	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** **1. Birmingham and Solihull Mental Health Foundation Trust** **2. Secretary of State for Health**
1	**CORONER** I am Louise Hunt Senior Coroner for Birmingham and Solihull
2	**CORONER'S LEGAL POWERS** 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.
3	**INVESTIGATION and INQUEST** On 5 January 2023 I commenced an investigation into the death of Mohammed Khalid HUSSAIN. The investigation concluded at the end of the inquest. The conclusion of the inquest was; Natural causes
4	**CIRCUMSTANCES OF THE DEATH** At around 01.30 on 28/11/22 Mr Hussain was found collapsed on the bathroom floor at his home address. An ambulance was called by his sister when she arrived at the property but sadly he was confirmed deceased at 02.09. He had been seen by his sister the day before when he was noted to be well. He had been diagnosed with treatment resistant schizophrenia and depression and had been under the care of Mental health team since 1997. He was established on clozapine in 2004 which requires monthly monitoring due to its potential toxic effects. His clozapine level was 904 ug/L on 03/05/22. Arrangements were made to set up a review appointment and he continued to attend monthly for bloods tests. He was reviewed on the telephone on 14/10/22 when a decision was made to reduce his medication but this did not occur. At the time there were no signs of toxicity. He was seen by his care coordinator on 15/11/22 when no concerns were noted about signs of toxicity. Post-mortem toxicology showed a high level of clozapine - however his nor clozapine level was noted to be reducing in life and he had no signs of the toxic effects of this drug. Following a post mortem, the medical cause of death was determined to be: **1a** Sudden cardiac death in Schizophrenia **1b** **1c** **II**

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. **Monitoring clozapine levels:** The inquest heard evidence that there was a clear system to monitor monthly blood test results looking for low white cell count, however there was no clear system for monitoring the actual clozapine and nor clozapine levels. In addition the inquest heard how there was no safe system to communicate high levels of clozapine.

2. **Medication changes:** After a review on 14/10/22, when a high level of clozapine was noted from a blood test on 03/05/22, the consultant indicated that medication should reduce on the next prescription. This was communicated by email to the care coordinator however this was not read or acted upon. The inquest heard how there was no safe system to effect medication changes.

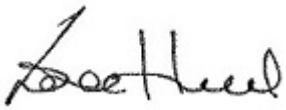
3. **How to record high clozapine levels:** The clozapine and nor clozapine levels are recorded in the pharmacy section of the records. There was no system for highlighting high clozapine results in the rio notes which are routinely used by all clinicians.

4. **Understanding of clozapine:** I heard evidence that there was a lack of understanding of when to measure clozapine levels, how to interpret high clozapine levels and then how to respond to a high level.

5. **August 2020 Regulation 28 report:** I sent a Regulation 28 report in August 2020 (case of Ian Allen) which identified that there was no system in place to ensure abnormal clozapine levels were escalated and acted upon and that there was a lack of understanding of the importance of clozapine monitoring and how frequently levels should be monitored. Given this report there is a concern that the Trust has not learnt from the previous Regulation 28 report.

6. **Quality of the internal investigation process**: The initial investigation report did not raise significant issues regarding the monitoring of clozapine and importantly whether Mr Hussain did in fact have toxicity. It was only when [redacted] wrote a report on 26/03/23 (7months after the death) that this issue was highlighted and addressed. This raises a concern about the quality of the internal investigation process and whether it is able to identify central issues in a particular case.

7. **Pharmacy resourcing:** The inquest heard evidence that processes within the pharmacy were not effective due to a lack of resources.

6	**ACTION SHOULD BE TAKEN** 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 7 September 2023. 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.
8	**COPIES and PUBLICATION** I have sent a copy of my report to the Chief Coroner and to the following Interested Persons: Mr Hussain's family I have also sent it to the regional Medical Examiner, ICS, NHS England, 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	**12 July 2023** Signature:  **Louise Hunt** **Senior Coroner for Birmingham and Solihull**