

From Maria Caulfield Minister for Mental Health and Women's Health

> 39 Victoria Street London SW1H 0EU

Our ref: PFD - 24-05-07 - RILEY

HM Coroner Linda Lee Warwickshire Justice Centre Newbold Terrace Leamington Spa CV32 4EL

By email:

28 June 2024

Dear Linda,

Thank you for the Regulation 28 report of 7 May sent to the Department of Health and Social Care (DHSC) about the death of David Riley. I am replying as the Minister with responsibility for Patient Safety.

Firstly, I would like to say how saddened I was to read of the circumstances of Mr Riley's death, and I offer my sincere condolences to their family and loved ones. The circumstances your report describes are concerning and I am grateful to you for bringing these matters to my attention.

The report raises concerns over national guidance available to clinicians regarding the pausing of a direct oral anticoagulant (DOAC) and the considerations to be applied in making that decision and effective communication between medical staff for essential patient care.

I note that the National Institute for Health and Care Excellence (NICE) and NHS England are also recipients of this report. Departmental officials have made enquires with both organisations and the Care Quality Commissions (CQC).

I am informed that CQC's medicines team will be contacting the Trust Chief Pharmacist to establish whether the pharmacy was informed and involved in the outcomes of the Trust investigation from a medicine management perspective. They will also be querying lessons learnt from this case and whether there are any other safety aspects to be reviewed. CQC would expect acute hospitals to follow national guidance when designing guidance/policy for staff and would expect there to be something to guide staff on pausing DOACs. CQC's inspection team requested a copy of the guidance/policy used by staff at South Warwickshire University NHS Foundation Trust (SWFT) on 17 June 2024 for an assessment. They received this document on 19 June 2024. CQC note that the hospital's policy was updated this month (June 2024) in response to learning from an incident. The policy has been written using up to date national guidance, however, there is no reference to pausing anticoagulation medication in the case of surgery.

SWFT had not shared details of this death with CQC. CQC inspectors requested a copy of the Root Cause Analysis on 17 June 2024 and received this on 24 June 2024. CQC will continue to monitor the Trust and will determine next steps once they have reviewed the relevant documents and made contact with the Chief Pharmacist.

CQC note there is NICE guidance for managing atrial fibrillation <u>Recommendations | Atrial fibrillation: diagnosis and management | Guidance | NICE</u> with a section '1.11 Stopping anticoagulation'. There is also further guidance available from the British Society for Haematology and the NHS on pausing DOACs: <u>Peri-Operative Management of Anticoagulation and Antiplatelet Therapy (b-s-h.org.uk)</u>.

NICE will be responding directly to your concern about national guidance on DOACs. As you will be aware, the National Institute for Health and Care Excellence (NICE) is an executive non-departmental public body, sponsored by the DHSC. It is the independent body responsible for developing evidence-based guidelines for the National Health Service, following a rigorous process and extensive engagement with stakeholders and expert input to develop the scope of the guidelines. However, it is important to note that NICE guidelines do not override a clinician's responsibility to make decisions appropriate to individual patients. NICE guidelines describe best practice, and the Government expects NHS commissioners to take them into account in designing services that meet the needs of their local populations.

NHS England is operationally responsible for delivering health services across the country and will be responding directly to your concerns at length. NHS England is an executive non-departmental public body, sponsored by the Department of Health and Social Care.

It is vital that lessons are learnt collectively, and changes are made to reflect where things have gone wrong, which is essential to ensure the NHS provides safe, high-quality care.

I hope this response is helpful. Thank you for bringing these concerns to my attention.

