Open Letter from UK doctors: Safety and Ethical Concerns Surrounding COVID-19 Vaccination in Children to Dr June Raine, Chief Executive, MHRA

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.[1]

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".[2] Teaching materials circulated to London schools contain emotionally loaded questions and inaccuracies[3]. In addition, there has been disturbing language used by teaching union leaders, 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.[4] Rhetoric such as this is irresponsible and unethical, and encourages the public to demand the vaccination of minors with a product still at the research stage and about which no medium- or long-term effects are known, against a disease which presents no material risk to them. A summary of our reasons is given below and a more detailed fully referenced explanation is available.[5]

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 specifically for which patients or sections of the population is the risk/benefit ratio acceptable. For COVID-19 vaccines, the potential benefits are clear for the elderly and vulnerable, however, for children, the balance of benefit and risk would be quite different. We are raising these concerns as part of an informed debate, which is a vital part of the proper, scientific process. We must ensure that there is no repeat of any past tragedies which have occurred especially when vaccines are rushed to market. For example, the swine flu vaccine, Pandemrix, rolled out following the pandemic of 2010, resulted in over one thousand cases of narcolepsy, a devastating brain injury, in children and teenagers, before being withdrawn.[6] Dengvaxia, a new vaccine against Dengue, was also rolled out to children ahead of the full trial outcomes, and 19 children died of possible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) before the vaccine was withdrawn.[7] 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, who said "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."[8]

Children do not need vaccination for their own protection

Healthy children are at almost no risk from COVID-19, with risk of death as low as 1 in 2.5 million[9]. No previously healthy child under the age of 15 died during the pandemic in the UK and admissions to hospital or intensive care are exceedingly rare[10] with most children having no or very mild symptoms. 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[11] [12]. The inflammatory condition, PIMS, was listed as a potential adverse effect in the Oxford AstraZeneca children's trial[13]. Naturally acquired immunity will give broader and better lasting immunity than vaccination[14]. Indeed, many children will already be immune[15]. Individual children at very high risk can already receive vaccination on compassionate grounds[16].

Children do not need vaccination to support herd immunity

Already, two thirds of the adult population have received at least one dose of a COVID-19 vaccine[17]. Models that assume vaccination of children is required to reach herd immunity have failed to account for the proportion who had immunity prior to March 2020 and those who have acquired it naturally[18]. Recent modelling suggested that the UK had achieved the required herd immunity threshold on 12 April 2021[19].

Children do not transmit SARS-CoV-2 as readily as adults, moreover adults living or working with young children are at lower risk of severe COVID-19[20]. Schools have not been shown to be the focus on spread to the community, teachers have a lower risk of COVID -19 than other working age adults[21].

Short-term safety concerns

As of 13th May, the MHRA[22] has received a total of 224,544 adverse events, including 1,145 deaths in association with SARS-CoV-2 vaccines. Reports of strokes due to cerebral venous thromboses were initially in low numbers but as awareness increased, many more reports led to the conclusion that AstraZeneca vaccine should not be used for adults under 40 years of age and this unpredicted finding has also led to the suspension of the Oxford AstraZeneca children's trial.

Similar events have been noted with Pfizer & Moderna vaccines on the US adverse reporting system (VAERS)[23] and it is likely that this is a class effect related to production of spike protein. New UK guidelines on managing Vaccine-Induced Thrombotic Thrombocytopenia (VITT)[24] include all COVID-19 vaccines in their advice. 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[25] and concerns have been raised about reports of altered menstrual cycles and abnormal bleeding in young women following the vaccine.[26]

Most concerning with regard to possible vaccination of children, is that there have now been a number of deaths associated with vaccination reported to the VAERS system in the US, despite the vaccines only being given to children within trials and a very recent rollout to 16-17 year olds[27].

Long-term safety concerns

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 adult safety data available. In addition, many are using a completely new mRNA vaccine technology, which has never previously been approved for use in humans[28]. The mRNA is effectively a pro-drug and it is not known how much spike protein any individual will produce. Potential late-onset effects can take months or years to become apparent. The limited children's trials undertaken to date are totally underpowered to rule out uncommon but severe side effects.

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. A number of specific concerns have been raised already, including autoimmune disease and possible effects on placentation and fertility.[29] A recently published paper raised the possibility that mRNA COVID-19 vaccines could trigger prion-based, neurodegenerative disease[30]. All potential risks, known and unknown, must be balanced against risks of COVID-19 itself, so a very different benefit/risk balance will apply to children than to adults.

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. This is particularly the case when considering mass intervention in a healthy population, in which situation there must be firm evidence of benefits far greater than harms. 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. 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".*[31] 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 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 the regulators 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, risks the health of children.

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