University Hospitals of Leicester
NHS Trust

Chief Executive Office
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[redacted]

29th May 2026

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Dear HM Senior Coroner Smith,

Following receipt of the Regulation 28: Report to Prevent Future Deaths in April 2026, University Hospitals of Leicester NHS Trust (UHL) undertook a comprehensive review of the circumstances surrounding the death of a dialysis patient following catastrophic haemorrhage caused by detachment of a haemodialysis central venous catheter (CVC) component at a DaVita-operated dialysis unit.

The incident occurred on 7 October 2025 and was immediately reported to the Coroner, the Medicines and Healthcare products Regulatory Agency (MHRA), the device manufacturer, and relevant national renal safety forums. A Patient Safety Incident Investigation (PSII) was commenced and led by DaVita, with representation from both UHL and the Lincoln renal team.

During the subsequent investigation, a second similar non-fatal incident was identified at another DaVita-operated dialysis unit. This additional event supported the conclusion that the incidents were most likely attributable to mechanical device failure rather than patient or staff actions.

A formal risk assessment has since been completed by the UHL renal service. This concluded that:

- The likelihood of recurrence is low;
- There is currently no evidence of widespread device failure either locally or nationally;
- Routine elective replacement of long-term haemodialysis catheters would introduce greater patient risk, including procedural complications, venous stenosis, and potential loss of vascular access, when compared with continued use supported by enhanced surveillance and monitoring arrangements.

The UHL renal team has therefore concluded that continued use of the current haemodialysis CVCs remains clinically appropriate, proportionate, and consistent with international best practice guidance, including KDOQI recommendations, provided that additional assurance and surveillance measures are maintained.
The Trust is assured that the risks associated with these devices are understood, actively monitored, mitigated where possible, and subject to ongoing governance and organisational learning processes.

At the time of the incident, immediate emergency treatment was provided by dialysis staff and ambulance services. Despite these efforts, the patient sadly died shortly afterwards in hospital due to catastrophic haemorrhage.

The incident was promptly escalated through both DaVita and UHL governance systems, including RADAR and DATIX reporting mechanisms, and senior renal staff within both organisations were informed immediately. Support was offered to staff involved, and DaVita engaged with the patient's family to understand any concerns or questions they wished to be addressed as part of the investigation process.
The incident was reviewed through renal morbidity and mortality meetings and the weekly executive incident review process. DaVita convened an initial multidisciplinary meeting involving senior medical and nursing representatives from DaVita, UHL, and Lincolnshire nephrology services, following which DaVita led the formal Patient Safety Incident Investigation.

Early consideration was given to whether patient-related factors may have contributed to the incident. However, the subsequent investigation findings, together with the second similar non-fatal incident on 11 December 2025, strongly supported concerns that mechanical integrity failure of the catheter was the primary contributory factor.

The UHL Deputy Head of Nursing and Renal Matron escalated the matter to the Coroner, MHRA, the device manufacturer, the UK Kidney Association (UKKA) Patient Safety Group, and the Midlands Regional Operational Kidney Network. To date, UHL has not been informed of any specific actions undertaken by either the MHRA or the manufacturer in response to these reports.

The UKKA Patient Safety Group advised that no further similar incidents had been identified nationally despite widespread use of these catheters throughout the United Kingdom.

Following the incidents, DaVita issued a national safety bulletin across all of its UK dialysis units. Within UHL, the incident and associated learning were shared with all dialysis nursing teams, and staff were instructed to undertake mandatory checking of the luer connection during every dialysis session. The incident and actions taken were also discussed at the Midlands Lead Dialysis Nurses Forum. In addition, education and guidance regarding luer-end integrity checks and escalation procedures were provided to home haemodialysis patients using dialysis catheters.

The Regulation 28 report was further discussed at the Leicester, Leicestershire and Rutland Learning from Deaths meeting on 16 April 2026, and it was proposed that this case be presented to NHS England as an example of organisational learning relating to medical devices.

As part of the Trust's ongoing response and learning from this incident, the following actions have been agreed:

- Development of a central electronic record of dialysis catheter type, insertion date, and insertion location across the renal network by Q3 2026;
- Updating patient information materials to include advice regarding actions to take if catheter integrity is compromised by Q2 2026;
- Updating dialysis access care plans to formally document luer-end checks and catheter details by Q2 2026;

- Implementation of three-monthly catheter site photography aligned to arteriovenous fistula surveillance processes;
- Raising issues relating to catheter longevity and device learning at national renal forums by Q3 2026;
- Continued work to reduce the proportion of patients dialysing via CVCs across the dialysis network toward the nationally recommended target of less than 20%.

These actions will continue to be monitored through the appropriate governance routes, including the Renal Board, local audit processes, morbidity and mortality review meetings, and renal nursing oversight arrangements.

Yours sincerely,

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Group Chief Executive
University Hospitals of Leicester NHS Trust and University Hospitals of Northamptonshire NHS Group