Health Services Safety Investigations Body

Investigation report

Medication not given: anticoagulation before and after a procedure

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Theme:
Medication,Communication and decision making,Continuity of care

Contents

A note of acknowledgement

We would like to thank the family of the patient whose experience is documented in this report. We would also like to thank the healthcare staff who engaged with the investigation for their openness and willingness to support improvements in this area of care.

About this report

This report presents the findings of an investigation into a patient safety event at an acute hospital trust and identifies factors relevant to learning in other NHS organisations. It is intended for NHS organisations, patient safety leads, healthcare staff, patients and their families and carers, to help improve patient safety in relation to the use of anticoagulation (medication that reduces the ability of a patient’s blood to clot) before and after a procedure. This investigation does not explore inpatient venous thromboprophylaxis (prevention of hospital acquired blood clots) as this was not relevant to the safety event. For readers less familiar with this area of healthcare, healthcare terms are explained in section 1.

This report is intended to support local improvements in patient safety in relation to anticoagulant medication use before and after a procedure. It also identifies learning in relation to electronic prescribing and medicines administration (ePMA) systems. However, the learning may also be relevant to providers and staff in other health and care settings. This investigation will be used, alongside learning from past HSSIB and Healthcare Safety Investigation Branch investigations, to inform an upcoming national investigation into the safe use of ePMA systems in acute hospitals.

Terms used in the report

In September 2024, the Department of Health and Social Care and the British Medical Association agreed to change the title of ‘junior doctor’ to ‘resident doctor’. To reflect this change, the term ‘resident doctor’ is used in this report.

A variety of different terms are used in healthcare to describe temporarily stopping a patient’s medication before a procedure and then restarting it afterwards, including ‘suspended’, ‘interrupted’ and ‘withheld’. For consistency this report uses the term ‘paused’ throughout.

The term ‘procedure’ is used in this report and relates to both medical procedures such as insertion of a chest drain and surgical procedures (operations).

Executive summary

Background

This is the second in a series of investigations exploring why medications intended to be provided to patients were not provided. Patients who need medications can suffer harm if these are not provided.

This investigation explored the systems and processes in place to support staff when a patient who is usually taking an anticoagulant undergoes a procedure. An anticoagulant is a medication that reduces the ability of a patient’s blood to clot. The investigation also explored the role played by electronic prescribing and medication administration (ePMA) systems and electronic patient record (EPR) systems in supporting care in this area.

To examine these issues, the investigation explored a patient safety event involving a man aged 87 years who was admitted to hospital. He usually took an anticoagulant medication (apixaban) to reduce the risk of having a stroke. A stroke is a serious medical condition that occurs when the blood supply to part of a person’s brain is lost.

The patient safety event

The patient was taken to hospital with shortness of breath and nose bleeds. He was transferred from the emergency department to a medical ward while waiting for a procedure.

The medical team paused the patient’s regular apixaban, initially because of his nose bleeds. The apixaban continued to be paused while the patient was waiting for his procedure. However, delays to the procedure taking place meant that apixaban was not given for a total of 10 days. After the procedure, the apixaban was not restarted as intended. Two days after the procedure the patient had a stroke and later died.

Medical staff needed to make informed prescribing decisions, balancing the patient’s risk of developing a blood clot, his everyday risk of bleeding, with the risk of bleeding from the required medical procedure. The investigation explored the range of complex, dynamic and interacting clinical and wider hospital factors that led to the difficulties in managing the patient’s anticoagulation.

The investigation

This is one of a series of investigations exploring patient safety events that took place in NHS organisations to understand the local factors that may contribute to patients not receiving medications as planned.

A number of national stakeholders told the investigation that there would be value in understanding more about how situations arise where patients do not receive appropriate anticoagulation before and after a procedure. The investigation shares findings from the patient safety event and highlights opportunities for local-level learning in NHS acute hospitals, and across healthcare more widely, to help improve patient safety in this area.

Findings

- The patient’s apixaban was appropriately paused in the emergency department.

- Past clinical information about the patient that would have supported anticoagulant risk assessments was not easily available to staff.
- Variations in the hospital care processes supported some working practices, but created uncertainty about when the patient’s procedure could happen. This made dynamic clinical decision making challenging.
- A lack of specialist nursing and/or administrative support limited the ability for respiratory referrals to be followed up by the respiratory team in a timely way.
- There was no reassessment of the ongoing decision to pause the patient’s apixaban when the procedure did not happen as expected.
- It was clear to staff that the patient’s apixaban was paused on the ePMA system, but the system did not prompt staff to re-review the paused apixaban.
- An assessment of the risks and benefits of pausing the patient’s apixaban was not documented which prevented a shared understanding of the decision for other staff involved in the patient’s care.
- Workforce challenges created conditions on the acute general medical ward that limited the resources available to follow up on the patient's medication status and delayed discussions around the patient’s transfer to the respiratory ward.
- A mismatch between demand and capacity within the respiratory service prevented the patient being transferred to the respiratory ward or receiving regular specialty respiratory input while he was being cared for on the acute general medical ward.
- Some local clinical guidance available to staff on the management of patients’ anticoagulant medication was overdue for a review and did not reflect updated national guidance.
- Local clinical guidance was sometimes hard to access using the Trust’s computer systems and some staff were unaware of relevant guidance that was in place.
- There were no cues in the post-procedure documentation to prompt staff to consider restarting the patient’s anticoagulation medication.
- Phased implementation of the Trust’s EPR system meant that sometimes staff were duplicating entries across paper and electronic record systems.

