NHS England

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24 February 2025

Dear Coroner,

Re: Regulation 28 Report to Prevent Future Deaths – Alexandra Bronte Roberts who died on 14 May 2023

Thank you for your Report to Prevent Future Deaths (hereafter "Report") dated 2 January 2025 concerning the death of Alexandra ('Alex') Bronte Roberts on 14 May 2023. In advance of responding to the specific concerns raised in your Report, I would like to express my deep condolences to Alex's family and loved ones. NHS England are keen to assure the family and the Coroner that the concerns raised about Alex's care have been listened to and reflected upon.

Your Report raised concerns over the minimum amount (300 units) of insulin available to be prescribed at the time of Alex's death and the risk this poses to patients at risk of taking an overdose.

NHS England's National Clinical Directors for Diabetes and Prescribing have considered your Report and have input into this response.

As your Report notes, the smallest quantity of insulin within a single pen device is currently 300 units of insulin. You may wish to refer to the Medicines and Healthcare products Regulatory Agency (MHRA) as the UK's regulator of medicines regarding your concerns, as they would be the more appropriate organisation to respond on the insulin doses currently available to patients.

Any risks associated with the prescription of insulin must be weighed against the risk of a person with Type 1 diabetes running out of their insulin supply, or being issued with less than required, as this can result in the onset of diabetic ketoacidosis (DKA), an acute hyperglycaemic emergency, that can potentially be life-threatening. DKA can also be precipitated when insulin is missed or withheld, whatever the mode of insulin delivery.

Insulin can be delivered to people in two ways, either via self-administration with an insulin pen, or with an automated insulin pump, a small electronic device that releases the regular insulin the patient's body needs throughout the day and night. In general, and in line with the National Institute for Health and Care Excellence (NICE)

guidelines, the NHS only prescribes insulin pumps to adults with Type 1 diabetes who cannot get to their target HbA1C (average blood glucose levels for the last two or three months) without having severe hypoglycaemia (low blood sugar level) or whose HbA1c remains high despite carefully trying to manage their diabetes.

Because of the risk of DKA, it is a general rule of thumb that people with Type 1 diabetes should always have access to an insulin pen, even where an insulin pump is being used, as the insulin pen is an essential back-up in the case of pump failure.

Insulin therapy should however be individualised, according to the specific needs of the person with diabetes. An individualised insulin regimen takes account of many factors, including individual preference, the time action profile required to best fit the individual's glucose profile, lifestyle, activity and various other factors, the amount or dose of insulin required, the device required for administration, as well as several additional personal and medical factors.

There are some insulin pens available that do allow for half unit dosing. These are more commonly used in paediatric care, as they allow for smaller incremental adjustments. However, the total amount of insulin available within the prescription is still 300 units.

My regional colleagues for governance and assurance in the North West have also engaged with Cheshire and Merseyside Integrated Care Board (ICB), the commissioner of services provided by Cheshire and Wirral Partnership NHS Foundation Trust regarding the concerns raised in your Report. We are advised that the Head of Patient Safety and Quality - Medicines Optimisation at Cheshire and Merseyside ICB has contacted the ICB's Heads of Medicines Optimisation for Cheshire and the Safety Pharmacist to highlight the PFD Report and the Coroner's concerns. Your Report will also be included for discussion by the Cheshire and Merseyside Patient Safety Community of Practice. The purpose of the Community of Practice is to provide opportunities to build on the work carried out around patient safety and to ensure a learning focused community.

Further discussion has also taken place between Cheshire and Merseyside ICB's Head of Patient Safety and Quality - Medicines Optimisation, the Medicines Optimisation Pharmacist, Head of Medicines Management and the Head of Quality and Safety within the Cheshire Place Team. In relation to the Coroner's concerns, NHS England is advised that the following actions will be undertaken:

- There will be a recommendation to ensure that when the annual medication review is undertaken, consideration is given to the patient's mental health and wellbeing if high risk medicines are being prescribed (insulin being one of those following this case).
- There will be a review of the prescription quantities to ensure that there is no over-supply, to reduce the risk of accumulation (stock piling) of high-risk medicines.
- The team plan to discuss this case with the GP concerned to establish any learning as a result of this case, and any useful information will be shared.

It would not be appropriate for NHS England to provide further comment or clinical opinion on Alex's case, based on the organisation's remit and the information provided in your Report.

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 Alex, 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