

Chief Nursing Officer

Trust HQ

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9th March 2021

Dear Mr Pegg

Please find below our response to your Regulation 28: Report to Prevent Future Deaths which you issued on the 15th December 2020. As you aware, the Trust was unfortunately not informed that you had issued this report at the time and was only sent a copy on 12th January 2021.

Your concerns:

When found on the floor the deceased stated that he had a head injury. The Trust has a policy for the assessment and early management of head injuries. The policy was, on the evidence, drafted in 2016. The Trust policy is said to reflect the National Institute for Health and Care Excellence guidance on the assessment and early management of head injuries. The deceased was receiving the anticoagulant enoxaparin whilst in hospital. The present Trust policy states that a computerised tomography scan of the head should be undertaken within 8 hours of the injury if a patient is receiving anticoagulant treatment. The evidence suggested that enoxaparin is a "low dose anticoagulant" which did not place the deceased within the Trust policy where a computerised tomography scan should be provided within 8 hours of a head injury. The Trust were not aware of the September 2019 variation in National Institute for Health and Care Excellence guidance which now advises that patients who are on any anticoagulant should have a computerised tomography scan within 8 hours of a head injury. The Trust's policy does not presently reflect the National Institute for Health and Care Excellence revised guidance, in place since September 2019. It was accepted in evidence that the deceased would have had a computerised tomography scan within 8 hours of a head injury if the revised National Institute for Health and Care Excellence guidance had been applied and reflected in the Trust policy. The deceased's computerised tomography scan was undertaken 30 hours after the deceased had suffered a head injury

Our response:

Firstly, I would like to reassure you that the Trust has a procedure in place for ensuring that all NICE guidance is reviewed on publication and that all relevant Trust policies and procedures are subsequently updated, where appropriate.

On investigation, it is not clear why the Trust's policy was not updated following the publication of Clinical Guideline [CG176], in September 2019. However, I can assure you that this does appear to be an isolated incident. Furthermore, the Trust has satisfied itself that its procedure for checking NICE guidance and updating its internal policies and procedures in a timely way is robust.

In respect of NICE Clinical Guideline [CG176], I can confirm that the Trust's policy has now been amended so that it is clear that patients receiving therapeutic anticoagulant treatment including Direct Oral Anticoagulants (DOACs) should undergo a CT scan within 8 hours of a suspected head injury.

The Trust launched the updated policy on the 26th January 2021, our head of patient safety e mailed out to the clinical teams (including consultants, nursing, pharmacy and therapy staff) to notify them of the updated policy and highlight the key changes including the NICE guidance. We also included the updated policy on the clinical updates section on our staff intranet.

There has been a great deal of discussion between my clinical colleagues as to whether patients who are receiving a prophylactic dose of say Enoxaparin would also require a CT scan within 8 hours of a suspected head injury given that the NICE guidelines appear to specifically relate to therapeutic doses of DOAC's, Warfarin etc.

Enoxaparin is widely used in the hospital environment at a prophylactic dose for prevention of Venous Thromboembolic disease. This dose is effective at reducing thromboembolic disease by up to 70%. However, it is not sufficient in order to result in the levels of anticoagulation required for proven DVTs, PEs or for acute ischaemic events to develop.

This is evidenced in the medical literature which seem to show a difference in the bleeding risk between prophylactic and treatment doses. For example, the Electronic Medicines Compendium [Clexane pre-filled syringes - Summary of Product Characteristics \(SmPC\) - \(emc\) \(medicines.org.uk\)](https://www.medicines.org.uk/emc/summaryofproducts/23000/000/SmPC) states,

“At doses used for prophylaxis of venous thromboembolism, enoxaparin sodium does not influence bleeding time and global blood coagulation tests significantly, nor does it affect platelet aggregation or binding of fibrinogen to platelets.”

In relation to treatment specifically given to the elderly, it goes on to state,

“No increased bleeding tendency is observed in the elderly with the prophylactic dosage ranges. Elderly patients (especially patients eighty years of age and older) may be at an increased risk for bleeding complications with the therapeutic dosage ranges.”

On the basis of the current medical literature on the subject, patients who are receiving a prophylactic dose of Enoxaparin are not routinely given a CT scan following a fall unless they are exhibiting clinical signs that are suggestive of a bleed.

The consensus opinion among Medicine for Older People colleagues is that providing a CT scan for all patients on a prophylactic dose of enoxaparin, without other clinical signs and symptoms being evident, would not influence the outcomes for those patients. However, it could overwhelm a hospital's scanning capacity, meaning that there is a risk that other patients, who do require a CT scan, may face a delay in obtaining this to the potential detriment of their health.

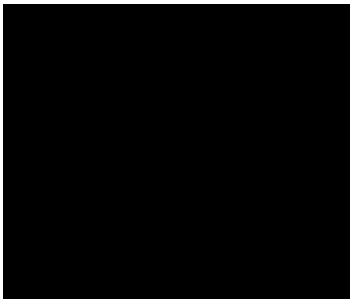
Unfortunately, NICE's Clinical Guideline [CG176] fails to provide specific guidance on this point. We, therefore, contacted the National Falls Lead at NHSE/I who confirmed that *“we are aware that concordance with the guidelines by acute providers is problematic”*. We understand that there is to be a full review of the evidence, undertaken by NICE, in order to clarify whether prophylactic anticoagulants should trigger the same requirements as therapeutic doses of DOACs and Warfarin.

The scope of this review, can be found at <https://www.nice.org.uk/guidance/GID-NG10164/documents/draft-scope> We note that the issue of prophylactic anticoagulants does not appear to be specifically referred to although NICE should be able to confirm to you whether they are considering this as part of their review.

We have also contacted the Falls Special Interest Group Lead in the British Geriatric Society to highlight this omission in NICE guidance not least so that a consensus approach can be developed nationally for these patients in the meantime.

Finally, I would like to assure you that, whilst further guidance from NICE is awaited, the Trust will continue to ensure that all patients receiving a prophylactic dose of Enoxaparin, who develop clinical signs and symptoms following a fall, will undergo a CT scan within 8 hours of a suspected head injury in addition to all those patients who have received a therapeutic dose of DOAC's, Warfarin etc.

Yours sincerely,



Chief Nursing Officer

cc.  CEO
 Inspection Manager, Care Quality Commission