NHS England

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[redacted]

14 April 2025

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Dear Coroner,

Re: Regulation 28 Report to Prevent Future Deaths – William Stephen Green who died on 9 July 2023.

Thank you for your Report to Prevent Future Deaths (hereafter "Report") dated 28 February 2025 concerning the death of William Stephen Green on 9 July 2023. In advance of responding to the specific concerns raised in your Report, I would like to express my deep condolences to William's family and loved ones. NHS England are keen to assure the family and the Coroner that the concerns raised about William's care have been listened to and reflected upon.

Your Report raises the concern that there is no written record explaining or counselling patients on the side-effects, and what to do if side-effects are experienced, when a patient at The Royal Shrewsbury Hospital is initiated on a new prescribed drug during an admission. Your Report also raises that there is no provision in place for patients who lack capacity to understand an explanation of the side-effects of prescribed drugs, even when this may be offered. In William's case, he was prescribed an anti-epileptic and seizure drug called Lamotrigine between 5 June 2023 and 8 July 2023.

My response to the Coroner has been aided by engagement with NHS England's National Clinical Director for Prescribing and two experienced Clinical Pharmacologists.

When administering a new prescribed drug to patients, there should be shared decision-making and potential risks or complications relevant to the patient should be verbally discussed with them, even if very rare. The counselling of patients on their medications, including documenting a record of these discussions (or a lack of capacity to engage with such discussion) is a matter of professional duty and is described by both professional and organisational regulatory bodies.

It is not standard practice in hospitals to document or record if a patient has been counselled about the risk of medicines, apart from in certain circumstances where consent is required (e.g., completing an Acknowledgement of Risk form for the prescription of isotretinoin) or to provide written information on the risk.

However, NHS England will take your concern about counselling, and keeping a written record of such counselling, to an appropriate forum for further discussion and consideration of any actions we need to take.

It should also be noted that, on discharge from hospital, patients will be provided with the 'original pack' medication, and these will contain the Patient Information Leaflet (PIL) which outlines the risks and side-effects. In the case of Lamotrigine, the PIL states:

'A small number of people taking Lamotrigine get an allergic reaction or potentially life-threatening skin reaction, which may develop into more serious problems if they are not treated. These can include Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). You need to know the symptoms to look out for while you are taking Lamotrigine Tablets. This risk may be associated with a variant in genes in people from Asian origin (mainly Han Chinese and Thai). If you are of such origin and have been tested previously carrying this genetic variant (HLA-B* 1502), discuss this with your doctor before taking Lamotrigine Tablets.'

Your Report does not mention whether William was given the original pack medication on discharge from hospital.

Regarding the capacity of patients, there is clear NHS guidance on how to proceed with treatment when someone may lack capacity. There is also legislation (The Mental Capacity Act 2005), which provides a framework for decision-making on behalf of people who lack capacity. We would expect Trusts to have their own local policies on the administration of new medications, and most Trusts' Medicine Policies will contain guidance on counselling patients. However, as above, they may not direct that this counselling needs to be recorded in the patient's notes, as this is not standard practice.

NHS England has also engaged with NHS Shropshire, Telford and Wrekin Integrated Care Board (ICB), the responsible commissioner for services delivered by Shrewsbury and Telford Hospital NHS Trust, on the concerns raised in your Report. We are advised that the Trust have developed a Safety Improvement Plan, with actions including:

- A Working Group to review patient counselling and informed consent regarding medications being prescribed in hospital
- Learning from William's case to be used to deliver training to junior doctors
- A new Stevens-Johnson Syndrome / Toxic Epidermal Necrolysis (severe muco-cutaneous reactions usually caused by certain medicines) pathway to be developed and published within the Trust.

I would also like to provide further assurances on the national NHS England work taking place around the Reports to Prevent Future Deaths. All reports received are discussed by the Regulation 28 Working Group, comprising Regional Medical Directors, and other clinical and quality colleagues from across the regions. This ensures that key learnings and insights around events, such as the sad death of William, are shared across the NHS at both a national and regional level and helps us

to pay close attention to any emerging trends that may require further review and action.

Thank you for bringing these important patient safety issues to my attention and please do not hesitate to contact me should you need any further information.

Yours sincerely,

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National Medical Director