

Re: Yellow Card Reference Number: [REDACTED]

From [REDACTED] (KING'S COLLEGE HOSPITAL NHS FOUNDATION TRUST) [REDACTED]
Date Mon 2021-02-15 17:55
To Yellow Card Mailbox <yellow.card@mhra.gov.uk> [REDACTED] CROYDON HEALTH SERVICES NHS TRUST) [REDACTED]

Dear MHRA,

Please see additional information regarding this case - provided by Dr [REDACTED] Consultant Haematologist, KCH Thrombosis Team (my comments in red, [REDACTED] in blue):

Dear Dr. [REDACTED]

Local Identification Number: [REDACTED]

Patient Initials: [REDACTED] **Patient Age:** 32 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 a diagnosis was confirmed for the events of thrombocytopenia and thrombosis? No unifying diagnosis confirmed.
- Could you please confirm the cause of death as stated on the post-mortem report or death certificate?

Cause of death already sent

- Could you provide us with the post-mortem report, or alternatively could you provide us with contact details for where we might obtain this?

No post mortem undertaken, case not referred to the Coroner

- Could you please confirm if there was involvement of any other cell lines, or if platelets were the only cell line affected? Isolated thrombocytopenia at presentation.
- Please provide information on any other potential causes of thrombocytopenia excluded eg: infectious causes, malignancy including metastatic disease, leukaemia, myelofibrosis lymphoproliferative disorders, TTP, DIC, HITT syndrome Rapid progression to death from admission (within hours) therefore all potential causes for thrombocytopenia unable to be excluded. No evidence of blasts on film or other abnormalities to suggest leukaemia or myelofibrosis. No red cell fragments reported on film to raise strong suspicion of either TTP or DIC. Clotting times normal, which goes against DIC. No previous exposure to heparin so not HIT. Nil from history to suggest underlying malignancy. *ICU may wish to comment further on likelihood of latter and any infection.*
- 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). None of the risk factors listed were apparent. No evidence of nephrotic syndrome. No family history of thrombosis declared. Not tested for additional acquired prothrombotic state (antiphospholipid syndrome, paroxysmal nocturnal haemoglobinuria).
- Was there a known history or new diagnosis of autoimmune/ inflammatory disease eg: SLE, antiphospholipid syndrome? No

- Were any medications with a potential thrombocytopenic effect or ITP known to be taken concomitantly prior to the event eg: heparin, alemtuzumab, sodium valproate. None that treating team were aware of.
- Please provide nadir platelet counts and relevant blood results where available. Plts 30 at presentation. Plts fell to nadir of 10. Pt subsequently died. No historical blood results available.

MBBS PhD. FRCPATH RCPATHME

Department of Histopathology
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Denmark Hill
London
SE5 9RS
+44 (0)2032999000
Office supervisor -

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

Sent: 15 February 2021 13:28

To: (KING'S COLLEGE HOSPITAL NHS FOUNDATION TRUST)

(CROYDON HEALTH SERVICES NHS TRUST)

Subject: RE: Yellow Card Reference Number:

Dear

Thank you for providing this additional information, it has been added to your report.

Kind regards

Yellow Card (Side Effects) Service Team Manager

Vigilance and Risk Management of Medicines Division
Medicines and Healthcare Products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU
Email: yellow.card@mhra.gov.uk
Stay connected: mhra.gov.uk/stayconnected

From: (KING'S COLLEGE HOSPITAL NHS FOUNDATION TRUST)

Sent: 15 February 2021 12:36

To: Yellow Card Mailbox <yellow.card@mhra.gov.uk>; (CROYDON HEALTH SERVICES NHS TRUST)

Subject: Re: Yellow Card Reference Number:

Dear

Many thanks for your email and list of questions. I made the submission at the request of the family and in my role as Trust Medical Examiner. I did not know or care for this patient in life. The role of the Medical Examiner is to identify situations such as this and make the appropriate referrals, whether that be to the local Coroner (not done in this case) or regulatory organisations such as yourself and PHE etc.

I have asked the Trust to identify someone who can assist you in this matter. Two questions I can answer:

The cause of death:

- 1a) Brainstem infarction
- 1b) Spontaneous intracranial haemorrhage
- 1c) Sagittal venous sinus thrombosis
2. -

I can confirm the case was not referred to the Coroner and a post mortem examination has not been undertaken.

I have cc'd in [REDACTED] the [REDACTED] so [REDACTED] has sight of this.

Regards,

[REDACTED]

[REDACTED] MBBS PhD. FRCPATH RCPATHME

[REDACTED]

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SE5 9RS
+44 (0)2032999000
Office supervisor - [REDACTED]

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

Sent: 15 February 2021 12:14

To: [REDACTED] (KING'S COLLEGE HOSPITAL NHS FOUNDATION TRUST) <[REDACTED]>

Subject: Yellow Card Reference Number: [REDACTED]

Dear Dr. [REDACTED]

Local Identification Number: [REDACTED]

Patient Initials: [REDACTED] **Patient Age:** 32 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 a diagnosis was confirmed for the events of thrombocytopenia and thrombosis?
- Could you please confirm the cause of death as stated on the post-mortem report or death certificate?
- Could you provide us with the post-mortem report, or alternatively could you provide us with contact details for where we might obtain this?
- 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, TTP, DIC, HITT syndrome
- 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)
- Was there a known history or new diagnosis of autoimmune/ inflammatory disease eg: SLE, antiphospholipid syndrome?
- Were any medications with a potential thrombocytopenic effect or ITP known to be taken concomitantly prior to the event eg: heparin, alemtuzumab, sodium valproate.
- Please provide nadir platelet counts and relevant blood results where available.
- Was there any relevant medical history?
- Were there any other concurrent events that may have contributed to the event?
- 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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