Local-level learning prompts for acute hospitals

HSSIB investigations include local-level learning where this may help organisations and staff identify and think about how to respond to specific patient safety concerns at the local level.

The following prompts are provided by HSSIB to help acute hospitals to improve the safety of patients who are taking anticoagulation medication who need to have a procedure. These prompts may also be useful in other settings.

Anticoagulant prescribing

- How does your organisation support staff to identify and document decision making at critical decision points where anticoagulation should be reviewed?
- How does your patient record system support staff to document and clearly display the rationale behind any decision to pause anticoagulant medication?
- Does your organisation have systems and processes in place that support regular risk assessment of anticoagulants that have been paused?
- Does your organisation have a process for ensuring that guidelines that cross-refer to other relevant guidelines are reviewed together to ensure they provide consistent advice?
- How do you ensure that all members of the multidisciplinary team with relevant expertise are included in clinical guideline reviews?
- Does your organisation have processes in place to ensure that when new evidence on newer anticoagulants becomes available it is considered for inclusion in local guidance as soon as possible?
- How does your organisation support staff to find and readily access anticoagulation related guidelines?

Care processes supporting inpatients on anticoagulants

- Do your organisation’s bed management meetings include a review of patients who have been waiting more than 24 hours for transfer to a specialty ward?
- Does your organisation have effective processes in place to ensure inpatients accepted by a speciality, but awaiting a specialty bed, receive a specialty review on a regular basis?

- Does your organisation have a process in place for the prioritisation of inpatient transfer to specialty services?
- Does your organisation have a process in place for the prioritisation of inpatients who need investigations (including imaging) and procedures?
- Do your organisation's post procedure processes include a prompt to review anticoagulation?

EPR/ePMA systems supporting anticoagulation

- Does your organisation ensure it is easy for staff to access information in patients' records relevant to decision making about anticoagulant medication?
- Does your ePMA system identify patients with paused time-critical medication that may warrant a review?
- How does your organisation consider factors relating to equipment which may affect the successful implementation of EPR/ePMA systems?

1. Background

1.1 Introduction

1.1.1 This investigation focuses on the systems and processes in place to support staff in identifying the need for, and making decisions about, the prescribing and administering of anticoagulant medication before and after a procedure. It also explores the role of electronic patient record (EPR) and electronic prescribing and medicines administration (ePMA) systems in supporting care in this area.

1.2 Anticoagulant medication

1.2.1 Anticoagulant medication works by making a person's blood less likely to clot. It does this by letting the body break down existing blood clots and preventing new blood clots from forming. Anticoagulant medication increases a person's risk of bleeding. Anticoagulants are used to:

- treat health conditions caused by a blood clot
- help prevent blood clots in people at high risk of having them in the future.

A blood clot can be very serious and needs prompt treatment (NHS, 2021a).

1.2.2 Currently there is a range of anticoagulant medications that work in different ways and are approved for use in different clinical conditions. This means that the same anticoagulant medication could be used in different people, at different doses, for different reasons.

Atrial fibrillation

1.2.3 Anticoagulant medication can be used to treat a complication of atrial fibrillation (AF), a heart condition that causes an irregular and often fast heart rate. AF can allow blood clot(s) to form in a person's heart chambers. Such blood clot(s) can travel through the circulation and cause blockages in the blood vessels supplying the brain. If this occurs, a person may suffer an ischaemic stroke (clot stroke). A stroke is a serious medical condition that occurs when the blood supply to part of the brain is lost. AF is the most common heart rhythm disturbance, affecting around 1.4 million people in the UK, and is more common in men and older people (NHS, 2021b).

1.2.4 In 2021, the National Institute for Health and Care Excellence updated its guideline on the management of AF (National Institute for Health and Care Excellence, 2021). This guideline recommends the use of anticoagulant medication in the management of AF to reduce the likelihood of an ischaemic stroke in those who were at risk.

