Medical Directors Office
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Private and Confidential
Mr H Shah
Assistant Coroner
The Guildhall
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[redacted]

[redacted]

9 May 2025

Dear Mr Shah

Mr Dominic Martin Philip: Regulation 28 Report

I write to formally acknowledge receipt of the above Regulation 28 Report issued to this Trust and to provide a response detailing the actions we have taken.

You raised a concern that, whilst the trust asks all patients who undergo a CT contrast study whether they have any allergies or are allergic to the contrast, patients that have not been exposed to contrast will not know if they have an allergy. You requested that the trust explores whether allergy testing prior to a planned contrast study would be beneficial.

Anaphylaxis is a severe, potentially life-threatening allergic reaction that can occur rapidly after exposure to an allergen. Any medication, substance or environmental factor has the potential to trigger an anaphylactic reaction in susceptible individuals. In considering the benefit to patients who are attending the hospital for a planned CT contrast diagnostic test, it should be noted that life threatening reactions following CT contrast, account for less than 0.2% of patients attending. Mortality following contrast is less than one death per 100,000 patients. Kim MH, et al *Anaphylaxis to iodinated contrast media: clinical characteristics related with development of anaphylactic shock.* (2014) 16;9(6)

It should further be noted that there is currently no reliable or standardised test to predict patients that may have a reaction to contrast without any history of adverse symptoms.

In patients who have shown a reaction previously to contrast and who require further testing to accurately determine allergy status there are a combination of 3 tests including a skin prick test, an intradermal test and a provocation test (where a small

amount of contrast is introduced to determine whether there is a true allergy to the contrast).

This immunology testing is not available at either of the hospitals within the University Hospitals of Northamptonshire (UHN) and patients would need to be referred to tertiary centres such as Leicester, Oxford or Addenbrooke's to obtain this test. This process would have a potential significant impact on patients in the Northamptonshire area in terms of time, travel and cost.

Last year UHN performed 59,598 CT scans with contrast. The number of individual patients may be slightly less due to some patients receiving multiple scans, but the immunology services would not be able to absorb this number of extra patients within its service, and significant national investment would be required. It should also be noted that, often patients are referred for CT contrast studies within a cancer pathway to determine diagnosis. There is a risk in introducing a routine allergy test there will be delays in these diagnostic pathways and ultimately treatment of cancer. Therefore, on the balance of risk to both the NHS in the use of resources and the potential impact on patients it is not considered that routine testing would be viable.

The Royal College of Radiologists refer to the Royal Australian and New Zealand College of Radiologists in its recommendations for managing the risk of contrast anaphylaxis and cite the diagnosis of anaphylaxis and appropriate emergency preparedness as being essential in managing and mitigating the risks associated with anaphylaxis.

The trust is assured that staff are trained in the management of emergency situations within the departments and that appropriate equipment is available to support patients in these rare and life-threatening situations.

There have been developments in the safety of contrast used in diagnostic testing with newer contrasts that are used by the trust thereby having an improved safety profile.

There was a concern raised that Lidocaine was found to be present on the toxicology report Mr Dominic Phillips and despite investigation it was not possible to determine where the lidocaine came from. You asked us to review the possibility of there being contaminated medication containing lidocaine

The Medicines and Healthcare Products Regulatory Agency (MHRA) is the UK's primary regulatory body for medicines, medical devices and blood products. The MHRA regulates all aspects of medicines, from their development and manufacture to their use and safety monitoring.

The MHRA uses a yellow card scheme to collect information about suspected side effects and adverse incidences including those related to contaminated medication. For any contamination of medication, the MHRA would initiate a recall, send a defect notification, and safety communications to inform the public and healthcare professionals about potential safety issues.

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A review of the MHRA alerts revealed one alert nationally relating to product contamination and this involved a tablet of loperamide. There were no incidences concerning Lidocaine. Therefore, it is unlikely that the patient was given contaminated medication from a manufacturer.

It is unclear from the toxicology report the amount of lidocaine that was present to enable an understanding of potential sources of administration.

The trust can therefore not determine the source of the lidocaine, despite its extensive investigations and noting that there has been no alert in respect of contaminated medications.

Yours sincerely

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Medical Director