Health Services Safety Investigations Body

Investigation report

Investigation report: Management of venous thromboembolism risk in patients following thrombolysis for an acute stroke

Date Published:
05/05/2021

Theme:
Acute

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A note of acknowledgement

We would like to thank the patient and her family for their time and support in sharing their experiences and allowing the investigation a valuable insight into the patient's care. We would also like to express our gratitude to the healthcare professionals who cared for the patient and gave their time to assist with the investigation, providing open and honest accounts of events to support learning and improve patient safety.

Executive Summary

A 78-year-old woman had 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 and initiated the Trust's protocol for the assessment and treatment of stroke.

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 (a blockage of the blood supply to the brain, which can be caused by a blood clot). The doctors assessed that she was suitable to receive thrombolytic drugs and she was given this treatment. Thrombolytic drugs break down clots in the blood and are effective for eligible patients who have had an ischaemic stroke.

During the consultant ward round, a doctor completed the required initial risk assessment for venous thromboembolism (VTE), a condition in which a blood clot forms in a vein. This can detach and travel through the venous system to the lungs and may cause a pulmonary embolism (PE). This risk assessment recorded that the risk of bleeding was high, and therefore

the patient could not be administered a preventative anticoagulant medication (treatment to prevent a blood clot). An intermittent pneumatic compression (IPC) device was considered an appropriate treatment for the patient 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 help the veins return blood to the heart in immobile patients. In order for IPC devices to be fitted, the Trust's process was for the doctor to document the order to fit the IPC device on the patient's prescription 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 15, 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, and she responded well to these. On the following day, during a therapy session, the therapist observed that the patient was experiencing shortness of breath and informed the medical team of this.

The patient was seen the next day (day 17) by the same therapist, who again noted that the patient was displaying shortness of breath. It was suspected that the patient had suffered a 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, the patient was diagnosed with 'pulmonary emboli including saddle embolism' and anticoagulant medication, the standard treatment for PE, was prescribed.

The patient was transferred to the Medical High Dependency Unit (MHDU) so that her condition could be monitored closely; she 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 no IPC device had been fitted. The patient then returned to the Stroke Unit and continued to receive rehabilitation for a month before being discharged home.

Focus of the investigation

The Healthcare Safety Investigation Branch (HSIB) investigation focused on:

- the management of VTE risk in inpatients following thrombolysis for an acute stroke
- detection of medical problems (that impact on VTE risk) occurring in inpatients following thrombolysis for an acute stroke.

Findings

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

- The generic inpatient VTE assessment does not take into account the specific circumstances for patients who have had a stroke.
- The generic VTE assessment does not produce a stratified risk – that is, it does not determine the level of a patient's risk of VTE.
- There is a general belief that IPC devices must be written on the prescription chart to allow them to be fitted and a VTE risk assessment needs to be carried out before IPC devices are fitted to a patient who has had a stroke.
- Non-pharmacy items, orders (an instruction from a doctor to carry out a specific treatment or procedure) and tasks that are considered important are being written on the prescription chart. There are no nationally approved standards for inpatient documentation relating to medicines, non-pharmacy items, orders and tasks.

HSIB makes the following safety recommendation

Safety recommendation R/2020/090:

It is recommended that the Intercollegiate Stroke Working Party with support from the Joint Stroke Medicine Committee and NHS England and NHS Improvement develop a stroke specific venous thromboembolism (VTE) assessment tool and system for ordering the associated treatment for patients who have suffered a stroke. HSIB recommend that the Intercollegiate Stroke Working Party supports development of a tool that ensures that important information is recorded and reviewed at appropriate intervals. The following points should be considered in the development of this tool:

- The aetiology/type of stroke (ischaemic and haemorrhagic).
- A record of the individual risk factors for VTE that are identified.
- Contraindications for VTE treatment measures.
- The VTE preventative treatment recommendation.
- The record of administration of that treatment.
- The reason that treatment is not administered.
- Patient's level of mobility and activity (in relation to IPC administration).
- Frequency of IPC devices checking.
- Record of patient's consent and understanding of risk/benefits of intervention, including patient's decision.

HSIB makes the following safety observations

Safety observation O/2020/070:

There is no validated venous thromboembolism (VTE) risk assessment tool in the UK that produces a stratified risk for predicting a patient's likelihood of developing a deep vein thromboembolism or pulmonary embolism. If it is not possible to produce a stratified VTE risk assessment, it may be beneficial to consider amending the title of the published VTE risk assessment tool in NICE guideline NG89 (National Institute for Health and Care Excellence, 2018). This would reflect its true purpose as a prompt for clinicians to develop an appropriate treatment plan rather than creating the perception that it produces an assessment of risk.

Safety observation O/2020/071:

It would be beneficial for future venous thromboembolism (VTE) guidelines in relation to stroke to explicitly state when further VTE assessments are required during a patient's stay in hospital.

Safety observation O/2020/072:

The advantages of multidisciplinary team (MDT) working are well known. It would be beneficial for organisations to ensure that stroke units are structured to ensure the optimal functioning of the MDT. To achieve this requires strong leadership, planning and a culture that empowers and encourages staff to speak up when issues arise. Stroke care involves many healthcare disciplines and in order for them to work efficiently and achieve the best results for patients, it may be beneficial to have formalised, tested and practised joint working with escalation routes known by all.

HSIB identified the following local considerations

Consideration for commissioners

It would be beneficial for local commissioners to agree a scheduled programme of audits to ensure that patients assessed for risk of acquiring a venous thromboembolism (VTE) receive appropriate mechanical or pharmacological prophylaxis.

Considerations for trusts

It would be beneficial for trusts to review and amend their local procedures for the ordering and fitting of intermittent pneumatic compression (IPC) devices to allow any trained and competent person to fit them at the earliest opportunity. It would be beneficial for trusts to give patients who have had a stroke and their families/carers information about anticoagulation and VTE prevention, in particular the importance of IPC devices. They would then have the correct information to help them decide on whether or not to wear IPC devices.

1 Background and context

1.1 Stroke

1.1.1 Every year in the UK over 100,000 people have a stroke, and it is the fourth most common cause of death in the UK (Stroke Association, 2018). A major clinical trial in 2013 (CLOTS3) recommended methods for managing patients at risk of venous thromboembolism (VTE) (see 1.2) who have received thrombolysis (a drug to break down a blood clot). These recommendations led to national guidelines being created (CLOTS (Clots in Legs or sTockings after Stroke) Trials Collaboration, 2015).

1.1.2 Stroke is a neurovascular condition, which means it relates to the blood supply to, and blood vessels in, the brain. In a stroke, brain cells (neurons) are killed by a lack of oxygenated blood, causing disability or death. A stroke occurs due to either a bleed (a haemorrhagic stroke) or, more commonly (in 85% of patients), a blood clot (an ischaemic stroke).

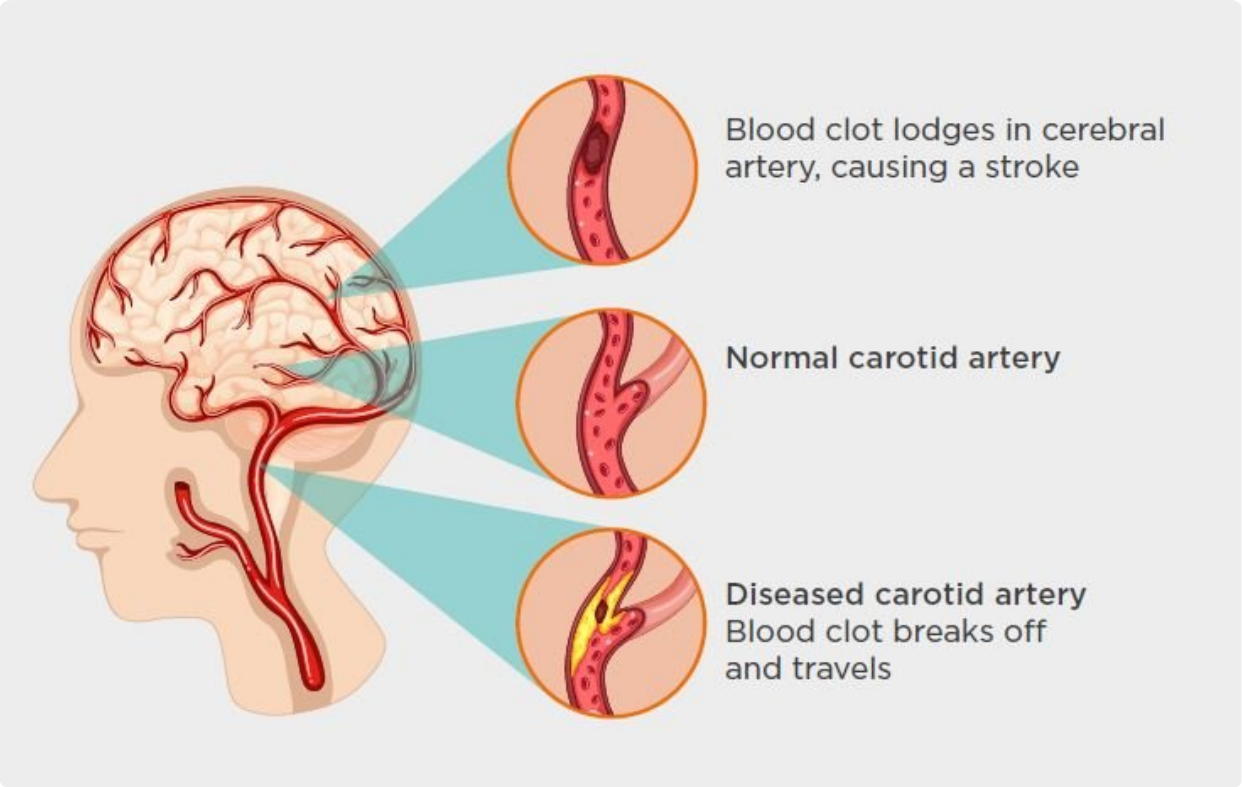
1.1.3 One in 10 patients who have a stroke in the community die before reaching hospital (Stroke Association, 2018). In the case of ischaemic stroke, the clot may develop in a blood vessel that serves a very large part of the brain and cause catastrophic neurological dysfunction and death.

1.1.4 Patients who survive this initial stage and survive to the point of admission to hospital may experience a plateau in their signs and symptoms. These signs and symptoms may improve over time or leave the patient with a permanent disability requiring ongoing care, rehabilitation and supported living.

1.1.5 Ischaemic strokes

- Ischaemia means that the tissues affected have an inadequate blood supply, which in turn means that there is also a lack of sufficient oxygen. In ischaemic stroke, the blood vessels which carry blood to the affected part of the brain become blocked (Figure 1).
- Blockages are generally caused by clots which can result from conditions including atrial fibrillation (a heart condition that causes an irregular and often abnormally fast heart rate) and those which narrow blood vessels such as atherosclerosis (fatty deposits) (Royal College of Physicians, 2016).
- These blockages prevent oxygen and nutrients reaching the affected part of the brain, causing a cascade of events which leads to the death of the tissue in that area. The damage caused to the brain is permanent and its effects have a rapid onset.
- Ischaemic strokes cause dysfunction in the body dependent on the damage caused to the affected part of the brain. The classic signs of a stroke – persistent facial drooping, weakness down one side of the body and difficulty in speaking – can be tested by the ‘FAST Test’ (Face, Arms, Speech, Time) (Royal College of Physicians, 2016). The blockage often affects areas of the brain involved in control of muscle tone; this can lead to facial palsy (droop) and loss of motor function in the limbs. It can also cause slurring of words due to loss of fine muscle control associated with speech. In some cases, the area of the brain involved in speech is affected, causing the patient to have difficulty in finding the right words or understanding what is being said; this is known as dysphasia.

Figure 1: The effect of a clot on the blood vessels in the brain



1.1.6 Haemorrhagic strokes

- Haemorrhagic strokes make up around 15% of all stroke cases. They occur due to damage to the brain's blood vessels and lead to bleeding into the brain (Stroke Association, 2018) (Figure 2). The blood loss compresses the brain tissue causing the patient to have stroke symptoms.
- There are two main causes of haemorrhagic stroke. It can be caused by a blood vessel developing an aneurysm (a weakening of the wall of the blood vessel), which causes the blood vessel to 'balloon' and eventually rupture. The second cause is a malformation of the blood vessel (arteriovenous malformation) which can also progress to the point of rupture. Both types cause the same kind of stroke, with a similar onset of symptoms. However, patients who have a haemorrhagic stroke are more likely to die within the first three months than patients with ischaemic stroke.
- Patients with haemorrhagic stroke will experience the same damage and disabling symptoms, but in more severe cases the signs and symptoms continue to progress, rather than reaching a plateau. This suggests that bleeding is continuing, and more areas of the brain are being affected due to compression.

Figure 2: The effect of a haemorrhagic stroke on the blood vessels in the brain



Diagnosis of stroke

1.1.7 Suspicion of stroke is often based on clinical signs, particularly when the stroke occurs outside of a healthcare setting. The development of the FAST Test has led to more patients being identified by members of the public who witness someone becoming unwell and symptomatic. This earlier identification means that the public are calling 999 sooner, and intervention can begin sooner.

1.1.8 Formal diagnosis of stroke is undertaken in hospital. Patients undergo a range of diagnostic tests, including blood samples, physical examination and X-ray/ computerised tomography (CT) imaging. Most areas in the UK have dedicated stroke centres (acute stroke units). Increasingly hyper-acute stroke units (HASUs) (Royal College of Physicians, 2016) are being set up to deal with strokes in a centralised way, similar to the improvements made in the pathways of care for heart attack and trauma patients.

Treatment of haemorrhagic stroke

1.1.9 The treatment options for haemorrhagic stroke are limited. Some patients may undergo an operation called a craniotomy which involves a section of skull being removed over the affected area of the brain. The treatment goal is to reduce the build-up of pressure in the brain which can cause further damage.

Treatment of ischaemic stroke

1.1.10 Patients who have had an ischaemic stroke can receive thrombolysis, a ‘clot-busting’ drug, which dissolves the clot and restores blood flow to the brain. Thrombolysis needs to begin within 4.5 hours of the onset of symptoms, as after this period the clot will become too developed and will not respond to the drugs (National Institute for Health and Care Excellence, 2019a).

1.1.11 For some patients who have a clot in a larger blood vessel, a procedure called a thrombectomy may be undertaken (Royal College of Physicians, 2016). This is a procedure which physically removes the clot from the blood vessel. It is done by passing a catheter (a flexible tube) into the blood vessel and advancing a small instrument towards the clot.

1.1.12 Once the initial treatment is completed, patients may receive other treatments. These may include drugs to prevent further clots (anticoagulants), to address irregular heartbeats (atrial fibrillation) which can cause clots due to the turbulent blood flow, and to lower high blood pressure (Royal College of Physicians, 2016) (National Institute for Health and Care Excellence, 2019a). Tests to assess the cause of the stroke such as carotid doppler ultrasound scan, electrocardiograms (ECG) and echocardiogram (ECHO) may also be undertaken.

1.2 Venous thromboembolism

1.2.1 Venous thromboembolism (VTE) is the collective term used to describe the formation of blood clots (thrombus) which can block blood a vessel (embolism).

1.2.2 A range of risk factors can increase the likelihood of a VTE occurring. These include immobility, recent traumatic injury (for example, long-bone fractures), clotting disorders, recent surgery and stroke.

1.2.3 VTE is an overarching term for two specific conditions:

- Deep vein thrombosis (DVT) – this is a blockage caused by a blood clot, usually in the deep veins in the lower leg/calf, although DVT can also occur in other veins. A DVT that occurs in the most common location in the lower leg can cause pain, swelling and reddening of the affected limb. There is a risk that parts of the DVT can break off and cause other serious diseases.

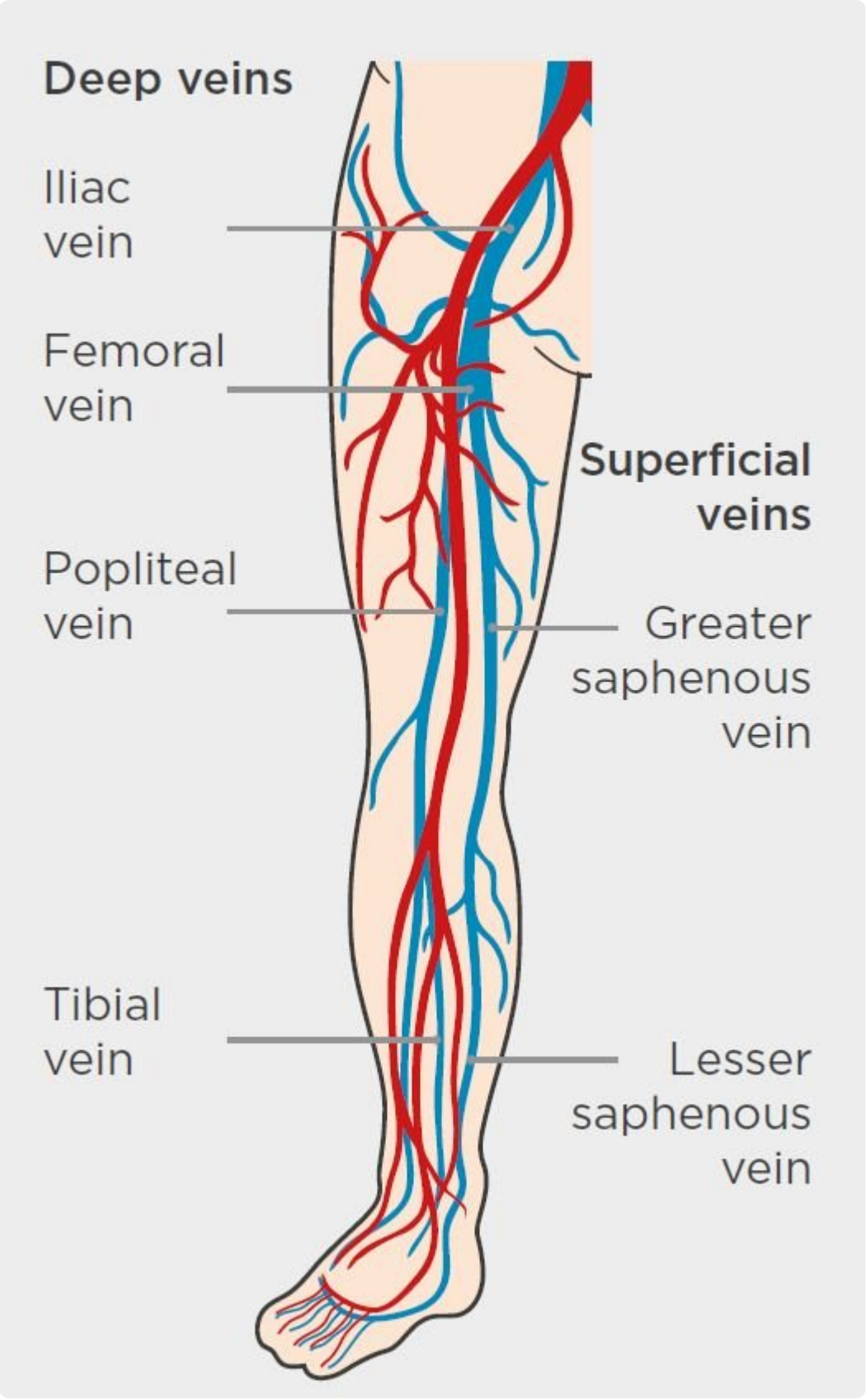
- Pulmonary embolism (PE) – this is usually caused by a small piece of clot breaking away. This clot can travel through the body to a pulmonary (lung) artery (or arteries) where it can partially of fully block the artery. Full, sudden blockage of the pulmonary artery may prove fatal. Small clots lodging in smaller vessels further on in the pulmonary circulation system may cause serious, unpleasant symptoms such as chest pain and shortness of breath and may cause death if not treated.
- Both DVT and PE may be sub-clinical, that is, show no signs or symptoms. PE arising from sub-clinical DVT is a particular challenge as it may occur without warning.

