Regulation 28: Prevention of Future Deaths report

Yemisi Cielto-Opaleye (died 13.12.2023)

	THIS REPORT IS BEING SENT TO: (1) [redacted] Chief Executive North London Mental Health Partnership Partnership Headquarters 4th Floor, East Wing St Pancras Hospital 4 St Pancras Way London NW1 0PE (2) [redacted] Chief Medical Officer North London Mental Health Partnership Partnership Headquarters 4th Floor, East Wing St Pancras Hospital London NW1 0PE
1	**CORONER** I am: Edwin Buckett Assistant Coroner Inner North London St Pancras Coroner's Court Camley Street London N1C 4PP
2	**CORONER'S LEGAL POWERS** I make this report under the Coroners and Justice Act 2009, paragraph 7, Schedule 5, and The Coroners (Investigations) Regulations 2013, regulations 28 and 29.
3	**INVESTIGATION and INQUEST**

	On the 21st December 2023 Assistant Coroner Ian Potter began an investigation into the death of Yemisi Cielto-Opaleye who died aged 47, on the 13th December 2023 at St Pancras Hospital, London, N1. The investigation concluded at the end of an inquest, with a jury which took place over 5 days between 11th - 15th November 2024. This was conducted by myself, Assistant Coroner Edwin Buckett. The jury made a determination that the deceased died within 3 hours of being administered an Olanzapine depot injection which caused Olanzapine toxicity, whilst a psychiatric in-patient on Sapphire Ward, St Pancras Hospital, London N1. The jury returned a Narrative Conclusion which found that neglect contributed to her cause of death.
4	**CIRCUMSTANCES OF THE DEATH** The circumstances of the death are set out in the Narrative Conclusion of the Jury which was as follows: "On 5th April 2022 Yemisi was admitted to St Pancras Hospital as a psychiatric inpatient with long standing treatment-resistant schizophrenia. On the 22nd June 2023 she was transferred to Sapphire Ward. She was treated with a wide variety of psychiatric medication administered both orally and by depot injection. Following admission to Sapphire Ward, a decision was made by the consultant along with other hospital staff to introduce Olanzapine to Yemisi's treatment. Yemisi was administered Olanzapine orally for 3-4 days, falling below the recommended trial period advised before moving to administering by depot injection and was therefore inadequate. As Olanzapine is a non-formulary drug for the Trust, additional requirements are in place to support prescribing decisions. The justification relied upon by the consultant and lead pharmacist for prescribing the drug was unsuitable as the drug does not meet the criteria outlined in Section 62 of the Mental Health Act of being a) life-saving, or b) reversible. In addition, the requirement to seek a second opinion from an independent doctor in certain circumstances when changing medications was not fulfilled as the first depot injection was administered to Yemisi before approval was received from the SOAD. Owing to Yemisi's known and documented history of refusing vital signs checks requiring participation, the prescribing decision took into account the expected difficulties with conducting these checks. However, there was no robust contingency

	plan for ensuring these checks took place, the plan itself was insufficient to accommodate Yemisi's circumstances and went no further than what is mandated in the Olanzapine policy. Yemisi received a first Olanzapine depot injection on the 13th of November, where she also did not comply with vital signs checks requiring participation. There were no adverse effects noted and staff indicated following this depot injection her mental state improved somewhat. Yemisi's non-compliance with vital signs checks requiring participation led to the decision being made that both depot injections would be administered relying solely on assessing Respiratory Rate and Level of Consciousness, departing from the Trust's Olanzapine depot policy. On the 13th of December 2023, the plan in place was for one of the nurses on Sapphire Ward that day who had completed the Olanzapine training to both prepare and administer the injection, and as per the Olanzapine policy conduct the first set of vital signs checks, and be available for the duration of the 3 hour observations unless this responsibility is delegated to an appropriately qualified member of staff. However this is not what transpired on the day. The responsibility for preparing, administering, monitoring and witnessing of these processes was unclear, and divided among multiple members of staff which did not allow for effective continuity resulting in inadequate levels of oversight. Yemisi did not consent to any of the staff members on Sapphire Ward that day administering the injection, and so a qualified member of staff from another ward was asked to come and assist. They did not witness the preparing of the solution but were satisfied that the dose and preparation were as described. This nurse and the preparing nurse initially went to Yemisi's room to conduct pre-injection vital signs checks but those requiring participation were refused. The absence of a full set of observations should have been escalated to a doctor prior to administering the depot injection, but this was not done. At this stage there was also a missed opportunity to reiterate potential side effects of the drug or symptoms of post-injection syndrome to Yemisi that she may have been able to flag as concerns. One nurse was then asked to leave the room and therefore there was a failure to follow protocol both by not having two members of staff present during the administration of the depot injection, and also that it was administered despite the requisite pre-injection vital signs checks requiring participation not taking place.

