Department of Health & Social Care

From Andrew Stephenson CBE MP
Minister of State for Health and Secondary Care

39 Victoria Street
London
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Dianne Hocking
Assistant Coroner
Leicester City Council
115 Charles Street
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2 May 2024

Dear Mrs Hocking,

Thank you for your Regulation 28 report to prevent future deaths dated 7 February 2023 about the death of Richard Nigel Kew. I am replying as Minister with responsibility for Health and Secondary Care.

Firstly, I would like to say how saddened I was to read of the circumstances of Mr Kews' Death, and I offer my sincere condolences to their family and loved ones. The circumstances your report describes are very concerning and I am grateful to you for bringing these matters to my attention. Please accept my sincere apologies for the delay in responding to this matter and thank you for the additional time provided to the department to provide a response.

The report raises concerns over the safety of Medicines and Healthcare Products. In preparing this response, Departmental officials have made enquiries with NHS England, The Medicines and Healthcare Products Regulatory Agency (MHRA) and the Health Care Safety Investigation Branch (HSIB), now the Health Services Safety Investigations Body (HSSIB) since 1 October 2023.

Central venous catheters are generally considered safe when used according to guidelines, yet MHRA recognises the potential for air ingress due to inadvertent errors. In a critical incident investigated by HSIB in 2022, a tragic event unfolded when a haemodialysis catheter was left uncapped and unclamped, leading to a fatal air embolism in another patient. This incident showed the importance of addressing the risks associated with central venous catheters, particularly in haemodialysis settings where patients are vulnerable to such complications.

Following this investigation, HSIB presented MHRA with a crucial safety recommendation: to amend its 2022 'Dialysis Guidance' to explicitly address the safety risk posed by unclamped haemodialysis catheters. The recommendation highlighted the necessity of updating guidelines to reflect emerging safety concerns and mitigate potential risks to patient safety. This call to action prompted MHRA to reassess and update its guidance to better address the specific challenges and risks associated with haemodialysis catheters.

MHRA's guidance, initially developed in collaboration with the UK Kidney Association Kidney Patient Safety Committee serves as a vital resource for healthcare professionals and

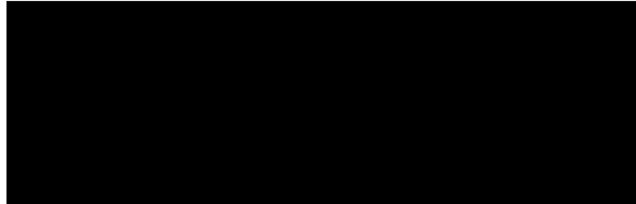
patients.The guidance aims to summarise known safety issues, communicate risk mitigation measures, and provide essential information for safe and effective patient care. However, the tragic event highlighted by HSIB emphasised the need for continuous improvement and adaptation of guidelines to address evolving safety concerns and ensure optimal patient outcomes.

In response to HSIB's recommendation, MHRA collaborated with key stakeholders to update the guidance, focusing specifically on the safe handling of haemodialysis catheters to prevent air embolisms. The updated guidance, published on June 21, 2023, includes detailed recommendations and protocols aimed at reducing the risk of air embolisms associated with catheters. These include measures such as proper training for staff, adherence to manufacturer guidelines, and the importance of conducting risk assessments before accessing central venous catheters. By incorporating these critical updates, MHRA aims to enhance patient safety and improve outcomes for individuals undergoing treatment.

The HSIB report also notes that the Association of Anaesthetists has committed to integrating content on catheter-related air embolism into its updated 'Safe vascular access guidelines' based on the findings and safety recommendations outlined in the HSIB investigation report. When the Association of Anaesthetists update their guidance, the NHSE National Patient Safety Team will publicise this new guidance in their newsletter to all Patient Safety Specialists.

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

Yours sincerely,



Rt. Hon Andrew Stephenson CBE MP

Minister of State Health and Secondary Care