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NHS Foundation Trust

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Private and Confidential
Assistant Coroner Edwin Buckett
Inner North London
St Pancras Coroner's Court
Camley St
London N1C 4PP

17th January 2025

Dear Coroner Buckett

Re Inquest touching the death of Yemisi Cielto Opaleye

I am writing following the inquest for Yemisi Cielto Opaleye which concluded on 15th November 2024 and following which you issued a Prevention of Future Deaths report to the Trust. Ms Cielto Opaleye died following administration of Olanzapine depot injection on one of the Trust's inpatient wards. The matters of concern raised in your report were as follows:

(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 postinjection 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.

Firstly we wish to express our sincere condolences to the family and friends of Ms Cielto-Opaleye.

As stated in our letter to you of 17th October 2024, we accept, as you outline in your report, that the failure to carry out the observations of Ms Cielto-Opaleye's vital signs, which should have been carried out in accordance with the Trust's Olanzapine Depot Guidelines dated February 2021, at 14.48 hours (20 mins); 15:08 hours (40 mins); 15:28 hours (60 mins); 15:58 hours (90) mins and 16:28 hours (120 mins) represents a failure on the part of the Trust's staff who were responsible for carrying out those observations.

The Trust would like to repeat its apology as stated in that letter and apologise unreservedly to the family of Ms Cielto-Opaleye for these failures and accept that in all likelihood they contributed to Ms Cielto-Opaleye's death on Sapphire ward on the 13th of December 2023.

In relation to your report and addressing each of your concerns:

Matter of concern 1: *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.*

Trust Response: As discussed in court, our olanzapine depot prescribing policy was reviewed and re written in March 2024. Section 9.2.1 of that policy states:

> If olanzapine depot is considered, the team *must* provide medication counselling for olanzapine depot to patient. The information must include advice about the three-hour post administration observations. The patient must be given a copy of the olanzapine depot alert card in appendix 1. The key messages to discuss with the patient before administration are:
>
> - Olanzapine depot carries a small risk of post-injection syndrome.
> - Most symptoms appear within one hour following injection and resolve within 24-72 hours.
> - A patient information leaflet can be obtained from the Choice and Medication link on the Trust intranet (» Printable leaflets (choiceandmedication.org))
> - The patient must be advised not to leave prior to completion of the three hour observation period. If the patient indicates he/she will leave prior to end of the three-hour period, the depot must not be administered and the medical team advised as soon as possible.

We acknowledge that the small risk of *death* from post injection syndrome is not explicitly highlighted within this literature and this will be reviewed within the policy.

Matter of concern 2: *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.

Trust Response: The olanzapine depot policy dated March 2024 section 10.1.2 states that 'the nurse must be available for the duration of the three-hour post-administration observation.' Section 10.1.7 states that 'An appropriately trained and /or professional member of staff, other than a nurse, can take the subsequent clinical observations if delegated by the administering nurse'.
We agree that this policy will be reviewed and in instances of olanzapine depot administration in an inpatient setting an extra qualified member of staff will be booked on shift with the sole responsibility of preparing, administering and delivering post administration observations of the patient for the three hour period.

***Matter of concern 3**: 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.*

Trust Response: The role of the pharmacist is not referenced within the Mental Health Act 1983. In the case of Yemisi Cielto-Opaleye, a valid T3 form and SOAD approval was in place for the administration of the depot on the 13th December 2023. On the date of the first olanzapine depot administration on the 13th November 2023 a S62 'Urgent Treatment Form' was in place dated 10th November 2023 and treatment was administered legally under clause b, that is, '(not being irreversible) immediately necessary to prevent a serious deterioration in their condition'.
In terms of the irreversibility, the White Paper that preceded the 1983 Act defined it as "treatments which necessitate the removal or destruction of brain tissue or are designed to effect irreversible change in cerebral or bodily function" and at the 1982 special standing committee on the bill the under-secretary of state gave the removal of a brain tumour or a diseased thyroid as examples.

***Matter of concern 4**: 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.*

Trust Response: We accept that this is reasonable and in the case of patients known to refuse vital signs that alternatives to olanzapine depot should be thoroughly explored.

I hope that this response provides the necessary assurance. Please contact me if you have any queries.

Yours sincerely

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Chief Medical Officer