



UK Health
Security
Agency

By email

Our ref: 14/07/22/JS/472

10 August 2022

Dear xxxxx,

Re: FOI Request - Covid Vaccine Associated Enhanced Disease

Thank you for your request received on 14 July 2022 addressed to the UK Health Security Agency (UKHSA). In accordance with Section 1(1)(a) of the Freedom of Information Act 2000 (the Act), I can confirm that UKHSA does hold some of the information you have specified.

Request

This is a request under the Freedom of Information Act.

VAED is identified as a risk in the Risk Management Plans for all of the COVID vaccines in use in the UK. The Market Authorisation Holders' ongoing clinical trials all include assessment of VAED risk.

The Medicines and Healthcare products Regulatory Agency (MHRA) has confirmed (in a reply to a FOI request) that it is also monitoring VAED risk by analysis of Yellow Card reports. However, this is wholly inadequate since it suffers from a massive bias which you would fully acknowledge : the proportion of adverse events reported is extremely low.

I am also well aware that :

- a) UKHSA, in conjunction with the ONS, publishes data on rates of infection, hospitalisation and death by vaccination status. However, this is not indicative of VAED either way; and***
- b) it is extremely difficult to assess the involvement of VAED in individual cases.***

However, there is a further way of investigating the risk of VAED apart from MAHs' clinical trials; namely, analysis of population-level data. This would indicate (or not) statistically significant differences in clinical outcomes of Covid positive hospitalised patients between those vaccinated and unvaccinated. For example, things like rates of clinical deterioration, length of clinical course, complications and new morbidities, stratified by factors like time since Covid vaccination, age, gender and prior co-morbidities.

The analysis would be either of all Covid positive patients or just of those suffering particular categories of adverse event or complication. I would therefore request that you confirm whether or not UKHSA has conducted or commissioned any such analysis and, if you have, a copy of the analysis.

Response

In accordance with Section 1(1)(a) of the Act, UKHSA can confirm that it does hold some of the information you have specified.

Population wide analyses of vaccine effectiveness are being conducted on a regular basis and these have continuously shown that those who are vaccinated and go on to become infected with COVID-19 have less severe disease than those who are unvaccinated. Further information is available at:

<https://www.gov.uk/government/publications/covid-19-vaccine-weekly-surveillance-reports>

This is evidenced, for example, by higher effectiveness against hospitalisation and death than against infection. *Effectiveness of COVID-19 vaccines against Omicron and Delta hospitalisation: test negative case-control study* is available at:

<https://www.medrxiv.org/content/10.1101/2022.04.01.22273281v1>

The COVID-19 enhanced surveillance system was used to monitor infection and disease in a cohort of vaccine eligible participants in order to identify risk factors for and outcomes of vaccine failure, and to investigate household transmission dynamics. Currently analyses are being undertaken to investigate outcomes of COVID-19 following vaccination. These data will be published in due course.

Vaccine safety signals are investigated by UKHSA in collaboration with other partners. Please see the attached reports.

If you have any queries regarding the information that has been supplied to you, please refer your query to the Information Rights Team in writing in the first instance. If you remain dissatisfied and would like to request an internal review, then please contact us by emailing InformationRights@UKHSA.gov.uk.

Please note that you have the right to an independent review by the Information Commissioner's Office (ICO) if a complaint cannot be resolved through the UKHSA internal review procedure. The ICO can be contacted by calling the ICO's helpline on 0303 123 1113, visiting the ICO's website at www.ico.org.uk or writing to the ICO at Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF.

Yours sincerely,
Information Rights Team