Deep vein thrombosis

1.2.4 As shown in Figure 3, blood enters the legs via the left and right femoral arteries, which arise from the division of the aorta (the body's main artery). The blood flows through smaller arteries and arterioles before entering the capillary bed (the place where oxygen exchange takes place within the tissue). The blood is returned on the other (venous) side of the capillary bed and these converge to form the various veins deep in the legs. These vessels eventually become the large femoral and iliac veins and flow into the inferior vena cava, the large vein which takes deoxygenated blood back to the heart for onward pumping to the lungs.

1.2.5 Unlike arteries, veins in the limbs have valves along their length which help prevent backflow of blood to the tissue. Backflow is a particular problem in the lower extremities where the blood is flowing toward the heart, against gravity. To further assist, the muscular contraction in the legs promotes venous return, and there is also some assistance from the negative pressure created in the thorax (chest) during inhalation.

Figure 3: The deep leg vein system



1.2.6 DVTs may occur during stays in hospital, following elective (planned) surgery or sudden, acute conditions. They also occur spontaneously and in healthy people, for example when sitting in one position during a long-haul flight. Half of patients who undergo orthopaedic surgery, for example hip or knee surgery, and who do not receive chemical thromboprophylaxis

(medicine to prevent clotting) are found to have DVT. A quarter of patients who are admitted with a heart attack, and half of patients who are admitted with ischaemic stroke have a DVT, including where the presentation is, initially, sub-clinical. 1.2.7 Some DVTs lead to the patient dying from a PE (up to 5% of patients) (Scottish Intercollegiate Guidelines Network, 2014).

1.2.8 DVTs are caused by abnormalities in blood flow, the blood vessel itself, and the physiological chemical cascade which causes clotting. These three separate aspects (blood flow, vessels, clotting) are known as Virchow's Triad, and combine to create clots which can obstruct normal blood flow, often following long periods of immobility, therefore putting hospital inpatients at risk.

1.2.9 The actual process of DVT formation involves the proliferation of cells adhering to the lining of the blood vessels around one of the valves in that vessel. This is caused by poor blood flow, and the fact that the valves protrude into the blood vessel and do not have their own blood supply. The clot itself is made up of a web of fibrin which traps red blood cells. Fibrin is a protein that is formed as part of the normal clotting process, albeit it in an unwanted place.

1.2.10 DVTs which arise in the lower calf are usually asymptomatic (cause no symptoms), do not usually cause serious PEs and resolve through spontaneous dissolution. DVTs which arise higher up the calf are more likely to cause symptoms and can form larger, more serious PEs (Wong and Chaudhry, n.d.).

Diagnosis of DVT

1.2.11 Diagnosis of DVT is made by taking a history of the patient's symptoms and carrying out a physical assessment to prompt the use of a Wells DVT Score, validated in non-pregnant adults (National Institute for Health and Care Excellence, 2012), which is a validated tool used to predict the likelihood of a patient having a DVT. A positive Wells DVT Score should lead to further diagnostic tests, including a blood test called a D-dimer which looks for a specific protein fragment which is present when clotting has taken place. Ultrasound scanning may also be used to detect DVT, and in some cases a special X-ray may be taken which uses a contrast agent to identify the DVT.

Pulmonary embolism

1.2.12 The circulation of blood around the body is divided into the systemic and pulmonary systems (Figure 4). The systemic part of the circulation takes oxygenated blood from the left ventricle of the heart and serves the tissues in the body (organs) and returns deoxygenated blood to the right atrium in the heart. The pulmonary circulation takes the deoxygenated blood from the right ventricle to the lungs and returns to the left atrium, and on to the left ventricle for the next cycle.

1.2.13 Arteries carry blood away from the heart, and veins carry blood towards the heart. Generally, arteries carry oxygenated blood, but in the case of the pulmonary circulation the role of arteries and veins are reversed; the pulmonary arteries carry the deoxygenated blood away from the heart to the lungs.

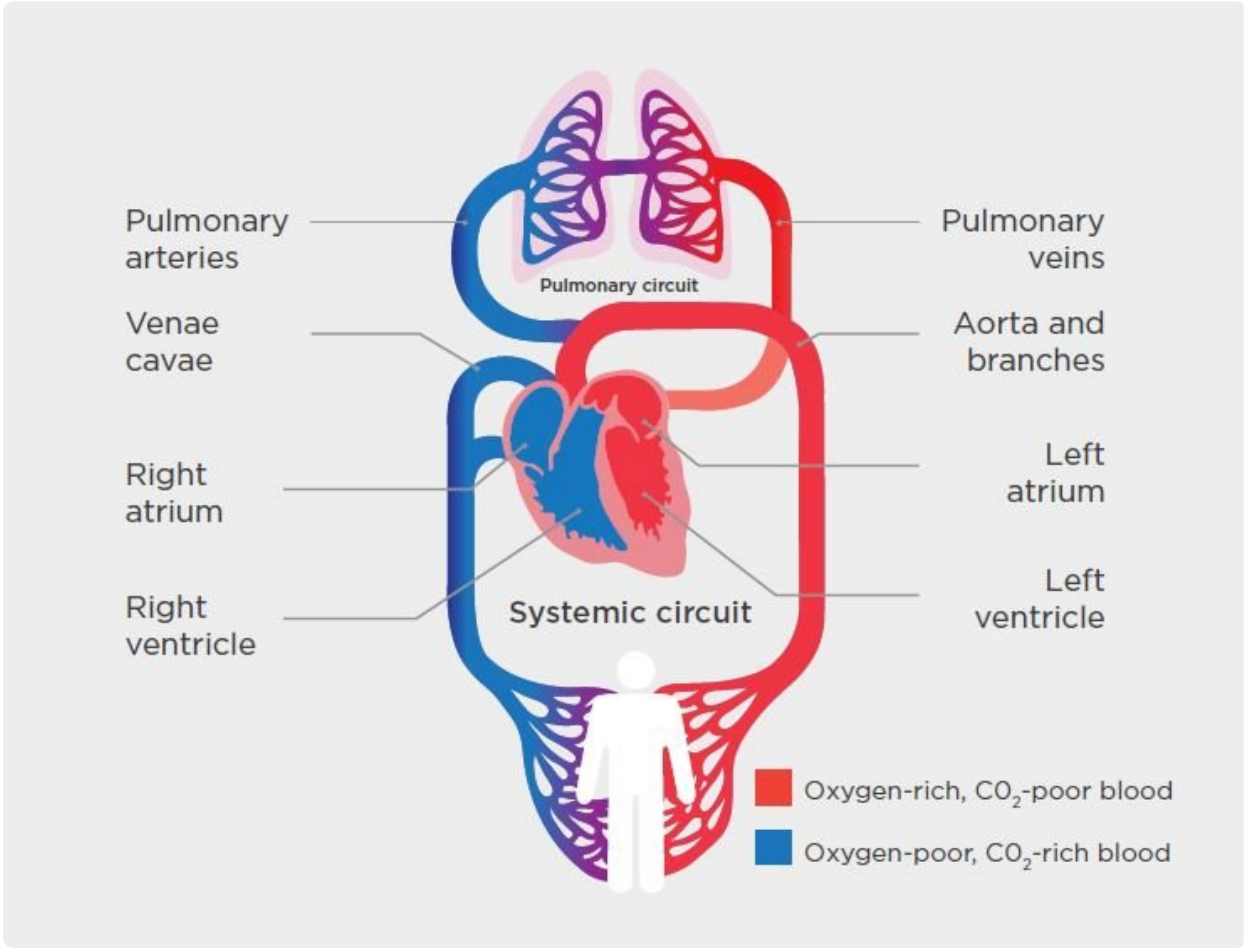
1.2.14 There are two pairs of pulmonary veins and a single pair of pulmonary arteries. This means that a blockage in a pulmonary artery can cause total occlusion (a complete blockage) and sudden death.

1.2.15 The disease process of pulmonary embolism (PE) is complex. The way the PE can affect the patient ranges from mild symptoms through to sudden cardiac arrest.

1.2.16 The impact on the patient is grouped into three areas:

- mechanical occlusion (physical blockage of the vessel by the clot)
- chemical mediators (effect caused by chemical changes)
- haemodynamic impact (the impact on blood flow to the tissues).

Figure 4: The pulmonary and systemic circulation systems



Diagnosis of PE

1.2.17 The diagnosis of PE begins with obtaining a history from the patient and carrying out a physical examination, considering any evidence of DVT. There is a specific version of the Wells scoring system for predicting PE (the PE Wells Score) which is detailed in the National Institute for Health and Care Excellence's 'Guidance for venous thromboembolic diseases: diagnosis, management and thrombophilia testing' (National Institute for Health and Care Excellence, 2012) for VTE.

1.2.18 Other more specific imaging investigations (X-rays and scans) and an electrocardiogram (ECG) may also be used to support the diagnosis of PE.

1.3 Treatment of VTE

1.3.1 The aim of treating VTE is to restore blood flow to the affected areas and to prevent further clot formation. Anticoagulation medicines are used to change the clotting factors in the blood making clots less likely.

1.3.2 For clots which already exist, medicines known as thrombolytics can be used to try to break down the clot. This technique was used extensively in the treatment of heart attacks, which are also caused by clots.

1.3.3 Some patients, particularly those with a large pulmonary embolism, may have the clot removed using a technique called pulmonary thrombectomy.

1.4 Complication of stroke care relating to VTE

1.4.1 Patients admitted to hospital with stroke, either ischaemic or haemorrhagic, are likely to have the risk factors for developing VTE as an inpatient. Medication which can reduce the likelihood of developing a VTE is usually contraindicated for these patients.

1.4.2 There are other strategies to reduce the risk of VTE, including early mobilisation of patients (activity such as sitting out of bed, standing and walking) and/or the use of intermittent pneumatic compression (IPC) devices (see 1.5).

1.5 Intermittent pneumatic compression (IPC) devices

1.5.1 IPC devices (Figure 5) are the recommended mechanical thromboprophylaxis (method of thrombosis prevention) for patients that have had an acute stroke (CLOTS (Clots in Legs or sTockings after Stroke) Trials Collaboration, 2015). Unlike low molecular weight heparins (LMWH: a form of anticoagulant medicine), IPC devices are indicated for use in all immobile patients who have had a stroke (haemorrhagic and ischaemic). They are cuffs which fit around the lower and upper leg and are fed by an electric air compressor. The cuffs inflate and deflate

according to a predetermined programme and assist the venous return of blood to the heart in immobile patients. Mobile patients do not require IPC devices because this function is carried out by the leg muscles.

Figure 5: Intermittent pneumatic compression (IPC) devices fitted to a patient



Image reference: 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.

1.6 Hospital admission

1.6.1 The hospital admission process captures information about patients including details such as their GP practice, patient demographics, social context, individual requirements, health history, medications and medical devices (Professional Record Standards Body, 2018).

2 The reference event

2.1 At 21:15 hours on a Sunday evening (day 1), a 78-year-old woman was walking into her dining room at home when she collapsed to the floor and became unresponsive. The patient's husband heard her fall and tried to rouse her. When he could not, he dialled 999 for an ambulance. Upon their arrival, the ambulance crew assessed the patient. The crew recorded that she appeared pale and decided to conduct an electrocardiogram (ECG). They documented that her heart was beating normally but noted that there were occasional extra beats. When they moved the patient her blood pressure fell, which was resolved by elevating her legs and

commencing fluid therapy (giving intravenous fluids). The ambulance crew used the Glasgow Coma Scale [1] to assess the patient's level of consciousness and recorded an initial score of 9 out of 15, which worsened to 8 out of 15 while the crew were on scene. Prior to this episode of illness, the patient, who lived at home with her husband, had led an independent and active life. She had high blood pressure (hypertension) and high cholesterol for which she was taking an anti-hypertensive medication and a cholesterol lowering drug daily.

2.2 The patient's husband told the ambulance crew that she had experienced a number of fainting episodes over the last few months, which the crew recorded as being potential episodes of transient ischaemic attack (often referred to as a mini stroke caused by temporary interruption of blood supply to the brain). The crew were able to identify her signs and symptoms as being consistent with a stroke, requiring urgent treatment in hospital. While on the way to the hospital with the patient, the crew alerted the emergency department (ED) that they were bringing in a patient with a suspected stroke. The ED then informed the oncall acute stoke nurse (ASN), who made their way to the resuscitation room within the ED.

2.3 The ambulance arrived at the hospital at 22:21 hours and the crew took the patient to the resuscitation room. They were met by the ASN who, along with the medical team, initiated the Trust's stroke assessment and treatment protocol. The patient underwent a CT (computerised tomography) brain scan at 23:01 hours which supported a working diagnosis of an ischaemic stroke (a stroke caused by a clot rather than a bleed) and facilitated immediate treatment. Following this, the patient was admitted to the Hyper-Acute Stroke Unit (HASU) and admitted to the ward by a doctor. He discussed the treatment options available to him with the on-call consultant on the telephone, who agreed for the medical team to proceed with thrombolysis (giving the patient a clot-busting drug which aims to disperse the clot and return the blood supply to the brain). The doctor formulated a treatment plan which included prescribing the thrombolytic drug as per the stroke protocol, along with the administration of IV (intravenous) fluids, assessment by a speech and language therapist (SaLT), followup CT scan the next day, a review by the stroke team and a medicines review, leading to stopping the anti-hypertensive medicine.

2.4 The CT scan was reviewed by a radiologist, who provided a report to the doctor on the HASU at 23:48 hours. With the diagnosis now confirmed, the doctor initiated the administration of the initial 9mg intravenous dose (10% of the overall dose) of the previously prescribed alteplase. This was administered at 00:06 hours on Monday (day 2). The patient remained on the HASU and received the remaining 90% of the prescribed dose of alteplase (77mg) over one hour commencing at 00:10 hours.

2.5 The HASU's nurse in charge was also the ASN who initiated the Trust's stroke protocol when the patient arrived in the ED. She became aware that at the time the patient was clerked (part of the ward admission process) onto the ward, her venous thromboembolism (VTE) risk

assessment had not been carried out. The nurse in charge then recorded in the comments section of the nurse in charge checklist that there was ‘1xVTE outstanding’, referring to the patient.

2.6 The patient was seen on the HASU by her designated stroke consultant at 08:00 hours on day 2. The consultant reviewed the diagnosis and the treatment of the acute ischaemic stroke and to initiate further assessment and therapy.

2.7 The SaLT started an initial assessment of the patient at 09:25 hours that morning. The SaLT recorded in the patient’s notes that the patient was ‘drowsy but did not open eyes, no attempt to follow command ... offered tspn [teaspoon] fluid. No attempt to lip seal.’ The SaLT concluded ‘that the patient was unsafe for oral intake and that the medical team should manage her nutrition as appropriate’.

2.8 Later that morning (time unknown) the patient’s case was reviewed during the consultantled ward round. The review documented that the ‘patient in bed appears comfortable’ and also stated that she had rightsided weakness, visible rightsided facial droop and aphasia (inability to speak). The medical team documented the following ongoing plan for the patient over the next 24 hours:

- chest X-ray
- repeat of CT scan
- echocardiogram (heart scan)
- nasogastric tube insertion (tube passed into the stomach to allow the provision of nutrition in patients who are unable to swallow safely)
- assessment by an occupational therapist and physiotherapist
- intravenous fluids.

2.9 At an unknown time on day 2 a bladder scan was performed, due to the patient not passing urine. The scan showed that she had 663ml of urine in her bladder, which she was not able to pass due to her stroke. Therefore, it was decided that she needed to be fitted with a urinary catheter.

2.10 At 11:00 hours a foundation year two (FY2) doctor conducted the Trust’s initial VTE and bleeding risk assessment. They documented that the patient’s ‘risk of bleeding greater than risk of VTE therefore does not require Enoxaparin [2]’ (National Institute for Health and Care Excellence, 2018) and decided that low molecular weight heparin (LMWH) was not a suitable treatment. LMWH is contraindicated due to an increased risk of bleeding into the damaged area of the brain. This was because of the presence of an ischaemic stroke. The VTE and bleeding risk assessment form records that, for stroke patients, intermittent pneumatic compression

(IPC) devices should be fitted to the patient's legs (full length encompassing calves and thighs) 'unless contraindicated'. The requirement for the IPC device was not transferred to the patient's prescription chart [3], which is the Trust's method for prescribing this and other, non-pharmacological and non-formulary, items [4]. The Trust also had an additional Stroke Unit VTE risk assessment with a pathway for fitting IPC devices, however this was not completed.

2.11 At 13:20 hours a physiotherapist positioned the patient on the edge of her bed and noted she had 'independent sitting balance but fatigued [therefore] transferred back into bed'. The subsequent physiotherapist assessment resulted in the initial rehabilitation goals for the patient of sitting out in a high-backed chair and, in due course, standing.

2.12 From day 2 until day 20, the patient remained on the HASU as she had a total arterial circulation infarction leading to malignant middle cerebral artery syndrome, (a swelling of the brain around the site of the stroke, which is a potentially fatal complication of severe stroke) and therefore required close monitoring. She was seen daily on the consultant ward round and for the majority of the time was either sitting in a chair or laid in bed. In addition to the daily consultant ward rounds, she had daily rehabilitation sessions with a physiotherapist and/or occupational therapist, which focused on improving sitting, standing, walking with assistance and daily living tasks such as washing, drinking and so on. Each rehabilitation session lasted for approximately 45 minutes. Throughout this period, the ward staff considered the patient not to be independently mobile as she was not able to walk to the toilet without the assistance of another person. During the daily therapy sessions, the patient was walking up to 40 metres with assistance. On day 14 the patient walked 30 metres with the assistance of one physiotherapist.

2.13 On day 15 a physiotherapist found the patient 'slumped' over her table. The physiotherapist immediately called the doctors who assessed the patient and diagnosed her with dehydration and a urinary tract infection (UTI). The patient was treated with intravenous fluids and antibiotics.

2.14 On day 16, during a therapy session, an occupational therapist (OT) noted that the patient was experiencing shortness of breath while sitting on the edge of the bed. This was the first documented episode in the patient's notes of shortness of breath which was then verbally alerted to a doctor; there was no response recorded in her medical record by the medical team. The next day, the same OT visited the patient and found that she was still experiencing shortness of breath on exertion. This episode was also escalated to a doctor and documented in the patient's notes at 14:30 hours on day 17. During the consultant ward round on the same day, it was documented that the patient had a suspected pulmonary embolism (PE), was dehydrated and had a UTI; her oxygen saturations were 95% on room air, which was within the expected range. The patient's notes recorded that the consultant requested a computerised tomography pulmonary angiogram (CTPA) to confirm the diagnosis of a potential PE. At the point of suspicion of the PE no treatment was initiated.

2.15 The requested CTPA was carried out on day 19 at 18:30 hours. It showed a ‘pulmonary emboli including saddle embolism’ and the report was sent to the HASU immediately afterward. On day 19, a junior doctor prescribed a treatment dose of low molecular weight heparin (LMWH), dalteparin, which was used to prevent and treat VTE. This was administered subcutaneously (via an injection under the skin) at 08:00 hours on day 20. The investigation was not able to determine from the patient’s notes at what time the LMWH was prescribed.

