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Royal Cornwall Hospitals NHS Trust

Chief Medical Officer's Office
Royal Cornwall Hospital
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[redacted]

12th July 2023

Mr Andrew Cox
Senior Coroner for Cornwall and the Isles of Scilly
H.M Coroner's Office
Pydar House, Pydar Street
Truro, Cornwall
TR1 1XU

Dear Mr Cox

Re: Death of Julie Louise Hancock – Response to Regulation 28 Report to Prevent Future Deaths

I write in response to the Regulation 28 Report to Prevent Future Deaths, dated and received on the 17th May 2023, issued as a result of the adjourned inquest into the death of Mrs Julie Louise Hancock. I note a provisional date for the resumed hearing has been listed for 11 October 2023.

I would like to take this opportunity to express my sincerest condolences to the family of Mrs Hancock for their loss.

During the course of the inquest, the evidence revealed matters giving rise to concern. These are as follows:

- Mrs Hancock was prescribed [redacted] days of aspirin and, in apparent error, one unidentified doctor also prescribed Dalteparin which was stopped after a single dose. It is of concern that the doctor cannot be identified and there is no record of the decision making;
- Ambiguity between the Trust's Guideline Summary for Thrombosis Prevention and Anticoagulation following elective knee replacement and the Thrombosis Prevention and Anticoagulation Policy V9 dated February 2022.

Please find below the response from the Trust and the detail of the actions being taken in relation to each concern.

Medication prescribing, identity of doctor and evidence of decision making:

After discussion with Pharmacy and a review of the ePMA (Electronic prescribing & Medicines Administration) records there is a clear audit trail of who prescribed the Dalteparin and when.

From the ePMA records [redacted] prescribed Dalteparin as a stat dose at 22.39 on the 4th March 2022, this was administered by [redacted] at 22.48 (screenshot 1 and 2)

[redacted] then prescribed Dalteparin regularly for the patient (screenshot 3) once a day at night, so Mrs Hancock's next dose would have been due in the evening of the 5th March 2022. Mrs Hancock was discharged before this and the discharge prescription, written by [redacted] (screenshot 4), included aspirin rather than Dalteparin.

It will assist further to note that Mrs Hancock received a dose of aspirin on the 2nd March 2022 (@22:53) and 3rd March 2022 (@22:03) (screenshot 6) The aspirin was suspended at 22:11 on the 4th March by [redacted] (screenshot 5). The Dalteparin was then prescribed at 22:39 on the 4th March by [redacted] (screenshot 3).

There is clear evidence in the notes of the decision making and rationale of [redacted]. At page B384 of the inquest bundle shows the hand-written entry of [redacted], dated 4th March 2022 timed at 22:00 hrs. This entry records due to episodes of Mrs Hancock vomiting, aspirin was suspended and a dose of Dalteparin prescribed and administered that evening.

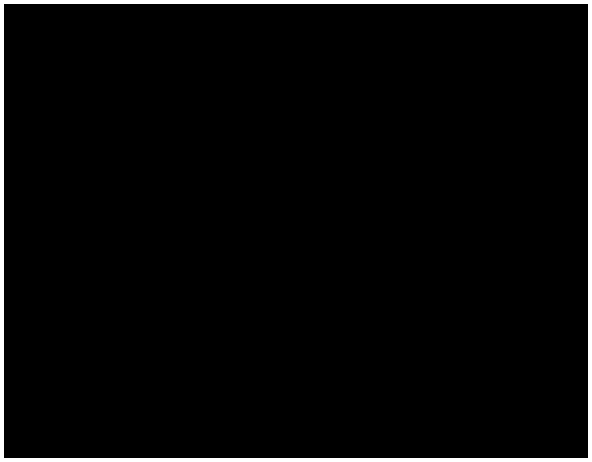
Screenshot 1: Prescription of the initial stat dose of dalteparin

[redacted]

Screenshot 2: record of the administration of dalteparin

[redacted]

Screenshot 3: Inpatient dalteparin ongoing prescription



Screenshot 4: Discharge Prescription

Screenshot 5- showing the suspended aspirin prescription (whilst dalteparin was prescribed)

Screenshot 6- administration of the aspirin

Mrs Hancock's Procedure and ambiguity with Guidelines and Policy:

As the Senior Coroner will be aware from the papers, Mrs Hancock had been diagnosed with the following conditions: (1) Bilateral knee arthritis (2) Seropositive rheumatoid arthritis, and (3) Hypertension. She had a raised BMI of 35 and was on the following medications: Baricitinib [redacted] mg, Methotrexate [redacted] mg, Omeprazole [redacted], Lisinopril, Felodipine, Adcal D3 Folic acid.

