

## **National Medical Director**

NHS England & NHS Improvement Skipton House 80 London Road London SE1 6LH

Ms Emma Serrano, Area Coroner Stoke-on-Trent & North Staffordshire Coroner's Court, Coroner's Chambers, 547 Hartshill Road, Hartshill, Stoke-on-Trent ST4 6HF

26th April 2021

Dear Ms Serrano.

## Re: Regulation 28 Report to Prevent Future Deaths – Jamie Lee Poole (2<sup>nd</sup> July 2017)

Thank you for your Regulation 28 Report dated 15/03/2021 concerning the death of Jamie Lee Poole on 2<sup>nd</sup> July 2017. Firstly, we would like to express our condolences to Jamie Lee Poole's family.

The regulation 28 report concludes Jamie Lee Poole's death was a result of Acute Cerebral Oedema and acidosis secondary to low Magnesium and Calcium levels.

Following the inquest, you raised concerns in your Regulation 28 Report to NHS England regarding routine testing of post-transplant patients for magnesium levels.

We are deeply saddened to hear about the tragic loss of Jamie Lee Poole, aged 27. The cause of death has been attributed to acute cerebral oedema and acidosis secondary to low calcium and severe which had been diagnosed on blood testing during a clinic review. Hypomagnesemia is a recognised electrolyte disturbance associated with both Tacrolimus and Proton Pump Inhibitors (PPI), both of which she was taking at the time. Symptomatic severe hypomagnesemia leading to fatality in established kidney transplant patients on isolated Tacrolimus or other Calcineurin inhibitor (CNI) therapy is rarely reported in literature. However, several factors such as elevated drug levels and drug interactions with PPI and others can exacerbate the risk through altered magnesium handling by the body.

We wish to convey our sincere condolences to the family and have taken the matter extremely seriously to prevent future occurrence. We will be instituting the following remedial actions:



- A National Patient safety alert (Level 2) on the risk of severe hypomagnesemia in the context of Tacrolimus and Proton pump inhibitor use in transplant recipients and other conditions
- The advice for monitoring Mg levels periodically is already in place for PPI's <u>Proton pump inhibitors (PPIs) | Prescribing information | Dyspepsia - unidentified cause | CKS | NICE) & MHRA (2012) Proton pump inhibitors in long term use: <u>reports of hypomagnesaemia. Drug Safety Update 5(9).</u> Although this guidance is in place, it may not be practiced reliably. A Reminder Alert will be sent out on Magnesium monitoring in patients on PPI and at risk of hypomagnesemia as recommended by NICE.</u>
- An Expert Clinical review to make recommendations on magnesium monitoring in patients on Immunosuppression, and a review of prescribing PPI and H2 antagonists in patients on CNI. This would be undertaken jointly by the professional societies of UK Renal Pharmacy Group and British Transplant Society/Renal Association. Dissemination of updated guidance will be to all clinical teams involved in the care of kidney transplant recipients through the Renal Networks.

Thank you for bringing this important patient safety issues to our attention and please do not hesitate to contact us should you need any further information.

Yours sincerely,



National Medical Director