2.16 On day 20, the stroke team referred the patient to the Medical High Dependency Unit (MHDU) as they felt she would benefit from closer monitoring over the weekend. At this time the patient was also diagnosed with ‘atrial flutter’ and the relevant tests were requested, however the patient’s notes recorded that she ‘looks well – alert’.

2.17 During the consultant ward round on the MHDU, the consultant identified that no IPC devices had been fitted throughout the patient’s stay on the HASU. The clinical team completed an incident report form which subsequently initiated a Trust serious incident investigation. The consultant also recognised that the second VTE risk assessment had not been completed on day 3 as per Trust policy, so completed this at 16:30 hours on day 20.

2.18 On day 25, the patient was transferred from the MHDU to the Stroke Unit where she continued to receive rehabilitation and stroke care. She was receiving daily doses of dalteparin to treat her PE, which was changed to an oral anticoagulant prior to discharge. On day 53 the patient was discharged home, where she continued to receive care from the community rehabilitation team.

3 Involvement of the Healthcare Safety Investigation Branch

3.1 Referral of reference incident

3.1.1 Following a review of the Strategic Executive Information System (StEIS), the NHS central serious incident reporting system, the Healthcare Safety Investigation Branch (HSIB) identified issues associated with inpatient stroke care. HSIB identified a reference event relating to a patient who had an ischaemic stroke and developed a pulmonary embolism (PE). An intelligence review report was written and presented at an HSIB Scrutiny Panel meeting where the decision was made to launch a scoping investigation.

3.1.2 The focus of the scoping investigation was to understand the management of venous thromboembolism (VTE) risk for patients following thrombolysis for an acute stroke.

3.2 Decision to investigate

3.2.1 Based on the evidence gathered during the scoping investigation, the safety issues represented by the reference event met the criteria for a national investigation, which HSIB's Chief Investigator authorised.

3.2.2 A summary of the analysis against HSIB's investigation criteria follows:

Outcome impact – What was, or is, the impact of the safety issue on people and services across the healthcare system?

- If measures known to reduce the risk of VTE are not applied, patients who have had a stroke and are immobile are at high risk of developing a deep vein thrombosis. This may lead to a PE which can be fatal.

Systemic risk – How widespread and how common a safety issue is this across the healthcare system?

- The safety issue impacts all specialist stroke units and other wards where stroke recovery is managed in the NHS. It may also impact patients who are immobile for other reasons where pharmacological thromboprophylaxis (drug treatment to prevent a thrombosis) is contraindicated.

Learning potential – What is the potential for an HSIB investigation to lead to positive changes and improvements to patient safety across the healthcare system?

- Despite national guidelines being in place relating to the management of VTE in patients that have had a stroke, incidents of harm continue to occur. For example, intermittent pneumatic compression (IPC) devices, which are shown to be an effective method of reducing the risk of VTE and improving survival in patients who are immobile after a stroke, are not routinely fitted. National audits have shown that there is a low compliance rate for fitting IPC devices.

3.3 Timescale

3.3.1 The investigation was completed between October 2018 and February 2020.

3.3.2 Investigative approach

3.3.2.1 HSIB does not seek to apportion blame or liability in its investigations. It considers the healthcare system in its entirety to identify the factors that have contributed to the reference event.

3.3.3 Investigation team

3.3.3.1 The HSIB investigation team members were from a range of backgrounds including: • healthcare systems • engineering and human factors • clinical and non-clinical subject matter advisors (SMAs).

3.3.4 Engagement with those involved in the reference event

3.3.4.1 The patient and her husband were contacted and interviewed to establish their perspective on the reference event. The staff directly involved in the reference event were interviewed and included:

- three Hyper-Acute Stroke Unit nursing staff (including clinical nurse specialists and acute stroke nurses)
- three consultant stroke physicians
- one consultant respiratory physician
- one consultant haematologist
- two VTE nurse specialists
- two therapy team members
- two Stroke Unit support staff.

3.3.5 National Investigation

3.3.5.1 Following the scoping investigation, HSIB analysed the evidence gathered and identified the potential for national learning. The following safety risks were identified:

- There is no proactive, stroke-specific, VTE assessment management programme to monitor VTE assessments and no check that the requirements and recommendations that result from an assessment have been undertaken.
- There is a low compliance rate of fitting IPC devices to patients who have had a stroke.

3.3.5.2 The identification of these issues led to a decision to broaden the investigation and identify healthcare settings to collect further information to understand the national context.

3.3.6 Stakeholder engagement

3.3.6.1 Stakeholders across the healthcare system were identified to seek their perspective on the management of VTE in stroke care, these included:

- NHS England and NHS Improvement Clinical Policy Unit
- NHS England and NHS Improvement Patient Safety Team

- National Institute for Health and Care Excellence
- Sentinel Stroke National Audit Programme
- Royal College of Physicians
- Royal College of Nursing
- Royal Pharmaceutical Society
- consultant haematologists
- consultant stroke physicians
- Professional Records Standards Body.

3.3.7 Evidence gathering

3.3.7.1 Evidence was gathered and reviewed by the investigation, including:

- the patient's clinical records
- the Trust's policies, procedures and practice
- relevant incidents reported to StEIS and the National Reporting and Learning System
- national guidelines and standards
- observation visits
- literature relevant to the identified safety risks.

3.3.7.2 The evidence gathering process adopted an iterative approach; as further information was gained, additional sources were identified. The investigation gathered both interview and observational evidence from the healthcare settings.

3.3.8 Analysis

3.3.8.1 The analysis process had the following aims:

- to develop an understanding of the healthcare systems directly relating to the patient's care
- to create a timeline of the events, analysing communications, interactions and decision making
- to develop safety recommendations to mitigate the risks at a national level.

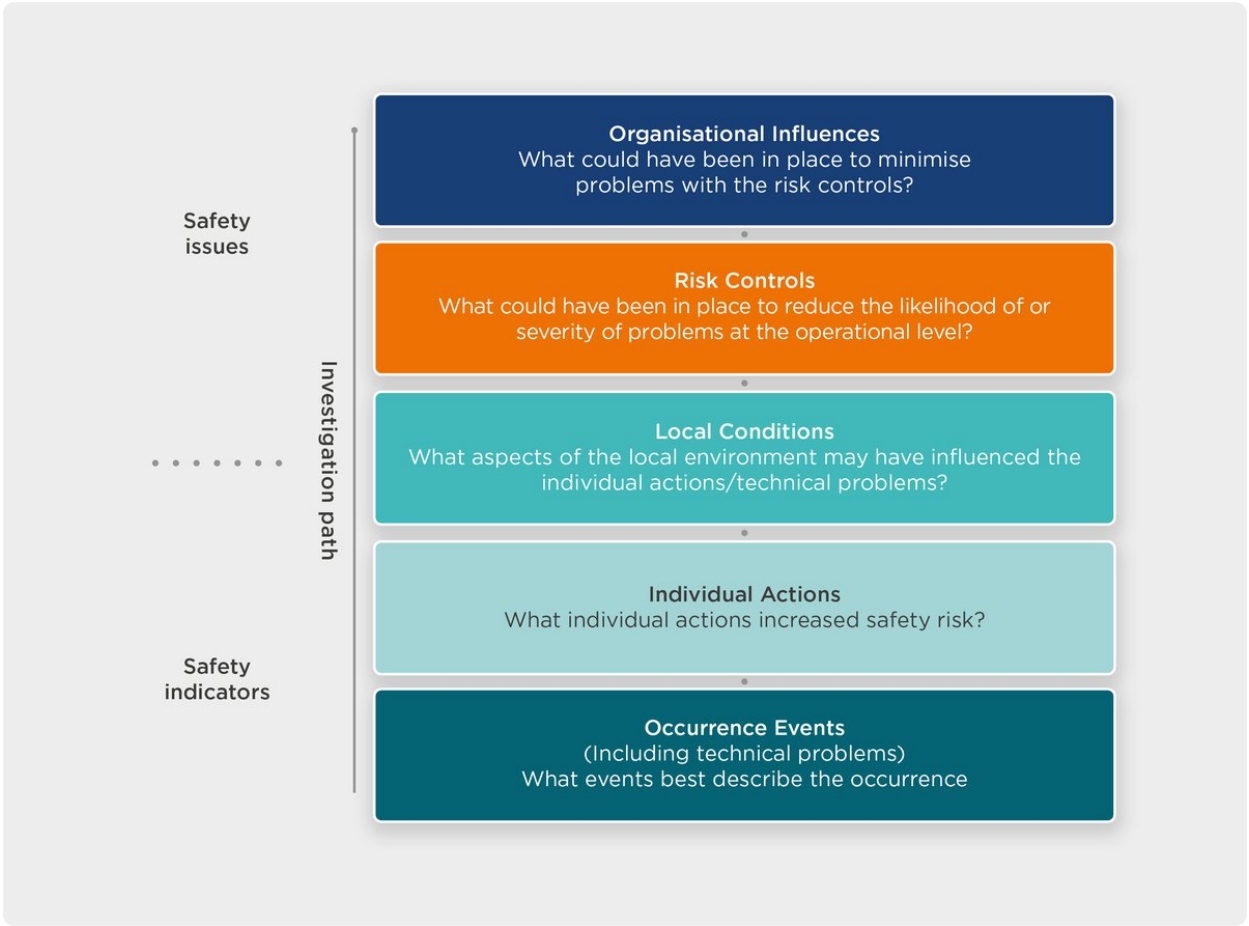
3.3.8.2 These aims were achieved through the application of the Australian Transport Safety Bureau (ATSB) accident investigation model (Australian Transport Safety Bureau, 2008) (Figure 6). The ATSB model provides a general framework that can guide evidence collection and analysis activities during an investigation. The model represents the operation of a system via

five levels. The first three levels correspond to ‘safety indicators’ dealing with the individual or local aspects of an accident/event. The upper two levels address ‘safety issues’, that is, safety factors associated with organisational or systemic issues.

3.3.9 Stakeholder consultation

3.3.9.1 The findings were shared with the stakeholders identified by the investigation. This enabled checking for factual accuracy and overall sense-checking. The stakeholders contributed to the development of the safety recommendations based on the evidence gathered.

Figure 6: Australian Transport Safety Bureau accident investigation model (2008)



4 Findings and analysis – the reference event

4.1 National guidelines

4.1.1 At the time of the reference event, the preventative treatment options for venous thromboembolism (VTE) in hospitals were varied and included mechanical and chemical methods for thrombosis prevention (thromboprophylaxis). When an ischaemic stroke patient has received thrombolysis (see 1.1.10) there were limited treatment options available.

Thrombolysis increases the risk of haemorrhage, therefore chemical thromboprophylaxis was contraindicated. The National Institute for Health and Care Excellence (NICE) guideline NG89 (National Institute for Health and Care Excellence, 2018) recommends the use of intermittent pneumatic compression (IPC) devices as a VTE preventative measure.

> "There appears to be a lack of clarity in the use of the term ‘Risk Assessment’ combined with role ambiguity and under-specification of the roles of team members."
>
> Human factors and ergonomics subject matter advisor

4.2 Trust policy

4.2.1 The Trust’s overarching VTE policy, which reflects national standards (NHS England, 2018) was for all inpatients to receive a VTE risk assessment within 12 hours of admission (national guidance states within 24 hours). This policy applied to all inpatients admitted regardless of the type of admission (unplanned or planned) or the reason for admission. A second risk assessment was to be conducted after 24 hours. NICE guideline NG89 (National Institute for Health and Care Excellence, 2018) states that further VTE risk assessments were required if the patient’s clinical condition changed.

4.2.2 There was a national quality requirement in place at the time of the reference event for 95% of patients to have a VTE risk assessment ‘as soon as possible after admission’ (NHS Improvement, 2018). This was a contractual requirement and was to be reported to commissioners on a monthly basis and entered into a national database that was monitored by NHS England and NHS Improvement. If a trust did not achieve the target, fines could be applied by the clinical commissioning group (CCG) that managed the contract with the trust. In the reference event the Trust achieved its own target for risk assessment on admission (at ‘clerking’ but no later than 12 hours after admission), but in this case it did not lead to the patient receiving the appropriate VTE preventative measure. The Trust’s overarching VTE policy provided conflicting information about when the VTE risk assessment should be carried out. In one part it states ‘Within 12 hours of admission to the Trust’ and in another ‘The VTE and Bleeding Risk Assessment Tool must be completed in full, dated and signed by the Medic or designated Registered Nurse on admission’.

4.2.3 The investigation identified that the contractual requirement for VTE risk assessments was leading to a focus on meeting the target rather than conducting a quality VTE risk assessment. The Trust’s overarching VTE policy did not define an assurance process to ensure that VTE risk assessment actions were carried out.

4.2.4 In the reference event, after the patient received the immediate care that she needed, she received her first VTE risk assessment on the Hyper-Acute Stroke Unit (HASU) in line with both the Trust policy and national quality requirement (NHS Improvement, 2018).

4.2.5 The second VTE risk assessment, which the Trust required to be undertaken within 24 hours of admission, was not completed until after the patient's pulmonary embolism (PE) was diagnosed (20 days after admission). This second VTE risk assessment was not subject to the same internal monitoring and external reporting as the initial VTE risk assessment.

4.2.6 In addition to the Trust VTE risk assessment form, the Stroke Unit had further documents to be completed for patients admitted with an acute stroke. One of these documents was the 'Stroke Integrated Care Pathway' record and the other was the 'Intermittent Pneumatic Compression (IPC) use in stroke patients guideline', which had an additional VTE assessment form. In the reference event, during the patient's stay neither the IPC element of the Integrated Care Pathway record or the VTE assessment form and associated care plan were completed.

4.2.7 The investigation observed that when the 'Intermittent Pneumatic Compression (IPC) use in stroke patients guideline' (locally referred to as the "Stroke Unit VTE assessment") was followed, the intended outcome was to decide whether the IPC device should be 'written up' on the patient's prescription chart and fitted. The decision was dependent on the inclusion and exclusion criteria set out in the form (for example, skin breakdown on the lower legs would exclude fitting an IPC device). Therefore, the investigation observed that the Stroke Unit's VTE assessment form was in fact an IPC device assessment. The assessment was intended to lead to the application of IPC devices to reduce the risk of VTE. It was not possible to determine if the 'Intermittent Pneumatic Compression (IPC) use in stroke patients guideline' was followed in the reference event.

4.2.8 Due to the fact that there were multiple forms in place and there were overlaps in the stated purpose of these forms, the investigation observed that this could have led to confusion, which in turn could have led to patients not receiving the correct treatment. There was no overarching standard operating procedure that defined which forms should be completed by which staff and when. This would have been particularly useful for staff who are not familiar with the environment, such as locum doctors and junior doctors on rotation.

4.3 VTE risk assessment

4.3.1 The Trust's overarching VTE policy required the use of its VTE risk assessment form (which was designed by the Trust and based on the Department of Health's template contained within NICE guideline NG89 (National Institute for Health and Care Excellence, 2018). The

stated purpose of this form was to give the medical team a way to assess a patient's VTE and bleeding risk. The investigation's human factors and ergonomics (HFE) subject matter advisor (SMA) concluded:

'Although titled 'VTE and Bleeding Risk Assessment', it is a decision flowchart that leads to a treatment recommendation (a risk assessment leads to an assessment of risk whereas a decision flowchart leads to a decision).'

The investigation observed that the 'VTE and Bleeding Risk Assessment' form was not a risk assessment tool, despite its title, as it did not describe the VTE risk that the patient was exposed to.

4.3.2 In relation to the Trust's overarching VTE risk assessment form (Figure 7), the investigation observed that:

- the proforma was not structured to create a record of a patient's specific risk factors relating to VTE or bleeding risk
- there were two risk assessments (initial and within-24-hours risk assessments) on one form but only space to document one treatment outcome
- the form was intended to cover all inpatients, but it was less relevant to stroke patients in the early/ acute phase of their admission
- it was designed as a flowchart, but the user can end up with no treatment option
- the proforma doesn't fulfil the purpose statement in the Trust's policy
- policy states that the risk assessment must be completed within 12 hours, whereas the form states it should be done on 'clerking' (part of the admissions process).
- the proforma gave options for VTE prevention methods which included prescribing low molecular weight heparin (LMWH), application of antiembolism stockings or application of IPC devices.

Figure 7: Reference event Trust's 'VTE and bleeding risk assessment' form

Patients who are at risk of VTE

Triggers for medical inpatients

1. If mobility significantly reduced for 3 days or
2. If reduced mobility relative to normal state plus any VTE risk factor (below).

Triggers for surgical patients and trauma Inpatients

1. If total anaesthetic + surgical time > 90 minutes or
2. If surgery involves pelvis or lower limb and total anaesthetic +surgical time > 60 minutes or
3. If acute surgical admission with inflammatory or antra-abdominal condition or
4. If Inpatient & expected to have significant reduction in mobility Or L if Inpatient and any VTE risk factor (below) Is present

VTE risk factors

- Active cancer or cancer treatment
- Age > 60 years
- Critical care admission
- Dehydration
- Known thrombophilias
- Obesity (BM > 30 kg/m?)
- One or more significant medical comorbidities (eg: heart disease; metabolic. endocrine or respiratory pathologies; acute infectious diseases; inflammatory conditions)
- Personal history or first degree relative with a history of VIE
- Use of oestrogen - containing contraceptive therapy
- Varicose veins with phlebitis

4.3.3 During discussions with nurses at the Trust, staff told the investigation that there were other considerations that needed to be taken into account when deciding whether or not to fit IPC devices. Nurses and therapists were concerned that a patient who was ‘confused’ as a result of their stroke could try to get out of bed; if IPC devices were fitted, this could increase their risk of falling. This was because the IPC devices are connected via tubes to a compressor,

effectively limiting patients' mobility and creating a trip hazard. The Trust's VTE risk assessment did not consider these issues and therefore did not provide an opportunity to carry out a complete assessment of the treatment options.

4.4 The VTE risk assessment process

4.4.1 The VTE risk assessment process was defined in the Trust's overarching VTE policy and required all doctors to complete a proforma. The purpose of the process was to act as a decision aid to identify treatment options to mitigate any identified VTE or bleeding risk. Staff told the investigation that the VTE risk assessment was usually undertaken when a patient was admitted as part of the admission process, as required by the Trust's overarching VTE policy. A locum doctor admitted the patient but omitted to carry out the VTE risk assessment at that time. The nurse in charge of the ward recognised this fact and wrote it in the nursing handover proforma so that it could be addressed on the next shift. The nurse in charge of the following shift spoke to the medical team about the VTE risk assessment not being completed.

4.4.2 The first VTE risk assessment was undertaken at the next consultant ward round, the morning after the patient's admission, by a junior doctor. This was within 12 hours, in compliance with both Trust policy and NICE guidelines. The patient was at high risk of bleeding following thrombolysis to treat her acute stroke, therefore low molecular weight heparin (LMWH) was contraindicated, and antiembolism stockings have been shown to be ineffective for stroke patients (CLOTS (Clots in Legs Or sTockings after Stroke) Trials Collaboration, 2013). This meant that the only thromboprophylactic measure available to the patient was the application of IPC devices. The junior doctor indicated this selection on the VTE risk assessment form, but the prescription was not 'written up' on the patient's prescription chart; it is unclear why this did not happen. In the opinion of the HFE SMA:

'… although the assessment was conducted and logged, the final step to complete the task – to write the requirement to apply the IPC device on the prescription chart was not carried out and the device was not applied. This may have been due to a lack of familiarity with the VTE Policy or simply a lapse of attention (Health and Safety Executive, 2009).'

