Glen Burley
Chief Executive
Warwick Hospital
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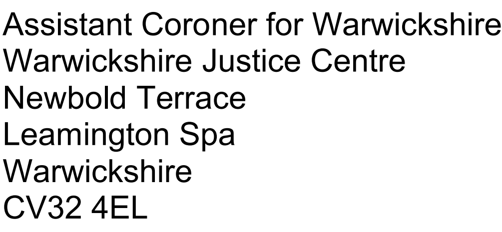
Our ref: GWB/ci

12 July 2024


Mrs Linda Lee
Assistant Coroner for Warwickshire
Warwickshire Justice Centre
Newbold Terrace
Leamington Spa
Warwickshire
CV32 4EL

Dear Mrs Lee,

Regulation 28 report - Mr David Riley DoB 01/10/1950 DoD 10/06/2023

Thank you for your Regulation 28 report dated 7 May 2024 relating to your investigation into the death of Mr David Riley. I was sorry to read of your outstanding concerns following the 26 April inquest and hope that the following information will provide you with further reassurance. I am also grateful for the extra time granted to allow the Trust to respond.

Following receipt of your report, the Trust convened a Working Group to review, and critically reappraise, the care and decision-making relating to Mr Riley in light of the concerns you raised in your report. The Group consisted of the Trust's Chief Medical Officer and his Deputy, our Acute Medicine General Manager, our Cardiology Operational Manager, our Chief Nursing Officer and one of our Cardiology Consultants.

It may be helpful to begin this response by acknowledging that the Trust has revised its view that an air embolus was a more likely cause of the stroke than a clot following a multidisciplinary discussion and review of the CT scans. In particular we have recently been given access to CT scans undertaken at University Hospitals Coventry & Warwickshire which do not show evidence of air embolus. We agree that 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" and recognise that lessons can be learnt regarding the pausing of DOACs – irrespective of whether this "pausing" contributed towards Mr Riley's stroke and death.

To address your specific concerns I have, for ease of reference, repeated your concerns **in bold** below. The Trust's response follows.

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.

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Although the decisions to stop, restart and then stop again Mr Riley's Apixaban were not, in themselves, wrong, they highlighted insufficient documentation in Mr Riley's medical notes. There was no note to say that Apixaban had been stopped, when it should restart, and no related note explaining this decision in the context of risks vs benefits.

The Trust will address this as follows:

- By reminding all staff, via a Safety Practice Alert, and at a Grand Round meeting in July, of the importance of documenting in a patient's medical records when a DOAC is stopped or restarted. Those same communications will reemphasise the importance of recording the risk vs benefits analysis behind such decisions, and also that patients who have had their DOAC stopped must have this decision reviewed by an appropriate clinician on a daily basis until the DOAC is restarted.

- The two points above will be incorporated into the Trust's updated SWH 01778 Oral Anticoagulant Guideline and will be subject to a future audit to check compliance has been embedded.

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.

I can only apologise that, over a year after his death, Mr Riley's case has still not been presented at the Trust's Grand Round. His case will be presented by one of our Cardiology consultants to Grand Round on 19 July – and will incorporate the learning from the concerns you have raised in your Regulation 28 report.

Grand Round is an "open to all staff" learning forum – held weekly both in person and online – and there are always a large number topics vying for attention. This, combined with staff availability, means that there can sometimes be a significant time lag between an incident occurring and the learning being shared. That said, the delay in this particular instance is unacceptable, and we have asked our Medical Education Co-ordinator (who manages the programme) to ensure that priority slots are given to those cases where a formal investigation recommends that a case be discussed at Grand Round.

Decisions regarding pausing of Direct Oral Anticoagulants (DOAC).
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.

National guidance is available in The British Journal of Haematology's Guideline: Peri-operative management of anticoagulation and antiplatelet therapy.

In addition, the Trust has its own Oral Anticoagulant Guide

- *SWH 01778 Oral Anticoagulant Guideline*

This guideline has now been updated to include a link to the UK Clinical Pharmacy Association's Handbook of Perioperative Medicines which provides national guidance re perioperative medicine.

The Trust's haematology lead advised the Working Group that, despite guidance and resources being available to staff, there has been a tendency to ask the haematology department for case-by-case advice. Whilst this will remain an import resource we intend to further update our Oral Anticoagulant Guideline to provide clearer guidance.

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.

Whilst some of the above points are covered in actions set out above, to ensure clear documentation of decision-making, the Trust will also:

- work towards a dedicated consultant to consultant in person handover, with nursing handovers managed separately. This work will be led by the Cardiology Operational Manager and Clinical Lead. Of note, a medical handover sheet is now being used on the ward, separately to nursing handover and managed by the Physicians Associate and Doctors in Training.

- Seek to ensure that our future Electronic Patient Record system (Cerner) better highlights information around pausing medication and that medical staff are aware of that functionality as the training in Cerner rolls out. We are aware that it affords more functionality in highlighting temporary stops/prompts for review, than our current system.

I am grateful that your Regulation 28 Report provided us with a further opportunity to consider and improve our care to patients prescribed DOACs.

The latest position on all of the actions arising from both our RCA Investigation and the further review arising from your Regulation 28 Report can be found at the foot of this letter.

I hope that this provides you with the assurance that you require but if, having read this letter, you have outstanding concerns, please do not hesitate to contact me.

Yours sincerely

Chief Executive

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Actions	Recommendation	Action to Address Recommendation	By whom?	By when?	Evidence of Progress and Completion	Evidence that will demonstrate the risk has been reduced
1	Incident to be fed back to UHCW stroke team regarding the outcome of the review.	Report to be sent to UHCW	Patient Safety Team	31/10/2023	26/09/2023: Report sent to UHCW	
2	The incident to be presented by the cardiology consultants at Grand Round	Presentation at Grand round	Cardiology Consultant	31/10/2023	Incident to be presented at Grand Round on 19 July 2024.	
3	Incident to be fed back to nursing staff regarding the escalation process when there is a change in a patient's condition or change in GCS score.	Feedback to Nursing staff	Clinical Lead	31/10/2023	15/02/204: Update from Ops Manager: Bespoke Immediate Life Support (ILS) sessions have been run across the Cardiology unit, delivered by the Resus Team and Cardiology ACPs. The Clinical Lead continues to work hard supporting the junior nursing team and is working with the new ward manager to ensure a robust training plan is in place to support junior staff.	
4	Remind all staff of the importance of clear documentation re stopping and re-starting of DOACS, and recording risk vs benefits of decisions.	Safety Practice Alert	Patient Safety Team	31/07/2024		
5	Advise all staff that patients who have had their DOAC stopped must have this decision reviewed by an appropriate clinician on a daily basis until the DOAC is restarted.	Safety Practice Alert	Patient Safety Team	31/07/2024		
6	Recommendations 5 and 6 (above) to be incorporated into the Trust's updated SWH 01778 Oral Anticoagulant Guideline.	Update guideline	Haematology lead	31/10/2024		
7	Improve processes for both nursing and medical handovers on the cardiology wards.	Consultant to consultant in-person handover.	Cardiology Operational Manager and Clinical Lead	31/10/2024		
8	Ensure that our future Electronic Patient Record system (Cerner) better highlights information around pausing medication and that medical staff are aware of that functionality as the training in Cerner rolls out.	Introduction of new Electronic Patient Record system (Cerner)	IT/ Innovate	Late 2025		
9	Recommendations 4 and 5 to be audited to ensure compliance is embedded.	Clinical audit of patient records	Cardiology medical team	February 2026		