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INTERIM BULLETIN

MANAGEMENT OF VTE RISK IN PATIENTS FOLLOWING THROMBOLYSIS FOR AN ACUTE STROKE

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This interim bulletin contains facts which have been determined up to the time of issue. It is published to inform the NHS and the public of the general circumstances of events and incidents and should be regarded as tentative and subject to alteration and correction if additional evidence becomes available.



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IDENTIFICATION OF EVENT AND DECISION TO INVESTIGATE

If a patient has suffered an acute stroke, they are at increased risk of developing deep vein thrombosis (DVT) due to immobility, which may result in a pulmonary embolism (PE)¹. The Healthcare Safety Investigation Branch (HSIB) identified the management of Venous Thromboembolism (VTE) for patients that have suffered an ischaemic stroke and received thrombolysis as a significant patient safety risk.

Following a detailed scoping investigation, the Chief Investigator authorised a full investigation as it met the following criteria:

Criteria 1: Outcome Impact – What impact does the safety issue have on people and services across the healthcare system?

Without applying measures known to reduce the risk of VTE, stroke patients are at high risk of DVT. This may lead to a PE which can be fatal².

Criteria 2: Systemic Risk – How widespread and how common is the safety issue across the healthcare system?

The safety issue impacts all specialist stroke units and other wards where stroke recovery is managed in the NHS. VTE has been detected in 20–42% of patients in hospital who have had an acute stroke³.

¹ Rinde, Ludvig B.; Småbrekke, Birgit; Mathiesen, Ellisiv B.; Løchen, MajaøLisa; Njølstad, Inger; Hald, Erin M. et al. (2016): Ischemic Stroke and Risk of Venous Thromboembolism in the General Population: The Tromsø Study. In Journal of the American Heart Association: Cardiovascular and Cerebrovascular Disease 5 (11).

² Kelly J, Rudd A, Lewis R, Hunt BJ. Venous thromboembolism after acute stroke. Stroke. 2001; 32:262–267.

³ The CLOTS Trials Collaboration. Thigh-length versus below-knee stockings for DVT prophylaxis after stroke: a randomized trial. Ann Int Med 2010; 153: 553–62



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Criteria 3: Learning Potential - What is the potential for an HSIB investigation to drive positive change and improve patient safety?

Despite national guidelines being in place relating to the management of VTE in patients that have suffered a stroke, incidents of harm continue to occur. For example, intermittent pneumatic compression (IPC) is an effective method of reducing the risk of VTE and improving survival in patients who are immobile after stroke⁴, but can fail to be applied.

HISTORY OF THE EVENT

A 78 year-old female suffered a stroke while at home, where she had been living an active and independent life with her husband. She was taken by ambulance to hospital where an acute stroke nurse saw her immediately on arrival in the Emergency Department (ED) and initiated the stroke protocol.

Following an urgent computerised tomography (CT) scan of her brain, the patient was transferred to the Hyper-Acute Stroke Unit (HASU), where she was diagnosed with an acute ischaemic stroke. She was administered alteplase, which is standard treatment for patients with ischaemic stroke.

During the consultant ward round, a doctor completed the required initial VTE risk assessment. This recorded that the risk of bleeding was high, and therefore the patient could not be administered an anticoagulant medication. An IPC device was considered appropriate and the relevant box on the VTE risk assessment form was ticked. IPC devices are cuffs which inflate and deflate according to a predetermined programme and assist the return of blood to the heart in immobile patients. In order

⁴ CLOTS 3 Trials Collaboration (2013): Effectiveness of intermittent pneumatic compression in reduction of risk of deep vein thrombosis in patients who have had a stroke (CLOTS 3): a multicentre randomised controlled trial. In *The Lancet* 382 (9891), pp. 516-524



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for IPC devices to be fitted, the Trust's process was for the doctor to document the intent to fit the IPC device on the patient's drug chart; this step was not completed. A subsequent VTE risk assessment that should have been conducted 24 hours after the first was not completed.

For the next 13 days the patient received therapy as per her care plan, including sitting, standing and walking with assistance. On day 14, the therapy team found the patient slumped over her table. She was diagnosed with dehydration and a urinary tract infection for which she was given fluids and antibiotics. She responded well to these. The following day, during a therapy session, the patient was observed to experience shortness of breath and the medical team was informed.

On day 16 the patient was seen by the same therapist who again noted that the patient was displaying shortness of breath. She was suspected to have suffered PE and a CT scan of her chest was arranged. No treatment for the suspected PE was started until the CT scan was performed two days later. As a result of the scan, she was diagnosed with a '*pulmonary emboli including saddle embolism*' and anticoagulant medication, which would be standard treatment for PE, was prescribed.

The patient was transferred to the Medical High Dependency Unit (MHDU) so that she could be monitored closely and remained there for the next six days. On admission to the MHDU, it was noted that '*No IPC*' had been recorded in the patient's notes and that none had been fitted. She then returned to the Stroke Unit and continued to receive rehabilitation for a month before being discharged home.



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NATIONAL CONTEXT

Every year in the UK over 100,000 people have a stroke, with 95% of them admitted to hospital. It is the fourth most common cause of death in the UK⁵. A major clinical trial (CLOTS3) in 2013 recommended methods for managing patients at risk of VTE who have received thrombolysis, which led to national guidelines being created⁶.

IDENTIFIED SAFETY ISSUES

The following safety issues were identified during the HSIB scoping investigation and will form the basis of the wider investigation:

There is no proactive, stroke-specific, VTE risk management programme to monitor risk assessments and no check that the risk assessment requirements and recommendations have been undertaken.

NEXT STEPS

The HSIB investigation will continue to explore the identified safety issues and welcomes further information that may be relevant, regardless of source.

The HSIB will report any significant developments as the investigation progresses.

⁵ Stroke Association. State of the Nation: Stroke Statistics 2017 as reported in NIHR Dissemination Centre (2017) THEMED REVIEW - ROADS TO RECOVERY Organisation and Quality of Stroke Services. <https://www.dc.nihr.ac.uk/themed-reviews/stroke-recovery-services-research.htm>

⁶ CLOTS 3 Trials Collaboration (2013): Effectiveness of intermittent pneumatic compression in reduction of risk of deep vein thrombosis in patients who have had a stroke (CLOTS 3): a multicentre randomised controlled trial. In *The Lancet* 382 (9891), pp. 516-524.)