> “Although the VTE Policy instructs the medic [doctor] to write the IPC requirement on the prescription chart, the decision flowchart on the VTE assessment form does not.
>
> Lacking a salient cue to bring the task to a successful conclusion, completion of the admin may have become a self-satisfied goal that ended the task prematurely. This suggests that there was a mismatch between the instructions given in the policy, the design of the flowchart and the requirements of the task. This mismatch may have been made more likely by use of the term ‘risk assessment’ to describe the process guided by the VTE form since a risk assessment does not, in itself, lead to any subsequent actions.”
>
> Human factors and ergonomics subject matter advisor

4.4.3 The Stroke Unit had additional documentation for the assessment of VTE risk and IPC devices. This documentation was not used for the patient in the reference event.

4.4.4 For the IPC devices to be applied, the Trust’s overarching VTE Policy was for the doctor who conducted the VTE risk assessment to write the requirement for IPC devices on the patient’s prescription chart. Following this, a member of the nursing team would then measure and fit the appropriate devices. The expectation was that the IPC devices should be fitted once the VTE risk assessment had been carried out, and no later than 72 hours after admission (National Institute for Health and Care Excellence, 2018). Doctors told the investigation that they recognised it was the role of a doctor to write up the IPC devices on the prescription chart following the risk assessment, but they all questioned the need for this step. They felt that once the requirement for IPC devices was identified by a doctor on the VTE risk assessment form, nurses should have been able to apply the IPC devices without the requirement being ‘written up’ on the prescription chart.

4.4.5 The nurse in charge, who prompted the missed VTE risk assessment to be completed, told the investigation that she recognised that IPC devices were identified as being required on the VTE risk assessment form. However, due to the fact they had not been recorded on the prescription chart the nurses could not apply them. The nursing team told the investigation that the IPC devices were a prescription item and therefore nurses would not be able to write them on the prescription chart or fit them until a doctor had prescribed them.

4.4.6 Staff told the investigation that there was a “tick box culture” on the ward and within the wider Trust, with a focus on the steps required to confirm completion of the task (undertaking the VTE risk assessment), but that this did not necessarily lead to the required action being completed (in this case, the IPC devices being ‘written up’ and fitted). This was further confirmed when the investigation spoke to members of the Trust’s VTE team, who confirmed

that there was a focus on complying with the national VTE risk assessment standards (NHS England, 2016). The VTE team told the investigation that there was no internal audit process that checked the VTE risk assessment against the treatment that the patient received.

> In the opinion of the human factors and ergonomics specialist, the focus on compliance with standards through administrative action may act as a substitute goal that displaces the delivery of care, bringing the task to an end prematurely (Norman, 1984).

4.5 Prescription chart

4.5.1 The Trust‘s overarching VTE policy set out the requirement for recording IPC devices on the prescription chart. Medical, nursing and therapy staff told the investigation that they did not know the reason behind documenting the requirement for IPC devices on the prescription chart (as opposed to any other place in the patient’s notes). In the CLOTS3 trial (CLOTS (Clots in Legs Or sTockings after Stroke) Trials Collaboration, 2013) IPC devices were written on the prescription chart three times a day to provide auditable data and ensure they were checked regularly. The investigation spoke to pharmacy staff who stated that it had become common practice to add non-formulary [5] items to the prescription chart (for example IPC devices and food thickeners [6]). The pharmacy team had no direct oversight of these items or responsibility for their dispensing or application. This further reduced the opportunity to ensure that IPC devices were fitted, as the pharmacy team did not check compliance with non-formulary items when conducting ward rounds.

4.5.2 The Trust’s overarching VTE policy stated that the doctor carrying out the VTE risk assessment ‘must ensure’ that IPC devices were written on the prescription chart [7]. The policy did not define IPC devices as a formulary item, and while the Trust’s senior pharmacists were aware of the use of the prescription charts to record IPC devices and other non-formulary items, they had not been engaged in the design of the process. The pharmacist on the stroke ward told the investigation that the prescription chart was an ‘intent to administer’ a medicine (and a place to record administration), rather than a prescription against which medicines were to be dispensed. The investigation observed that the prescription chart had morphed into a written prescription and a record of administration of formulary items, non-formulary items and medical devices. Recording IPC devices on the prescription chart was the penultimate step prior to fitting them and if this step was missed it could increase the chance of them not being fitted.

4.5.3 While the generic Trust VTE policy states that the ‘Medic [doctor] must ensure if mechanical or chemical prophylaxis is required that the prescription chart is written to reflect the treatment regime’, it does not require the doctor to check that prophylaxis is given. Furthermore, the policy states:

‘Once completed the VTE and Bleeding Risk Assessment (paper document) must be placed in the patients’ medical records. On completion the VTE and Bleeding Risk Assessment must be logged on the [electronic] system. This is the responsibility of the Registered Nurse in the ward/ department.’ In neither case does the policy require either the doctor or the nurse to fit the IPC device or check that it has been fitted if prescribed on the treatment board.

4.5.4 The prescription chart used in the reference event had a section titled ‘Regular Anticoagulants’ which contained a place to record ‘VTE Risk assessment carried out Y/N’. This was accompanied by the details of the person carrying out the VTE risk assessment. Despite the need for doctors to write IPC devices on the prescription chart, there was not a dedicated pre-printed IPC device section in ‘Regular Anticoagulants’ to record the possible actions resulting from that assessment. In the reference event, there were no details entered in this section and it seemed that the prescription chart was another place that the VTE risk assessment should have been documented.

> “… the chart was variously described as a ‘Medication Chart’, ‘Prescription Chart’, ‘Drug Chart’ or ‘Treatment Board’. During a visit to an acute teaching hospital, the chart was described as the ‘Inpatient Board’. In the reference case, only ‘Treatment Board’ seems correct since it lists the treatments that are intended to be delivered.”
>
> Human factors and ergonomics subject matter advisor

4.5.5 The requirement for IPC devices was not recorded on the prescription chart and therefore no staff member had the written instruction to fit them. There was no cross-reference between the ‘Regular Anticoagulants’ section in the prescription chart and the VTE risk assessment form, nor was there a prompt to ensure that the requirement for IPC devices was recorded. This was the only way a nurse would have known to fit IPC devices and the lack of instruction likely led to the IPC devices not being fitted.

> “It seems likely that the nurses did not consider that they had the necessary authorisation to fit the IPC device. If the nurses had not seen the complete VTE risk assessment form, they may have assumed that IPC was therefore contraindicated. Given that the VTE risk assessment was not repeated within 24 hours, any such assumptions would have remained unchallenged.”
>
> Human factors and ergonomics subject matter advisor

4.5.6 In the reference event, the patient's prescription chart contained several entries of food thickeners and bladder wash-out procedures [8]; neither of these items required a prescription (non-formulary items). These had been added to the prescription chart by a non-prescribing SaLT and by doctors. The investigation observed that lack of clarity on what can be recorded on the prescription chart and how it is documented could have led to missed or incorrect prescriptions.

4.5.7 The pharmacist covering the Stroke Unit reported situations where a patient had food thickeners added to the prescription chart and on discharge these were not reconciled in the Treatment to Take Away/Out (TTA/TTO) prescription. As a result, the patient had gone home without any food thickeners and had an episode of aspiration (where food or drink fails to be swallowed and enters the lungs instead of the stomach – this can cause infection or other damage to the lung structure and/or function).

4.6 Mobility

4.6.1 If a patient is completely immobile or has reduced mobility, the muscular action of moving (for example, walking and standing) which assists blood flow from the deep veins in the legs is reduced. This can lead to clot formation in the deep veins of the legs (deep vein thrombosis (DVT)) and therefore patients are also at risk of developing a pulmonary embolism (PE) should any part of that DVT break off and become lodged in the pulmonary circulation (see 1.2.3).

4.6.2 During the first 12 to 24 hours following admission the patient involved in the reference event was almost completely immobile as a result of her stroke. Twenty-four hours after thrombolysis her neurological condition had improved but she was left with reduced mobility that lasted several weeks and she could not walk unaided.

4.6.3 During her stay on the HASU, in the daytime when she was not undergoing therapy, the patient was either lying in bed or out of bed and sitting in a chair. She received daily therapy from occupational therapists and physiotherapists, each lasting approximately 45 minutes per session, with varied amounts of mobilisation. By day 14 the patient had progressed with therapy to the extent that she could walk up to 40 metres with the assistance of one therapist.

4.6.4 The patient was not completely "immobile", however, she met the CLOTS3 definition of immobile and therefore remained indicated for IPC devices. The CLOTS3 definition of immobility is 'immobile (i.e. unable to walk independently to the toilet)'. (CLOTS (Clots in Legs or sTockings after Stroke) Trials Collaboration, 2015). Despite this ongoing reduced mobility, at no time during her stay on the HASU did any staff member identify that the patient should have had IPC devices fitted.

> “Staff may well have been aware that the assessment had been carried out and recorded, it is likely that they did not refer to the completed assessment subsequent to it being logged. Failing to carry out an action that is required is known as an ‘error of omission’ (Health and Safety Executive, n.d.). Such errors are often difficult to detect until they have consequences, in this case, the development of symptoms of VTE …”
>
> Human factors and ergonomics subject matter advisor

4.6.5 The CLOTS3 trial stated: ‘IPC is an effective and inexpensive method of reducing the risk of DVT and improving survival in immobile stroke patients.’ (CLOTS (Clots in Legs Or sTockings after Stroke) Trials Collaboration, 2013)

4.6.6 The Trust’s overarching VTE policy did not define mobility or immobility for any hospital inpatient. The investigation observed that the professional groups had different perspectives on mobility, for example the medical team stated that a patient was mobile if they were able to walk to the toilet unassisted. In contrast, therapy colleagues described mobility using a more objective assessment tool (the 1 to 5 muscle power scale) (Collen et al., 1991) as well as more descriptive terminology to describe the patient’s ability to walk (for example, ‘walks with the assistance of one’). The nursing team did not describe mobility using a fixed definition.

4.6.7 The lack of a shared understanding of mobility is also reflected in some of the documentation. The Trust’s guideline for the use of IPC devices for patients who have had a stroke defines immobility as unable to walk independently to the toilet, whereas the reference event Stroke Integrated Care Pathway Record has a four-point scale to define mobility: immobile; wheelchair; walks with one aiding; independent.

4.6.8 There was no formal collective definition of mobility, reduced mobility or immobility. This could have led to different interpretation by professional groups, leading to different understanding of the requirements for IPC devices. Staff told the investigation that the lack of clarity relating to the terms around mobility increased the potential for confusion and therefore might result in variations in how patients are cared for and treated.

4.6.9 During a visit to the reference event Stroke Unit, the investigation observed that there were no patients on that unit with IPC devices fitted. It was also observed that there were no pictorial (for example, posters, whiteboards) or documentary reminders (prompts within patient notes) that IPC devices were a specific method of reducing the risk of VTE in stroke patients following thrombolysis, and therefore an intrinsic aspect of holistic stroke care.

> “The lack of a shared understanding of mobility may have made it less likely that staff would detect that the IPC device had not been fitted when it was required.”
>
> Human factors and ergonomics subject matter advisor

4.6.10 The nurses perceived that the identification and initiation/ prescription of IPC devices was solely the responsibility of the medical team. The Trust’s generic VTE policy states:

‘Nursing staff are responsible for: Ensuring that they are up to date with VTE training. Ensuring that all patients in their care have been assessed for their risk of VTE and bleeding and that this risk assessment is up to date. Administering both mechanical and chemical thromboprophylaxis as prescribed and ensuring that this is in accordance with guidelines.’

Nursing staff told the investigation that if IPC devices were not fitted, they would not routinely question the medical team irrespective of whether they felt that the patient required the devices. This was because they did not feel it was their responsibility to identify whether IPC devices were required or not. Since the introduction of IPC devices into the care pathway, there was no evidence that the change management process at the reference event Trust considered the need to facilitate a behavioural change to one where IPC device use was the norm and exceptions were escalated.

4.7 Ongoing management of VTE risk

4.7.1 Patients on the HASU and ASU received daily consultant ward rounds. The Trust used a ‘Consultant Ward Round’ proforma to document these, which included a section with a box to tick which said ‘VTE review’. There was no specific area to document what the VTE review entailed, only to tick the box that VTE had been reviewed. In the notes of the patient involved in the reference event, the VTE review box was ticked on most occasions. None of the consultant ward round proformas in the patient’s notes between day 1 and day 19 recorded that the patient did or did not have IPC devices fitted.

4.7.2 The investigation observed a consultant ward round of 12 patients on the reference event HASU. Among other checks, the consultant exposed the lower limbs of patients to check for discolouration and oedema (an excess of watery fluid collecting in the cavities or tissues of the body), and some patients had their lungs listened to. The consultant was therefore in a position to see whether IPC devices were fitted or not.

4.7.3 The junior doctors were responsible for creating a documentary record of the consultant ward round, including filling in the various sections of the ‘Consultant Ward Round’ proforma. One doctor was observed to tick the ‘VTE review’ box at the beginning of each patient’s review. The investigation observed no formalised process for recording the VTE review, and when the

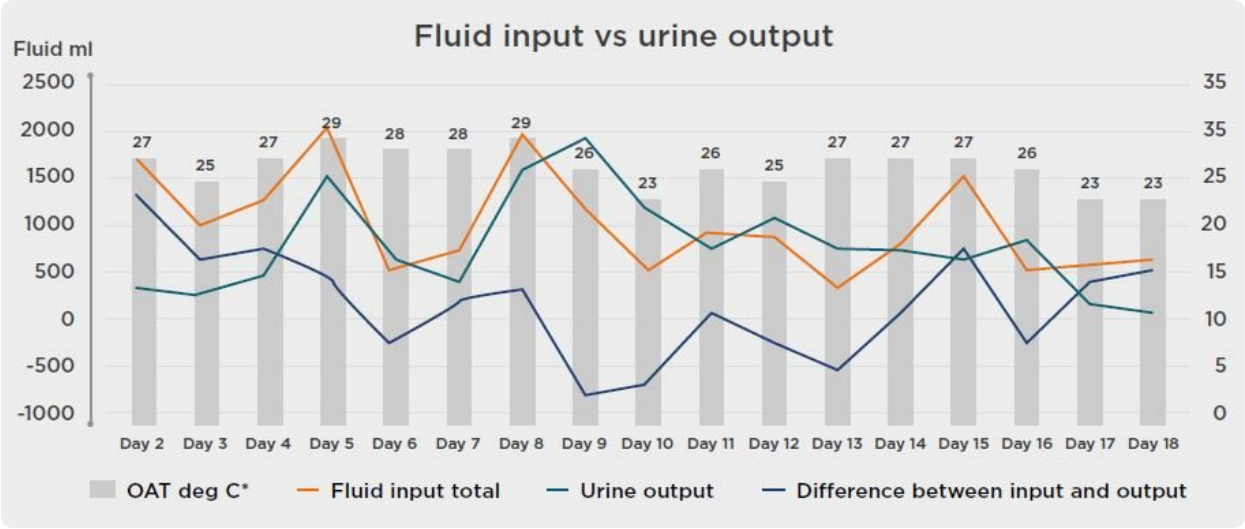
junior doctor was replaced during the ward round by another junior doctor, the incoming doctor did not tick the box for any of the patients. The variance in how the junior doctors recorded the VTE review suggests that there was no standardised process for them to follow. During the observation, there did not appear to be any discussion with the consultant regarding the VTE review for any patient seen on the round. From the observations it was unclear what the purpose of the VTE review was, that is, whether it was an opportunity to reassess VTE risk, or to look for new symptoms that could suggest that the patient had a DVT or PE.

4.7.4 The CLOTS3 trial (CLOTS (Clots in Legs Or sTockings after Stroke) Trials Collaboration, 2013) showed IPC devices to be effective when fitted within 72 hours of admission. There was no research to support either fitting or not fitting IPC devices after 72 hours of admission for acute ischaemic stroke. For the first three days following the patient's admission there was an opportunity within the VTE review element of the daily consultant ward round to discuss the ongoing decision regarding IPC devices (that is, following a change to the patient's clinical and functional picture). If the stroke unit team had identified that IPCs had not been fitted after the 72 hour period, they told the investigation that they would not have then fitted them based on the lack of evidence from the CLOTS3 trial (CLOTS (Clots in Legs or sTockings after Stroke) Trials Collaboration, 2015).

4.7.5 During the observed ward round, the previous days' 'Consultant Ward Round' proformas in the patient's notes were referred to but the medical team did not seem to read or consider nursing observations or therapy notes. Staff told the investigation that the consultant ward round should comprise members from the medical, nursing and therapy teams. It was expected that they would all have an active input into the ward round, highlighting any relevant documented findings (such as therapy notes). During the observation, the investigation did not see a nurse or therapist in attendance on the ward round. It was unclear to the investigation why this was the case as therapists and nurses were on the ward at the time of the consultant ward round.

4.7.6 The investigation observed that the attendance at the consultant ward round was impacted by the operational availability of doctors and nurses at the time. At the start of the observed ward round there was a consultant and a junior doctor, and more junior doctors joined as the round continued. No nurses or therapy team members joined the ward round. The investigation observed that this could lead to a lack of information being presented verbally to the consultant, who could then only rely on the patient's notes.

Figure 8: Fluid balance graph based on data from the patient's notes



4.7.7 The patient's notes contained several observations conducted by nursing and other staff. One of these observations was to record fluid intake and urinary output on the 'Fluid Balance Chart'. From the information recorded on the 'Fluid Balance Chart' in the patient's notes, there was a gradual change in fluid balance [9] between day 5 and day 15 (Figure 8). On day 15 the patient was found slumped over a table and was diagnosed as being clinically dehydrated; she had also developed a urinary tract infection.

4.7.8 During a therapy session on day 16, occupational therapists found the patient to be short of breath on exertion. This was written in the therapy section of patient's notes, which were only reviewed by other therapy staff but available to all. These notes were contained in the same folder that held the all the notes relating to the patient, including the VTE risk assessment, consultant ward round records and prescription chart. The lack of a holistic review of the patient's notes led to a missed opportunity to identify the changing functional and clinical picture which related to a potentially changing VTE risk.

4.7.9 The patient was seen daily on the consultant ward round and a box was ticked to indicate a VTE review had taken place. Despite this, at no time were IPC devices written on her prescription chart or fitted during her stay. Furthermore, there was an opportunity to re-assess the patient's IPC device requirements during this VTE review. The lack of multidisciplinary team attendance at the consultant ward round could lead to a reduced holistic clinical and functional picture of the patient. This is explored further in section 5.

4.8 Multidisciplinary team

4.8.1 Daily care on the stroke pathway is provided by a multidisciplinary team (MDT) of nurses, allied health professionals [10] and other staff. The Trust's 'Stroke Unit Standard Operating Procedure (2018)' does not include the medical team as members of the MDT. The MDT

members work individually and collectively throughout the day and have formal meetings, including daily MDT ward rounds [11] (referred to as board rounds on the stroke unit), and a weekly MDT meeting.

4.8.2 The weekly MDT (NHS England, 2015) meeting was held each week on the same day on the Stroke Unit. In the reference event, the patient was on the HASU for three weekly MDT meetings, however documentation could only be found for one MDT meeting (day 5) in her notes.

4.8.3 The Trust's 'Stroke Unit Standard Operating Procedure (2018)' did not detail the requirement for a weekly MDT meeting, however these meetings did happen in practice. The investigation observed a weekly MDT meeting and found that the purpose of these meetings was to decide which patients were suitable to be transferred between wards or discharged, and how best to safely achieve this, rather than a discussion about patients' ongoing care. There was no overall chairperson leading the meeting. A junior doctor from each ward led the discussions on the patients that they had oversight of. Input was provided by nursing and therapy staff as required based on their knowledge of the patients. For the first 30 minutes of the MDT meeting, a consultant was not available due to operational pressures (two patients were admitted and required thrombolysis). A nurse recorded key decisions on a computer during the meeting, however the investigation did not observe information being entered into the patient's notes.

