Regulation 28 Report to Prevent Future Deaths

Coroners and Justice Act 2009
Coroners (Investigations) Regulations 2013

THIS REPORT IS BEING SENT TO:

- NHS England
- The Chief Executive Officer of University Hospital of Coventry and Warwickshire NHS Trust.
- The Chief Executive Officer of George Eliot Hospital NHS Trust.
- UK Kidney Association.
- British Transplant Society.
- Renal Association.

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1. **CORONER**:
   I am Linda Lee, Assistant Coroner for the coroner area of Coventry and Warwickshire

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2. **CORONER'S LEGAL POWERS**:
   I make this report under paragraph 7, Schedule 5 of the Coroners and Justice Act 2009 and Regulation 28 of the Coroners' (Investigations) Regulations 2013.

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3. **INVESTIGATION AND INQUEST**:
   On 9 January 2024, an investigation was commenced into the death of John Frederick Doyle, who died on the 30 December 2023 aged 60.

   The investigation concluded at the end of the inquest on 8 November 2024.

   The conclusion was:

   1a Multiple Organ Failure

   1b Cytomegalovirus Infection

   1c Chronic kidney disease (unknown aetiology, kidney transplant in 2022)

   II Hypertension

   Natural causes against a background of missed opportunities to diagnose and treat cytomegalovirus infection, together with the impact of the resident (formerly junior) doctors' strike on the provision of consistent patient care.

4. **CIRCUMSTANCES OF THE DEATH**:

In March 2022, John underwent a kidney transplant at Manchester Royal Infirmary and subsequently received follow-up care and regular reviews at the Royal Derby Hospital (RDH). He was first admitted to George Eliot Hospital (GEH) on 2 December 2023, presenting with rectal bleeding and a persistent cough.

Evidence was presented that GEH, like many hospitals, does not have an in-house renal team. As a result, GEH relied on telephone consultations with specialist hospitals for advice on investigations and treatment for renal-related issues.

During John's treatment, the team at GEH sought guidance from both RDH and University Hospital Coventry and Warwickshire (UHCW), the latter being the nearest specialist centre. Following John's admission, tests were ordered to rule out cytomegalovirus (CMV) colitis. However, without receiving these test results, John was discharged on 6 December, despite evidence suggesting he was still very unwell. He was re-admitted via emergency ambulance on 8 December. Unsuccessful attempts were made to test for the presence of CMV during his stay at GEH.

John's condition continued to deteriorate, and he was transferred to UHCW on 21 December. A diagnosis was not made until 28 December, when tests showed he had 27 million copies of CMV per millilitre of blood, an extremely high count. Treatment with ganciclovir and anti-CMV immunoglobulin was commenced. By this stage, it is likely that John had developed CMV encephalitis. He was intubated and ventilated, but his condition declined, leading to multiple organ failure. John died on 30 December 2023.

Evidence was received that whilst CMV rarely causes more than cold or flu-like symptoms in the general population, it is one of the most common infectious complications of solid organ transplantation and is reported to increase graft loss and patient mortality. It was acknowledged that an earlier diagnosis and treatment of CMV could have potentially changed the outcome for John and would have increased the likelihood of successful treatment.

Consultants from both hospitals testified that, due to the junior doctors' strike, they had to assume additional responsibilities and manage a higher patient load, which affected their ability to maintain a consistent overview of patients' conditions and treatments. In John's case, the impact was the failure to notice that the test results had not been received at both GEH and UHCW.

The patient safety incident investigation by GEH identified human error and systemic issues in handling CMV testing and the care of renal patients:

1. **Sample Collection Errors**: Multiple errors were identified in sample collection for CMV testing:
    - The laboratory operated by UHCW failed to freeze one sample and one sample was incorrectly rejected as unusable
    - Clinicians used the wrong tubes, failing to use the necessary, purple-topped tube that prevents the blood collected from clotting.
    - Human error led to prompts for correct tube selection being ignored and the use of paper labelling did not prompt the use of the correct tube.
    - Expedited testing needs were not clearly communicated, leading to delays.
    - Staff were unaware of the testing schedule in place at UHCW for CMV testing
2. **Documentation and Communication**: Medical notes lacked thorough documentation on the selection and dispatch of samples, contributing to inefficiencies and miscommunication among staff.
3. **Delayed Transfer to Specialist Care**: John should have been transferred earlier to UHCW, which has the necessary renal services, including dialysis and specialised renal diets. GEH/UHCW lacked the protocols for timely patient transfer. The report also recommended that patients who are at risk of transplant failure should be managed proactively.