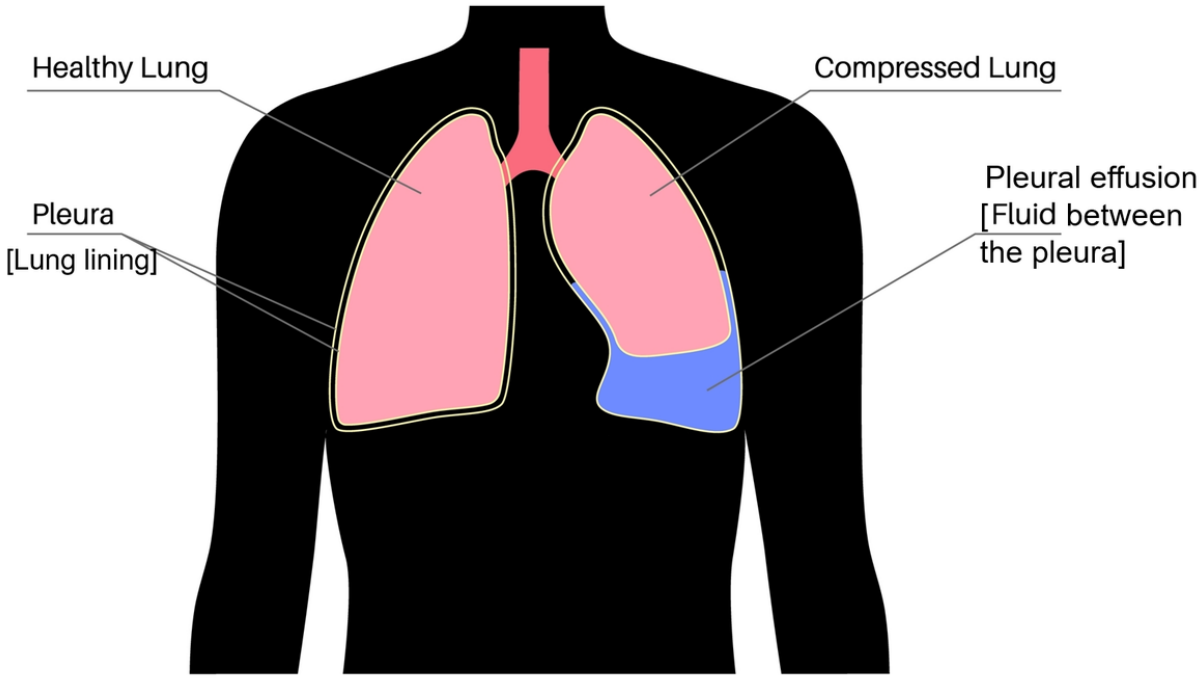
1.2.5 The guideline further states 'for most people the benefit of anticoagulation outweighs the bleeding risk' (National Institute for Health and Care Excellence, 2021). Healthcare practitioners are advised to review patients with AF who take an anticoagulant at least annually, or more often if events occur that affect the bleeding risk or anticoagulation (National Institute for Health and Care Excellence, 2021).

1.3 Pleural aspiration and drain insertion

1.3.1 The patient whose care is explored in this investigation had a pleural effusion, which is a condition that affects the lungs and breathing. A person's lungs are wrapped in two layers of tissue called the pleura; the inner layer covers the lung, and the outer layer lines the chest wall. A thin film of fluid separates the two pleura which allows them to slide over each other during breathing. A pleural effusion is a build-up of excess fluid in this space between the pleura (see figure 1) which can affect one or both lungs.

1.3.2 A pleural effusion can be treated by removing the excess fluid (pleural aspiration) and preventing it from collecting again. Where the patient has difficulty breathing, the fluid may need draining using a procedure called a pleural aspiration. This involves inserting a needle or small tube through the patient's chest wall to drain fluid from the pleural space. Where there is a large pleural effusion, it may not be possible to drain all the fluid in one go, and a drain may need to be left in the pleural space to safely collect the fluid over a longer time.

Figure 1 A pleural effusion



1.3.3 The British Thoracic Society (BTS) revised its guideline on pleural disease and published a clinical statement on pleural procedures in July 2023 (Asciak et al, 2023; Roberts et al, 2023). The guideline provides evidence-based guidance to UK-based clinicians caring for adults, including hospital inpatients, with a pleural effusion (Roberts et al, 2023). The clinical statement recommends that pleural procedures are performed during 'normal working hours' whenever possible in a clean, dedicated procedure room by appropriately trained staff (Asciak et al, 2023).

Managing anticoagulation in patients having non-urgent procedures

1.3.4 For most patients who take anticoagulant medication, this medication is paused before they undergo a pleural procedure and restarted after it, because of the increased risk of bleeding. Some patients who are at high risk of developing a

blood clot may need to continue their anticoagulation. This may involve changing the anticoagulant to another type that is more easily adjusted before and after the procedure, called ‘bridging therapy’.

1.3.5 The BTS states that there is no robust evidence base to accurately determine the bleeding risk associated with pleural procedures in patients who take anticoagulants. However, it advises that for planned pleural procedures the risk and benefits of pausing medication, or bridging therapy, should be discussed with the patient. This may also need to be discussed with specialty teams in high-risk cases (Asciak et al, 2023). Where a decision is made to pause anticoagulation, the BTS advises following national guidance by the British Society for Haematology (BSH) (Keeling et al, 2016; Saja, 2022).

1.3.6 The 2024 BSH guidance on anticoagulation and invasive procedures recommends that apixaban (a type of anticoagulant) is paused for 2 days before a planned procedure associated with a bleeding risk. If the patient’s blood clots after the procedure and there are no bleeding problems, the apixaban can be restarted 6 to 8 hours after the procedure, or when their next routine dose is due beyond this timeframe (Lester at al, 2024).

1.4 EPR and ePMA systems

1.4.1 An EPR is an electronic platform that brings patient information together in one place with the intention of making it more easily accessible for patients and healthcare professionals.

