

# Regulation 28: Prevention of Future Deaths Report

David RILEY

## THIS REPORT IS BEING SENT TO:

Warwick Hospital

Department of Health/Secretary of State

NHS England and NHS Improvement

NICE

Copies to Family and [REDACTED]

## 1. CORONER

I am: Linda Lee, Assistant Coroner for Warwickshire, Warwick Justice Centre, Newbold Terrace, Royal Leamington Spa.

## 2. CORONER'S LEGAL POWERS

I make this report under the Coroners and Justice Act 2009, paragraph 7, Schedule 5, and The Coroners (Investigations) Regulations 2013, regulations 28 and 29.

## 3. INVESTIGATION and INQUEST

On 17 June 2022, I commenced an investigation into the death of David RILEY (aged 72 years). The investigation concluded at the end of the inquest on 26<sup>th</sup> April 2024 at Warwick Coroners Court. The medical cause of death was confirmed as:

- 1a Multiple Cerebral Infarcts
- 1b Resolving Haemopericardium
- 1c Ablation for Atrial Fibrillation

## 4. CIRCUMSTANCES OF THE DEATH

David Riley had symptomatic atrial fibrillation. A DC cardioversion had been performed but Mr Riley relapsed to atrial fibrillation after a few days. After considering the treatment alternatives, Mr Riley opted for lifestyle modification and AF ablation. The ablation was performed at the BMI Priory Hospital Edgbaston on 3 May 2023 without incident. Mr Riley was discharged with a sinus rhythm. Due to the increased risk of clots due to the ablation procedure, it was recommended that Mr Riley take Apixaban, a direct oral anticoagulant (DOAC) for at least 6 weeks following the AF ablation.

Mr Riley developed chest pain and shortness of breath. Initially it was thought that this was an expected side effect of the procedure, and no other cause was found. An echocardiogram performed on 24 May 2023, whilst Mr Riley was on holiday in Montenegro, did not show a pericardial effusion but this was present after his admission on 31 May 2023 to the Warwick hospital.

Initial investigations at the Warwick hospital did not reveal the cause of the pericardial effusion or Mr Riley's symptoms of pain in the chest and back (unaffected by breathing in or out).

The CHA2DS2-VASc score is a means of assessing the risk of stroke in a patient with atrial fibrillation. Evidence was given that whilst he was an inpatient at Warwick, Mr Riley's score was four.

Evidence was given that DOACs have a reduced risk of bleeding compared to Warfarin and that DOACs can be discontinued for a shorter period of time, if at all. An assessment as to the need for pausing or the period of pausing the DOAC has to be made on a case-by-case basis, depending on the clinical assessment of the patient and the procedure under consideration.

Evidence was given that there is an inconsistency in decisions taken to pause DOACs not only from hospital to hospital but within different teams within the same hospital and much depended on consultant 'confidence' in the ability to pause DOACs.

A decision was taken to perform a pericardiocentesis to drain the extra fluid from the pericardial cavity. The pericardiocentesis took place on 2 June 2023. It was not performed as an emergency procedure but primarily for the purpose of diagnostic testing and to a lesser extent as a means of relieving Mr Riley's symptoms. In the event no fluid was obtained during the procedure, but no untoward event occurred.

Evidence was given that in Mr Riley's case, consideration could have been given to not pausing the Apixaban or to pausing it for only a short period of time before and after the pericardiocentesis. However, the decision to pause the Apixaban had already been taken by someone other than the Consultant who was to perform the pericardiocentesis. The instruction given by the Consultant once he had performed the pericardiocentesis to restart the Apixaban was not acted on promptly. The Apixaban was eventually restarted and then again paused for reasons that are not clear. The clinical records do not indicate who took the decisions to pause the Apixaban and what consideration was given as to the duration of the pause. The precise duration of the pausing of the Apixaban is not clearly recorded, but it appeared to have been paused for longer than was required.

Mr Riley was under the care of three consultants and numerous middle grade doctors during his time as an inpatient at Warwick hospital. Concern was expressed in evidence as to the continuity of care Mr Riley received and the efficiency of communication between the medical staff engaged in his care. Evidence was also given that staff had difficulty in entering information on the computerised record and accessing that information, due to lack of familiarity with the system.

The postmortem examination and the subsequent review did not reveal a definitive cause of the clotting which led to the stroke suffered by Mr Riley on the 9 June 2023, and his death on 10 June 2023.

The pausing of the Apixaban may have increased the risk of Mr Riley suffering a stroke but it cannot be said to have caused it.

## **5. CORONER'S CONCERNS**

During the inquest, the evidence and information 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:**

During the course of the investigation my inquiries 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.

Although the Warwick hospital conducted a Root Cause Analysis Investigation Report (RCAIR) of 6 July 2023 which indicated that the pausing of the DOAC was a lesson learned, it did not indicate what was learned. The only further action was limited to the incident being presented at the Grand Round, but this had not taken place at the time of the inquest, some 9 months after publication of the RCAIR. There are remaining outstanding matters of concern.

The MATTERS OF CONCERN are as follows:

**1. Decisions regarding pausing of DOACs.**

It was not clear if there is national guidance available to clinicians regarding the pausing of DOACs and the considerations to be applied in making that decision. If there is such guidance, it is not widely understood or on the evidence given, followed consistently from hospital to hospital or within different teams. The inconsistency of approach appears from the evidence to increase the risk of misunderstanding and to put patients with atrial fibrillation at risk.

**2. Effective communication**

From the evidence, there was a failure to effectively communicate, recognise and act on directions that were time critical, such as restarting the DOAC as directed. It does not appear that there was any consideration as to the timing of the pericardiocentesis to ensure that the DOAC was paused for a short a time as possible. The evidence suggested that this may be due to lack of continuity of care and the difficulties in the way in which computerised clinical/pharmacy records are updated and accessed. Clear communication between medical staff is essential to patient care.

**6. ACTION SHOULD BE TAKEN**

In my opinion, action should be taken to prevent future deaths and I believe that 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 1 July 2024 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 following:

1. HHJ Teague QC the Chief Coroner of England & Wales Chief Coroner's Office, 11th Floor Thomas More, Royal Courts of Justice, Strand, London, WC2A 2LL. chiefcoronersoffice@judiciary.gsi.gov.uk
2. The family of David RILEY

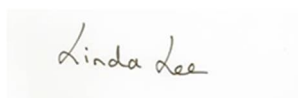
I am also under a duty to send a copy of your response to the Chief Coroner and all interested persons who in my opinion should receive it.

I may also send a copy of your response to any other 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.

Date: 7 May 2024

A rectangular box containing a handwritten signature in cursive script that reads "Linda Lee".

Linda LEE

Assistant Coroner for Warwickshire