ANNEX A

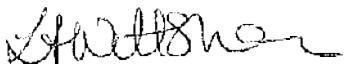
REGULATION 28: REPORT TO PREVENT FUTURE DEATHS (1)

*NOTE: This form is to be used **after** an inquest.*

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** **1. Devon Partnership NHS Trust** **2. The Pembroke Medical Practice** **3. Devon ICB** **4. Medicines and Healthcare Projects Regulation Authority**
1	**CORONER** I am Louise Wiltshire, assistant coroner, for the coroner area of the County of Devon, Plymouth and Torbay
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 17 November 2021 I commenced an investigation into the death of William Antony NORTHCOTT. The investigation concluded at the end of the inquest on 17 January 2025. The narrative conclusion of the inquest was as follows: William Anthony Northcott died from a sudden cardiac arrhythmia caused by the combined effect of background of an enlarged heart and left ventricular hypertrophy. The medical cause of death was: 1a Mixed Drug Toxicity 1b 1c II Left ventricular hypertrophy
4	**CIRCUMSTANCES OF THE DEATH**

	William Antony Northcott suffered from treatment resistant schizophrenia. He was on medication for this condition, which included clozapine and fluoxetine. Both of these medications were appropriately prescribed and maintained at therapeutic levels prior to his death. On 13 July 2021, William was found deceased in his room at Georgian House. Post mortem examination revealed an enlarged heart and left ventricular hypotrophy. Clozapine and fluoxetine were identified during toxicological analysis post mortem at levels which were consistent with therapeutic use in life. Amphetamine was found at levels consistent with recreational use. Clozapine, Fluoxetine and amphetamine are all cardio-toxic drugs, which carry risk of causing sudden cardiac arrhythmia. An enlarged heart and left ventricular hypertrophy also carry a risk of sudden cardiac arrhythmia. The combination of clozapine, fluoxetine and amphetamine on the background of William's enlarged heart caused William to suffer a sudden fatal cardiac arrhythmia. He died on 13 July 2021 at Georgian House, Park Hill Road, Torquay, Devon.
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. – (1) During the inquest I heard evidence that there should be regular repetition of information to patients suffering from treatment resistant schizophrenia about the risks and red flags associated with the side effects of taking Clozapine. Since William's death Devon Partnership NHS Trust has set up Clozapine clinics which provide the opportunity for staff who are familiar with the side effects associated with Clozapine to discuss these with patients attending for their monthly phlebotomy appointments (required for the purpose of monitoring their white blood cell count). At these appointments healthcare professionals will specifically ask patients about their smoking habit, caffeine intake, bowel movements, hypersalivation, sedation, nausea, incontinence, heartburn, infection, and medication changes, in addition to open questions about any other side effects a patient might be experiencing. I am also assured that Devon Partnership NHS Trust will be including additional questions to be discussed at this appointment surrounding recent physical illnesses, palpitations, chest pain, breathlessness and dizziness. Currently around 60% of the cohort of patients prescribed Clozapine who are under the care of Devon Partnership Trust have access to these clinics. The other 40% will attend their GP surgery for their monthly Clozapine phlebotomy service. The phlebotomy service provided at a GP practice is usually an appointment with a non-qualified member of staff, who will not have been specifically trained in the side effects of Clozapine. I am therefore concerned that the level of care provided to patients attending Clozapine clinics on a monthly basis, is likely to be superior from the care provided to those patients who attend their GP practice. In particular, I am concerned that any discussion

	and repetition of information surrounding reg flags and side effects associated with Clozapine, and advice about when to seek medical attention, will be significantly more limited for those patients attending their GP practice than for those attending the monthly Clozapine clinics. I am also concerned that this limitation is likely to extend further than the 40% of patients in receipt of Clozapine under the care of Devon Partnership NHS Trust and that this may be a national issue. (2) At post mortem examination William was found to have a significantly enlarged heart and left ventricular hypertrophy. This was not known to those caring for William in life. Clozapine is a cardiotoxic drug, and is often used in conjunction with other drugs which may also have a cardiotoxic effect. The risk of myocarditis is reasonably well explained in Devon Partnership NHS Trust's policy documentation, but there is less of a focus on cardiomyopathies which would include left ventricular hypertrophy. I understand that the Trust's guidance is based on national guidance. Annual ECGs are required for patients prescribed Clozapine and questions about cardiac function will now be asked at monthly Clozapine clinics. However, I understand that ECGs are not a diagnostic tool used to assist in the diagnosis of cardiomyopathies such as left ventricular hypertrophy and that left ventricular hypertrophy can be asymptomatic. I also understand that an echocardiogram may be able to identify such cardiomyopathies, but that this is not currently required on initiation of Clozapine or routinely at any other time whilst a patient is taking Clozapine. I am concerned that these cardiomyopathies could therefore go undetected in patients prescribed Clozapine and leave them at unknown increased risk of fatal cardiac arrythmias, as occurred in William's case. Given that the Trust's guidance is based on national guidance I am concerned this may be a national issue. (3) It is clear that patients suffering with treatment resistant schizophrenia are complex, and as such there are often a number of different agencies involved in an individual's care. In addition, there are often multiple members of the same team involved in an individual's care. During the inquest it became clear that, at times, communication of important issues was not as clear as it should have been. I note that Devon Partnership NHS Trust has significant training available for its staff and other agencies it engages with in relation to patients who are prescribed Clozapine. However, it would be of great assistance to understand what Devon Partnership NHS Trust is doing to ensure that optimum communication of key information is achieved within the community mental health team, and when dealing with its other agencies involved in a patient's care.
6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe your organisation has 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 28 March 2025. 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; the family, Viatris and Georgian House. I have also sent it to NHS England and the Royal College of Psychiatrists 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	 **Louise Wiltshire** **27 January 2025**