Open letter to the MHRA

- Dr June Raine, Chief Executive, MHRA
- Professor Lim, Chairman, JCVI COVID-19 subcommittee
- Hon Sajid Javid, Secretary of State for Health and Social Care
- Professor Sir Chris Whitty, Chief Medical Officer for England
- Sir Patrick Vallance, Government Chief Scientific Adviser
- Dr Jenny Harries OBE, Chief Executive, UKHSA

19 January 2022

Dear Dr Raine, Professor Lim, Mr Javid, Professor Whitty, Sir Patrick Vallance & Dr Harries,

URGENT

RE: Signals that Covid-19 Vaccines may have caused death in children and young adults

We write to demand an immediate, urgent investigation to determine whether the Covid-19 vaccines are the cause of significant numbers of deaths seen recently in male children and young adults.

We also request that anonymised data and information known to be available, showing how many children have died following a Covid-19 vaccine and within how many days, be published for full transparency, in the public interest.

On Thursday 13th January 2022, at a hearing in the High Court[1] in London, evidence was presented showing a significant increase in the number of young male deaths following roll out of the Covid-19 vaccinations compared with the prior five-year average between 2015 and 2019. It is important to look at male deaths separately, given what is known about higher risks from myocarditis in young males.

Between 1st May to 24th December 2021 there were

- 402 registered deaths in 15–19-year-old males, 65 more than the 337 five-year average;
- by contrast, 163 registered deaths in females, 12 less than the 175 five-year average; and

- combining those, 565 deaths of males and females registered in total, 53 more than expected.

The Office for National Statistics has accepted that the increase in young male deaths is a statistically significant increase, with the mortality rate falling outside the expected confidence intervals from earlier years' data.

Even more concerning is the fact that the actual number of deaths occurring of young males in this period is likely to be significantly higher than those registered. This is because the ONS estimates that owing to delays in registration, on average registered deaths in the period account for only 62% of actual deaths occurring. Any death where there was uncertainty about the cause will have been referred to the coroner and such deaths can take a long time to be registered. The fact that a signal is already evident in registered deaths is therefore a great concern.

Allowing for the ONS estimate, the 65 excess male deaths could represent 105 excess deaths of these young men, assuming the proportion of deaths that have been referred to the coroner is similar to previous years. If there have been more coroner's referrals this year, the figure could be higher.

Since at least 13 October 2021, the Secretary of State and JCVI have been made aware of this increase in male deaths through their representation by the Government Legal Department in High Court proceedings. In addition, the ONS has itself now recognised that more work could be undertaken to examine the mortality rates of young people in 2021 and has confirmed in writing that it intends to undertake that work "when more reliable data are available."

There are already signals of risk

The incidence of higher mortality in young males in 2021 coinciding with the roll out of Covid-19 vaccines cannot be dismissed as coincidental, since there have already been warning signals of serious adverse events in this age group. For this reason, the decision to offer the Covid-19 vaccine to under 18-year-olds has not been without controversy.

The JCVI previously declined to recommend that the Covid-19 vaccines be administered to healthy 12-15 year olds as the balance of benefit to risk was only marginal at best in the face of the very low risk to children of serious illness or death from Covid-19 disease, the considerable uncertainty of the potential harms of the Covid-19

vaccines, the known signals of harms from the vaccines already identified and the absence of complete and long term safety data in circumstances where the vaccines have been rapidly brought to market, long before the normal phase III clinical trials used to assess safety have been completed. On 3 September 2021 the JCVI said:

"*Overall, the committee is of the opinion that the benefits from vaccination are marginally greater than the potential known harms (tables 1 to 4) but acknowledges that there is considerable uncertainty regarding the magnitude of the potential harms. The margin of benefit, based primarily on a health perspective, is considered too small to support advice on a universal programme of vaccination of otherwise healthy 12 to 15-year-old children at this time. As longer-term data on potential adverse reactions accrue, greater certainty may allow for a reconsideration of the benefits and harms. Such data may not be available for several months*."

The JCVI's decision was overturned by the four chief medical officers of England, Wales, Scotland and Northern Ireland, not because they found there was a health benefit to children in respect of the Covid-19 vaccines but because, based on modelling analyses, they concluded that the Covid-19 vaccines were likely to reduce school absences. Notwithstanding that theoretically preventing a few days of absence for mild, cold-like symptoms could never reasonably be regarded as justification for administering vaccines with unknown long-term effects, this was the justification given for the vaccination of school-age children. Since then, data must have been obtainable and should have been collected and reviewed to determine whether vaccinations have in fact reduced school absences, and the extent to which absences have occurred by reason of (a) administration of the vaccination program and (b) adverse reactions to the vaccines.