1.4.2 An NHS hospital trust can buy a single EPR software product from a single supplier, buy different parts of an EPR from different suppliers, or build all or part of their EPR software in house (NHS England Digital, 2024).

1.4.3 The Trust in this investigation primarily had an EPR software product from one supplier, which included its ePMA system (see 1.4.4). However, some other parts of its EPR system, such as laboratory tests and imaging, were provided by a different supplier.

1.4.4 An ePMA system is defined as follows:

‘The utilisation of electronic systems to facilitate and enhance the communication of a prescription or medicine order, aiding the choice, administration and supply of a medicine through knowledge and decision support and providing a robust audit trail for the entire medicines use process.’ (NHS Connecting for Health, 2009)

1.4.5 In practical terms, an ePMA system in a hospital is intended to support the safe, effective, and cost-effective use of medication from a patient's admission to hospital until their discharge. An ePMA system may exist as a standalone system or be integrated with an organisation's wider EPR systems. EPMA system functionality does not include the supply of medications from the hospital pharmacy.

1.4.6 The Healthcare Safety Investigation Branch has previously investigated the role of ePMA in weight-based medication errors in children (Healthcare Safety Investigation Branch, 2022) and ePMA systems and safe discharge (Healthcare Safety Investigation Branch, 2019).

2. The patient safety event

The investigation used the following patient safety event to explore the patient safety implications posed by pausing anticoagulant medication before a pleural aspiration procedure (see 1.3) which was delayed. This included decision making about continuing to pause the anticoagulant medication and not promptly restarting the medication after the procedure.

The safety event involved a patient aged 87 years who usually took an anticoagulant medication (apixaban) to reduce his risk of stroke.

Day 1

2.1 The patient woke up short of breath with a feeling of heaviness in his chest. He was assessed by ambulance staff and taken from his home to the emergency department (ED). On initial assessment the patient felt short of breath and had a nose bleed. The patient's observations were taken (such as heart rate and blood pressure) and tests were requested while he waited for review by a doctor.

2.2 An ED resident doctor examined the patient, reviewed his observations and test results and noted his past medical history and his usual medication. The patient had a number of known cardiovascular conditions (associated with the heart and blood vessels) including high blood pressure, heart failure, and atrial fibrillation (see 1.2.3). His usual medication included the anticoagulant apixaban, to reduce the likelihood of having an ischaemic stroke (see 1.2.3 to 1.2.5).

2.3 The ED doctor noted in the electronic patient record (EPR) that there was 'evidence of clot' in the patient's right nostril but that this was not currently bleeding. The patient was started on intravenous antibiotics for a likely chest

infection and a chest X-ray was requested. The chest X-ray showed that the patient had a large left and small right pleural effusion (see 1.3.1) and he was admitted to hospital.

2.4 That afternoon the patient had a severe nose bleed. His nose was packed to stop the bleeding. The patient was transferred to the acute medical unit (AMU) later that afternoon.

2.5 The patient was seen on the AMU ward round at 19:48 hours. The consultant who led the ward round was a respiratory doctor (a specialist in conditions of the lungs and breathing problems). During examination the patient was noted to be ‘alert, talking’ and not short of breath. The doctors updated the patient’s medical history to include that he had had rheumatic fever as a child. Rheumatic fever is a very rare complication following a bacterial throat infection where a person’s body overreacts. It can affect a person’s heart and joints.

2.6 The patient’s blood test results showed that his blood clotting was outside the expected range for him. Examination of the patient’s chest confirmed a diagnosis of pleural effusion and pneumonia. A plan was made to:

- continue the patient’s antibiotics
- request a computed tomography (CT) scan of his chest (a scan that uses X-rays and a computer to create detailed images of the inside of a person’s body)
- ‘hold’ the apixaban due to his nose bleeds
- continue his other usual medications
- add oxygen and other medication to make it easier for him to breathe.

From this point, the patient did not receive any further doses of apixaban during his time in hospital.

2.7 It is documented in the EPR that the patient was to be transferred to the ‘respiratory ward only’ as he needed a pleural aspiration (see 1.3.2).

Day 2

2.8 The patient was reviewed on the medical ward round, and it was noted in his EPR that he was ‘stable’. He was due to ‘only’ have antiembolism stockings for prevention of hospital acquired blood clots, and to ‘hold apixaban’.

2.9 The plan was to continue antibiotics, follow up on when the requested CT scan would happen and transfer the patient to the respiratory ward for his ongoing care.

2.10 An on-call doctor noted in the EPR that they would send an electronic referral for a pleural aspiration (see 1.3.2) on the electronic referral system as ‘this [a referral] has not been done as far as I can see’. This doctor also noted that the CT scan had already been requested and for the ‘day team to ring radiographers tomorrow and try to expediate scan if able’.

Day 3 and 4

2.11 On day 3, the patient was reviewed on the medical ward round. The plan was to continue with the plan from the previous day and to contact the ear, nose and throat specialty doctor to remove the patient’s nasal packing. Staff contacted radiology and documented in the EPR that the CT scan was ‘unlikely to be done today/tomorrow’ and would likely be at the weekend (that is, day 5 or 6).

