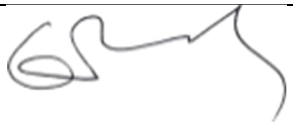
REGULATION 28: REPORT TO PREVENT FUTURE DEATHS (1)

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** **1. The Chief Executive, Nottingham University Hospitals NHS Trust**
1	**CORONER** I am Dr Elizabeth Didcock, Assistant Coroner, for the coroner area of Nottinghamshire
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 and INQUEST** On 23.8.24, I commenced an investigation into the death of Mrs Gemma Louise Poterajko The investigation concluded at the end of the inquest on the 27th June 2025 The conclusion of the inquest was a narrative as follows: Gemma died from a rare, unexpected, but recognised complication of a pacemaker lead extraction. She died from multi organ failure caused by catastrophic haemorrhage from two venous tears in the left innominate vein and left subclavian vein, sustained during the lead extraction. No identified issues of care have, on balance, caused or made a more than minimal, negligible or trivial contribution to her death.
4	**CIRCUMSTANCES OF THE DEATH** Gemma died on 22.8.24 at the City Hospital in Nottingham following a pacemaker Lead Extraction procedure. During the advancement of the Tightrail cutting sheath used to cut through fibrous scar tissue surrounding the lead, to aid lead extraction, the cutting blades likely caused two tears in the wall of the left subclavian and left innominate veins. These tears occurred at sometime between 14.35 and Gemma's collapse with low blood pressure at 14.48 hours on that day. Whilst the exact mechanism of venous tearing is unclear, and is a very unusual occurrence, the vein walls were likely to be additionally vulnerable because of the stuck fibrous tissue around the pacemaker lead also being stuck to the vein inner wall. No evidence of careless or incorrect technique has been established to have led to these tears. Bleeding from these tears was catastrophic, likely the most significant bleed being from the higher tear in the subclavian vein, where the Tightrail sheath was found protruding from the vein at 16.55 hours. The first venous tear was found at 16.11.hours. Managing events from 14.48 onwards was challenging for the team of senior clinicians present, as there was a need to search for and potentially deal with, a more common bleeding site, that is from the Right Atrium or from a Superior Vena Cava tear, before a higher venous tear was considered. Rendering all appropriate resuscitative measures, including cardiopulmonary bypass was necessary before further bleeding sites were searched for, as Gemma had such a

	profound circulatory collapse with a cardiac arrest at 15.00 hours requiring ongoing cardiac compressions and full and continuing advanced life support. The extent of bleeding from the venous tears was likely unsurvivable once it had occurred, although it was entirely appropriate to continue all measures to try and save Gemma's life up until sadly the situation was futile with evidence of established multi organ failure later that evening.
5	**CORONER'S CONCERNS** During the course of the inquest the evidence revealed matters giving rise to concern. In my opinion there is a risk that future deaths will occur unless action is taken. In the circumstances it is my statutory duty to report to you. The **MATTERS OF CONCERN** are as follows: 1. The lack of a formalised documented system of risk stratification for Lead extraction. The consequence is that there is a lack of clear planning for what may be needed from the cardiac surgical team, in terms of urgent surgical expertise, theatre staff support and perfusion team support, for any given lead extraction 2. The lack of a written Trust Standard Operating Procedure for Lead extraction that includes a record of the planning discussion, and sets out realistic cardiac surgical involvement when this is necessary 3. The lack of clarity as to how the full cardiac surgical team can within their resources currently, or planned for, provide necessary attendance in a timely way at a given Lead extraction procedure, as per international expert consensus I am not reassured that necessary actions to address these serious issues identified are in place.
6	**ACTION SHOULD BE TAKEN** In my opinion, action should be taken to prevent future deaths and I believe you 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 the **4th September 2025.** 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: 1. The family

	I am also under a duty to send a copy of your response to the Chief Coroner and all interested persons who in my opinion should receive it. I may also send a copy of your response to any person who I believe may find it useful or of interest. The Chief Coroner may publish either or both in a complete or redacted or summary form. He 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	 **10th July 2025 Dr E. A. Didcock**