

29 September 2025

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Trust Headquarters
225 Old Street
Ashton Under Lyne
Lancashire
OL6 7SF

Private & Confidential

Chrstopher Morris
HM Area Coroner
Coroner's Court
1 Mount Tabor Street
Stockport
SK1 3AG

Dear Mr Morris,

RE: Inquest touching on the death of Sasha Drysdale

I set out below the Trust's response to your letter to Pennine Care NHS Foundation Trust (PCFT) and the issuing of a Prevention of Future Deaths Notice (Regulation 28), arising from the inquest into the death of Sasha Drysdale and the proceeding Judicial Review.

May I take this opportunity to extend my own condolences to the family of Sasha and apologise that you had to raise concerns relating to the services she accessed prior to her sad death.

The Trust sets out its response to the points below raised by HMC's as areas of concern:

Whilst it is understood regular blood tests represent an important monitoring requirement for patients taking Clozapine in view of the serious potential side effects of neutropenia and particularly agranulocytosis, I am concerned that the emphasis on these complications raises a risk that the potential significance of other abnormal results may not be readily or promptly appreciated or acted upon, and remain overlooked or possibly incorrectly attributed to Clozapine therapy.

Full Blood Count monitoring:

Leucocyte (white blood cells) and neutrophil monitoring is a mandatory requirement for all patients treated with Clozapine in the UK. Summary of product characteristics: Clozaril

In addition to the mandatory white blood cells (WBC) and neutrophil monitoring other full blood count parameters are currently monitored as standard either via Point of care haematological testing (PoCHi) or local lab analysis including Products Detail.



WBC (white blood cells), RBC (red blood cells), HGB (heamoglobin), HCT (haematocrit), MCV (Mean Corpuscular Volume), MCH (Mean Corpuscular Haemoglobin), MCHC (Mean Corpuscular Haemoglobin Concentration), PLT (platelets), LYM (#,%) (lymphocytes), MXD (#,%) (mixed white blood cells), NEUT (#,%) (neutrophils),

These full blood count (FBC) parameters would be recommended as standard for assessment of haematological cancers Ref: Haematological cancers - recognition and referral | Health topics A to Z | CKS | NICE

Abnormal results, including neutropenia but also other abnormalities in FBC differentials obtained within a community setting are escalated to medical staff for review. Results for inpatient monitoring conducted via local labourites would be review directly by medical staff and appropriate action taken for abnormalities, neutropenia or otherwise.

Medical staff would following NICE guidelines Haematological cancers - recognition and referral regardless of the original indication for Full Blood Count investigation.

<u>Pharmacovigilance Risk Assessment Committee (PRAC) recommendations</u> for routine blood count monitoring

PRAC has recently endorsed a direct healthcare professional communication (DHPC) about revised recommendations for the monitoring of the blood count to minimise the risk of severe neutropenia and agranulocytosis with Clozapine Ref: Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 7 – 10 July 2025 | European Medicines Agency (EMA)

New evidence from the scientific literature suggests that, although Clozapine-induced neutropenia can occur at any time during treatment, it is predominantly observed during the first year, with the incidence peaking in the first 18 weeks of treatment. After this the incidence decreases becoming progressively lower after two years of treatment in patients without previous episode of neutropenia.

Therefore, PRAC recommended less frequent blood count monitoring. For example, in patients without neutropenia, the frequency of monitoring is reduced to every 12 weeks after one year, and to once a year after two years of treatment.

The product information for all Clozapine-containing medicines will be updated to reflect the monitoring frequency for the risk of Clozapine-related agranulocytosis and the revised ANC thresholds for treatment initiation and continuation. This is anticipated in Autumn 2025.

The DHPC for Clozapine will be disseminated to healthcare professionals by the marketing authorisation holders in September 2025, and published on the <u>Direct healthcare professional communications</u> page and in <u>national registers</u> in EU Member States.

Currently the monitoring requirements for Clozapine within the UK remain unchanged however the emerging evidence for scientific literature is well known by

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clinicians and will be circulated clearly to all PCFT prescribers and pharmacists. This will further increase the scrutiny of any abnormal full blood count results in patients on established treatment due to the known unlikelihood of Clozapine as a causative factor.

I hope that the information within this response has provided you with the assurance that you were seeking in relation to learning from these events. Should you require any further information or clarification on the details within this letter, please do not hesitate to get in touch with me again.

Yours sincerely

