be fully assessed for suitability according to the characteristics of the age cohort and of the individuals concerned, weighing up the risk versus benefit profile for each cohort and the individuals within a group. This approach was outlined last October, by the head of the Government Vaccine Task Force, Kate Bingham, stated, “We just need to vaccinate everyone at risk. There’s going to be no vaccination of people under 18. It’s an adult-only vaccine, for people over 50, focusing on health workers and care home workers and the vulnerable.”<sup>vii</sup>

### **Children do not need vaccination for their own protection**

Healthy children are at almost no risk from Covid-19, with the recovery rate in this age group calculated at 99.997%.<sup>viii,ix</sup> No previously healthy child under the age of 15 has died during the pandemic in the UK and admissions to hospital or intensive care are exceedingly

rare.<sup>x,xi</sup> Although Long-Covid has been cited as a reason for vaccinating children, there is little hard data. It appears less common and much shorter-lived than in adults and none of the vaccine trials have studied this outcome<sup>xii xiii</sup>. The inflammatory condition, PIMS, was listed as a potential adverse effect in the Oxford AstraZeneca children's trial<sup>xiv</sup>. Children have also been shown to be less likely to transmit the infection.<sup>xv,xvi,xvii</sup> Indeed, the risk from Covid-19 to young people is so low that a human challenge trial, to deliberately infect a cohort of young people with SARS-CoV-2, has recently been approved.<sup>xviii</sup>

### **Developing Population/Herd Immunity to SARS-CoV-2**

1. The argument that vaccination of children is needed to achieve population or herd immunity, which will minimise further transmission in the community, is not supported by the evidence.

Interim clinical trial data is clear that Covid-19 vaccination does not necessarily prevent infection with or transmission of SARS-CoV-2. These vaccines have only been shown to reduce the incidence of symptomatic cases (symptoms plus a positive test), thus benefiting the recipient, and may have less impact on reducing circulation of the virus in the population.<sup>xix xx</sup> Recent epidemiological data purporting to show a reduction in transmission of the virus in vaccinated people is not conclusive.<sup>xxi</sup>

It is estimated that 20-50% of the population have pre-existing immunity to SARS-CoV-2 through cross-reactive immunity from common coronaviruses.<sup>xxii</sup> As a result of immunity, acquired naturally from exposure to SARS-CoV-2 or from vaccination, the ONS Coronavirus (COVID-19) Infection Survey calculated that by 28 April 2021, 68.3% of the English population had antibodies (and therefore immunity) to SARS-CoV-2 (around 60% for Scotland, Wales and Northern Ireland).<sup>xxiii</sup> By 8 May 2021, 67% of the population over 18 years had received at least one dose of a Covid-19 vaccine.<sup>xxiv</sup>

Although there are overlaps between these three groups, so the percentages are not cumulative, there is no doubt that we have now achieved remarkably high levels of population immunity. This was confirmed by a University College London modelling team who recently announced that the UK had achieved the herd immunity threshold on 12 April 2021.<sup>xxv</sup> Vaccination of children below 18 years is therefore not needed to control community transmission.

David Nabarro, special envoy to the World Health Organization on Covid-19, stated in October 2020 that addressing the coronavirus crisis was “not going to be a case of everyone getting vaccinated” and said, “We’re not fundamentally using the vaccine to create population immunity, we’re just changing the likelihood people will get harmed or hurt. It will be strategic.”<sup>xxvi</sup>

Furthermore, there is no evidence that children are a significant factor in transmission of SARS-CoV-2 to adults. A study of over 300,000 NHS Scotland Healthcare workers in 2020 concluded that living with young children was associated with a reduced risk of developing COVID-19 and COVID-19 requiring hospitalisation. There was no evidence that living with young children increased adults’ risk of COVID-19, including during the period after schools reopened.<sup>xxvii</sup> These findings are backed up by another study of over 9 million adults, where it was observed that living with children was not associated with increased risks of SARS-CoV-2 infection, COVID-19 related hospital or ICU admission, but was associated with reduced risk of COVID-19 death.<sup>xxviii</sup> Therefore, contact with children, either in homes or in schools, may even be protective for adults.

In addition, it is clear, from data collected over the last year, that schools are not a major focus of community outbreaks and when schools returned in March 2021 only 0.06% of the mass tests carried out were positive, and were likely to be mainly false positives.<sup>xxix</sup> People who work in schools, together with school children and their parents, can be reassured that schools are essentially a safe environment that need no particular protective measures against Covid-19. The stirring up of fear and panic by union leaders, and various other parties, is reprehensible and can only lead to poor decision-making and worse outcomes for all concerned.