In addition, on 4 August 2021 the JCVI initially recommended only one dose to healthy 16–17-year-olds, recognising that there was an enhanced risk in young males of myocarditis from the Covid-19 vaccines, especially following a second dose, as identified by the FDA in the U.S. and from data emerging in Israel. It is notable that when, in November 2021, the JCVI advised that 16–17-year-olds should be administered a second dose, it did so without including any express statement that it considered the benefits of the Covid-19 vaccine outweighed the risks in that age group. Instead, it recognised that information on the longer-term risks (months to years) of myocarditis was unclear and would only become available with the passage of time.

The risk:benefit concerning roll out of vaccines to under 18s had been said by the Secretary of State and those advising him to be finely balanced. Several months have passed and data as to registered deaths and school absences, together with the reduced risk from Omicron, must give cause to consider whether that fine balance must have tipped away from recommending vaccination in the young.

An investigation must be conducted

In light of the increase in deaths in young males and the known safety concerns, an investigation must be conducted. It is not suggested that the observed increase in mortality *proves* that the Covid-19 vaccines are causing death, whether via myocarditis or some other mechanism, but a connection cannot be excluded. The potential signal is strong enough that urgent investigations should commence immediately to rule out that possibility. Each recipient of this letter has a duty to investigate. It would be a grave dereliction of duty not to do so.

The JCVI has an ongoing duty to keep its advice under review with the emergence of new data. It has expressly stated on several occasions that more data is either needed or awaited.

The MHRA is tasked with responsibility for vaccine surveillance in real time and has a duty to monitor Covid-19 vaccine data for safety signals. It does this through the Yellow Card reporting system, but its role should not be confined to one passive surveillance system alone. It is accepted by the Commission on Human Medicines Expert Working Group, which was established to advise the MHRA on its safety monitoring strategy for Covid-19 vaccines, that passive surveillance relies on someone suspecting or 'making a connection' between the medicine or vaccine and an unexplained illness, and then reporting it, and that therefore it is important that other forms of vigilance are included to supplement the Yellow Card scheme.

It is therefore beyond doubt that the MHRA has a duty to investigate incidence of excess mortality in young males within ONS held data, regardless of whether or not Yellow Card reports have been submitted.

The Secretary of State, as the person responsible for the government's vaccination programme, also has a paramount duty in the public interest to monitor the safety and effectiveness of the Covid-19 vaccines.

The data are available and can be readily examined

These concerns should not be difficult to investigate. The ONS has confirmed (to the Court) that it is able to provide precise anonymised data including the number of days between vaccination and death. No suggestion has been made that there is any difficulty in gathering or analysing the data. If, for example, the data reveal a concentration of deaths happening close in time to the date of vaccination, this may strengthen concerns of a positive causal link (e.g. under the Bradford Hill criteria) and further, more detailed investigations would be merited. Higher incidence of mortality in children after vaccination is a major cause for concern and could indicate a need to pause the vaccination program immediately. If no indication of causal connection is apparent, this may help to reassure the public as to safety of the vaccines.

Although a halt to the Covid-19 vaccination programme in children is what a High Court legal challenge has sought to achieve, so far the courts have taken the view that mass roll out to under 18s has been a political decision for the Secretary of State with which the Judiciary is unable to interfere. That view from the court, dealing with particular legal principles of judicial review, does not in any way hinder the investigation we demand. Indeed, the Honourable Mr Justice Jay remarked during one hearing, at which the Secretary of State was represented, that he expected the JCVI would be "clamouring for the data" relating to the incidence of death after vaccination.

Information has already been requested of and promised by the Secretary of State

This request for information relating to deaths following vaccination is not novel. On several occasions this issue has been raised in the House of Commons. For example, on 25 March 2021, in answer to questions from Mr William Wragg MP and Sir Christopher Chope MP about incidence of deaths within three weeks following Covid-19 vaccination, the then Secretary of State, Matt Hancock, assured Parliament that this was exactly the sort of thing he was looking at and that, if there was any data not published, he would look into publishing it because the government wanted to be completely open and transparent to reassure people that the risks are extremely low.

