Department of Health & Social Care

[redacted]
Parliamentary Under-Secretary of State for
Patient Safety, Women's Health and Mental Health

39 Victoria Street
London
SW1H 0EU

Our ref: [redacted]

Mr Andrew Harris
Assistant Coroner
London Inner South Coroners Court
1 Tennis Street
London
SE1 1YD

By Email: [redacted]

25 April 2025

Dear Mr Harris,

Thank you for your Regulation 28 report of 21 February 2025 sent to the Secretary of State about the death of Luke Alexander Worrell. I am replying as the Minister with responsibility for patient safety and mental health.

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. The circumstances your report describes are deeply concerning and I am grateful to you for bringing these matters to my attention.

Your report raises concerns over levels of awareness of clinical staff around the potentially fatal side effects of clozapine and the use of a Community Treatment Order (CTO) to support Mr Worrell when there may have been sufficient evidence to detain Mr Worrell under the Mental Health Act.

I note that you have also addressed these matters of concern to NHS England, the Medicines and Healthcare Products Regulatory Agency (MHRA), the Royal College of Psychiatrists, and the Care Quality Commission. I look forward to working together with these bodies where appropriate to avoid a repetition of the tragic events of this case.

I understand your concern that clinical staff administering clozapine need to have a firm understanding of the drug's potential side effects. I am aware that the Chief Executive of Medicines and Health Care products Regulatory Agency has provided a response to your report, which sets out the protocols it has in place to ensure clinicians are aware of the side effects of clozapine. This includes ensuring that the special warnings and precautions for use section of the Summary of Product Characteristics (SmPC) for clozapine includes information on the medicine's anticholinergic effects and ensuring that labelling and Patient Information Leaflets accurately reflect the risk of gastrointestinal disorders.

In its response, the MHRA has considered the evidence provided in your report and acknowledges the concerns relating to the level of awareness of clinical staff around the potentially fatal side effects of clozapine. Whilst the MHRA is unable to comment on the specific clinical decisions made in Mr Worrell's case, the MHRA is currently reviewing the product information for clozapine which will carefully consider the information provided to healthcare professionals, patients and their families and carers and whether this can be improved to provide greater clarity on the side effects of clozapine. The MHRA will engage with stakeholders to ensure the regulatory documents for clozapine meet the needs of both patients and prescribers. I understand this review is expected to be completed this year and that the MHRA will inform you of the outcome.

I am aware that the National Medical Director of NHS England has written to you setting out the additional measures that have been taken to ensure responsible clinicians are aware of the potentially fatal side effects of clozapine. These include ongoing work to raise awareness in the health community around the potential risks of clozapine.

I understand your concerns around whether the use of a CTO was the appropriate course of action for Mr Worrell's treatment, as opposed to detaining him under the Mental Health Act. Whilst I am unable to comment on the specific decision made by the psychiatrist to place Mr Worrell under a CTO, the CTO should not have been a barrier to providing better support Mr Worrell.

CTOs are a form of supervised community treatment where an individual can be quickly recalled to hospital to be detained and treated. CTOs are intended to maintain ongoing contact with mental health services to provide support and help prevent relapse. In certain circumstances, patients subject to a CTO may be recalled to hospital under the Mental Health Act. Under section 17E of the Act, a patient can be recalled to hospital if they require medical treatment in hospital for their mental disorder and there would be a risk of harm to the health or safety of the patient or to other persons if the patient were not recalled to hospital for that purpose.

I am aware that the National Medical Director has advised that, in cases like Mr Worrell's, inpatient mental health teams still have the option to use section 17 to recall individuals to hospital. He has also advised that clear guidance is available within the Mental Health Act Code of Practice[1] for responsible clinicians to make decisions on guardianship, section 17 leave, and CTOs. This guidance outlines circumstances for clinicians to consider when making decisions on whether a CTO or section 17 leave would be the most suitable course of action for a patient.

This guidance states that section 17 leave is only suitable for short-term absences from inpatient services for a fixed period or purpose. Section 17 may also be suitable in the longer-term (for more than seven consecutive days) where the clinical team wish to see how the individual manages outside of hospital before making a decision to discharge. For patients who are able to live in the community, a CTO should be considered a better option than longer-term leave for the management of their care. Where longer-term leave is considered under section 17 (for more than seven consecutive days), the responsible clinician must first

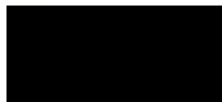
[1] Code of practice: Mental Health Act 1983 - GOV.UK

consider whether the patient should be discharged on a CTO instead. Any decision to authorise section 17 leave for more than seven days on a second occasion should be fully documented, including why a CTO discharge is not appropriate.
Through the Mental Health Bill, which is currently making its way through Parliament, we are introducing further professional oversight in decisions regarding the use and operation of CTOs. The community clinician (the approved clinician who is responsible for overseeing the patient's care as a community patient) will be involved in decision making in addition to the hospital-based responsible clinician. This includes the decision to make a person subject to a CTO, to vary or suspend conditions made under a CTO, to recall to hospital a patient subject to a CTO, to revoke a CTO after a patient has been recalled, and to discharge the patient from the CTO. This will help ensure better join up between inpatient and community clinical teams and make sure that patients subject to a CTO are benefitting from the framework they provide.

I agree with the point your report raises around the importance of involving the patient, family and carers, and clinicians in communities when planning and supporting an individual to be discharged from hospital. Statutory guidance on discharge from mental health inpatient settings[2] should be referred to by responsible clinicians to ensure that decisions on discharge are firmly centred around patients and their chosen carers and that they are actively involved throughout the process with appropriate input from relevant professionals involved in their ongoing care.

I hope this response is helpful. Thank you for bringing these concerns to my attention.

Yours sincerely,



[2] Discharge from mental health inpatient settings - GOV.UK