2.12 A respiratory consultant accepted the patient referral to their service via the electronic referral system. This consultant was the same consultant that led the ward round on the AMU on day 1. They asked for the patient to be transferred to the respiratory ward and then closed the patient’s referral on the system.

2.13 The patient’s nasal packing was removed, and after some initial bleeding, the patient did not have any further nose bleeds for the remainder of his hospital stay.

2.14 On day 4, the medical ward round documented a plan in the EPR to continue the current treatment plan, ‘continue to hold apixaban’ as the patient would need a chest procedure. It was also noted that the patient may be moved to ‘any medical ward’ while waiting for the CT scan.

2.15 That evening the patient was transferred to an acute general medicine (AGM) ward.

Day 5 and 6

2.16 Nursing documentation in the EPR shows that the patient was settled, with ‘no concerns’. The patient was not seen by medical staff as it was the weekend and there was no routine review of patients on the AGM ward at weekends.

Day 7 and 8

2.17 On day 7, the patient was reviewed on the AGM ward round. The management plan noted that a respiratory consultant had accepted the patient’s referral and that he should be transferred to the respiratory ward for a pleural procedure. Also noted

was to chase the CT scan, continue antibiotics, pause apixaban, and request blood tests for the following day, including for clotting, as these would be needed before the patient could have his pleural procedure.

2.18 The CT scan of the patient's chest was completed that afternoon. The scan revealed that he had an enlarged heart, a collapsed left lower lung lobe, and bilateral (that is on both sides) pleural effusions, with the left pleural effusion larger than that on the right side.

2.19 On day 8, the findings of the CT scan were explained to the patient on the ward round.

Day 10 and 11

2.20 On day 10, the patient was reviewed on the AGM morning ward round. The doctors examined the patient's chest and recorded their clinical impression to be a 'worsening effusion'. The patient was re-referred to the respiratory team, via the electronic referral system, asking whether the patient could be sent from the AGM ward to have his chest procedure and then sent back to the AGM ward.

2.21 That afternoon the patient was transferred to the procedure room on the respiratory ward and had a procedure to drain both pleural effusions. The specialty doctor listed care plan actions for the AGM ward medical team to follow up. The care plan actions did not mention the patient's usual apixaban.

2.22 On day 11, the doctors on the AGM ward examined the patient and their documented impression was 'stable - effusion improving'. The plan was to request blood tests that day and if the patient's haemoglobin level was stable, to restart his apixaban. A resident doctor reviewed the patient's blood test results later that day, noting that his haemoglobin level was stable. This doctor intended to prescribe the patient's apixaban on the electronic prescribing and medicines administration (ePMA) system to restart that evening, but this did not happen.

Day 12, 13 and 14

2.23 On day 12, a nurse noticed that the patient had a left-sided facial droop, slurred speech and weakness in his left hand while sitting in his chair. The nurse took the patient's observations and asked for a medical review. The patient was seen by the weekend resident doctor at 11:30 hours who queried whether the patient had had a stroke. They prescribed an immediate dose of aspirin 300 mg by suppository, requested an urgent CT scan of the patient's head, and discussed the patient with the stroke specialist nurse.

2.24 The specialist stroke nurse arrived on the ward and assessed the patient. The specialist nurse confirmed that the patient had had an acute stroke and began co-ordinating his future care.

2.25 On day 12, the patient continued to be cared for in the hospital and was transferred to the stroke ward under the care of the stroke team. On day 14, the patient's health continued to deteriorate as a result of his stroke, and he died.

3. Analysis and findings

The investigation explored the factors that may have led to the patient's anticoagulant medication being paused for 10 days and not restarted after his procedure. The investigation met with a range of staff involved in the patient's care, not all of whom could recall the specifics of the patient's care. Therefore the investigation relied on documented information and an exploration of how care is usually delivered.

This section includes local learning prompts, which aim to help acute hospitals to improve the safety of patients receiving anticoagulant medication before and after a procedure.

3.1 Anticoagulant prescribing

Initial decision to pause the patient's anticoagulation

3.1.1 The patient had been taking apixaban at home before his hospital admission and was on the appropriate dose for his age, weight, kidney function and reason for treatment (Bristol-Myers Squibb-Pfizer, 2024; National Institute for Health and Care Excellence, 2021).

3.1.2 When the patient was in the emergency department (ED) a deliberate decision was made to pause the patient's apixaban because of his nose bleeds. This decision was confirmed on the post take ward round (the first assessment of new patients by the consultant clinician, following assessment on admission by the resident doctor). The investigation was told that at this time, the risk of the patient continuing to take his apixaban while experiencing nose bleeds outweighed the benefits of still taking the apixaban in terms of reducing the likelihood of having a stroke.

Decision to pause the patient's anticoagulation while awaiting the pleural procedure

3.1.3 The investigation found there were a range of complex, dynamic and interacting clinical and organisational factors that impacted on the decision making about the patient's anticoagulation management plan before his planned pleural procedure.