## 2. Naturally acquired immunity is a safe and effective way to for children to develop immunity to SARS-CoV-2

We argue that for children, vaccine-induced antibody-dependent immunity is inferior to natural immunity, as it does not cover the full spectrum of protective immunity (mucosal immunity, IgA, and T-cell immunity to the whole virus) and may be only short-lived. Naturally acquired immunity, which is completely safe for children to obtain, is expected by scientists to be long-lasting<sup>xxx</sup> as it has been from SARS-CoV-1, where those infected have been found to retain memory T-cell immunity 17 years post-infection.<sup>xxxi</sup> Natural immunity is therefore likely to be a better strategy for children, avoiding the need for multiple, recurrent vaccine booster doses over a lifetime.

## Potential Risks to Children from Experimental Covid-19 Vaccines

### 1. Experimental vaccines using new technologies

All Phase 3 Covid-19 vaccine trials are ongoing and not due to conclude until late 2022/early 2023. The vaccines are, therefore, currently experimental with only limited short-term and no long-term safety data available. In addition, many are using a completely new mRNA vaccine technology, which has never previously been approved for use in humans<sup>xxxii</sup>. Some are using a different technology - viral vector DNA vaccines - that has only had limited use before, in Ebola vaccines.

None of the current Covid-19 vaccine Phase 3 trials included children, so there is no safety data for use of Covid-19 vaccines in those under 16 years<sup>xxxiii</sup>. A small trial of 300 children has just started with the Astra Zeneca vaccine<sup>xxxiv</sup>, which is grossly underpowered for obtaining safety data. Similar trials on children as young as 6 months old are also being carried out by Pfizer and Moderna, who requested approval from the regulators after only around 3 months of data on 12-15-year-olds.<sup>xxxv xxxvi</sup>

Based on the lack of expected benefits for healthy children, we argue that recruiting children to Covid-19 vaccine trials is unethical at this stage, whilst Phase 3 adult trials are ongoing, and the vaccines are not fully licensed but only have Temporary/Emergency Use Authorisation. Current Government advice is that children with serious neuro-disability in respite care may be offered vaccination, with parents/carers informed of “the paucity of safety data for the vaccine in children”.<sup>xxxvii</sup>

### 2. Reports of Serious Adverse Reactions and Deaths

Several databases around the world are now capturing adverse events that have occurred in relation to the administration of Covid-19 vaccines.

- In the UK, the MHRA has reported a total of 215,939 adverse events, including 1102 deaths as of 6 May 2021.<sup>xxxviii</sup>
- The European EudraVigilance database records 354,177 adverse events and 8430 deaths as of the 24 April 2021.<sup>xxxix</sup>
- The US Vaccine Adverse Event Reporting System (VAERS) database has recorded 3837 deaths relating to Covid-19 vaccines as of 30 April 2021,<sup>xl</sup> which is over fifteen times the average number of all vaccine-related deaths normally reported to VAERS (under 200 per year) and in a period of only 4 months. 46% of these deaths occurred in people who fell ill within 48 hours of being vaccinated.<sup>xli</sup> This includes 7 children under 18 years of age. These must be taken seriously and cannot all be dismissed as coincidental.

Specifically, regarding the AstraZeneca vaccine, there have been reports of multiple cases of cerebral venous thrombosis and thrombocytopenia with fatal outcomes, leading to temporary suspension in 24 countries,<sup>xlii</sup> and subsequent advice to avoid this vaccine in younger age groups. The German Paul Ehrlich Institute justified their decision for suspension, indicating that seven such cases were reported, three of them fatal, when only one might have been expected to occur.<sup>xliii</sup> The following week, a report noted a total of sixteen such cases in Germany, four of them with fatal outcome, and all but one occurring in women aged between 20 and 63 years.<sup>xliv</sup>

In countries which have already started to vaccinate teenagers there have been reports of serious injuries and deaths, including an 18-year-old girl in the US who developed brain clots following her Johnson & Johnson vaccine and is critically ill, having undergone 3 brain surgeries.<sup>xlv</sup> There are already reports appearing on the VAERS website of deaths in healthy children, for example in Colorado a 15-year-old healthy boy died of heart failure two days after having the Pfizer vaccine.<sup>xlvi,xlvii</sup> These children and others with severe but non-fatal adverse effects were among only a few thousand recipients of the vaccines, which are not yet licensed for routine use.