4.8.4 In relation to MDT meetings, the Trust's 'Stroke Unit Standard Operating Procedure (2018)' states: 'These take place daily with lead nurse, physiotherapist, occupational therapist and other health professionals involved with the patient being discussed. Daily consultant ward rounds are fed by [daily] MDT input and use of the care pathway.' The standard operating procedure does not refer to doctors in its description of the MDT. The investigation found that the was the daily MDT meeting was referred to as the board round. These were held daily at approximately 10:30 hours, after commencement of the consultant ward round at 09:00 hours.

4.8.5 The investigation observed a daily Stroke Unit board round attended by the Stroke Unit Coordinator, clinical nurse specialist, nurse in charge and members of therapy teams. Although doctors were not detailed as members of the MDT in the Trust's Stroke Unit standard operating procedure, a junior doctor was also in attendance on the HASU and ASU board round (but not on the Rehabilitation Ward). The investigation observed that the board round discussions were a review of a patient's medical condition over the previous 24 hours, whether their condition had changed and what their discharge planning status was. This included the ongoing requirements to support discharge (for example, social care funding, packages of care, care home placements and so on). There was no discussion of VTE risk or IPC device status during the board round.

4.8.6 The consultant ward round on the HASU started before the board round, therefore it was not possible for the output of the board round to be fed into that day's consultant ward round as stated in the 'Stroke Unit's Standard Operating Procedure (2018)'. It was unclear to the investigation whether it was the daily MDT board round or the output of the weekly MDT meeting that met the procedure's requirement that the 'Daily consultant ward rounds are fed by MDT input'.

4.8.7 The therapy notes contained in the patient's medical records were available to the consultant during the ward round. These were detailed, but it was not easy for nursing or medical teams to quickly separate and identify clinical issues from daily therapy record keeping. When an issue was identified outside of planned meetings by one professional group, there was no unified system to make the other professional groups aware, therefore escalation of issues relied on ad hoc verbal communication.

4.8.8 Due to the sequence of the daily MDT board round and the consultant ward round, there was a missed opportunity for the medical team to gain knowledge of any new issues, such as increased shortness of breath as in the reference event. Furthermore, there was no dedicated document in the patient's notes that could have been used for identifying significant changes to a patient's clinical and functional condition. This would have allowed all MDT members to document concerns, actions or points for escalation.

4.8.9 There was detail in the Trust's 'Stroke Unit Standard Operating Procedure (2018)' that defined the daily MDT meeting. The procedure did not define the purpose of the weekly MDT meeting, who should regularly attend or what governance structure surrounded it. The investigation observed that this could have led to sub-optimal decisions being made due to variation in the make-up of the decision-making group. Additionally, the definition of the MDT included several professional groups but did not include doctors in its definition.

4.8.10 Therapists at the reference event Trust told the investigation that removing and fitting IPC devices was a barrier to therapy sessions. Removing and refitting the devices before and after moving the patient took time, thus reducing the time available to spend on the therapy sessions.

> "The tasks leading to correct application of the IPC device were distributed between different team members with different roles and responsibilities. If key steps are omitted, the process defaults to 'no IPC' …"
>
> Human factors and ergonomics subject matter advisor

4.9 Nursing handover

4.9.1 The Trust operated a 12-hour shift system split into day and night nursing shifts. These shifts ran 24 hours a day handing over at 07:00 hours and 19:00 hours. A handover was conducted at the beginning and end of each shift, the purpose of which was to communicate issues relating to individual patients, tasks that were outstanding and the requirements for the upcoming shift. There were separate handovers for the nursing team and the nurses in charge. Nurses were required to either start their shift early or finish late to ensure that a full handover was given.

4.9.2 During the handover the nursing team discussed the care and status of each patient in turn, using a printed list of patients and raising any concerns or outstanding tasks to be completed. Once the handover was finished, the oncoming nurses started their work on the ward and the off-going nurses finished their shift.

4.9.3 The off-going nurse in charge briefed the incoming nurse in charge, meeting in a room on the ward. The Trust used a proforma to facilitate and document this handover and to ensure relevant safety items for the ward were discussed. One of the items on the list was whether VTE risk assessments had been completed for all patients.

4.9.4 In the reference event, at approximately 07:00 hours on day 2, the off-going nurse in charge documented on the handover proforma that ‘1 x VTE outstanding [patient’s name redacted]’. On this handover sheet, the patient is specifically named. Staff told the investigation that the purpose of this entry on the handover proforma was to act as a prompt for the oncoming nurse in charge to ask the doctors to conduct a VTE risk assessment at the next opportunity.

4.9.5 On the proforma there was a box titled ‘VTEs checked and uploaded’ [12]. Staff told the investigation that if this was not ticked, it indicated that a first and/or second VTE risk assessment had not been carried out for all patients. This meant that it was unclear to the nursing team if IPC devices were required or not, or if they were recorded on the prescription chart. It was therefore possible that IPC devices were not fitted because the VTE risk assessment had not been undertaken. Despite the handover proforma being specific to the Stroke Unit, there was no prompt to check the IPC device status of all patients at handover. This further highlights the potential gaps in the process required to identify the need for IPC devices and subsequently fit them.

4.9.6 In subsequent shift handovers, the box was ticked to confirm that the VTE risk assessments had been checked and uploaded but had a comment ‘x 1 needs completing’. Staff told the investigation this indicated that one patient’s VTE risk assessment was outstanding and acted as a prompt for the on-coming nurse in charge to escalate this to the medical team. There

was no patient's name against this comment, so it is not possible to confirm whether this referred to the reference event patient's missing second VTE risk assessment or a first or second risk assessment for another patient.

4.9.7 After the first nurse in charge handover where the patient's name was recorded, there were no subsequent records on the handover notes of the patient's requirement for a VTE risk assessment to be completed. From the patient's notes, there was evidence that the second VTE risk assessment was not carried out until she was transferred to the Medical High Dependency Unit (MHDU) on day 20.

4.9.8 The nursing handover represented a twice daily opportunity to raise concerns regarding missed status of VTE risk assessments and the requirement for IPC devices on a patient-by-patient basis. This was in addition to verbally raising ad hoc concerns with the nurse in charge at the point of identification of issues. In the reference event, after the first nurse in charge handover which specified the reference event patient, subsequent handover information available to the oncoming nursing staff became less detailed and was anonymised. After further handovers the information was not included in the handover notes.

4.10 Detection of the patient's pulmonary embolism

4.10.1 There were several changes in the patient's clinical and functional picture during her stay on the HASU. On day 15, an occupational therapist (OT) found the patient sitting out of bed in a chair but slumped over her table. This was escalated to the medical team and led to the diagnoses of clinical dehydration and urinary tract infection. NICE guideline NG89 (National Institute for Health and Care Excellence, 2018) states that 'all people with acute stroke should have their hydration assessed on admission, reviewed regularly and managed so that normal hydration is maintained'. From analysis of the 'Fluid Balance Charts' contained in the patient's notes, there was a documented progressive imbalance in fluid input versus urine output. This imbalance led to the patient becoming clinically dehydrated and needing intravenous fluids to restore normal hydration. Dehydration may increase the risk of a patient acquiring a VTE.

4.10.2 The following day, day 16, an OT noted the patient was short of breath when she was sat on the edge of the bed; the OT escalated this verbally to the medical team and documented it in the patient's therapy notes. On day 17 at approximately 12:10 hours, during another therapy session, the same OT noted severe shortness of breath on exertion, and again reported this to the medical team and documented it. Later that day at 14:30 hours, the patient was seen on the consultant ward round and a suspected pulmonary embolism (PE) was diagnosed; a computerised tomography pulmonary angiogram (CTPA) was requested directly after the consultant ward round. The CPTA was carried out on day 19 and reported to confirm a saddle embolism on the same day. There was no evidence available to the investigation that indicates how the medical team reacted to the escalation of shortness of breath by the OT on day 16.

4.10.3 The ‘National clinical guideline for stroke’ (Royal College of Physicians, 2016) states: ‘Patients with ischaemic stroke and symptomatic deep vein thrombosis or pulmonary embolism should receive anticoagulant treatment provided there are no contraindications.’ In the reference event, despite the fact that treatment for a suspected PE in accordance with NICE guidelines was indicated, dalteparin [13], a low molecular weight heparin (LMWH), was not started until day 20.

4.10.4 In the reference event there was a delay of three days (day 16 to day 19) between the initial escalation of shortness of breath by the OT and dalteparin being prescribed. It is not clear why dalteparin was not prescribed until after the CTPA results had been received and reviewed. The dalteparin was not administered until the following day (day 20) and no evidence was provided to the investigation to explain this further delay.

4.10.5 A subject matter advisor (SMA) to the investigation stated that treatment should be commenced immediately following suspicion of a PE. The SMA also stated that in many trusts, a CTPA to confirm diagnosis would usually be expedited and undertaken on the same day as the PE was suspected. The NICE Clinical Knowledge Summary (CKS) for PE (National Institute for Health and Care Excellence, 2019b) states: ‘This recommendation is based on the expert opinion of the NICE guideline development group (GDG) [National Clinical Guideline Centre, 2015]. ‘The GDG considered the costs, potential adverse effects of treatment, and the risk of death from untreated PE and concluded that if a person has a likely probability of PE, treatment with either low molecular weight heparins (LMWH [dalteparin, enoxaparin, and tinzaparin]) or fondaparinux should be started while waiting for confirmation, and stopped if the scan result is negative.’

4.10.6 The investigation discussed giving LMWH as anticoagulation to reduce the risk of VTE in planned stroke aftercare (in lieu of IPC devices) with a consultant at the Trust involved in the reference event. The consultant stated they would not routinely give LMWH post-stroke as an anticoagulant until 14 days after a patient was admitted with an acute ischaemic stroke and received thrombolysis. They said that a neighbouring trust would routinely give LMWH as an anticoagulant after seven days. The investigation did not find any evidence relating to the routine prescribing of LMWH based on either of those timeframes. In relation to the management of acute suspected PE, the NICE guideline for management of PE (National Institute for Health and Care Excellence, 2019b) states that the risk of death from PE is greater than the ‘potential adverse effects’ of the LMWH and therefore treatment should not be delayed.

4.10.7 The NICE CKS for PE (National Institute for Health and Care Excellence, 2019b) recommends that an ‘interim therapeutic dose of anticoagulation therapy’ (for example, dalteparin) is given on suspicion of PE and stopped if the CTPA reports that there has not been

a PE. In the reference event, the failure to immediately follow up on the concerns raised by the OT and subsequent delays in diagnosis and treatment placed the patient at a higher risk of harm from potential recurrent PEs.

4.11 Findings from the reference event

4.11.1 The Trust's overarching VTE policy met the recommendations of NICE guideline NG89 (National Institute for Health and Care Excellence, 2018). The Trust's policy was followed for the initial VTE assessment (carried out within 12 hours of admission). The Trust's policy required that inpatients had a second VTE assessment within 24 hours of admission, however this did not take place in the reference event. It is not clear from the evidence why the second VTE assessment was not carried out. However, the investigation observed that there was not an embedded culture of checking if treatment options had been given, and that no individual bore overall responsibility for the complete process.

4.11.2 It is not possible to determine that, if the second VTE risk assessment had been undertaken at the appropriate time, the patient would have had the requirement for IPC devices written on the prescription chart and then fitted. The investigation heard from the Stroke Unit ward clerk that it was uncommon for the second VTE risk assessment to be missed completely, but it was common for the medical team to be prompted to complete documentation of the second assessment.

4.11.3 For the CLOTS3 trial (CLOTS (Clots in Legs Or sTockings after Stroke) Trials Collaboration, 2013), the recording of the IPC device requirement was carried out on the prescription chart. In the reference event Trust this has led to the policy that IPC devices must be prescribed by a doctor in the same way that a medicine is prescribed, despite IPC devices being a medical device and not a formulary item. This has driven behaviour, attitude and process leading to single ownership of the IPC devices by the medical team. There is a missed opportunity to share responsibility for fitting devices across the whole MDT. The extra documentation step of transferring the IPC requirement from the VTE assessment form to the prescription chart appears to have led to an increased chance of IPC devices not being fitted. There was an opportunity to identify the missed second VTE assessment and lack of IPC device fitting on the daily consultant ward rounds during the VTE review.

4.11.4 The decision to use IPC devices is based on whether a patient is considered to be immobile. There was no common technical definition of the terms relating to mobility, reduced mobility and immobility, therefore the requirement for IPC devices could be missed by the MDT through a lack of consensus on the terminology and therefore the indication to use IPC devices. This lack of common terminology for mobility could cause confusion between staff groups.

4.11.5 A lack of a shared awareness of the patient's functional and clinical picture and poorly defined escalation processes led to a missed opportunity to identify the patient's PE. The patient's earlier breathlessness was documented in her notes three days prior to the confirmed diagnosis of a PE. The consultant ward round observed by the investigation did not include a nursing or therapy team member and did not receive input from the daily board round. The consultant ward round started before the board round, so even if issues needed to be escalated, this would have to happen outside the ward round. This was compounded by segmentation of the patient's notes into medical, nursing and therapy sections; there was no single shared document to escalate significant issues that all staff members needed to be aware of. The lack of positive response to concerns raised by therapists relating to the patient's shortness of breath, and the subsequent delay in prescribing and administering LMWH, placed the patient at higher risk of harm.

4.11.6 The standard operating procedure for the Stroke Unit did not include doctors in its description of the MDT. The MDT attendance at the consultant ward rounds was poor, meaning that a patient's medical condition was considered but with no input from nursing or therapy teams.

4.11.7 There was not a culture of expectation that IPC devices should be fitted to all acute ischaemic stroke patients (irrespective of any contraindications). When staff members attended a patient, they were not consciously or sub-consciously looking for them to be fitted or questioning when they were not fitted. This could prevent challenge and escalation when patients are found not to have IPC devices fitted.

4.11.8 The Trust's overarching VTE policy required a doctor to 'prescribe' the IPC devices before a nurse could fit them. If this step was missed, nurses would not fit the IPC devices, in the same way that they would not administer a medicine that was not written on a prescription chart. The pharmacy team did not have any involvement in IPC devices and were not engaged with the decision to use the prescription chart for writing up IPC devices. Therefore, the pharmacy team was not able to provide assurance or oversight of IPC devices because they are not a formulary item and therefore not within their area of responsibility.

4.11.9 The design of the Trust's overarching 'VTE and Bleeding Risk Assessment' form did not describe the patient's VTE risk. Completion of the VTE form does not lead to an assessment of risk but to treatment recommendations to mitigate the risk. The form leads the user to decide on a treatment plan which is nearly always to fit IPC devices for patients who have had an ischaemic stroke unless contraindicated.

4.11.10 There was a 'tick-box' culture relating to VTE risk assessments, in that there was a 95% national target to meet. This target was met by the Trust; however, its focus was to meet the risk assessment element of the task. It did not assess the action part of the task, that is, the

outcome of the assessment and fulfilment of indicated treatment such as fitting IPC devices. There was no Trust clinical audit specific to the fitting of IPC devices which meant that the Trust could not be assured that care was optimised in line with the evidence base.

4.11.11 Failure to prescribe IPC devices increased the likelihood that the DVT and subsequent PE developed.

4.11.12 Four steps are required to fit IPC devices to a patient: VTE assessment; IPC form; recording the requirement for IPC on the patient's prescription chart; application of IPC device including assessing contraindications. This process defaulted to no fitment of IPC devices if the treatment was not entered on the prescription chart.

4.11.13 There was no robust follow-up check in place to ensure that patients received the correct VTE preventative treatment.

4.11.14 There was a significant delay in undertaking the CTPA and giving LMWH after suspicion of PE was identified.

4.11.15 Non-formulary items and orders/tasks were added to the patient's prescription chart because there was no dedicated document to record their need or instruct their use. 4.11.16 The patient was diagnosed as clinically dehydrated on day 15. National guidelines state that patients' hydration should be maintained to prevent VTE.

4.12 Safety actions carried out by the reference event Trust

4.12.1 The relationship built between the investigation and the Trust allowed early communication of issues which required immediate action by the Trust.

4.12.2 The Trust provided evidence that it was actively managing the issues raised by the investigation. These issues included the delay in giving LMWH after suspicion of PE (including missed first dose of LMWH) and the lengthy wait for a CTPA.

4.12.3 The length of time that a patient has to wait for a CTPA has improved significantly, with patients waiting no longer than 24 hours.

4.12.4 The Trust is in the process of implementing an electronic prescribing and medicines administration (EPMA) system which will allow missed doses of medicines to be tracked.

4.12.5 The Trust is also implementing the required VTE assessment for all inpatients in their electronic patient record system, which will be carried out whenever a patient is admitted to the Trust.

5 Findings and analysis – the national investigation

5.1 Risk

5.1.1 A risk is a combination of the likelihood of an event (hazard [14]) happening and the potential outcome of that event (Health and Safety Executive, n.d.). A risk can be either an undesirable outcome (downside risk) or an opportunity that could be exploited (upside risk). In the context of this investigation, the risk of venous thromboembolism (VTE) is a downside risk (that is, it is undesirable).

5.1.2 There are different ways of assessing risk. The Health and Safety Executive (HSE) recommends five steps: ‘Identify the hazards; Decide who might be harmed and how; Evaluate the risks and decide on precautions; Record your significant findings; Review your assessment and update if necessary’. (Health and Safety Executive, n.d.)

5.1.3 Once a risk has been evaluated and described, an easy way to record the assessment of that risk is to use a consistent and simple risk assessment form (Health and Safety Executive, n.d.). The form is particularly important when risk needs to be assessed on a case-by-case basis and provides a basis to revisit the risk as required.

5.1.4 When a risk assessment form is completed, it provides the risk assessor with an indication of the magnitude of that risk and the seriousness of the outcome. The risk assessor then uses the individual organisation’s prescribed method to assess both the likelihood and consequence together to produce a stratified risk. This method could use numbers (for example, 1 to 5), colours (for example, Red Amber Green (RAG)) or words (for example, High, Medium, Low) to provide a stratified risk assessment. Whatever strategy for assessing risk is adopted, the risk assessment outcome (a stratified risk) should guide the risk assessor to look at how to mitigate that risk (that is, what to put in place to reduce the likelihood of the risk being realised).

5.1.5 In order to ensure that hazards are controlled (and therefore the risk is being mitigated), one of the key components of this approach is ‘Review your assessment and update if necessary’ (Health and Safety Executive, n.d.). Without this step, it is not possible for an organisation to assure itself that risks are being mitigated to as low a level as is reasonably practicable.

5.1.6 Patients who have had an acute stroke are at high risk of developing deep vein thrombosis (DVT) and pulmonary embolism (PE) (CLOTS (Clots in Legs Or sTockings after Stroke) Trials Collaboration, 2013). The mitigation options for VTE risk in immobile patients are limited to fitting IPC devices unless contraindicated (CLOTS (Clots in Legs or sTockings after Stroke) Trials Collaboration, 2015).

5.2 Risk assessment

5.2.1 The National Institute for Health and Care Excellence (NICE) guideline NG89 (National Institute for Health and Care Excellence, 2018) endorses the use of the Department of Health's (DH's) [15] risk assessment form titled 'Risk assessment for venous thromboembolism (VTE)' (Figure 8) (Department of Health, 2018), which trusts can use and amend as required. This form is not mandated, and trusts could develop their own risk assessment form, however, NICE guideline NG89 (National Institute for Health and Care Excellence, 2018) states that the DH form is the 'most commonly used'.

