Regulation 28: REPORT TO PREVENT FUTURE DEATHS

NOTE: This form is to be used **before** an inquest.

	REGULATION 28 REPORT TO PREVENT DEATHS **THIS REPORT IS BEING SENT TO:** 1. **Medicines and Healthcare Products Regulatory Agency** 2. **University Hospitals of Leicester NHS Trust** 3. **Medtronic Limited**
1	**CORONER** I am Paul D SMITH, HM Senior Coroner for the Coroner area of Greater Lincolnshire
2	**CORONER'S LEGAL POWERS** I make this report under Paragraph 7, Schedule 5, of the Coroners and Justice Act 2009 and Regulations 28 and 29 of the Coroners (Investigations) Regulations 2013.
3	**INVESTIGATION** On 20 November 2025 I commenced an investigation into the death of Benjamin Daniel Rowley aged 51 (DOB 20/09/1974). The investigation has not yet concluded, and the Inquest has not yet been heard.
4	**CIRCUMSTANCES OF THE DEATH** On the morning of 7 November 2025 Benjamin Daniel Rowley attended the Skegness Dialysis Centre shortly before 07.30 am for kidney dialysis. That Unit is operated by University Hospitals of Leicester NHS Trust. He had been attending the Centre since 11 December 2023 and attended each Monday, Wednesday and Friday. Mr Rowley had fitted a Central Venous Catheter (CVC) for dialysis. That had been fitted on 14 November 2023 at Leicester General Hospital. That was a Covidien Palindrome Chronic Dual Lumen Catheter. The Batch number was 2232700137. The Reference number was 8888145016P. After the dialysis commenced on 7 November there were a number of pressure alarms generated by his machine. As a consequence of those repeated alarms the arterial line was flushed with saline, after which the flow appeared to be better. Shortly before 09.00 am an alarm sounded on Mr Rowley's machine indicating a low pressure issue. He was checked and the machine reset. There were no other concerns. A few moments later, at around 09.10am, he was noted to be in distress. The blue connector forming part of the venous line had disconnected from the CVC and blood was pumping out. The machine was immediately reconnected. CPR was commenced, together with the administration of oxygen and an Ambulance was summoned. He was treated by the Ambulance crew upon their arrival and was then taken to Boston Pilgrim Hospital where his death was later confirmed. A post-mortem examination has subsequently provided a clinical cause of death of: 1a; Haemorrhage from a tunnelled haemodialysis catheter port (end stage chronic renal disease), in combination with Ischaemic and Hypertensive Heart Disease. 2; Type 2 Diabetes Mellitus and Cerebrovascular Disease.
5	**CORONER'S CONCERNS**

	During the course of this investigation my inquiries have revealed matters giving rise to concern. In my opinion there is a risk that future deaths could occur unless action is taken. In the circumstances it is my statutory duty to report to you. The MATTERS OF CONCERN are as follows: In addition to the circumstances described above, as part of my investigation I was made aware of a second similar incident which occurred on 11 December 2025 at the Boston Dialysis Centre. That Centre is also operated by University Hospitals of Leicester NHS Trust. Within that second incident there was an apparent disconnection of the CVC, giving rise to blood loss in similar circumstances to the incident with Mr Rowley. Fortunately, the patient in that incident was successfully treated and there was no further loss of life. That patient was also fitted with a Covidien Palindrome Chronic Dual Lumen Catheter. The Batch number was 230200134. As part of my investigation, I seized the CVC used by each of these two patients. I arranged for those to be examined by an independent Consultant Nephrologist. I have now received a preliminary report. Whilst that is not currently in a form that I can disclose, the relevant section of that report in relation to the death of Mr Rowley states: "The CVC consists of a number of parts that are assembled during the manufacturing process. The two ports consist of a brown and a blue plastic Luer Lock connector permanently bonded to silicone rubber tubes that enter the 'Y' shaped connector. A white plastic sleeve is present at the point the ports enter the rubber tubing. These ports are not intended to ever be removed or detached from the silicone rubber tubes. The integrity of the permanent bond between the ports and the tubing is essential for the safety of the CVC. [Mr Rowley] died due to exsanguination caused by a mechanical failure of the CVC. The direct cause was failure of the bond between the venous port of the CVC and the tubing, allowing the port to detach thereby causing blood returning from the machine to the patient to be expelled." In relation to the later incident of 11 December 2025, the relevant section of the preliminary report states: "The nature of the failure of this CVC appears to be identical to that of Mr Rowley, namely detachment of one port of the CVC from the silicone rubber tube. The direct cause was failure of the bond between the venous port of the CVC and the tubing, allowing the port to detach thereby causing blood returning from the machine to the patient to be expelled. The nature of the failure appears identical…" The report concludes that: "I am concerned that these events could represent a more widespread vulnerability of this brand or batch of dialysis lines and recommend reporting these events to the Medicines and Healthcare products Regulatory Agency (MHRA)." I endorse those concerns.
6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe you (and/or your organisation) have the power to take such action.
7	**YOUR RESPONSE**

	You are under a duty to respond to this report within 56 days of the date of this report, namely by May 26, 2026. I, the Coroner, may extend the period. Your response must contain details of action taken or proposed to be taken, setting out the timetable for action. Otherwise, you must explain why no action is proposed.
8	**COPIES and PUBLICATION** I have sent a copy of my report to the Chief Coroner and to the following Interested Persons: • Mr Rowley's family • University Hospitals of Leicester NHS Trust • Medtronic Limited I have also sent it to • United Lincolnshire Teaching Hospitals NHS Trust who may find it useful or of interest. I am also under a duty to send the Chief Coroner a copy of your response. The Chief Coroner may publish either or both in a complete or redacted or summary form. She may send a copy of this report to any person who he believes may find it useful or of interest. You may make representations to me, the Coroner, at the time of your response about the release or the publication of your response by the Chief Coroner.
9	**Dated: 01/04/2026** **Paul D SMITH** **HM Senior Coroner for** **Greater Lincolnshire**