|   | REGULATION 28 REPORT TO PREVENT FUTURE DEATHS  |
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|   | THIS REPORT IS BEING SENT TO: The Chief Executive of the Worcestershire Acute Hospitals NHS Trust  |
| 1 | CORONER  |
|   | I am Miss Emma Brown, HM Area Coroner for Birmingham and Solihull  CORONER'S LEGAL POWERS  |
| 2 | I make this report under paragraph 7, Schedule 5, of the Coroners and Justice Act 2009 and regulations 28 and 29 of the Coroners (Investigations) Regulations 2013.  |
|   | INVESTIGATION and INQUEST  |
| 3 | On 14 September 2021 I commenced an investigation into the death of Jack HURN. The investigation concluded at the end of the inquest on the 27th May 2022. The conclusion of the inquest was:  |
|   | "Death was due to a rare but recognised complication of the Astra Zeneca COVID19 vaccination."   |
|   | CIRCUMSTANCES OF THE DEATH   |
| 4 | At the age of 26 Jack Hurn died at the Queen Elizabeth Hospital Birmingham at 13:06 on the 11 <sup>th</sup> June 2021. He had received a first dose of the Astra Zeneca vaccination for COVID-19 at the Dudley and Netherton primary care network vaccination centre at the Revival Fires Church on the 29 <sup>th</sup> May 2021. At that time the Joint Committee on Vaccines and Immunisation had advised that it was preferable for adults aged under 40 years without underlying health conditions to be offered an alternative to the Astra Zeneca COVID-19 vaccine unless that would cause substantial delay but people could make an informed choice to receive the Astra Zeneca vaccine to receive earlier protection. Jack was not given all the information to make an informed choice at the time of giving his consent to the vaccine. In particular, the risk of complications for his age group was understated. On the 6 <sup>th</sup> June Jack developed a headache which persisted and worsened leading to him being admitted to the Alexandra Hospital Redditch on the 8 <sup>th</sup> June 2021. Imaging revealed extensive superior sagittal sinus thrombosis and he was diagnosed with Vaccine-Induced Immune Thrombocytopenia and Thrombosis ('VITT'): a new but extremely serious condition caused by a rare complication of the Astra Zeneca vaccine. Following diagnosis Jack was admitted to a medical unit, he was not referred to a specialist neurology and haematology team in accordance with guidance on the management of VITT CVST and the regional VITT pathway. Jack deteriorated during the afternoon of the 9 <sup>th</sup> June and at approximately 1800 it was identified that his Glasgow Coma Score had dropped to 11/15 and he had developed dense right hemiplegia. Imaging showed extension of the previous thrombosis along with new areas of thrombosis and haemorrhage prompting contact with specialist services at the Queen Elizabeth Hospital into whose care he was transferred. Despite mechanical thrombectomy and decompressive craniectomy alongside full supportive measures Jack's condition deteriorated and beca |
|   | Following a post mortem carried out by Dr , Consultant Histopathologist, and evidence from Dr , Consultant Haematologist the medical cause of death was determined to be:  |
|   | 1a Cerebral venous sinus thrombosis.   |
|   | 1b Vaccine-induced immune thrombocytopenia and thrombosis (VITT)   |

1c ChAdOx1 nCOV-19 adenoviral vector vaccination.

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## CORONER'S CONCERNS

During the course of the inquest the evidence revealed matters giving rise to concern. In my opinion there is a risk that future deaths will occur unless action is taken. In the circumstances it is my statutory duty to report to you.