3.1.4 Staff on the acute general medical (AGM) ward told the investigation that they were guided on how to manage the patient's pleural effusions by the management plan developed on his admission, as this had been made with specialist respiratory advice. This plan was not updated to include the additional need to pause the apixaban for the pleural procedure when the patient referral was accepted, on day 3. This is likely to have been because the patient still had his nose packed at that time.

3.1.5 On day 4, the reason for pausing the patient's apixaban changed. It stated in the patient's electronic patient record (EPR) the reason for continuing to pause the apixaban was that he needed to have a pleural procedure. The investigation heard that the focus of the patient's care from this point was to transfer him to the respiratory ward for a pleural procedure which would make it easier for him to breathe. Also, the ongoing treatment of his heart failure was optimised, as that was believed to be the underlying cause of his pleural effusions.

3.1.6 The investigation learned that the expectation of the consultants who cared for the patient before his pleural procedure was that the procedure would happen in the next day or two. Furthermore, if the apixaban had been restarted, this could delay the procedure. One to two days was the same time period that apixaban needed to be paused before the pleural procedure. A range of factors outlined in this report interacted, which created uncertainty around when the patient's procedure would take place.

Respiratory ward bed capacity

3.1.7 Staff told the investigation that there were challenges with the number of respiratory beds available at the Trust and that this was exacerbated by high local needs due to a high prevalence of smoking and deprivation. The same challenges were said to exist for cardiac beds (for patients with heart-related conditions). The investigation reviewed bed availability on the respiratory ward, information about which is collated four times a day, and noted that there was one male bed available in the afternoon of day 2 and then no further availability until after the patient's procedure had taken place. There was a misalignment between the demand for specialist respiratory care and the resources available to the Trust to deliver it.

3.1.8 While the patient was waiting to be transferred to the respiratory ward there was no review of his treatment plan by the respiratory team. The investigation was told this was because when a referral had been accepted but a bed was awaited, the clinical responsibility for the patient remained with the consultant on the ward where they were located. These boundaries of responsibility meant that there was no opportunity for proactive specialist input into a revised care plan.

3.1.9 The investigation was told that the respiratory consultants did “not have the time and capacity to look back” at patients who had been referred and accepted and were awaiting transfer. The respiratory consultant explained that they relied on the patient being re-referred if there was too long a delay and specialist input was needed. This was a local adaptation, made because of the limitations in respiratory resources, to ensure patients were reviewed. In addition, the Trust did not have a specialist pleural (conditions affecting the lining of the lungs) nurse or dedicated administrative support as recommended by the Getting It Right First Time respiratory medicine national specialty report (Allen, 2021). The investigation was told that the Trust had previously had a pleural nurse in post but due to financial constraints no longer did.

3.1.10 The investigation was told that these specialist pleural nurse and administrative support posts played a key role in co-ordinating patient referrals, including those awaiting transfer. A national audit of pleural services in 2021 highlighted widespread noncompliance in these areas and national improvement objectives were set (Stanton and Evison, 2022). The Trust is undertaking a demand and capacity review of its inpatient respiratory service. In addition, patients accepted by the respiratory team but being cared for by another clinical team are now receiving specialty input while awaiting a specialty bed. In this Trust, this was different to patients who were considered ‘outliers’ (patients treated by the relevant medical team but in a different area of the hospital) as these patients received specialty input.

Prioritising patients for transfer to the respiratory ward

3.1.11 The lead nurse for the AGM ward told the investigation that patients who need a specialty bed are discussed on the morning board round (where patients are discussed by the multidisciplinary healthcare team), and the lead nurse takes on any patient flow related issues. The lead nurse did not specifically remember the patient whose case is examined in this report, so the investigation explored how ward transfers usually happen. Staff responsibilities were described as follows:

- AGM doctors complete the referral request.

- The specialty team reviews the request and accepts the patient if appropriate. Usually, the team asks for the patient to be transferred to the specialty ward.
- Once a patient is accepted by the specialty, the nurse co-ordinator or nurse looking after the patient, informs the site matron team which manages patient flow within the Trust.

3.1.12 The lead nurse highlighted that the process for prioritising patient flow would benefit from more medical input, explaining that a patient's "priority is not static" and the patient may "get better or worse". This was echoed in interviews with other staff.

3.1.13 Where a patient required a planned procedure on the respiratory ward, the patient either needed to be transferred to a respiratory ward bed or moved to the respiratory ward for the procedure and then returned.

3.1.14 The investigation heard that there was an escalation process via the matrons for patients who needed to be transferred but there was no bed available. The ward nursing staff were expected to use their clinical judgement to highlight patients they were concerned about. The lead nurse explained that they would only usually escalate an issue to the matron for consideration at their weekday virtual meeting on patient flow (attended by lead nurses and relevant matrons) if "higher authority was needed". These meetings may include staff from the relevant specialties, whose input into that decision making was beneficial.

3.1.15 The investigation was told that it was not uncommon to wait a week for a specialty bed to become available. In the patient's case, because of the lack of respiratory bed availability, staff developed a plan to send the patient from the AGM to the respiratory ward for the procedure, after which the patient would return to the AGM ward.