Following the injection, there was a total lack of clarity around responsibility and delegation of Post-injection checks, where the Nurse in Charge failed to allocate tasks consistent with safe implementation of the plan. Communication was inadequate and no staff member on Sapphire Ward was clear on their responsibility to conduct post-injection checks that day.

Collectively there was sufficient understanding among staff on the ward of the risks associated with Olanzapine depot injection, and the requirements for post-injection checks (regardless of whether they had completed the training). Despite an awareness of these risks, this failed to translate to adequate safety planning, management and coordination of staff responsibilities or action relating to Yemisi's care.

As a result, none of the vital signs checks stipulated in the Trust's Olanzapine policy were carried out, representing a gross failure to provide basic medical attention to Yemisi. Relevant documentation/templates for record keeping do not provide clear accountability for conducting these checks. The Trust's own documentation/templates for Olanzapine monitoring do not allow for the total number of checks stipulated (ie. at 90 minutes). The reasoning given for not completing some of the post-injection checks included a number of incidents on the ward that diverted staff resource – there was a failure to escalate high acuity and get additional support. The only check conducted was a General Observations check, not a post-Olanzapine injection check, at 15:30, an hour after administration. This check only involved visual observations from outside Yemisi's door, and could not have been sufficient to establish a patient's level of consciousness.

Yemisi was discovered lying face down on the floor in her room at around 17:20 by the nurse in charge who sounded the alarm and called for help from other staff. Multiple staff began attempts to resuscitate her including CPR/chest compressions and establishing whether the defibrillator could be used. An ambulance was called, and paramedics arrived at Yemisi's room at 17:40. No pulse or 'shockable rhythm' was detected by staff or defibrillators from the point she was discovered. London Ambulance Service continued attempts to resuscitate her but pronounced life extinct at 18:45.

	Yemisi died on the 13th December 2023 as a result of the toxic effects of the Olanzapine injection administered to her that day and neglect contributed to her cause of death."
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. Evidence was given that: (1) Olanzapine Depot injections have a known risk of Post Injection Syndrome which can lead to death. Although the risk is rare, the Trust was aware of 2 other instances of Post Injection Syndrome following the administration of some 10 Olanzapine injections in the recent past, with both individuals surviving because of early intervention by medical staff. (2) The importance of timely observations is crucial to preventing Post Injection Syndrome and preventing death in the event of an adverse reaction to the drug. (3) In order to administer an Olanzapine depot, a prescribing doctor must seek approval from a Lead Pharmacist in the Trust because the medication is a "non-formulary" medicine. (4) The trial period for administering oral medication to a patient for whom it is proposed should have a depot injection is approximately 2 weeks, whereas Yemisi only took Olanzapine tablets for 3-4 days before having her first Olazapine depot injection. Therefore, she took her oral medical for less than the recommended period. (5) The requirement to obtain a second opinion from an independent doctor (SOAD) when changing medication did not happen when Yemisi was administered her first Olanzapine depot injection on 13th November 2023. (6) In a busy psychiatric in-patient ward, staff can become distracted by having to tend to other patients, urgently, when events occur such as unexpected new patient admissions and disturbances.

	(7) Yemisi had a long history of refusing to take medication and refusing vital signs checks as a psychiatric in-patient. I am concerned that: (a) The risk of death from the use of Olanzapine depot injection needs to be made clear to patients who are going to be given that injection. Although it is very small risk, the fact that the risk can be largely eradicated by vital signs checks at intervals within the 3-hour period with early medical intervention, the risk needs to be stated to, and understood by, patients or those who represent their interests, before such a depot injection is given; (b) In a psychiatric in-patient setting, there are many demands on staff who can become distracted from their expected duties. Unless there is a suitably qualified medical member of staff whose sole duty it is to remain in the company of a patient, who has had an Olanzapine depot injection at all times during the 3 hour post-injection observation period, there is a risk that vital signs checks will be missed and that Post Injection Syndrome will not be detected early enough if it occurs; (c) There is a risk that approval from a Lead Pharmacist to initiate a non-formulary medicine such as an Olanzapine depot can occur without the Pharmacist knowing whether a SOAD has been obtained in relation to that medication and that patient; (d) In cases where psychiatric in-patients are known to have a history of refusing vital signs checks, careful consideration and scrutiny should be given as to whether an Olanzapine depot injection is a suitable medication for such patients, especially in view of the crucial post-injection monitoring requirements.
6	**ACTION SHOULD BE TAKEN** In my opinion, action should be taken to prevent future deaths and I believe that you and/or your organisation 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 **17th January 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 following. • HHJ Alexia Curran, the Chief Coroner of England & Wales • [redacted], the sister of Yemisi Cielto-Opaleye. I am 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	**DATE 18.11.2024** **SIGNED BY ASSISTANT CORONER** Edwin Buckett