	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 24/03/2020 I commenced an investigation into the death of Ian Allen. The investigation concluded at the end of an inquest on 17th August 2020. The conclusion of the inquest was Ian died from clozapine toxicity due to blood levels not being monitored and doses not being adjusted effectively.
4	**CIRCUMSTANCES OF THE DEATH** Ian collapsed suddenly and unexpectedly at the nursing home where he resided at around 13.50 on 31/12/19. He was taken to the Queen Elizabeth hospital where he was pronounced deceased soon after arrival. He suffered from paranoid schizophrenia and was prescribed clozapine, risperidine and fluoxetine. Toxicology examination after death confirmed a toxic level of clozapine. The most likely cause of the clozapine toxicity is not monitoring the levels sufficiently following cessation of smoking and not adjusting the levels prescribed. A raised clozapine level in February 2019 had not been acted upon which should have resulted in a lower dose which would have avoided his death. Following a post mortem the medical cause of death was determined to be: CLOZAPINE TOXICITY
5	**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. – **Birmingham and Solihull Mental Health Foundation Trust** 1. In February 2019 a blood test result confirmed that Mr Allen had a high level of clozapine in his blood. This was not acted upon and no further blood test was taken. The clozapine dose was not adjusted as it should have been. 2. There was no system in place at the time to ensure blood test results were escalated to the consultant to ensure action was taken. 3. There was a general lack of understanding at the inquest about the importance of monitoring clozapine levels and how frequently these levels should be monitored. **Department of Health** 4. I heard evidence at the inquest that there was a general lack of understanding about clozapine monitoring, which blood test to undertake and the general effect this drug can have on patients. I heard evidence that national guidance was required to clearly set out how frequently clozapine levels should be monitored and what type of blood test should be undertaken. 5. Further education is required of Mental Health practitioners on the importance of clozapine monitoring and level adjustment.

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 13 October 2020. 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 family. I have also sent it to the National Medical Examiner and Regional Medical Examiner, CCG, 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	17/08/2020 Signature  Louise Hunt Senior Coroner **Birmingham and Solihull**