Care Quality Commission
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Mr Andrew Harris
Assistant Coroner
HM Coroner for London Inner South Coroners Court
1 Tennis Street
London
SE1 1YD

08 May 2025

Dear Mr Harris,

Care Quality Commission:
Response to Regulation 28 Report to Prevent Future Deaths following the inquest into the death of Mr Luke Alexander Worrell.

Thank you for your Regulation 28 Report to Prevent Future Deaths dated 21 February 2025 about Mr Worrell's death. I am replying on behalf of the Care Quality Commission (CQC).

Firstly, I would like to say how saddened I was to read of the circumstances of Mr Worrell's death, and I offer my sincere condolences to his family and loved ones. Your report's circumstances are concerning, and I am grateful to you for raising these matters.

In the Regulation 28 Report to Prevent Future Deaths, the following concerns were raised to the CQC:

1. The lack of awareness by a series of clinical staff of the potential fatal side effects of Clozapine

2. Inappropriate use of community treatment order, when there was sufficient evidence to keep on a MHA section.

In response to the individual points raised:

1. The Care Quality Commission (CQC) recognises the serious concerns arising from the lack of awareness among some clinical staff regarding the potentially fatal side effects of Clozapine. As the regulator of health and social care in

England, we are committed to supporting safe, high-quality care for people receiving treatment with Clozapine, both in inpatient settings and in the community.

Clozapine remains an essential treatment for individuals with mental health conditions such as treatment-resistant schizophrenia; however, its use carries significant risks, including agranulocytosis, myocarditis, and gastrointestinal hypomotility, which require stringent monitoring and management. To ensure high standards of care, the assessment of Clozapine use, including through community Clozapine clinics and the monitoring of Clozapine related concerns, is conducted by our mental health inspectors within the CQC integrated assessment and inspection teams. These teams are further supported by our team of specialist medicines inspectors and our mental health senior specialists.

In addition, our medicines inspection team delivers targeted Clozapine training and awareness sessions for our mental health inspectors across our integrated assessment and inspection teams. These are delivered through dedicated face-to-face training sessions and development days to strengthen the knowledge and vigilance of our integrated assessment and inspection teams.

Our dedicated mental health senior specialists support our integrated assessment and inspection teams in monitoring intelligence and assessing providers. This includes evaluating the safe and lawful use of Clozapine.

Furthermore, the CQC medicines inspection team maintains regular engagement with the Health Services Safety Investigation Body (HSSIB), particularly in relation to investigations into Clozapine-related deaths in inpatient settings. Learning from these investigations is incorporated into our regulatory approach, enhancing our understanding of the safe use of Clozapine in inpatient and community settings.

2. The CQC is concerned by instances of the inappropriate use of Community Treatment Orders (CTOs), particularly where there is sufficient clinical and legal justification to maintain a person on a detention under the Mental Health Act (1983). The inappropriate application of CTOs can compromise both the safety of the individual and the effectiveness of their care and treatment.

   As the independent regulator of health and social care in England, we expect providers to ensure that all decisions relating to the use of the Mental Health Act, including transitions to CTOs, are based on clear clinical evidence, follow legal frameworks, and prioritise the individual’s rights and wellbeing.

   To support this, the CQC has a team of dedicated Mental Health Act Reviewers who work alongside our integrated assessment and inspection teams. These specialists provide expert advice and oversight in assessing the use and application of the Mental Health Act across both inpatient and community mental health services, including the use of CTOs.

   During the CQC assessment processes, our reviewers assess whether decisions regarding CTOs are legally compliant, clinically justified, and in the best interests of the person receiving care. They also monitor how well providers involve

individuals, carers, and advocates in the decision-making process, and whether services uphold people's rights under the Act.

Where we identify inappropriate use of CTOs or concerns about compliance with the Mental Health Act, we can undertake additional monitoring, engagement and regulatory action as necessary to drive improvement and hold providers to account. We aim to ensure that all people receiving care under the Mental Health Act are treated lawfully, safely, and with dignity and respect.

All system partners in the health and social care sector must recognise the potentially fatal side effects of Clozapine. Failure to monitor and manage these risks can lead to avoidable harm or death. Equally, the appropriate use of Community Treatment Orders is critical to ensuring individuals receive necessary treatment while maintaining oversight and safeguarding their rights. Collaborative awareness and accountability across services help provide safe, person-centred care and uphold the standards we are committed to as a sector.

The safety of people using mental health services remains a top priority for the CQC, and we will continue to take action where standards fall short to ensure that providers deliver safe, effective, and person-centred care.

Internally, the CQC incorporates information from incidents, notifications, and Regulation 28 Prevention of Future Deaths reports into its ongoing monitoring and assessment planning. Our internal Specific Incidents Guidance process evaluates whether incidents indicate avoidable harm or breaches of fundamental standards. Where necessary, further enquiries are made, and the CQC may undertake targeted or unannounced inspections. If risks are confirmed, regulatory actions such as requirement notices or enforcement measures may be taken to ensure compliance and drive improvements in care.

The Care Quality Commission's local integrated assessment and inspection teams actively monitor Oxleas NHS Foundation Trust and Lewisham and Greenwich NHS Trust through continuous engagement and risk-based assessments. This includes gathering intelligence from various sources such as patient feedback, incident reports, and partner organisations. Regular meetings with the trusts and attendance at key committees, like Oxleas' mortality surveillance committee, allow the CQC to review performance, address concerns, and seek assurance on improved care quality and safety. In addition to this local monitoring, the CQC has committed to a national review of adult community mental health services across England, following the 2024 Section 48 special review of Nottinghamshire Healthcare NHS Foundation Trust. This work includes inspections of services such as community-based mental health services for adults of working age and mental health crisis services and health-based places of safety to identify gaps in care quality, patient and public safety, and staff experience. The review will assess both individual trust services and provide a broader national overview of community mental health service provision.

We are grateful for the information you have shared. It is invaluable in helping us monitor the quality of care provided across services and ensure that providers meet the standards expected under the Health and Social Care Act (2008) and the associated Regulated Activities Regulations (2014). We appreciate the coroner raising these

concerns with us. We will continue to monitor the trusts and any information we receive in line with our internal processes and methodology. If you have any further queries, please do not hesitate to contact us.

Yours sincerely,

[redacted]

[redacted]
Deputy Director Operations
Care Quality Commission – London & East of England Network