Evidence given at the inquest showed there is currently no clear protocol at GEH regarding which hospital to contact for advice or when a patient should be considered for transfer to a specialist unit. Additionally, it was unclear whether the transfer should be initiated by the specialist centre or by GEH.

Evidence was received that some training had been delivered on the correct procedure regarding sampling and that draft protocols were being drawn up but were not yet finalised or published.

None of the consultants from GEH who gave evidence had expertise in renal medicine or experience with transplant patients. Additionally, although it was planned to develop guidance, only the renal consultant at UHCW was familiar with the Renal Association and the British Transplantation Society's guidelines, specifically the 'Clinical Practice Guideline Post-Operative Care in the Kidney Transplant Recipient'.

This guidance states:

"*This document is intended for those engaged in the care of kidney transplant recipients (KTR) who are non-experts. With increasing efforts to deliver healthcare locally, many renal transplant recipients are followed up in centres remote from the main surgical transplant unit. At the same time,*

transplantation medicine has evolved into an increasingly complex and specialised field of nephrology. The following guidelines reflect this alteration in clinical practice and are intended for those healthcare professionals who look after renal transplant patients. They are also intended to be useful to both medical and surgical trainees, general practitioners, nurse specialists and other associated healthcare professionals involved in the care of renal transplant patients."

It was noted that the guideline aims to inform and support non-experts caring for transplant patients, not to replace assistance from specialist centres. It does not appear that there is any specialist guidelines or examples of best practice regarding collaborative ways of working between specialist and non-specialist centres.

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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 could occur unless action is taken. In the circumstances, it is my statutory duty to report these concerns to you.

The **MATTERS OF CONCERN** are as follows:

Concern 1: Contacting Specialist Centres
Non-specialist medical staff may have varied understanding of the appropriate contacts and timing for engaging with specialist renal hospitals.

Concern 2: Information Sharing with Specialist Centres
The specific patient information that non-specialist staff should provide to specialist renal hospitals may not always be clearly defined.

Concern 3: Accessibility to Renal Care Guidelines
Non-specialist staff may experience varying levels of awareness or accessibility to guidelines and protocols for treating kidney transplant patients. This could lead to a misunderstanding of the significance and urgency of the actions recommended by specialist renal hospitals.

Concern 4: Transfer Responsibility
There may be some inconsistency across non-specialist hospitals and renal hospitals in understanding who is responsible for initiating patient transfers.

Concern 5: Decision-Making for Patient Location
Considerations regarding whether patients should remain in non-specialist

areas or be transferred may differ, potentially affecting consistency in care approaches.

Concern 6: Coordination Between Specialist and Non-Specialist Hospitals
There may be variation in how specialist renal hospitals engage with non-specialist hospitals that rely on their expertise, impacting collaborative efforts in patient care. Currently, there is no clear guidance on how specialist and non-specialist teams should work together effectively to ensure consistent, high-quality care for these patients.

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.

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7. **YOUR RESPONSE**:
You are under a duty to respond to this report within 56 days of the date of this report, namely by 7 January 2025. I, the coroner, may extend the period if necessary.
Your response must contain details of action taken or proposed to be taken, setting out the timetable for action. Alternatively, you must explain why no action is proposed.

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8. **COPIES AND PUBLICATION**:
I have sent a copy of my report to the following interested persons:
    - John's family
    - NHS England
    - The Chief Executive Officer of University Hospital of Coventry and Warwickshire NHS Trust
    - The Chief Executive of George Eliot Hospital NHS Trust
    - UK Kidney Association
    - British Transplant Society
    - Renal Association
    - I am also under a duty to send a copy of this report to the Chief Coroner and to publish it on the Judiciary website but may redact the report before publication if appropriate.

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9. **DATED**: 12 November 2024
Linda Lee
Assistant Coroner for Coventry and Warwickshire