3.1.16 The investigation learned that the patient may have needed a chest drain, which can only be managed by nurses trained to do this task. AGM nurses are not able to care for patients with a chest drain, so if the patient had had one, he would not have been able to return to the AGM ward. Learning from this safety event, the Trust is reviewing the training and competencies required for nurses on AGM wards to care for patients after pleural procedures.

3.1.17 Following the Trust's investigation of the patient's care it identified a number of opportunities for improvement related to bed management processes and the clinical prioritisation and oversight of patients awaiting specialty transfer. These

actions are intended to enhance the Trust's ability to anticipate what patients' future needs may be and co-ordinate these across the Trust's systems and processes.

Staffing and workload

3.1.18 The workload on the AGM ward was described as high. One consultant and three resident doctors were assigned to the ward. In addition, staff on the AGM ward described to the investigation a "lack of senior medical leadership". The 28 bedded AGM ward routinely had one or two additional patients being cared for by the AGM staff.

3.1.19 The investigation was told there was an expectation that a "middle-grade" doctor would be available to support the consultant with this many patients and varying levels of complexity, although staff told the investigation this was rarely the case. Having a middle grade doctor is supported by the Royal College of Physicians (2018) guidance on safe medical staffing. The investigation noted that there was an additional locum 'middle-grade' doctor on the ward when it observed how medical care was provided, although this was reported to be rare.

3.1.20 The team described discussing all ward patients at the consultant-led board round every weekday, then dividing patient reviews among the team. The consultant reviewed a different patient cohort each weekday, while prioritising those who needed a consultant-level review on a daily basis and any patients escalated to them. However, the consultant explained that they did not have the capacity to oversee all tasks that the medical team needed to complete. This may have a been a contributory factor in the patient's apixaban not being restarted when intended after his procedure.

3.1.21 The lead nurse for the AGM ward explained that during the day shift there were three nursing teams caring for patients on the ward and a fourth nurse allocated as a co-ordinator. While the patient was on the AGM ward awaiting his pleural procedure, there was a co-ordinating nurse on only one of the six day shifts. This limited the resource available to follow up on the patient's transfer to the respiratory ward.

3.1.22 The investigation was told that the co-ordinator role was "pivotal in helping with co-ordination and patient flow", explaining that the ward feels "more organised with better morale and patient experience when fully staffed". As a result of this safety event, the Trust is reviewing the staffing allocation to this AGM ward.

Local pleural guidance

3.1.23 A respiratory consultant explained that practice regarding the time that direct oral (taken by mouth) anticoagulants (including apixaban) were paused before a procedure had varied historically (see 1.3.4 and 1.3.5), so this had been standardised locally. Local guidance stated that it brought ‘together information from other National, International guidelines and guidelines from nearby NHS Trusts’. This included previous national patient safety alerts on pleural procedures.

3.1.24 The local guidance recommended that direct oral anticoagulants should be paused before non-urgent cases. It gave information on how long before a procedure each medication needed to be paused. The investigation noted that apixaban was listed twice in the table included in the guidance, and that the time periods varied without explanation (see figure 2).

Figure 2 Extract from local guidance with instruction on pausing anticoagulation before a pleural aspiration, with ambiguity highlighted

Medications	Instructions
Warfarin	Usually stopped 5 days before the procedure. Patient will need an INR 1-2 days before the procedure to make sure INR is below 1.5 to proceed
Aspirin	Does not require to be stopped
Clopidogrel (Plavix) Dipyridamole (Persantin) Ticagrelor (Brilique)	Usually stopped 7 full days before the procedure
Apixaban (Eliquis) Dabigatran (Praxada) Rivaroxaban (Xarelto)	Usually stopped 2 full days before the procedure
Apixaban (Eliquis) Dabigatran (Praxada) Rivaroxaban (Xarelto)	To be stopped 1 full day before the procedure
Dalteparin (Fragmin) Prophylactic dose	Does not require stopping

3.1.25 A respiratory consultant told the investigation that because this guidance was focused on pleural procedures it was only intended to be used by respiratory staff. Furthermore, the pleural guideline did not include representatives from pharmacy or haematology (blood specialists) as reviewers of the document. Input from these specialties would have supported the consideration of other local and national guidance and raised awareness of any conflicts.

3.1.26 Because the patient was being cared for on the acute medical unit (AMU) and an acute general medical (AGM) ward, the consultant responsible for the patient's everyday care was unaware of this guidance. However, the AGM consultants were responsible for making decisions about patients' anticoagulation. An AGM consultant told the investigation that they followed common principles relevant to the management of anticoagulation during the time around procedures; these were not procedure specific but provided guiding principles.

Anticoagulation bridging therapy guidance

3.1.27 National guidance recommends that bridging therapy (see 1.3.4 and 1.3.5) should be considered for patients who have had a previous stroke or transient ischaemic attack (temporary blockage of blood flow to the brain) and three or more of the following risk factors: heart failure, high blood pressure, aged over 75 years and diabetes mellitus (Keeling et al, 2016).