The suspicion of a causal relationship between Covid-19 vaccines and blood clotting disorders is plausible, as there is evidence of direct activation of the alternative complement pathway by SARS-CoV-2 spike proteins,<sup>xlviii</sup> as well as papers demonstrating the potential of spike proteins to cause cell to cell fusion, forming syncytia, which may lead to endothelial damage and clot formation.<sup>xlix</sup> As the production of spike proteins is induced by all the vaccines, this has the potential to be a class effect, affecting the Pfizer and Moderna mRNA vaccines too.

The European Medicines Agency (EMA) safety committee, after reviewing the data and declaring the AstraZeneca vaccine to be safe, while indicating that rare events cannot be ruled out, noted “concerns about the reports involving younger patients” with most cases affecting women.<sup>l</sup> They are also reviewing the reports of blood clots associated with the Johnson & Johnson Covid-19 vaccine that has led to the suspension of the vaccine in the US. The EMA’s Pharmacovigilance Risk Assessment Committee (PRAC) is continuing its assessment of reported cases, convening an expert group in the context of a “safety signal” that warrants further investigation.<sup>li</sup> The EU Commission has announced that they will not be renewing the AstraZeneca or Johnson & Johnson vaccines contracts and Denmark has stopped use of the AstraZeneca and Johnson & Johnson vaccines due to the safety concerns.<sup>lii liii</sup>

Guidance on the AstraZeneca vaccine was revised very recently, and the situation is changing daily around the world. The possibility of further unexpected safety issues cannot be ruled out. In Israel, where the vaccines have been widely rolled out to young people and teenagers, the Pfizer vaccine has been linked to several cases of myocarditis in young men<sup>liv</sup> and concerns have been raised about reports of altered menstrual cycles and abnormal bleeding in young women following the vaccine.<sup>lv</sup>

In this climate of emerging and unexpected side-effects, children must not be subjected to known and unknown risks - either in limited numbers in clinical trials, or in a mass rollout. Doctors around the world are echoing this demand, including 93 Israeli doctors in a recently published Open Letter, who stated, "*We believe that not even a handful of children should be endangered through mass vaccination against a disease not dangerous to them*".<sup>lvi</sup>

### 3. Potential Long-term Harms

The most critical data to obtain, before giving Covid-19 vaccines to children, is long-term safety data, which has ruled out potential late-onset effects that can take months or years to become apparent. Children have a lifetime ahead of them, and their immunological and neurological systems are still in development, making them potentially more vulnerable to adverse effects than adults. Numerous concerns have been raised already, regarding potential risks of the new mRNA vaccines inducing autoimmune disease or allergies and affecting fertility.<sup>lvii</sup> A recently published paper raised the possibility that mRNA Covid-19 vaccines could trigger prion-based, neurodegenerative disease<sup>lviii</sup> and carcinogenesis also must be considered. The limited children's trials undertaken to date are totally underpowered to rule out uncommon but severe side effects.

There is a plausible risk that Covid-19 vaccines may worsen clinical disease due to antibody-dependent enhancement (ADE), which has been observed in animal trials during previous attempts at developing a vaccine against coronavirus.<sup>lix</sup> Covid-19 vaccine trials have so far not addressed this significant concern, and this information must be shared prior to vaccination.<sup>lx</sup> Such concerns are real. As recently as 2016, Dengvaxia, intended to protect children from the dengue virus, increased hospitalizations in children who received the vaccine. This vaccine was withdrawn from market as a result<sup>lxi</sup>

The UK Government has already granted immunity from liability for harms to all Covid-19 vaccine manufacturers, which they demanded. An Astra Zeneca spokesperson said that "this is a unique situation where we as a company simply cannot take the risk if in ... four years the vaccine is showing side effects"<sup>lxii</sup>. If this risk is significant enough for the manufacturers to anticipate economic loss, children should not be expected to take the same risk, jeopardising their long-term health.

For an individual child with serious underlying health issues, Covid-19 vaccination may be considered to be the best way forward. This decision would involve careful consideration by doctors and parents, taking into account the condition and needs of the child concerned.

### Legal and Ethical Considerations re Experimental Trials on Humans

As the Covid-19 vaccines are still in Phase 3 clinical trials, and only being used under temporary, emergency authorisation, they are experimental and thus subject to strict legal and ethical requirements.