Figure 8: 'Risk assessment for venous thromboembolism' form (Department of Health, 2018)

Department of Health

RISK ASSESSMENT FOR VENOUS THROMBOEMBOLISM (VTE)

Mobility – all patients (tick one box)	Tick		Tick		Tick
Surgical patient		Medical patient expected to have ongoing reduced mobility relative to normal state		Medical patient NOT expected to have significantly reduced mobility relative to normal state	
Assess for thrombosis and bleeding risk below				**Risk assessment now complete**	

Thrombosis risk			
Patient related	**Tick**	**Admission related**	**Tick**
Active cancer or cancer treatment		Significantly reduced mobility for 3 days or more	
Age > 60		Hip or knee replacement	
Dehydration		Hip fracture	
Known thrombophilias		Total anaesthetic + surgical time > 90 minutes	
Obesity (BMI >30 kg/m^2)		Surgery involving pelvis or lower limb with a total anaesthetic + surgical time > 60 minutes	
One or more significant medical comorbidities (eg heart disease;metabolic,endocrine or respiratory pathologies;acute infectious diseases; inflammatory conditions)		Acute surgical admission with inflammatory or intra-abdominal condition	
Personal history or first-degree relative with a history of VTE		Critical care admission	
Use of hormone replacement therapy		Surgery with significant reduction in mobility	
Use of oestrogen-containing contraceptive therapy			
Varicose veins with phlebitis			
Pregnancy or < 6 weeks post partum (see NICE guidance for specific risk factors)			

Bleeding risk			
Patient related	**Tick**	**Admission related**	**Tick**
Active bleeding		Neurosurgery, spinal surgery or eye surgery	
Acquired bleeding disorders (such as acute liver failure)		Other procedure with high bleeding risk	
Concurrent use of anticoagulants known to increase the risk of bleeding (such as warfarin with INR >2)		Lumbar puncture/epidural/spinal anaesthesia expected within the next 12 hours	
Acute stroke		Lumbar puncture/epidural/spinal anaesthesia within the previous 4 hours	
Thrombocytopaenia (platelets< 75x10^9/l)			
Uncontrolled systolic hypertension (230/120 mmHg or higher)			
Untreated inherited bleeding disorders (such as haemophilia and von Willebrand's disease)			

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5.2.2 The form used in the reference event Trust contained the same essential elements as the DH's form in that it listed several risk factors which need to be considered but did not provide a stratified risk on completion. The DH form states:

'Review the patient-related factors shown on the assessment sheet against thrombosis risk, ticking each box that applies (more than one box can be ticked). Any tick for thrombosis risk should prompt thromboprophylaxis [measures to reduce the risk of VTE] according to NICE guidance.'

5.2.3 The investigation observed that the VTE assessment form recommended in NICE guideline NG89 (National Institute for Health and Care Excellence, 2018), and those in use in trusts, do not provide a stratified risk on completion of the 'risk assessment' process.

The VTE risk assessment form records the presence of the patient's individual risk factors but does not weight or score these factors. In its current form it is more suitable to aid decision making toward a treatment plan. Using the words 'risk assessment' in the title is misleading and could lead to clinicians not completing the appropriate actions required to ensure that patients receive the appropriate VTE preventative measures (Krpan, 2017).

> "The VTE Risk Assessment form may have acted as a negative prime – unfavourably influencing subsequent behaviour - because once the form is complete the task of risk assessment is complete and no further action is required except to log the assessment on the system. In other words, if the VTE risk assessment form had been called 'treatment plan' it may have been more likely to 'prime' the doctor to write IPC it to the [prescription] chart. Although completion of the form is part of the task, the name of the form is disassociated from the goal of the task."
>
> Human factors and ergonomics subject matter advisor

5.2.4 A consultant haematologist told the investigation that there is currently no validated risk assessment tool that produces a stratified VTE risk available for use in healthcare in England. He stated that the assessment published in NICE guideline NG89 (National Institute for Health and Care Excellence, 2018) lists several factors which may be present in isolation or collectively. The assessment only requires a single factor to be identified to indicate that there is an increased risk of VTE. Highlighting multiple factors in the assessment does not indicate an increased risk of VTE. Due to the numerous risk factors that influence a patient's VTE risk, a complex algorithm would be needed to determine the relationship between different risk factors in order to produce a stratified risk.

HSIB makes the following safety observation

Safety observation O/2020/070:

There is no validated venous thromboembolism (VTE) risk assessment tool in the UK that produces a stratified risk for predicting a patient's likelihood of developing a deep vein thromboembolism or pulmonary embolism. If it is not possible to produce a stratified VTE risk assessment, it may be beneficial to consider amending the title of the published VTE risk assessment tool in NICE guideline NG89 (National Institute for Health and Care Excellence, 2018). This would reflect its true purpose as a prompt for clinicians to develop an appropriate treatment plan rather than creating the perception that it produces an assessment of risk.

5.3 Policy

5.3.1 The current VTE risk assessment used within the NHS in England allows clinicians to check a patient's current risk of developing a deep vein thrombosis (DVT) or pulmonary embolism (PE) against a nationally agreed set of criteria. There are several national documents which reference VTE risk reduction and treatment for ischaemic stroke. These include:

- NICE guideline NG89, 'Venous thromboembolism in over 16s: reducing the risk of hospitalacquired deep vein thrombosis or pulmonary embolism' (National Institute for Health and Care Excellence, 2018)
- NICE guideline NG128, 'Stroke and transient ischaemic attack in over 16s: diagnosis and initial management' (National Institute for Health and Care Excellence, 2019a)
- NICE Clinical Knowledge Summary (CKS) 'Pulmonary embolism' (National Institute for Health and Care Excellence, 2019b)
- Royal College of Physicians (RCP), 'National clinical guideline for stroke' (Royal College of Physicians, 2016).

5.3.2 The Trust in the reference event followed the principles of the NICE guideline NG89 (National Institute for Health and Care Excellence, 2018) and had a policy in line with this for all hospital inpatient VTE risk assessments. NICE guideline NG89 states for patients who have had an acute stroke:

'Consider intermittent pneumatic compression for VTE prophylaxis for people who are immobile and admitted with acute stroke. If using, start it within 3 days of acute stroke.'

5.3.3 The NHS Standard Contract 2019/20 (NHS England, 2018) specifies that providers must report their VTE risk assessment compliance to NHS Improvement on a quarterly basis and to clinical commissioning groups (CCGs) on a monthly basis. This allows data to be collected and analysed to provide assurance to governing bodies that VTE risk assessments are being

carried out. The standard contract covers all patients specified in NICE guideline NG89 (National Institute for Health and Care Excellence, 2018) and requires a compliance level of 95% of patients receiving a risk assessment within 24 hours of admission. The national data collection only relates to the completion of the VTE risk assessment and does not collect data on the treatment option selected and if that option was given.

5.3.4 Service Condition 22 of the NHS Standard Contract (NHS England, 2016) states that trusts must ‘perform local audits of service users’ risk of venous thromboembolism and of the percentage of service users assessed for venous thromboembolism who receive the appropriate prophylaxis’. During observation visits, the investigation did not find evidence that this audit was carried nor was it able to establish how many patients were receiving VTE preventative treatment and what that treatment was. This will be explored further as part of an HSIB investigation relating to the timely treatment of pulmonary embolism.

HSIB identified the following local considerations

Consideration for commissioners

It would be beneficial for local commissioners to agree a scheduled programme of audits to ensure that patients assessed for risk of acquiring a VTE receive appropriate mechanical or pharmacological prophylaxis.

5.3.5 The CLOTS3 trial (CLOTS (Clots in Legs or sTockings after Stroke) Trials Collaboration, 2015) identified that patients who have had an ischaemic stroke would benefit from wearing intermittent pneumatic compression (IPC) devices to reduce the risk of VTE. The CLOTS1 trials stated that antiembolism stockings provided no benefit:

‘Findings from this study have shown that thigh-length GCS [graduated compression stockings] are not clinically effective at reducing the risk of proximal DVT after stroke and are associated with some adverse effects.’ (The CLOTS (Clots in Legs or sTockings after Stroke) Trial Collaboration, 2009)

The International Stroke Trial (International Stroke Trial Collaborative Group, 1997) concluded that low molecular weight heparin (LMWH) could increase haemorrhagic transformations of cerebral infarctions and more serious extracranial bleeds if the patient had received thrombolysis. Therefore, the benefits of treatment to reduce PE and DVT are outweighed by the complications of treatment. This could mean that a patient who had had an ischaemic stroke may be at higher risk of a haemorrhagic stroke.

5.3.6 Taking these risk factors into consideration, doctors treating patients who have had a stroke have limited VTE risk reduction measures available to them. In parallel with good stroke care (Royal College of Physicians, 2016), early mobilisation and IPC devices are the only options in the acute phase of their stroke care that have been shown to reduce the risk of VTE. The findings from the International Stroke Trial (International Stroke Trial Collaborative Group, 1997) have been recommended in national guidelines such as NICE guideline NG89 (National Institute for Health and Care Excellence, 2018) and the RCP's 'National clinical guidelines for stroke' (Royal College of Physicians, 2016).

5.3.7 The Sentinel Stroke National Audit Programme (SSNAP) was commissioned by the Healthcare Quality Improvement Partnership to monitor stroke care standards across all stroke units in England. Data covering key patient and team factors was recorded continuously and collected on a quarterly basis from all stroke units. One aspect of this data relates to IPC device compliance for stroke patients, collected from patient prescription charts. The analysis of the data collected assumes that IPC devices have been fitted because they have been recorded in the patient's prescription chart. There is not a physical check requirement. The SSNAP 'Clinical audit April 2013 – March 2018 annual public report' (Sentinel Stroke National Audit Programme, School of Population Health and Environmental Sciences, King's College London on behalf of the Intercollegiate Stroke Working Party, 2019) records that 27% of patients who had a stroke during 2017/2018 had IPC devices fitted while an inpatient.

5.4 Application of IPC devices

5.4.1 During observation visits, clinicians told the investigation that there are several reasons that IPC devices would not be fitted despite being 'prescribed'. The Medicines and Healthcare products Regulatory Agency (MHRA) told the investigation that an IPC device is a Class IIa medical device [16] and therefore does not need to be in a trust formulary list or to be ordered only by a prescriber. The term 'prescribe' in this instance is not a true description of the action being undertaken; it is in fact an order to fit the device. This is discussed further in section 5.6.

5.4.2 Clinicians told the investigation that the following were among the reasons for not fitting IPC devices:

- peripheral vascular disease (poor circulation)
- skin integrity (cuts and ulceration)
- fall hazard
- devices are noisy or uncomfortable to wear.

5.4.3 The CLOTS3 trial (CLOTS (Clots in Legs or sTockings after Stroke) Trials Collaboration, 2015) states that:

‘Contraindications included:

- local leg conditions with which the IPC sleeves would interfere such as leg ulcers or dermatitis
- severe arteriosclerosis, as indicated by absence of pedal [foot] pulses or history of definite intermittent claudication
- massive leg oedema [swelling caused by a build-up of fluids] or pulmonary oedema [excess fluid in the lungs] from congestive heart failure.’

5.4.4 The SSNAP dataset does not collect the reason why IPC devices are not ‘prescribed’ or fitted, only the fact that they are not. It is unclear to the investigation why 73% of patients who have had an ischaemic stroke did not have IPC devices fitted during the period of the audit. The CLOTS3 trial (CLOTS (Clots in Legs or sTockings after Stroke) Trials Collaboration, 2015) estimated that 50 to 60% of patients who have had a stroke would be suitable to have IPC devices fitted. The remainder of the patients either have a contraindication or mobilise quickly following their stroke.

5.5 Process

5.5.1 Both NICE guideline NG89 (National Institute for Health and Care Excellence, 2018) and the reference event Trust require that VTE risk assessments are carried out within 24 hours of a patient being admitted to hospital. The investigation carried out observation visits to understand how other trusts had interpreted the guidelines. Staff told the investigation that the VTE risk assessment required by their trusts was not tailored to patients who have had an ischaemic stroke. The VTE risk assessment for ischaemic stroke patients following thrombolysis has a predetermined outcome, that is, IPC devices are the only indicated risk reduction measure. Furthermore, a trust must report VTE risk assessment compliance to their CCG and NHS England and NHS Improvement, meaning that clinicians focus on filling out the risk assessment form rather than ensuring that the risk reduction measures are in place. The investigation observed that both issues have led to clinicians carrying out VTE assessments quickly (either on electronic or paper-based systems), mostly ‘ticking boxes’ which the investigation noted made no difference to the management of the risk.

5.5.2 The principle of using of a VTE assessment form is that it enables the assessor to identify a course of action pre-determined by another body of professionals. In this instance, the pre-determined action is to order IPC devices and can be considered a rule-based decision. The downside to this rule-based decision is that if the rule is incorrect or the form is inaccurate it can lead to the wrong action or no action being completed (Flin et al., 2008).

5.5.3 Patients who have had an acute ischaemic stroke are ‘at especially high-risk [of VTE]’ (CLOTS (Clots in Legs Or sTockings after Stroke) Trials Collaboration, 2013) and are not indicated for the fitting of IPC devices in the acute phase of their stroke. The current VTE assessment has limited applicability in its current form as the treatment decisions are very limited for this group of patients; most preventative measures are contraindicated. The CLOTS3 trial (CLOTS (Clots in Legs or sTockings after Stroke) Trials Collaboration, 2015) states: ‘The risk of DVT is highest in patients who are initially immobile: among these patients, it may affect about 20% within the first few weeks of stroke.’ Therefore, as patients who have had a stroke are already identified as high risk, carrying out a VTE assessment may be an unneeded step.

> A human factors and ergonomics subject matter advisor told the investigation this [focus on specific information or items that are prominent, ignoring those that are not] is known as ‘salience bias’. It is often more difficult to detect the absence of what is required than the presence of what is not required. In the reference case, the error was detected by its outcome – the patient’s health deteriorated due to the subsequent development of the PE.

5.5.4 The investigation found no evidence in the national guidelines (Royal College of Physicians, 2016) (National Institute for Health and Care Excellence, 2018) that there is a requirement to record or monitor IPC device status in a patient’s notes, after the initial order to fit them is made. During observation visits, staff told the investigation that the failure to recognise that IPC devices were not fitted to immobile patients (approximately 20% of patients who have had a stroke are considered immobile (CLOTS (Clots in Legs or sTockings after Stroke) Trials Collaboration, 2015)) may be due to staff not specifically looking for them or assuming they were contraindicated.

5.5.5 The lack of a routine follow-up check and its record means that if the initial order to fit IPC devices is not made, it is more likely that IPC devices would never be fitted to a patient. In the cases where missed IPC devices were identified, the investigation observed that this identification was mostly due to knowledge and experience of staff rather than through a formalised process. To provide assurance to patients and staff that the correct treatment and action has been carried out, the process needs to have a means to assess that all actions have been carried out (Stolzer, 2015).

5.5.6 A stroke physician told the investigation that in their trust every patient is reassessed for VTE risk daily as part of the consultant ward rounds. This included assessing the patient for their current VTE risk and checking that they are receiving the correct VTE preventative

measure. The reassessment and preventative measure check was recorded by inserting a sticker in the patient's notes. This sticker recorded all the relevant information relating to VTE preventative treatment regime currently being undertaken.

5.5.7 A number of consultants told the investigation that as the effects of thrombolysis wear off, it would be appropriate to undertake a reassessment of the patient's VTE risk. One doctor reflected that patients admitted and treated for stroke may be considered as being in the "mature" phase of their stroke (post-acute) approximately 72 hours after admission [17]. However, a senior stroke physician representing the Royal College of Physicians stated that patients who have had a stroke are most likely to develop a DVT in the first 48 hours. As with all patients admitted to hospital, a generic VTE assessment needs to be undertaken as soon as possible after admission. However, due to the factors present for patients who have had a stroke, drugs to prevent clots forming will be contraindicated. Therefore, IPC devices should be applied without delay.

5.5.8 Doctors told the investigation that patients who had had an acute stroke could be considered as post-acute following treatment and when the symptoms of the stroke have resolved or plateaued [18]. They stated that after the acute phase, it may be appropriate to undertake an additional VTE risk assessment as this represents a change in the patient's condition. This is supported in NICE guideline NG89 (National Institute for Health and Care Excellence, 2018) which states: 'Reassessment of risk of VTE and bleeding 1.1.8 Reassess all medical, surgical and trauma patients for risk of VTE and bleeding at the point of consultant review or if their clinical condition changes.'

5.5.9 If this practice were routinely undertaken, this might identify whether the patient is suitable to receive any appropriate thromboprophylactic (VTE preventative) measures. Such measures may include continuation of IPC devices or consideration of other therapies that were previously contraindicated.

HSIB makes the following safety observation

Safety observation O/2020/071:

It would be beneficial for future venous thromboembolism (VTE) guidelines in relation to stroke to explicitly state when further VTE assessments are required during a patient's stay in hospital.

5.5.10 Stroke physicians who spoke to the investigation stated that they did not understand the value of carrying out the current generic VTE assessment for ischaemic stroke patients on admission to hospital as required by NICE guideline NG89 (National Institute for Health and

Care Excellence, 2018) and the NHS Standard Contract. This is because stroke is an indicated risk factor for VTE, but stroke is also a contraindication for the majority of treatment options post thrombolysis. Stroke clinicians spoken to during the investigation believe that the current generic VTE risk assessment requires amendment to reflect the needs of patients who have had an ischaemic stroke, or that an alternative ischaemic stroke-specific risk assessment should be provided. They stated that this could then be followed up by a further VTE risk assessment within an agreed timeframe when the patient is judged to be post-acute. The purpose of a further risk assessment would be to assess if there have been any significant changes in the patient's clinical and functional condition with respect to their VTE risk or if other preventative treatment options cease to be contraindicated, such as LMWH.

5.5.11 The 'European Stroke Organisation (ESO) guidelines for prophylaxis for venous thromboembolism in immobile patients with acute ischaemic stroke' (European Stroke Organisation, 2016) recommend that IPC devices should be used for immobile patients who have had an acute ischaemic stroke. It also states that LMWH can be given if the risk of VTE outweighs the risk of intracranial haemorrhage (bleeding inside the skull). To support this position the ESO guidelines state that: 'Better methods are needed to help stratify patients in the first few weeks after stroke onset, by their risk of VTE and their risk of bleeding on anticoagulants.'

Currently, clinical opinion varies about when to administer LMWH post thrombolysis. There was no consensus among the doctors who spoke to the investigation regarding how many days after thrombolysis LMWH for VTE prevention could be commenced (examples of between 5 and 14 days were given). No research exists to support when it is safe to start a patient who has had a stroke post thrombolysis on LMWH, so it is left to clinical opinion and judgement. Consultant haematologists and stroke physicians told the investigation that it may not be feasible to carry out a trial into when it would be safe to commence LMWH as a VTE prophylaxis (preventative measure). This is because patients who have had a stroke are already at high risk of haemorrhagic transformation of a cerebral infarct.

5.5.12 A senior physician representing the Royal College of Physicians (RCP) told the investigation that there is currently not enough evidence to provide advice on when it is safe to give LMWH. The RCP's 'National clinical guideline for stroke' states that clinicians should not give LMWH as a VTE prevention option for patients who have had a stroke:

'Do not give heparin (in any dose) for the prevention of DVT and PE in patients who are immobile after acute stroke, and do not attempt to select those patients in whom the risk of VTE is sufficiently high to warrant the use of heparin.

