

RE: Yellow Card Reference Number: [REDACTED]

From [REDACTED] (THE UNIV OF NOTTINGHAM HEALTH SERV) [REDACTED]

Date Thu 2021-03-18 12:42

To Yellow Card Mailbox <yellow.card@mhra.gov.uk>

Good afternoon

Unfortunately we have very little further information.

We were informed by colleagues from [REDACTED] Medical school where the individual is a student. We administered the vaccine as a vaccination centre but he is not a registered patient of ours so we have no further clinical information beyond the following narrative from the medical school - [REDACTED] *medical student who had the Covid -19 vaccine recently fell unwell after getting the AstraZeneca vaccine. He had persistent headaches which finally culminated in him sustaining a cerebral venous sinus thrombosis, immune thrombocytopenia and intracranial bleeding. He is currently in ICU post-surgery.*

The patient involved was NHS number [REDACTED]. He received his vaccination at Cripps Health as a front line healthcare worker (medical student) but is not a registered patient of the practice. For the local team I have conducted a desk top review of the assessment and vaccination process and can confirm that they are all in line with the standard operating procedures. The consent and vaccination details were recorded into the clinical system in real time and the patient received this first dose of AZ ChAdOx1 Batch number AB0003 at [REDACTED] on the 27th January 2021.

Best regards

[REDACTED]
The University of Nottingham Health Service
The University of Lincoln Health Service
[REDACTED]

From: Yellow Card Mailbox [mailto:yellow.card@mhra.gov.uk]

Sent: 17 March 2021 16:43

To: [REDACTED] (THE UNIV OF NOTTINGHAM HEALTH SERV)

Subject: Yellow Card Reference Number: [REDACTED]

Importance: High

Dear [REDACTED]

Patient Initials: [REDACTED] **Patient Age:** 19 Years **Patient Sex:** Male

Yellow Card Reference Number: [REDACTED]

Thank you for taking the time to complete a Yellow Card report on a suspected side effect to the COVID-19 Vaccine AstraZeneca.

In view of the nature of the reaction you reported, please would you be kind enough to provide us with some additional details. You can return this information to us via email at yellowcard@mhra.gov.uk. Please quote the above Yellow Card reference number with all correspondence. In particular, it would be helpful to have the following information, if available:

- Could you please confirm if the diagnosis of immune thrombocytopenia was confirmed following haematology review?
- Was a unifying diagnosis for both thrombosis and thrombocytopenia confirmed?
- Could you please confirm if there was involvement of any other cell lines, or if platelets were the only cell line affected?
- Please provide information on any other potential causes of thrombocytopenia excluded eg: infectious causes, malignancy including metastatic disease, leukaemia, myelofibrosis, lymphoproliferative disorders, thrombotic thrombocytopenic purpura, disseminated intravascular coagulation, HIT syndrome

- Was there a known history or new diagnosis of autoimmune/ inflammatory disease eg: SLE, antiphospholipid syndrome?
- Were any medications with a potential thrombocytopenic effect to be taken concomitantly prior to the event eg: heparin, alemtuzumab, sodium valproate.
- Was the patient known to be on anticoagulation?
- Was there any evidence of preceding infection?
- Please provide the blood film/ blood smear report if available.
- Please provide nadir platelet counts and relevant blood results where available. If sequential blood results are available, please provide this.
- Please provide any radiological imaging reports or a summary of these reports.
- Was there any relevant medical history?
- Were any other vaccines administered recently? If yes, please could you specify which vaccines were administered?
- Please let us know about the outcome of the event eg: recovering, not resolved, ongoing?
- Please provide information about response to treatment eg: IVIg/ steroids.
- Were there any other concurrent events that may have contributed to thrombocytopenia?
- Please provide information on any other potential risk factors for thrombosis eg: active malignancy, intracranial malignancy, intracranial infection, significant dehydration, immobility, previous DVT, protein C and S deficiency, systemic inflammatory diseases, recent CNS trauma/ surgical intervention, acquired prothrombotic states (including nephrotic syndrome)
- Could you let us know if there is any other relevant information you can provide that has not already been addressed above.

All information provided is held in strict confidence and handled in line with our Yellow Card Privacy Policy, which can be found at <https://yellowcard.mhra.gov.uk/privacy-policy/>. If you wish to request a copy of the information we hold on your case or a copy of your report as it appears in our database, please write to us at the address above or email yellow.card@mhra.gov.uk citing your case reference number and details of your request.

Your contribution to the UK's Adverse Drug Reaction Reporting Scheme is greatly appreciated. This provides an important early warning of previously unrecognised adverse effects which allows us to take appropriate action to improve the safe use of medicines.

You can find out more about the suspected Adverse Drug Reactions we have received at www.mhra.gov.uk/yellowcard.

Additionally, you can stay up to date on the latest advice for the safe use of medicines by reading our monthly bulletin Drug Safety Update, which is available on our website at www.gov.uk/drug-safety-update.

You can receive a notification of each new bulletin by sending your email address to registration@mhradrugsafety.org.uk.

Yours sincerely,



Vigilance and Risk Management of Medicines

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