## The MATTERS OF CONCERN are as follows. -

- 1. The Level Two Comprehensive Investigation of the Worcestershire Acute Hospitals NHS Trust ('WAH') concluded the root cause of Jack's death was: "There was no official national guidance and no approved Trust guidance on managing VITT in place at the time this patient was admitted to AGH, therefore staff are unlikely to have been aware of the time-critical need to transfer the patient to a specialist centre (QEHB)." The following care and service delivery problems were identified: "There was no written Trust or national guidance on managing VITT at the time the patient was admitted, therefore staff are unlikely to have been aware of the time-critical need to transfer the patient to a specialist centre (QEHB)." The following Contributory factors were identified: The Neurosurgical team at QEHB were contacted for advice; had the Trust VITT guidance been in place at the time, it would have stipulated not to contact the Neurosurgical team, but instead to contact Haematology and Neurology at QEHB.
  - The Neurosurgical team at QEHB advised to continue medical management locally (at WAHT).
  - Had the Trust VITT guidance been in place at the time, the WAHT Haematologist would have been prompted to contact their counterpart Haematologist at QEHB which may have accelerated the process of transfer; this did not happen until the day after the patient's admission.
- 2. Within the course of the evidence at the inquest it was identified that, whilst there was no NICE Guidance or a local policy at WAH, there was a number of publications on the management of VITT and patients presenting with complications post Astra Zeneca Vaccination:
  - i. Guidance from the Expert Haematology Panel (EHP) on Covid-19 Vaccine-induced Immune Thrombocytopenia and Thrombosis (VITT) 28th May 2021
  - ii. Joint guidance from the Royal College of Emergency medicine, the Society for Acute Medicine and the Royal College of Physicians 'Management of patients presenting to the Emergency Department/ Acute Medicine with symptoms 5-42 days post Astra Zeneca vaccine' 24th May 2021
  - iii. 'Management of Cerebral Venous Sinus Thrombosis following COVID-19 vaccination. A neurosurgical guide.' from the British Society of Neurological Surgeons 19th April 2021
- 3. Evidence also identified that the University Hospitals Birmingham NHS Foundation Trust had also put in place a Regional VITT Pathway that was communicated to Haematologists and Neurologists across the region in March 2021. Prior to Jack's admission to the Alexandra Hospital on the 8<sup>th</sup> June 2021 4 patients had been transferred from the WAH to the QEH under the pathway including 1 patient from the Alexandra Hospital.
- 4. The WAH investigation did not identify the above guidance or Pathway and did not provide any explanation of why they were not followed in Jack's case.
- 5. Concerns were raised in the management of Jack's care whilst at the Alexandra Hospital, in particular the emergency department decision to refer to the medical and not neurology team, the level of observations whilst on ward 11 and the fact that family were reporting a concern that Jack was deteriorating during the afternoon of the 9<sup>th</sup> June 2021. The WAH investigation report does not record that these matters (or any other aspect of clinical care) were investigated, the conclusions reached or the bass for those conclusions.
- 6. This raises a concern that the investigation was not sufficient and as such has not served its purpose of safeguarding patients.
- 7. No adequate explanation was given in evidence to explain why the investigation was

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|   | incomplete.   |
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|   | 8. If WAH serious incident investigations are not sufficient the lessons arising will not be identified and necessary action will not be taken putting lives at risk.   |
|   | ACTION SHOULD BE TAKEN  |
| 6 | In my opinion action should be taken to prevent future deaths and I believe you have the power to take such action.   |
| 7 | YOUR RESPONSE   |
|   | You are under a duty to respond to this report within 56 days of the date of this report, namely by 3 August 2022. I, the coroner, may extend the period.   |
|   | Your response must contain details of action taken or proposed to be taken, setting out the timetable for action. Otherwise you must explain why no action is proposed.   |
|   | COPIES and PUBLICATION  |
| 8 | I have sent a copy of my report to the Chief Coroner and to the following Interested Persons:   |
|   | Jack's Family, University Hospitals Birmingham NHS Trust, Dr (Consenter), Dr (Clinical Director)  |
|   | I have also sent it to the Medical Examiner, CCG and CQC who may find it useful or of interest.   |
|   | I am also under a duty to send the Chief Coroner a copy of your response.   |
|   | The Chief Coroner may publish either or both in a complete or redacted or summary form. He may send a copy of this report to any person who he believes may find it useful or of interest. You may make representations to me, the coroner, at the time of your response, about the release or the publication of your response by the Chief Coroner. |
| 9 | 8 June 2022   |
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|   | Software  |
|   | Signature:  |
|   | Miss Emma Brown   |
|   | HM Area Coroner for Birmingham and Solihull   |