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| | REGULATION 28 REPORT TO PREVENT FUTURE DEATHS<br><br>THIS REPORT IS BEING SENT TO:<br><br>**1. Dr Clive Day, Chief Executive, King's College Hospital NHS Trust, Denmark Hill, London SE5 9RS**<br>**2. [redacted], Head of Enforcement MHRA, Medicines & Healthcare Produces Regulatory Agency, 151 Buckingham Palace Road, London SW1W 9SZ**<br>**3. [redacted] Director of Corporate Affairs, Amgen Limited, 240 Cambridge Science Park, Milton Road, Cambridge, CB4 0WD** |
| 1 | CORONER<br><br>I am Andrew Harris, Senior Coroner, London Inner South jurisdiction |
| 2 | CORONER'S LEGAL POWERS<br><br>I make this report under paragraph 7, Schedule 5, Coroners and Justice Act 2009 and regulations 28 and 29 of the Coroners (Investigations) Regulations 2013. |
| 3 | INQUEST<br><br>I opened an inquest into the death of Mr **Edward Hearn, who died on 5th February 2018 in King's College Hospital, (0395-18). An investigation was opened on 12th February 2018 and was concluded on 17th April 2019. A reserved judgment was delivered on 8th May 2019.**<br><br>The medical cause of death was:<br>1a Sepsis<br>1b Bronchopneumonia<br>1c Multiple myeloma (treated with Carfilzomid, Cyclophosphamide and Dexamethasone)<br>II Left Ventricular Hypertrophy (presumed cocaine related) and pathological acetabular fracture due to myelomatous deposit. |
| 4 | CIRCUMSTANCES OF THE DEATH<br><br>The Record of Inquest recorded:<br><br>Box 3: *A high globulin was identified in a blood test when Mr Edward Hearn attended A&E on 12th August 2018 with another illness. It was not followed up or repeated, but in retrospect was the first sign of multiple myeloma, which was diagnosed when he presented with systemic symptoms on 28th December, after three months of back and leg pains. He began chemotherapy and was discharged on 18th January without a safe care plan for minimizing the risk of fall and was readmitted on 29th January 2018 with a fracture, which immobilized him as he received chemotherapy. On 3rd February he suffered a sudden cardiac arrest, likely to have been contributed to by sepsis, bronchopneumonia and therapeutic chemotherapy medication. He died in hospital on 5th February 2018.*<br><br>Box 4: *Death was from a combination of natural disease and unintended consequences of necessary medical treatment. It was contributed to by a failure to make a safe care plan on discharge during the course of his chemotherapy.* |

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| 5 | CORONER'S CONCERNS<br><br>During the course of the inquest, the evidence revealed two matters giving rise to concern that in my opinion means that there is still a risk that future deaths will occur unless action is taken. In the circumstances it is my statutory duty to report to you.<br><br>The **MATTERS OF CONCERN** are as follows. –<br><br>1. The finding of a high globulin by a laboratory from a blood test in A&E was not followed up by either the laboratory or A&E department. It was not in College guidelines of tests which required urgent notification. It was indicative of a fatal disease, which was not diagnosed for approximately another 4 months. I accept the professional opinion of the haematologist that this was a system failure, which is not acknowledged by the Trust. The laboratory suggested an additional action to have an automated comment but that would still not deal with the problem of reports returning to physicians in secondary care. Evidence was heard that there is inconsistency in laboratory repeating and alerting of clinicians even between hospitals in the jurisdiction, and insufficient evidence of a safe system within the Trust.<br><br>2. The expert pharmaceutical physician gave a recommendation that the need for cardiac monitoring was made more definitive in the drug prescribing information for Carfilzomid (and possibly others), which was prescribed in the Cardamon Trial. |
| 6 | ACTION SHOULD BE TAKEN<br><br>In my opinion action should be taken to prevent future deaths. I believe that the following organizations would wish to learn of the circumstances of this death and are in a position to mitigate or prevent future deaths: deterrent<br><br>**1. KCH re Concern 1**<br>**2. MHRA and Amgen Limited re concern 2**<br><br>**I am also notifying The Secretary of State for Health, The Royal College of Pathologists and the Royal College of Emergency Medicine, who may be able to advise or take additional steps.** |
| 7 | YOUR RESPONSE<br><br>You are under a duty to respond to this report within 56 days of the date of this report, namely by Tuesday the 2nd of July 2019. I, the coroner, may extend the period.<br><br>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.<br><br>If you require any further information or assistance about the case, please contact the case officer, [redacted] |

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| 8 | COPIES and PUBLICATION<br><br>I have sent a copy of my report to the following Interested Persons:<br><br>[redacted] (Brother)<br>[redacted] for King's College Hospital<br><br>I am also sending this report to the following, who may have an interest, or as prevention may involve their organizations [redacted] general practitioner, [redacted] expert pharmaceutical physician [redacted] consultant haematologist, [redacted] Consultant chemical pathologist.<br><br>I am also under a duty to send the Chief Coroner a copy of your response.<br>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 | [DATE] 8th May 2019<br>[SIGNED BY CORONER] |