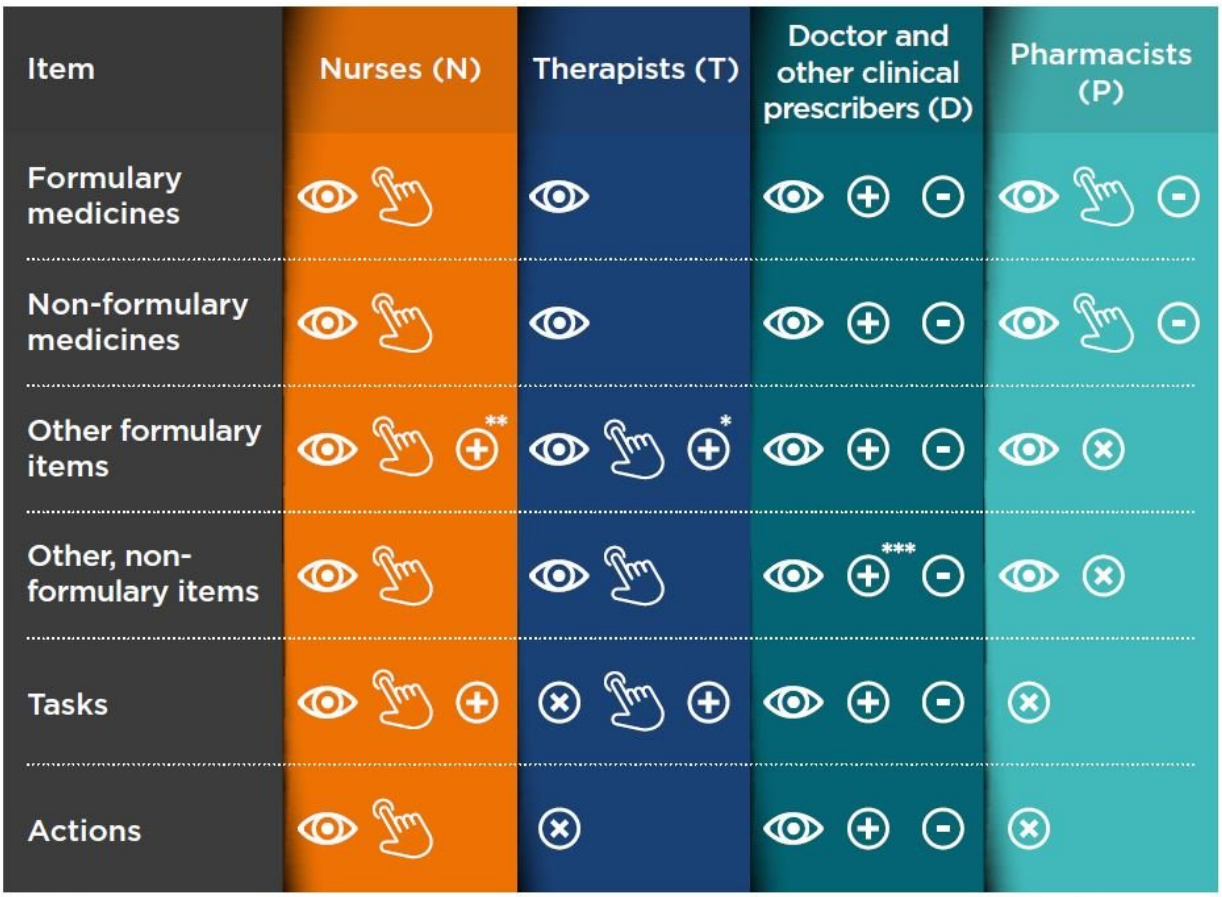
Do use intermittent pneumatic compression instead (Section 3.13).' (Royal College of Physicians, 2016)

5.6 IPC prescribing

5.6.1 The Royal Pharmaceutical Society (RPS) told the investigation that the stated purpose of a hospital inpatient prescription chart is an ‘intent to administer medication’ as directed by a prescriber. During visits to trusts, the investigation observed the following process for making an entry on a prescription chart (Figure 9):

5.6.2 Figure 9 shows that there are many decision and action points during the creation and use of a patient’s prescription chart. The investigation observed that drugs, orders [19], tasks and medical devices were all added to, and their follow-on action recorded on, the prescription chart. There are no national standards relating to the prescription chart which define the requirements for who can make entries on the chart, what can be added to the chart and how the chart is controlled, assured and audited.

Figure 9: Prescription chart - users and interactions



5.6.3 The process for prescribing medicines for administration is different to the process for prescriptions intended for dispensing. Prescriptions intended for dispensing, which are generally prescribed on an FP10 prescription form, are usually given to a patient from a primary care setting, for example a GP, and allow patients to collect medicines from a community pharmacy.

5.6.4 The RPS told the investigation that pharmacists working in trusts are generally only concerned with the items entered onto the paper or electronic prescription chart for which they have responsibility, that is, formulary items.

5.6.5 The investigation observed that it is common practice for prescription charts to be used for additional items and tasks other than the medicines that it was originally intended for (for example food thickeners and procedures such as bladder wash-out). The investigation observed that the use of the prescription chart has expanded to become a more generic record of interventions that need to be carried out.

5.6.6 Both NICE guideline NG89 (National Institute for Health and Care Excellence, 2018) and RCP's 'National clinical guidelines for stroke' (Royal College of Physicians, 2016) require that IPC devices are considered as a VTE preventative measure for immobile patients who have had an ischaemic stroke. During visits to trusts, the investigation observed that the practice was to carry out a VTE assessment and then order the fitting of IPC devices. This requires clinicians to carry out a two-part process and complete two separate documents in the patient's records (the VTE risk assessment and the prescription chart). However, during an observation visit one trust told the investigation that its clinicians carried out the VTE assessment and ordering of the VTE prevention methods on the patient's prescription chart. This meant that all the information was on one document and did not require staff to transfer decisions between documents.

> "Completing the VTE assessment may signify task completion in the mind of the person completing the form because it acts as a surrogate goal, particularly if the medic or stroke nurse is busy. The requirement for the IPC device will not be written on the chart."
>
> Human factors and ergonomics subject matter advisor

5.6.7 A human factors and ergonomics (HFE) subject matter advisor (SMA) told the investigation that the process described in the previous paragraph (5.6.6) can lead to an error of omission (Nemeth, 2004), that is, if the first or second step is omitted it is more likely that IPC devices will not be ordered or fitted.

"In each case, failure to apply the device when required is an ‘error of omission’ (failing to carry out an action that is required). Data from the CLOTS3 trial indicates that such errors increase the risk of a patient subsequently experiencing an adverse outcome such as DVT)."

Human factors and ergonomics subject matter advisor

5.6.8 The HFE SMA advised that if the default process was amended to require IPC devices to be fitted at an earlier stage, then it would be more likely to become normalised practice to order and fit IPC devices. It would also be more likely that instances where they were not fitted would be identified. The HFE SMA stated that if the fitting of IPC devices is missed at this early stage, there would be an error of commission. Safety science suggests that errors of commission are more likely to be identified and rectified earlier in the process.

5.6.9 During observations at several stroke centres the investigation identified differences between:

- compliance with national guidelines (work as prescribed)
- what staff told the investigation should happen (work as imagined)
- what staff told the investigation they do (work as disclosed)
- what the investigation observed (work as done).

This is a well-known distinction in safety research between what staff actually do to get the job done and what they are supposed to do in accordance with policy (Hollnagel, 2015).

5.6.10 Doctors told the investigation that they often ordered IPC devices during the admission process as they had the prescription chart in hand to prescribe other medication. Several nurses told the investigation that if they identified that a patient did not have IPC devices, they would fit them and then request that a doctor retrospectively order them to be fitted.

5.6.11 During observational visits the investigation noted that there was a combination of electronic and paper patient notes in use, but this did not affect how clinicians approached the ordering of IPC devices. Doctors told the investigation that they frequently ordered IPC devices to be fitted before the VTE risk assessment was conducted. This suggests that there is not a

direct relationship between the process of carrying out a VTE risk assessment and the ordering of IPC devices and that the fitting of IPC devices could be undertaken earlier in patients' care pathways.

5.6.12 The investigation asked a number of stroke consultants and VTE specialist nurses for their view on when it would not be appropriate to fit IPC devices to patients who have had an ischaemic stroke. The consensus was that IPC devices would not be fitted if the patient was contraindicated (normally due to skin integrity issues such as leg ulcers) or if the patient was at high risk of falling, or other considerations such as end-of-life care. Staff told the investigation that the level of potential harm caused by IPC devices being fitted to a contraindicated patient would be minimal. In the majority of cases the contraindications would be obvious. The CLOTS3 trial (CLOTS (Clots in Legs or sTockings after Stroke) Trials Collaboration, 2015) states that contraindications include:

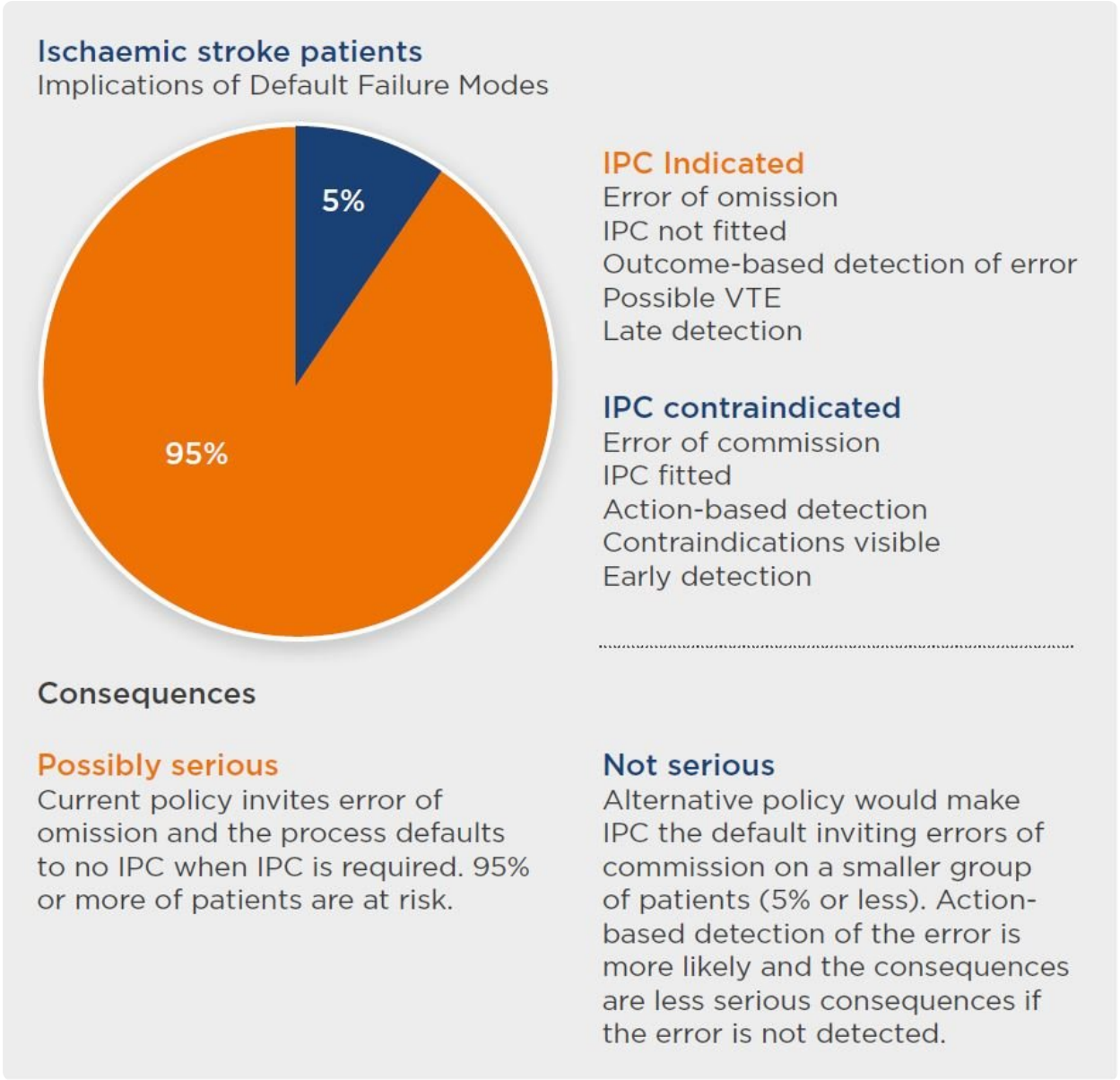
- 'local leg conditions with which the IPC sleeves would interfere such as leg ulcers or dermatitis
- severe arteriosclerosis, as indicated by absence of pedal pulses or history of definite intermittent claudication
- massive leg oedema or pulmonary oedema from congestive heart failure.
- Patients who already had swelling or other signs of an existing DVT. 'Such patients could be recruited once a DVT had been excluded by normal D-dimers [blood test for presence of components of a clot] or CDU [compression duplex ultrasound]. There was a concern that the application of IPC to patients who may already have a DVT might displace the thrombus and increase the risk of PE. However, this potential risk has not been documented in the RCTs [randomised control trials] so far. We have not identified any case reports that provide convincing evidence that this has occurred.'

5.6.13 Stroke consultants told the investigation that the potential level of harm for IPC devices not being fitted was significant (risk of developing a PE). The consultants stated that it would be appropriate to fit IPC devices to all immobile ischaemic stroke patients at admission, as this was nearly always going to be the treatment option irrespective of the VTE assessment (Figure 10). Stroke consultants told the investigation that approximately 5% of patients have contraindications for IPC devices.

"Errors of omission will place a large percentage of stroke patients at risk of adverse outcomes. Once the error has been made, it may have no immediate consequences nor be detected by staff (who may assume that IPC was not fitted because it was contraindicated)."

Human factors and ergonomics subject matter advisor

Figure 10: Error of omission versus error of commission (developed by the HFE SMA from evidence obtained during observation visits)



5.6.14 Nurses told the investigation they recorded that they had checked IPC devices in accordance with the treatment plan on the prescription chart, if IPC devices had been ordered. They also stated that if a nurse was experienced in stroke care, they would be more likely to recognise if IPC devices were needed and escalate to a doctor if they were not fitted. However,

nurses less experienced in stroke care may not recognise the lack of IPC devices or understand their importance. There is a commonly held belief across all staff groups that IPC devices are a prescription item, therefore they must be written on the prescription chart by a prescriber prior to a nurse applying them.

5.6.15 If a nurse is instructed to fit IPC devices and on attending the patient discovers a contraindication, they can make the decision not to fit them. This creates a conflict in their authority as they cannot make to decision to fit an IPC device but can make the decision not to fit one. The decision not to fit the IPC device is driven by nurses' perception that they are a prescription item and therefore they believe they do not have the authority to order or fit them.

5.6.16 A nurse told the investigation: "It's not rocket science, a nurse prescriber could do it, no harm really in fitting it to everyone."

5.6.17 As IPC devices are a Class IIa medical device, any trained and competent person could fit them to a patient without the need for them to be prescribed and written on the prescription chart. This was confirmed by a senior pharmacist representing the Royal Pharmaceutical Society (RPS) who stated that IPC devices are not a prescription item.

HSIB identified the following local safety consideration

Consideration for commissioners

It would be beneficial for local commissioners to agree a scheduled programme of audits to ensure that patients assessed for risk of acquiring a VTE receive appropriate mechanical or pharmacological prophylaxis.

5.6.18 A representative from the Royal College of Nursing (RCN) told the investigation that good practice would be to record IPC device status on handover and during routine nursing observations. They said that if this was followed, nurses would become more vigilant as process would be driving the requirement to check IPC device status. This would also raise the importance of IPC devices in their consciousness.

5.6.19 The RPS representative told the investigation that they recognised that the use of IPC devices needs to be recorded somewhere as a VTE preventative measure. The pharmacist stated that the prescription chart was the obvious place to do this. The CLOTS3 trial (CLOTS (Clots in Legs or sTockings after Stroke) Trials Collaboration, 2015) recorded the use of IPC devices in patients who have had a stroke on prescription charts (for trial audit purposes) and this has become adopted as common practice. This has led to the belief that IPC devices need to be prescribed before they are fitted to a patient.

HSIB makes the following safety recommendation

Safety recommendation R/2020/090:

It is recommended that the Intercollegiate Stroke Working Party with support from the Joint Stroke Medicine Committee and NHS England and NHS Improvement develop a stroke specific venous thromboembolism (VTE) assessment tool and system for ordering the associated treatment for patients who have suffered a stroke. HSIB recommend that the Intercollegiate Stroke Working Party supports development of a tool that ensures that important information is recorded and reviewed at appropriate intervals. The following points should be considered in the development of this tool:

- The aetiology/type of stroke (ischaemic and haemorrhagic).
- A record of the individual risk factors for VTE that are identified.
- Contraindications for VTE treatment measures.
- The VTE preventative treatment recommendation.
- The record of administration of that treatment.
- The reason that treatment is not administered.
- Patient's level of mobility and activity (in relation to IPC administration).
- Frequency of IPC devices checking.
- Record of patient's consent and understanding of risk/benefits of intervention, including patient's decision.

5.6.20 The investigation observed that other non-formulary items and ordered tasks are also being entered onto the prescription chart. This ensures that there is a record of their use and hence a record of the treatment that a patient receives. The RPS representative told the investigation that non-formulary items were regularly being added to the prescription chart, and that this was an issue with both paper-based prescription charts and electronic prescribing systems.

5.6.21 The RPS representative told the investigation that they were not aware of a formalised set of standards relating to prescription charts that give a framework for doctors, nurses and other healthcare professionals to work within. The RPS representative said that a set of standards would allow appropriately trained and experienced persons to understand what can

be entered on the prescription chart and by whom, how the treatment is administered and a record of that administration. The standards would also allow trusts to have a framework within which to design their prescription charts.

5.6.22 The RPS representative told the investigation that with the transfer from paper-based prescription charts to electronic systems, any issues that were evident on the paper-based chart were transferred to the electronic system. Their belief was that system developers took the format of the paper-based chart and recreated it electronically. Developers did not have a formalised set of standards to act as a foundation for the development of an electronic prescription chart. This issue was also identified by the HSIB report 'Electronic prescribing and medicines administration systems and safe discharge' (Healthcare Safety Investigation Branch, 2019).

5.6.23 A representative from NHSX told the investigation that there were no standards relating to items, such as medicines, order and tasks, pertaining to what should be recorded on prescription charts.

5.6.24The investigation identified an organisation called the Professional Records Standards Body which has produced standards for other documents relating to patient care. It told the investigation that it has not produced standards for prescription charts and did not believe that any were in existence.

5.7 Immobility in patients who have had a stroke while inpatients in hospital

5.7.1 In the reference event, the patient was considered immobile up to the point when she had a pulmonary embolism (PE) and received care relating to that PE. Patients who have had a stroke will have some level of neurological deficit and associated disability, most commonly affecting speech and mobility (see 1.1.5). Some of these impairments may resolve immediately after treatment and/or over a long period of recovery. In some cases, they may not resolve. The reduction in mobility increases the risk of developing a VTE, in the same way that a healthy person's VTE risk increases when sitting still for long periods (for example on long-haul flights). There is an additional statistical increase in VTE risk for patients who have had an acute stroke and are immobile (CLOTS (Clots in Legs or sTockings after Stroke) Trials Collaboration, 2015). The purpose of the IPC device is to mimic the action of the calf muscles in assisting the return of blood to the heart during the period of immobility.

5.7.2 In the reference event there was varied understanding of the term immobility between professional groups. The investigation conducted several observation visits as part of the national investigation and had discussions with professional bodies in order to gain a better understanding of the term immobility. The terminology around mobility, reduced mobility and immobility is important as it indicates a patient's potential VTE risk and appropriate risk

reduction measures (if required). The CLOTS3 trial (CLOTS (Clots in Legs or sTockings after Stroke) Trials Collaboration, 2015) concluded that IPC devices were an ‘effective and inexpensive method of reducing the risk of DVT and improving survival in immobile stroke patients’.

