

Ms Linda Lee

Assistant Coroner for Warwickshire Warwick Justice Centre Newbold Terrace Royal Leamington Spa CV32 4EL **National Medical Director**

NHS England Wellington House 133-155 Waterloo Road London SE1 8UG

8 July 2024

Dear Coroner,

Re: Regulation 28 Report to Prevent Future Deaths – David Riley who died on 10 June 2023.

Thank you for your Report to Prevent Future Deaths (hereafter "Report") dated 7 May 2024 concerning the death of David Riley on 10 June 2023. In advance of responding to the specific concerns raised in your Report, I would like to express my deep condolences to David's family and loved ones. NHS England are keen to assure the family and the Coroner that the concerns raised about David's care have been listened to and reflected upon.

I am grateful for the further time granted to respond to your Report and I apologise for any anguish this delay may have caused to David's family or friends. I realise that responses to Coroner Reports can form part of the important process of family and friends coming to terms with what has happened to their loved ones and appreciate this will have been an incredibly difficult time for them.

Decisions regarding pausing of DOACs

Your first concern relates to the national guidance available to clinicians regarding the pausing of direct oral anticoagulants (DOACs), in this case Apixaban, and the considerations to be applied in making that decision. You have raised that the evidence at the inquest indicated that there was inconsistency around decisions taken to pause DOACs, which may ultimately put patients with atrial fibrillation at risk.

It is not within NHS England's remit to publish the relevant clinical guidance on this matter. We would refer you to the National Institute for Health and Care Excellence (NICE), who we note you have also addressed your Report to, and who have published national guidance on the use of Apixaban, which was last updated in April 2024. The guidance states that patients may need to temporarily stop taking Apixaban if they require surgery or any other invasive procedure, and this depends on the patient's risk of having a thromboembolic event along with the bleeding risk associated with the procedure. For "procedures with a high bleeding risk, the last dose of apixaban should be taken 3 days before the procedure". We understand from follow-up correspondence with you that David's dose of Apixaban was paused for four days, 1-4 June 2023, and then paused again on the evening of 7 June 2023, because of further consideration about another attempt to aspirate the pericardial collection.

There is also further national free-to-access guidance for clinicians via the Apixaban UK Clinical Pharmacy Association (UKCPA) Handbook: Apixaban - UKCPA Handbook

<u>of Perioperative Medicines (ukclinicalpharmacy.org)</u>. The guide aids clinicians to decide how to manage DOACs perioperatively, including determining the dose, the bleeding risk of the surgery / procedure and the decision on pre-operative cessation. The guide also includes post-operative advice around timings for restarting Apixaban following a procedure / surgery, dependent on the bleeding risk.

The <u>2020 European Society of Cardiology Guidelines</u> for the diagnosis and management of atrial fibrillation recommends continuous anticoagulation for two months post atrial fibrillation ablation, with consideration of prolonged duration in those at high risk of thromboembolism. Pericardial effusion is a recognised complication of catheter atrial fibrillation ablation. The decision whether to withhold anticoagulation for pericardiocentesis depends on several factors including:

- the size of the effusion
- its location around the heart and patient physique (which determine ease of access to the effusion and influence the risk of the procedure).

The decision should be made in discussion with the individual performing the procedure. Where it is felt that temporary cessation of anticoagulation is required, this should be done for the minimum timeframe applicable.

The Regional Chief Pharmacist in the Midlands has also been asked to review your Report and consider whether any learnings need to be shared across the ICBs within the Midlands region.

Effective communication

You also raised the concern that there was a failure to effectively communicate, recognise and act on time critical directions, including restarting the DOAC, and that this may be due to a lack of continuity of care and difficulties in accessing and updating the computerised clinical / pharmacy records. We note that your Report has also been sent to Warwick Hospital (falling under the South Warwickshire University NHS Foundation Trust), and they would be best placed to address these concerns and their local arrangements.

My regional Midlands colleagues have made NHS Coventry and Warwickshire Integrated Care Board (CWICB) aware of the concerns raised in your Report, and how they relate to South Warwickshire University NHS Foundation Trust, for which they are the commissioner, and who we note you have also sent your Report to.

I would also like to provide further assurances on the national NHS England work taking place around the Reports to Prevent Future Deaths. All reports received are discussed by the Regulation 28 Working Group, comprising Regional Medical Directors and other clinical and quality colleagues from across the regions. This ensures that key learnings and insights around events, such as the sad death of David, are shared across the NHS at both a national and regional level and helps us to pay close attention to any emerging trends that may require further review and action.

Thank you for bringing these important patient safety issues to my attention and please do not hesitate to contact me should you need any further information.

Yours sincerely,



National Medical Director