Department of Health & Social Care

From Baroness Merron
Parliamentary Under Secretary of State for
Patient Safety, Women's Health and Mental Health

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Our Ref: [redacted]

Nigel Parsley
HM Senior Coroner for Suffolk
Coroners Service
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By email: [redacted]

17 September 2024

Dear Mr Parsley,

Thank you for your Regulation 28 report to prevent future deaths dated 22 July 2024 about the death of Gemima Christodoulou-Peace. 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 Gemima's death and I offer my sincere condolences to her family and loved ones. The circumstances your report describes are concerning and I am grateful to you for bringing these matters to my attention.

Thank you for highlighting your concerns about the need for treating clinicians to be able to quickly access and identify information on potential side effects when prescribing medicines; the recording of telephone calls at Norfolk and Suffolk NHS Foundation Trust; and the difficulties accessing mental health services and ensuring continuity of care.

In preparing this response, departmental officials have made enquiries with NHS England, Norfolk and Suffolk NHS Foundation Trust and the Medicines and Healthcare Products Regulatory Agency (MHRA).

I understand your concerns around the difficulties faced by a treating clinician in quickly identifying if a prescribed medication is known to increase suicidal behaviour in some patients.

Since 2021, all primary and secondary care organisations have been able to share a subset of the patient information they hold – the core information standard – between providers within their own integrated care board footprint as part of a shared care

record. This shared care record joins up information, including medications a patient has been prescribed, based on an individual rather than an organisation, and is a safe and secure way of bringing an individual's separate records from different health and care organisations together. NHS England is working on plans to make shared care records link together regardless of where a person lives or receive care in England.

The MHRA has advised me that it keeps the safety of all medicines and medical devices under continual review, including montelukast (which Gemima had been prescribed). It closely monitors reports from healthcare professionals, patients and parents or carers via the Yellow Card scheme, which is the UK system for collecting information on suspected side effects, and is used to investigate reports of suspected adverse reactions and other issues. Together with independent expert advice from the Commission on Human Medicines, the MHRA is responsible for ensuring that the overall balance of benefits and risks of all medicines is positive at the time of licensing and throughout the post-licensing period.

Information including the reported frequency of adverse drug reactions can be found in the Patient Information Leaflet and Summary of Product Characteristics which accompanies every licensed medicine marketed in the UK, including montelukast. The Summary of Product Characteristics forms the legal basis for the correct use of a medicinal product. It provides all the necessary information for prescribers to use a product safely and should be used to inform any discussions with a patient about the risks as well as the benefits of their treatment. The Patient Information Leaflet supplied with a patient's medicine also supports those discussions and can be a useful reference to ensure patients are informed about their treatment. It is the prescriber's responsibility to prescribe a drug based on the information contained within the Summary of Product Characteristics.

In 2023 the MHRA initiated a safety review of the known risk of neuropsychiatric side effects with montelukast to consider any new evidence, the impact of the risk minimisation measures already in place, and whether any additional measures were required. The review took into consideration the lived experiences of patients and caregivers, and independent clinical advice from paediatricians, specialists in mental and respiratory health, as well as experts in medicines safety at Expert Advisory Groups of the CHM. The MHRA's review confirmed that while the risk of neuropsychiatric reactions with montelukast remained unchanged, Yellow Card reports had indicated this risk was potentially not well known by healthcare professionals, patients and their caregivers.

As a result, the neuropsychiatric warnings in the Patient Information Leaflet and the Summary of Product Characteristics for all montelukast products in the UK were strengthened and highlighted within a black box for greater emphasis, with a reminder issued in April 2024. Additionally, a new Drug Safety Update was published on 29 April 2024 to communicate these changes. Drug Safety Updates allow healthcare professionals to be aware of and learn about new emerging safety issues relating to medicines and provide appropriate messaging to support conversations with patients. This remains an ongoing review and the MHRA is considering additional measures to better inform patients and healthcare professionals of this risk.

These warnings are also replicated in the British National Formulary, which is widely regarded by doctors, pharmacists and other healthcare professionals as an up to date and highly authoritative information resource on medicines prescribed in the UK and made available on the National Institute for Health and Care Excellence's website.

Turning to your concerns around the recording of incoming phone calls made to the Norfolk and Suffolk NHS Foundation Trust, I can appreciate the potential risks this may pose, as you have highlighted. The Trust has advised that it has recently considered the issue of recording clinical calls and taken the decision that it would be proportionate to extend clinical call recording from NHS 111 (option 2) only to within crisis teams within the organisation and all phone lines which have been designated as requiring recording facility have now been enabled.

The Trust's view was that it would be disproportionate to record all clinical calls within all clinical teams in the organisation. However, it is currently looking at how this works across other trusts, and has requested feedback on this via the Mental Health and Learning Disabilities Nursing Directors Forum.

Finally, turning to your concerns around Gemima not being able to access appropriate mental health services or receiving the continuity of care that she was looking for, I understand that, following wider concerns about the performance of the Trust and the risk to patients, the Trust implemented a revised Trust Strategy in May 2024 to improve services, outcomes and experiences for patients, families and carers and become a safer, kinder and better Trust with a clear and detailed improvement plan and new Trust values.

It has enhanced clinical leadership across the Trust and has implemented a new place-based leadership structure to reduce unwarranted clinical variation, improve quality and safety and deliver consistent, patient-centred care, as well as setting up a Service User and Carer Council to strengthen the voice of patients, carers and families. A Learning from Deaths group has also been established with membership from partners, patients, carers, bereaved families and Healthwatch.

More broadly, it is unacceptable that too many people, like Gemima, are not receiving the mental health care they need when they need it and we know that waits for mental health services are far too long. We are determined to change that. As part of our mission to build an NHS that is fit for the future and that is there when people need it, we will modernize the Mental Health Act to give greater choice, autonomy, enhanced rights and support, and ensure everyone is treated with dignity and respect throughout treatment and recruit an additional 8,500 mental health workers to reduce delays and provide faster treatment which will also help ease pressure on busy mental health services. These new workers will be specially trained to support people at risk of suicide.

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

Yours sincerely,

BARONESS MERRON