



Department of Health & Social Care

From the Chief Medical Officer
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Dear Mr Halfon,

Thank you for the opportunity to appear in front of the Education Select Committee on 22nd September 2021 alongside Professor Wei Shen Lim, Professor Jonathan Van-Tam, Dr Camilla Kingdon and Professor Sir Keith Willett. It was useful to set out the advice given on 12-15 year old vaccination.

I agreed to write to the committee with detail on two further points; the use of age-stratified data in the Medicines and Healthcare products Regulatory Agency (MHRA) Coronavirus (COVID-19) vaccine adverse reactions weekly summary of Yellow Card reporting and the reference to myocarditis and educational impact in the PHE and UKHSA documents that are available to children, parents and schools.

The publication of the Coronavirus (COVID-19) vaccine adverse reactions weekly summary of Yellow Card reporting is a matter for the MHRA, and colleagues from there have kindly supplied the below explanation of how the data will be reported.

The MHRA is able to stratify Yellow Card data by age or age group, and use this in our analysis. Age breakdowns may be useful for assessment of whether an adverse drug reaction (ADR) may occur more frequently in a specific age group and thus inform risk mitigation measures. However, there are several challenges in comparing between age groups; confounders include different background prevalence for disease conditions and health status across age groups and that reporting stimulated by publicity may have differential effects across time and age groups. This is particularly pertinent when considering the usage of the COVID-19 vaccines in the 12-15 age group, as until very recently the use was only in those who are clinically extremely vulnerable or household contacts of immunosuppressed individuals and therefore represent a specific patient population which would not be generalisable.

Consideration of the age groups used for stratification is also important to ensure sufficient exposure and reporting in the age group to provide any certainty in the estimated reporting rates. In addition, stratification may compromise reporter confidentiality where there is a very small number of reports per age bracket. The current reporting of suspected myocarditis/pericarditis following COVID-19 vaccination in the under 18 age group would not allow for further stratification of the data below 18 years for these reasons. Additionally, while we have estimates for the

background incidence of the events in the absence of COVID-19 vaccination, these have not been accurately determined in smaller age brackets in those under 18 years which would be important context for data interpretation.

The Yellow Card Scheme encourages any suspected adverse events to medicines and vaccines to be reported, however this means that not all reports will have any relation to the medicine or vaccine and initial reports may lack the detail to be considered a clinically validated case. This is particularly important for conditions like myocarditis and pericarditis, where clinical investigations are required for diagnosis.

As a result, where age breakdowns have been included in the weekly ADR publication, such as those provided for thrombosis with thrombocytopenia syndrome (TTS), suspected reports have undergone clinical validation against agreed criteria to ensure that any comparisons made across age groups are as accurate as possible.

As such the Commission of Human Medicine (CHM) COVID-19 Vaccines Benefit Risk Expert Working Group (VBR-EWG) and CHM has considered different case definitions for assessing suspected myocarditis and pericarditis reports from spontaneous data to ensure that the definition used for case validation would include sufficient clinical detail to confirm the diagnosis and assess the relationship between reports of suspected myocarditis/pericarditis cases and COVID-19 vaccination, without expecting a level of detail that is frequently not provided in spontaneous reports received through the Yellow Card Scheme.

The case definition agreed by the VBR-EWG and CHM is consistent with that used by the United States Centre for Disease Control. The definition allows for a designation of probable and confirmed cases depending on the diagnostic information available. Further assessment is also applied to determine whether cases are considered unlikely to be associated with the vaccine due to alternative factors being present such as recent or concurrent viral infection.

In order to allow publication of age stratified Yellow Card data for validated cases (i.e. meeting the case definition of probable or confirmed) of myocarditis and pericarditis, reports will initially be reviewed against this case definition by MHRA scientific staff to assess whether it meets the case definition criteria. For some reports we will need to follow up the report to obtain further details including on whether the individual was hospitalised, any treatment and the outcome. The overall assessment will then be adjudicated by a MHRA medical assessor, to check the initial assessment and provide clinical input on whether there could be any other identifiable cause of the symptoms and findings. In addition, for the initial process of assessing myocarditis and pericarditis reports against the case definition, the MHRA will seek external specialist cardiologist assessment, in order to ensure that cases are assessed accurately against the case definition and independently validate our assessment process.

Assessment of reports of myocarditis and pericarditis against the case definition will initially be prioritised for reports in the under 18 age as the vaccine rollout has recently begun for this age group, and will be available for publication following

review by the VBR-EWG and agreement of a communications plan between MHRA and DHSC.

The committee was also keen to have clarity on which of the UKHSA documents available to children, parents and schools reference myocarditis and which reference educational disruption.

The relevant documents are here:

<https://www.gov.uk/government/publications/covid-19-vaccination-resources-for-children-and-young-people>

<https://www.gov.uk/government/publications/covid-19-vaccination-resources-for-schools>

<https://www.gov.uk/government/publications/covid-19-vaccination-consent-form-for-children-and-young-people-or-parents>

The 'guidance for schools' and 'guidance for parents' documents reference education disruption:

Vaccinating children should help to reduce the need for children to have time off school and to reduce the risk of spread of COVID-19 within schools. The COVID-19 vaccination programme in secondary schools will therefore provide protection to children who are vaccinated and help to reduce disruption to face to face education this winter

Except for the 'invitation letter template' and the consent forms all of the documents refer to myocarditis following COVID-19 vaccination. They do this explicitly in all cases, except the 'easy read' document which understandably refers to inflammation of the heart.

It is worth noting there is also a risk of myocarditis following COVID-19 infection and current data implies myocarditis is more likely after infection than vaccination.

I hope this answers any outstanding questions you or colleagues had.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Chris Whitty', with a stylized, flowing script.

PROFESSOR CHRIS WHITTY