The Nuremberg Code judgment established a new standard of ethical medical behaviour for the post World War II human rights era and aimed to prevent the atrocities of involuntary human experimentation from ever occurring again. It enunciates the requirement of voluntary informed consent of all human subjects, to protect the right of the individual to control his or her own body.<sup>lxiii</sup> This 1997 article from the New England Journal of Medicine outlines the history behind, and the importance of the Nuremberg Code.<sup>lxiv</sup>

The landmark international Universal Declaration on Bioethics and Human Rights (2005) states that, “*Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned*”.<sup>lxv</sup> 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 Declaration of Helsinki, the World Medical Association policy adopted in 1964, 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.*”<sup>lxvi</sup>

The Medicines for Human Use (Clinical Trials) Regulations 2004 enact 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*”.<sup>lxvii</sup>

### Medical Paternalism v Informed Consent

The landmark case of *Montgomery v Lanarkshire* (2015)<sup>lxviii</sup> ended the practice of medical paternalism. All patients must be fully informed, with all risks disclosed, before any medical intervention. The medical and personal situation of each individual must be considered prior to administration of medical treatment, and blanket recommendations are no longer legal in Britain.

In the UK, “*Respect for patients’ autonomy is expressed in consent law; to impose care or treatment on people without respecting their wishes and right to self-determination is not only unethical, but illegal.*”<sup>lxix</sup> This is enshrined into law, professional guidelines, and the NHS constitution.<sup>lxx</sup>

For consent to be valid: the patient must be competent; the patient must have sufficient information to make a choice - including risks of harm, likelihood of benefit and time to ask questions; and the patient must be able to make that consent freely, with no coercion and enough time to consider the options.<sup>lxxi</sup> Additionally, The Declaration of the Rights of the Child states that, “*the child, by reason of his physical and mental immaturity, needs special safeguards and care, including appropriate legal protection*”.<sup>lxxii</sup>

### Conclusion

There is important wisdom in the Hippocratic Oath which states, “*First do no harm*”. All medical interventions carry a risk of harm, so we have a duty to act with caution and proportionality. The current, available evidence clearly shows that the risk versus benefit calculation does NOT support administering rushed and experimental Covid-19 vaccines to

children, who have virtually no risk from Covid-19, yet face known and unknown risks from the vaccines. As adults we have a duty of care to protect children from unnecessary and foreseeable harm.

We conclude that it is irresponsible, unethical and indeed, unnecessary, to include any children under 18 years in the national Covid-19 vaccine rollout. Clinical trials in children also pose huge ethical dilemmas, in light of the lack of potential benefit to trial participants and the unknown risks. The end of the current Phase 3 trials should be awaited as well as several years of safety data in adults, to rule out, or quantify, all potential adverse effects.

**We call upon our governments and society at large not to repeat mistakes from history, and to reject the calls to vaccinate children against Covid-19. Extreme caution has been exercised over many aspects of the pandemic, but surely now is the most important time to exercise true caution - we must not be the generation of adults that, through unnecessary haste and fear, risk the health of children.**

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<sup>iv</sup> <https://www.narcolepsy.org.uk/resources/pandemrix-narcolepsy>

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<sup>x</sup> <https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a>

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<sup>xii</sup> [Illness duration and symptom profile in a large cohort of symptomatic UK school-aged children tested for SARS-CoV-2](#)

<sup>xiii</sup> [Post-acute COVID-19 outcomes in children with mild and asymptomatic disease](#)

<sup>xiv</sup> [https://www.dropbox.com/s/l7sk4b7z3vm6996/COV006\\_Participant%20Information%20Sheet%20%2816-17%20years%29\\_V2.0\\_09Feb2021.pdf?dl=0](https://www.dropbox.com/s/l7sk4b7z3vm6996/COV006_Participant%20Information%20Sheet%20%2816-17%20years%29_V2.0_09Feb2021.pdf?dl=0)

<sup>xv</sup> <https://pediatrics.aappublications.org/content/pediatrics/early/2021/01/06/peds.2020-048090.full.pdf>

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<sup>xvii</sup> <https://onlinelibrary.wiley.com/doi/full/10.1111/jpc.14937>

<sup>xviii</sup> <https://www.gov.uk/government/news/worlds-first-coronavirus-human-challenge-study-receives-ethics-approval-in-the-uk>

<sup>xix</sup> <https://www.bmj.com/content/371/bmj.m4037>

<sup>xx</sup> <https://www.bbc.com/future/article/20210203-why-vaccinated-people-may-still-be-able-to-spread-covid-19>

<sup>xxi</sup> <https://www.zoeharcombe.com/2021/05/transmission-of-covid-19-post-vaccination/>

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