It is extremely worrisome that the data concerning deaths following Covid-19 vaccination does not appear to have been collected and analysed or, if it has been, a decision has been made not to publish it. Unfortunately, the impression given is not one of transparency, but rather that information is being hidden. The long-term impact on trust in elected representatives and in regulatory bodies that advise them

cannot be understated. Neither can the potential significance of the data signals which are apparently emerging.

Our demand and request

In light of the above and in all the circumstances, please would you confirm the following by return:

1. That each of you will investigate the increase in mortality over the period 1st May 2021 to 24th December 2021 (and beyond) in young males as recorded by the ONS, to determine the reason for the increase and whether causal connection to the Covid-19 vaccines can reasonably be excluded.

2. What steps have been taken so far, if any, to conduct the investigation required and if such an investigation has already commenced please confirm when that investigation started, what is its scope, what stage it has reached and when it is due to be concluded. If no steps have yet been taken, please explain why not.

3. That you will now seek to obtain from the ONS, without delay, the following data for all deaths aged 12-19 occurring on or after 1st May 2021 to date:

   a. Age (whether in the 12-15 or 16-19 age group)
   b. Sex
   c. Whether the individual had dose 1 of a Covid-19 vaccine (and whether Moderna or Pfizer)
   d. Whether the individual had dose 2 of a Covid-19 vaccine (and whether Moderna or Pfizer)
   e. If applicable, the number of days death followed dose 1 (if dose 2 was not administered) or the number of days death followed dose 2 (if administered)

4. That the Secretary of State will publish the data obtained or that he will procure that the ONS publishes such data.

5. Whether you have concluded, and if so when, that a causative link to the Covid-19 vaccines may be ruled out or considered a negligible possibility, and on what basis.

6. What you suggest might be the explanation for the statistically significant increase in deaths in young males in the period 1st May 2021 to 24th December 2021 other than a possible causative link to the Covid-19 vaccines.

7. That you will supply the principal sources of evidence relied upon, in respect of any explanation provided, to support and explain why this increase was not also seen in other periods (for example, in 2020, when the pandemic arose and when deaths of young males were less than average).

Notwithstanding that we do not accept that the modelled data on absences could have justified the decision to rollout the vaccines to school-age children, please also confirm by return:

8. That each of you will take steps to investigate the data available since decision of 13 September 2021 following the advice of the Chief Medical officers, as to (a) the level of school absences (b) whether the modelled benefit of avoiding school absences has been achieved and (c) the extent to which absence has been caused by each of (i) administration of the vaccination program and (ii) adverse reactions to the vaccination program.

9. What steps have been taken so far, if any, to investigate the data relating to school absences since that decision of 13 September 2021 and, if such an investigation has already commenced, please confirm when that investigation started, what is its scope, what stage it has reached and when it is due to be concluded. If no steps have yet been taken, please explain why not.

Publishing of data

We do not see any bar to publishing the data requested. The ONS expressed concerns in court that publication of the data requested could be disclosive, in that it would allow for identification of the individuals concerned when associated with news reports and other information in the public domain. However, we do not understand how this would be even conceptually possible given the generalised nature of the data requested. We also note the regional and daily data published by the ONS in relation to deaths involving Covid-19.

No names, regional data, date of birth or date of death data are requested. With assistance of the ONS, please provide an example so that we and the public may understand why the data asked for could be withheld on grounds that it could be disclosive.

Paramount urgency

Finally, the government's current message to children remains 'get vaccinated'. It used to be 'every life counts'. If likelihood of a causal

connection were established between increased incidence of death and the Covid-19 vaccines, that would be a most serious matter. The death of even a single child from a Covid-19 vaccine would be a tragedy. It therefore stands to reason that an investigation is of paramount urgency.

It cannot be ignored that 65 deaths in young males above the normal average deaths equates to 2 deaths per week each week between 1st May and 24th December 2021. Taking account of the estimated 38% unregistered deaths, the actual figure could be at least 3 per week. This, of course, is only for the 15-19 age group. In the same period, there were just 2 deaths registered in the same age group recorded as 'involving' Covid.

We look forward to your substantive reply as soon as possible and in any event within 7 days.

This letter has been published openly and we hope it is shared widely along with any response.

Yours sincerely,

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