5.7.3 The investigation observed that the most consistently understood application of the term ‘immobility’ is that used by the medical teams. It was derived from the CLOTS3 trial (CLOTS (Clots in Legs or sTockings after Stroke) Trials Collaboration, 2015) which defines immobile as ‘immobile (i.e. unable to walk independently to the toilet)’.

5.7.4 Physiotherapists and occupational therapists told the investigation that they use descriptive terms for mobility, such as “walking with the assistance of one” or describe it in terms of muscle power (on a rating of 1 to 5) (Collen et al., 1991) but did not have a commonly used definition of immobility or use this terminology in relation to VTE risk. Therapy team members told the investigation that they did not assess the need for IPC devices, and if they came across a patient that did not have IPC devices fitted, they would not question the need for them. The investigation observed that when therapists become involved in a patient’s rehabilitation, all the routine medical interventions are in place and there is an assumption that all required medication and devices have already been identified. Therefore, the therapy teams are not looking for any gaps or omissions in the patient’s medical care.

5.7.5 During observation visits, nurses told the investigation that they did not have a standard term relating to immobility and used a combination of the terms used by doctors and therapists. Nurses have the most contact with patients and are arguably best placed to recognise if IPC devices are missing.

5.7.6 A senior stroke physician representing the RCP agreed that the terminology around immobility was not consistent and could be confusing. Furthermore, in their experience and opinion a patient could be considered mobile if a patient who had had a stroke was able to walk with or without assistance. Despite this, they would still require IPC devices until they were assessed as independently mobile. The senior stroke physician stated that all patients should be encouraged to stand and walk as soon as possible, not only to prevent the formation of VTE but to assist their rehabilitation and ultimately to enable them to be discharged to the correct care setting.

5.8 Management of VTE risk

5.8.1 The investigation observed a number of occasions when IPC devices were removed for therapy sessions and not refitted afterwards. The investigation identified issues with some aspects of the care that the patient received in the reference event. These related to hydration,

escalation of issues by therapists, response to suspected PE and giving anticoagulation medication. The Trust involved has addressed these issues and put procedures in place which aim to prevent their reoccurrence.

Hydration

5.8.2 NICE guideline NG89 (National Institute for Health and Care Excellence, 2018) highlights the importance of maintaining hydration as one aspect of VTE risk reduction:

‘Do not allow people to become dehydrated unless clinically indicated.’

Furthermore, NICE guideline NG128 (National Institute for Health and Care Excellence, 2019b) states:

‘Assess, on admission, the hydration of everyone with acute stroke. Review hydration regularly and manage it so that normal hydration is maintained.’

5.8.3 During observation visits, staff were asked about fundamental standards of care including nutrition and hydration and how this links to the prevention of VTE. Staff told the investigation that they had policies for these and could articulate compliance with them. A senior stroke physician representing the RCP told the investigation that they would expect patients to receive an appropriate level of fluid to ensure hydration is maintained.

5.8.4 The avoidance of dehydration is an important part of the prevention of VTE in patients who have had an acute stroke.

Management of suspected pulmonary embolism

5.8.5 NICE guideline CG144 ‘Venous thromboembolic diseases: diagnosis, management and thrombophilia testing’ (National Institute for Health and Care Excellence, 2012) states that ‘immediate interim parenteral anticoagulant therapy [medicines given by injection to prevent blood clots forming in patients with risk factors]’ should be offered on suspicion of a PE [20] if a computerised tomography pulmonary angiogram (CTPA) was not carried out. The ‘National clinical guidelines for stroke’ (Royal College of Physicians, 2016) state:

‘Patients with ischaemic stroke and symptomatic deep vein thrombosis or pulmonary embolism should receive anticoagulant treatment provided there are no contraindications.’

5.8.6 NICE guideline NG128 ‘Stroke and transient ischaemic attack in over 16s: diagnosis and initial management’(National Institute for Health and Care Excellence, 2019a) states that:

‘People with ischaemic stroke and symptomatic proximal deep vein thrombosis or pulmonary embolism should receive anticoagulation treatment in preference to treatment with aspirin unless there are other contraindications to anticoagulation.’

5.8.7 During observation visits, doctors told the investigation that they either arrange for an immediate CTPA or start the patient on an anticoagulant treatment while awaiting the CTPA. However, evidence suggests that clinicians’ responses to suspected PE may vary. The National Confidential Enquiry into Patient Outcome and Death report, titled ‘Know the score: A review of the quality of care provided to patients aged over 16 years with a new diagnosis of pulmonary embolism’ (National Confidential Enquiry into Patient Outcome and Death, 2019), identified that there were delays in undergoing CTPA and in giving anticoagulation. It states:

‘… the first dose of anticoagulation should be given to patients suspected to have acute PE if delay in confirmation of diagnosis is anticipated. In this study, case reviewers were of the opinion that there was an avoidable delay in commencing treatment in 90/481 (18.7%) patients.’

5.8.8 A consultant haematologist told the investigation that if a PE is suspected, LMWH should be administered within one hour if it is not possible for the patient to undergo a CTPA (National Institute for Health and Care Excellence, 2013). He stated that the risk of bleeding must be considered and is low in most patients, but the consequences are high. He also stated that once a PE has developed, LMWH will assist in preventing it getting bigger or further emboli occurring. In patients with a normal level of activity the body will usually break down the PE on its own. If LMWH is not given to an immobile patient, they have a higher risk of the PE increasing in size and therefore blocking the blood vessels in the lungs. The consultant haematologist stated that on the balance of risk (internal haemorrhage vs PE increasing in size) it is appropriate in most cases to give LMWH.

Multidisciplinary team (MDT) working

5.8.9 The investigation observed that several trusts conducted board rounds and ‘safety huddles’ (see 5.9.10) prior to the consultant ward round and at the end of the working day. These meetings were well attended with representation from medical, nursing, therapy, pharmacy and social care teams. The investigation observed how these actively fed into the consultant ward rounds with input from all staff involved, covering aspects of patient care, issues to escalate and discharge planning. Staff told the investigation they felt empowered to speak out and believed that their opinion would be considered when delivering patient care.

Safety huddles

5.8.10 A safety huddle is a short MDT meeting, conducted on a ward, that aims to improve awareness of safety concerns through cooperative problem solving and prioritisation. Safety huddles have been found to improve communication, awareness and teamwork (Goldenhar et

al., 2013). They can provide an opportunity for raising concerns, increase efficiency of exchanging critical information, and increase staff's perception of the benefits of face-to-face discussion. They should take place at set times every day, be led by the most senior clinician and involve all staff. Safety huddles are increasingly used in the UK and have been shown to be effective and sustainable (Montague et al., 2019). However, efficacy is dependent on a commitment to a 'non-judgemental safe space' in which all staff can speak up. The use of safety huddles is advocated by NHS Improvement (NHS Improvement, 2019).

5.8.11 During a number of observation visits, the investigation shadowed consultant ward rounds. The investigation observed that summaries from electronic and paper-based notes were reviewed to identify issues and changes in the patients' functional and clinical picture over the previous 24 hours. During these consultant ward rounds representatives of the MDT were in attendance, and the investigation noted that there was a nominated individual responsible for documenting and updating the treatment plan in the patients' notes.

Consultant-led ward rounds

5.8.12 Guidance produced jointly by the RCP and the Royal College of Nursing sets out core recommendations and principles for best practice for conducting medical ward rounds (Royal College of Physicians and Royal College of Nursing, 2012). The guidance calls for the MDT team – doctors, nurses, pharmacists, therapists and allied health professionals – to be given dedicated time to participate. It is suggested that consultant-led ward rounds should be conducted in the morning to facilitate timely completion of tasks. Ward rounds should include a holistic assessment of each patient's needs, reviewing nutrition, hydration and mobilisation. Common issues arising from ward rounds include medication errors and omission of venous thromboprophylaxis (Soong, 2012). It is suggested that safety checklists empower all members of the team to participate in ensuring components are not missed (Herring et al., 2011).

HSIB makes the following safety observation

Safety observation O/2020/072:

The advantages of multidisciplinary team (MDT) working are well known. It would be beneficial for organisations to ensure that stroke units are structured to ensure the optimal functioning of the MDT. To achieve this requires strong leadership, planning and a culture that empowers and encourages staff to speak up when issues arise. Stroke care involves many healthcare disciplines and in order for them to work efficiently and achieve the best results for patients, it may be beneficial to have formalised, tested and practised joint working with escalation routes known by all.

Family members awareness of VTE preventative treatment options for patients who have had a stroke

5.8.13 NICE guideline NG89 (National Institute for Health and Care Excellence, 2018) recommends that a member of staff: ‘Explain to the person admitted with acute stroke and their family members or carers (as appropriate) that intermittent pneumatic compression:

- Reduces the risk of DVT and may increase their chance of survival
- Will not help them recover from stroke, and there may be an increased risk of surviving with severe disability.’

5.8.14 When the investigation met with the patient and family involved with the reference event, they said that she had received excellent care. A duty of candour discussion is an open and honest discussion between healthcare professionals and patients/family members/ carers relating to the patient’s care when something has gone wrong. This was conducted with the family after it was identified that IPC devices had not been fitted. The family told the investigation that they did not know what to expect regarding the patient’s treatment during her stay in hospital. The Stroke Association charity and RCP individually produce information for patients, families and carers, which is available on request or from their websites. However, this needs to be sought out by the patient or family member/carer. For patients with other medical conditions, such as cancer, patients and their family members/carers may be given information explaining their condition and what treatment and care to expect. During visits to stroke units, staff told the investigation that information was not routinely given to families relating to the treatment and care that patients would receive.

5.8.15 There is also information written specifically for families and carers about the treatment that the patient will receive. A stroke consultant told the investigation that families are strong advocates for patient care and will often challenge the stroke team if they do not believe that the patient is receiving the right level of care. The consultant told the investigation that one way of strengthening patient/family/carer awareness would be to give family members an information pack. This would include information on the disease process, treatment and the care expected in hospital and future rehabilitation. This could include information on VTE prevention measures, such as the patient having IPC devices fitted and the importance of using these while the patient remains immobile.

5.8.16 The investigation was told by clinicians during observation visits that many patients refused IPC devices due to discomfort or the noise that the compressors made. A consultant told the investigation that while staff explain that the IPC devices are important, patients can still decide to have them removed or remove them themselves. If families were aware of the benefit of IPC devices, they could help staff explain to the patient and help them make an informed decision that best suits their circumstances regarding the fitting of IPC devices.

HSIB makes the following safety observation

Safety observation O/2020/071:

It would be beneficial for future VTE guidelines in relation to stroke to explicitly state when further VTE assessments are required during a patient's stay in hospital.

6 Summary of findings, safety recommendation and safety observations

6.1 Intermittent pneumatic compression (IPC) devices are the only recommended venous thromboembolism (VTE) preventative treatment option for immobile patients who have had a stroke (National Institute for Health and Care Excellence, 2018) (Royal College of Physicians, 2016).

6.2 The VTE risk assessment form recommended in the National Institute for Health and Care Excellence (NICE) guideline NG89 (National Institute for Health and Care Excellence, 2018) does not lead the user to produce a stratified risk, but it is an aid to decision making. It details several risk factors, which if present, indicates to clinicians what appropriate VTE preventative measure is required.

6.3 There is currently no validated VTE risk assessment tool that produces a stratified risk.

6.4 The Medicines and Healthcare products Regulatory Agency classifies IPC devices as Class IIa devices, meaning that they do not require a prescription prior to their fitting.

6.5 The VTE risk assessment recommended in NICE guideline NG89 (National Institute for Health and Care Excellence, 2018) does not fit the needs of immobile patients who have had a stroke because the only VTE preventative measure available to them are IPC devices. In its current format the assessment is therefore an unnecessary documentary step.

6.6 National guidelines do not require a follow-up assessment or check to make sure that the required VTE preventative measure is in place.

6.7 There is a requirement to carry out a further VTE assessment on patients whenever their medical condition changes. In patients who have had a stroke this could be carried out whenever they are considered 'post-acute'.

6.8 Opinion varies between doctors about when to give low molecular weight heparins (LMWH) as a VTE preventative measure in patients who have had a stroke as there is lack of evidence on the subject.

6.9 Patient prescription charts are used to record drugs, orders, tasks and medical devices. There are no national standards for how or when these items are recorded in a patient's notes.

6.10 Doctors frequently order IPC devices during the admission process, before the VTE assessment has been carried out.

6.11 Fitting IPC devices to all immobile patients who have had a stroke outweighs the potential level of harm of fitting IPC devices to contraindicated patients.

6.12 In general, nurses only check the requirement for IPC devices against the prescription chart. If the IPC devices are not on the prescription chart, they will not fit them or check if they are required.

6.13 Any member of staff who is trained and competent can fit IPC devices without the need for an order or a prescription, however the investigation did not observe this in practice.

6.14 IPC devices are not routinely recorded during nursing observations. This means that IPC devices are not routinely checked to see if they are fitted.

6.15 Despite the CLOTS3 trial (CLOTS (Clots in Legs or sTockings after Stroke) Trials Collaboration, 2015) defining immobility relating to VTE in patients who have had a stroke, the investigation observed that there is not a consistently used or understood term across the multidisciplinary team (MDT) for immobility in patients who have had a stroke.

6.16 The avoidance of dehydration is an important part of the prevention of VTE in immobile patients who have had a stroke.

6.17 Safety huddles and MDT working are essential to ensure that patients receive the appropriate level of care. They improve communication, escalation of issues and concerns, and team working.

6.18 Consultant ward rounds should be made up of representatives from all the staff groups that are involved in a patient's care.

6.19 If patients, families and carers are given the appropriate information about the care a patient will receive during their stay in hospital, it may assist staff in explaining the importance of issues like IPC devices. Families and carers can then support clinicians in explaining the benefits of IPC devices to patients and this may increase the number of patients wearing them.

HSIB makes the following safety recommendation

Safety recommendation R/2020/090:

It is recommended that the Intercollegiate Stroke Working Party with support from the Joint Stroke Medicine Committee and NHS England and NHS Improvement develop a stroke specific venous thromboembolism (VTE) assessment tool and system for ordering the associated treatment for patients who have suffered a stroke. HSIB recommend that the Intercollegiate Stroke Working Party supports development of a tool that ensures that important information is recorded and reviewed at appropriate intervals. The following points should be considered in the development of this tool:

- The aetiology/type of stroke (ischaemic and haemorrhagic).
- A record of the individual risk factors for VTE that are identified.
- Contraindications for VTE treatment measures.
- The VTE preventative treatment recommendation.
- The record of administration of that treatment.
- The reason that treatment is not administered.
- Patient’s level of mobility and activity (in relation to IPC administration).
- Frequency of IPC devices checking.
- Record of patient’s consent and understanding of risk/benefits of intervention, including patient’s decision.

HSIB makes the following safety observations

Safety observation O/2020/070:

There is no validated venous thromboembolism (VTE) risk assessment tool in the UK that produces a stratified risk for predicting a patient's likelihood of developing a deep vein thromboembolism or pulmonary embolism. If it is not possible to produce a stratified VTE risk assessment, it may be beneficial to consider amending the title of the published VTE risk assessment tool in NICE guideline NG89 (National Institute for Health and Care Excellence, 2018). This would reflect its true purpose as a prompt for clinicians to develop an appropriate treatment plan rather than creating the perception that it produces an assessment of risk.

Safety observation O/2020/071:

It would be beneficial for future venous thromboembolism (VTE) guidelines in relation to stroke to explicitly state when further VTE assessments are required during a patient's stay in hospital.

Safety observation O/2020/072:

The advantages of multidisciplinary team (MDT) working are well known. It would be beneficial for organisations to ensure that stroke units are structured to ensure the optimal functioning of the MDT. To achieve this requires strong leadership, planning and a culture that empowers and encourages staff to speak up when issues arise. Stroke care involves many healthcare disciplines and in order for them to work efficiently and achieve the best results for patients, it may be beneficial to have formalised, tested and practised joint working with escalation routes known by all.

HSIB identified the following local considerations

Consideration for commissioners

t would be beneficial for local commissioners to agree a scheduled programme of audits to ensure that patients assessed for risk of acquiring a venous thromboembolism (VTE) receive appropriate mechanical or pharmacological prophylaxis.

Considerations for trusts

It would be beneficial for trusts to review and amend their local procedures for the ordering and fitting of intermittent pneumatic compression (IPC) devices to allow any trained and competent person to fit them at the earliest opportunity. It would be beneficial for trusts to give patients who have had a stroke and their families/carers information about anticoagulation and VTE prevention, in particular the importance of IPC devices. They would then have the correct information to help them decide on whether or not to wear IPC devices.

7 Endnotes

[1] The Glasgow Coma Scale provides a practical method for assessment of impairment of conscious level in response to defined stimuli. A score of 15 indicates ‘fully awake and alert’ while a score of 3 (the lowest score) indicates deep unconsciousness or coma.

[2] Enoxaparin is a low molecular weight heparin (LMWH) used to treat or prevent deep vein thrombosis (DVT). Contraindications include recent cerebral haemorrhage.

[3] In the Trust where the reference event occurred, the prescription chart is sometimes referred to as the drug chart.

[4] Non-formulary items are those that fall outside items that are included in the list of local formulary items. The local formulary includes items that have been approved by national bodies, or if this evidence is not available, if there is other supporting evidence for their use. Local formulary items are selected by a local decision-making group (National Institute for Health and Care Excellence, 2015).

[5] The formulary is a list consisting mainly of medicines but may also include certain medical devices or specialist dressings. Items included in a formulary will have been approved by a relevant committee within a local, regional or national organisation and reflect evidence based clinical guidance. Non-formulary items are those item that do not fall within the formulary list, either because they are not authorised for use or they have been locally authorised.

[6] Food thickeners are a powder which can be added to liquids such as tea, water and fruit juice to assist patients who are having difficulty swallowing. Food thickeners are only used following a swallowing assessment carried out by a speech and language therapist.

[7] The Trust's policy does not permit non-medical prescribers to order IPC devices.

[8] Bladder wash-out procedures are carried out in patients who have a catheter inserted. The purpose of the procedure is to prevent the catheter becoming blocked.

[9] In this case the recorded fluid intake and urine output were reducing.

[10] In the context of stroke care within the reference event Trust allied health professionals included physiotherapists, occupational therapists and speech and language therapists.

[11] Ward rounds consist of consultant, nursing and pharmacy ward rounds.

[12] 'Uploaded' in this context means that the VTE risk assessment was entered onto the Trust's electronic system to ensure that the requirement for achieving the contractual 95% compliance rate for VTE risk assessments carried out was met.

[13] Dalteparin is an anticoagulant indicated for the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) (collectively known as venous thromboembolism (VTE)) in adults.

[14] In this context a hazard is anything that may cause harm (Health and Safety Executive, n.d.).

[15] At the time of the reference event the Department of Health and Social Care was known as the Department of Health and the form contained in NICE guideline NG89 was titled as such.

[16] IPC devices fall under Class IIa medical device 'Rule 9 – Active therapeutic devices intended to administer energy' (European Commission, 2010).

[17] This may exclude patients who have a further stroke after admission.

[18] Stroke is a neurovascular condition (see 1.1.2). Once the initial vascular aspect has resolved the patient may be left with a neurological disability and their condition may be considered as being 'post-acute'.

[19] In this context, orders are procedures defined by doctors for nurses to carry out to ensure that patients are given the appropriate care.

[20] If a computerised tomography pulmonary angiogram (CTPA) could not be completed within one hour.

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