Mrs Hancock was assessed by Rheumatology and was referred to Orthopaedics for surgical management of knee arthritis.

Mrs Hancock attended the elective knee clinic at St Michaels Hospital on 10/12/2021 and was offered a staged bilateral total knee replacement. Risks and complications were discussed during the consultation. As per the NICE risk assessment tool, Mrs Hancock was at risk of developing a DVT due to planned surgery in a lower limb with combined anaesthetic and surgical time exceeding 90 minutes and BMI > 30. Other risk factors (active cancer or cancer treatment) age > 60, history of DVT, contraceptive pills or pregnancy) were negative. DVT prophylaxis protocol was explained to Mrs Hancock which included Aspirin 75 mg orally for 14 days. The importance of post-surgery weight bearing to prevent DVT was explained. No additional risks were identified.

Mrs Hancock had routine preoperative anaesthetic assessment and was considered anaesthetically fit for surgery. As per the advice of our Rheumatologist, Baricitinib [redacted] mg was stopped 2 days prior to surgery as this can potentially increase risk of DVT/PE. It was advised to restart 2 weeks postoperatively.

Mrs Hancock underwent a right cemented total knee replacement on 02/03/2022. The surgery was not complicated and did not exceed the average time for such a procedure. At the time of the operation a Flotron intermittent pneumatic calf pump was applied to the opposite calf to

prevent DVT. Mrs Hancock made satisfactory progress and was discharged home on day 3 post-operation and was prescribed Aspirin [redacted] mgs for 14 days.

NICE, BOA (British Orthopaedic Association), BASK (British Association for Surgery of the Knee), Royal College of Surgeons (England) and NHS patient information mention DVT as a potential complication following a Total Knee Replacement but do not quantify the risk. VTE prophylaxis NICE Guidelines do not consider risk stratification in their recommendation.

NICE also provides guidelines for prophylaxis of DVT (NG89 (1.11.8)). It does not suggest that one pharmaceutical agent is superior to others. NICE does not suggest that any regimen to be used depending on how many risk factors are identified. It does not suggest mixing or using more than one agent at any time.

Mrs Hancock had a DVT risk assessment prior to surgery. The Trust followed the NICE and RCHT elective knee replacement guidance and we have a standardised trust protocol based on these NICE Guidelines which was followed. Mrs Hancock has the correct prophylaxis prescribed. The orthopaedic surgeon who operated on Mrs Hancock is the orthopaedic audit lead and has been since 2011. Mandatory annual audit of DVT prophylaxis have been carried out and the Trust has been 100% compliant in correctly prescribing DVT prophylaxis in elective hip and knee replacement surgery.

DVT Policy:

We can advise the Policy referenced at the part heard inquest of Mrs Hancock, *Thrombosis Prevention & Anticoagulation Policy V9 dated February 2022* has ambiguity with regard how it presents local interpretation of NICE Guidelines on orthopaedic thromboprophylaxis. This policy had been refreshed in January 2022 by the VTE practitioner who has since retired. This policy did not go through the appropriate sub board groups for scrutiny, review and sign off. It has since been scrutinised by the Thrombosis Prevention and Anticoagulation Steering Group (TPAS; meeting 20th June 2023) who are satisfied that the acknowledged ambiguity in a single section of the document does not pose a greater risk to our patient population than removal of this guideline, which covers every inpatient specialty, would pose to many patients. On this basis TPAS have ratified the document in its current form with the understanding that it will be reviewed as part of a larger workstream to make the RCHT Thrombosis and Anticoagulation policy offerings more accessible and without ambiguity.

It is anticipated that this policy will be separated into smaller, digestible policies (e.g. Management of Suspected/confirmed VTE; Prophylaxis for medical and/or surgical patients; Elective Orthopaedics) This updated policy/policies will then go through the appropriate channels and groups (TPAS, Medicines Practice Committee, full engagement with Care Group and Clinical Directors, Clinical Effectiveness Group, Policy Review Group and Quality Assurance Committee) before formal sign off and before it can be uploaded onto our documents library. We will be more than happy to share copies any updated policy/policies when they have been through scrutiny and sign off.

In addition to the above and to provide further assurance, the Trust will audit the last 10 Policies uploaded on the document library to ensure the correct process and procedure has

been followed before being uploaded for staff reference. We will undertake this audit within the next three months and we can share the results of this audit when available.

I hope that this letter provides both you and Mrs Hancocks' family with assurance that the Trust has taken seriously the matter of concerns you raised in your report.

Yours Sincerely

[redacted]

[redacted], **Deputy Medical Director**

On behalf of

[redacted], **Chief Medical Officer**