3.1.28 The investigation saw handover documentation held on the EPR handover module (see 3.2.3) from the patient's previous admission under the care of the Trust's cardiology team. This stated that he had had a stroke in 2009. This was not documented in the patient's EPR by the medical team during the patient's more recent admission. To find this information, the investigation had to ask for additional EPR module records from the Trust; these records were not immediately accessible or available to the medical team that cared for the patient.

3.1.29 The investigation explored how readily available and accessible patient information was to the medical team when making prescribing decisions. Capturing information about the patient's medical history required healthcare staff to proactively search the patient's records or ask the patient/a relative. For healthcare staff, carrying out a proactive search for each patient in the context of a busy healthcare setting can be challenging, especially if information is not readily available or accessible. In addition, expecting a patient/relative to accurately recall and share critical information cannot be assumed to be a reliable process.

3.1.30 The Trust's bridging anticoagulation guidance stated that patients with atrial fibrillation (AF) with rheumatic valvular heart disease were classed as being at high risk of blood clots. The investigation did not explore whether this patient had AF due to rheumatic valvular heart disease. (Rheumatic valvular heart disease occurs when the heart valves are permanently damaged by rheumatic fever; the patient was known to have had rheumatic fever as a child – see 2.5). In line with the bridging anticoagulation guidance the patient's case required discussion at consultant level with haematology as 'bridging is likely to be [needed]'.

3.1.31 Trust guidance on bridging anticoagulation described the bleeding risk associated with some procedures, but stated that the guidance was ‘not comprehensive’ and that pleural procedures and chest drains were not included. This mirrors national guidance (Keeling et al, 2016), as it is not practical to list every different procedure for all specialties. A respiratory consultant told the investigation that pleural procedures, including pleural aspiration and chest drain insertion, even when done routinely were still classed as high bleeding risk.

3.1.32 The investigation noted that the bridging anticoagulation guidance did not contain reference to apixaban. For completeness, clinicians needed to cross-refer to an ‘interim guideline’ specifically about apixaban. This interim guideline stated it was valid until December 2016 with an ambition to include it within a combined bridging guideline when updated. At the time of the safety event this amalgamation had not taken place, and the interim guideline was more than 7 years old. The Trust told the investigation the guidance could not be accessed on its intranet at the time of this event.

3.1.33 The investigation learned that evidence around the use of anticoagulation is developing, leading to frequent changes in national guidance. This adds further complexity to decision making in relation to anticoagulants. In any areas where national guidance is being updated as emerging evidence and research is reported, it may be that the standard review period is too long, without any process to highlight that an earlier review may be needed.

Use of local guidance

3.1.34 Nursing staff on the respiratory ward told the investigation that it was common for patients who needed pleural procedures to be on anticoagulants. However, the investigation observed variability in knowledge of the existence of guidance, and of its use by staff. For example, one respiratory nurse told the investigation that there was no set guidance for managing anticoagulation for patients with pleural conditions. They stated that apixaban was paused 72 hours before a pleural procedure; this differs from local guidance which states 24 to 48 hours depending on the procedure (see figure 2).

3.1.35 In addition, a pleural consultant said that although there was a formal pleural procedure policy, it was not really used as it “takes so long to get to the document” on the Trust intranet. They showed the investigation how it was accessed, which demonstrated that it was available but not readily accessible. Because of this

challenge the key features had been included in a paper procedural document kept on the respiratory ward where the procedures were carried out, so that the information was readily available when it was needed.

3.1.36 The investigation saw the patient's completed paper record and noted that the doctor who carried out the pleural procedure had also documented the same information in the patient's EPR. The investigation heard that the document would be digital in the future. In the meantime, this duplication of tasks was needed as the Trust was still using a combination of paper and digital systems. Staff were having to adapt their practice as the Trust was moving in phases from a paper to an electronic system.

Delay to the patient's CT scan

3.1.37 The investigation explored whether the time it took for the patient to have a CT scan contributed to the delay to his pleural procedure. A respiratory consultant explained that they prefer to have the CT scan before the procedure but acknowledged it was not always essential. They commented that the time taken from requesting a CT scan to the scan taking place varied. It could happen on the same day or several days later, depending on how busy the CT scanner schedule was. Once a CT scan was done, it was usually reported (that is, the findings were made available to clinicians) the same day.

3.1.38 The investigation attempted to understand how or if CT scans are prioritised depending on patient needs and why it took 7 days for the patient's CT scan to be completed. The Trust was unable to provide specific information about what happened in this event, but did provide additional information on how CT scans were prioritised.

3.1.39 The patient's CT scan was ordered as a routine test. The Trust explained that CT scans were categorised as routine, or urgent, so that more urgent scans could take priority. If the demand for urgent CT scans was high it would not be unusual for a routine scan to 'wait a few days'. Additionally, a routine scan would not be booked at a weekend.

3.1.40 The investigation learned that CT scan priority could be escalated by a clinician upon providing additional clinical information, including at the weekend. The Trust told the investigation that without escalation the timescale for the patient's CT scan taking place was not 'an unusual delay'.

3.1.41 The investigation found records that medical staff were asked to escalate the need for the CT scan and spoke to the radiology team. The documentation by the medical team stated that the scan was likely to happen over the weekend. However, it is unclear whether the radiology team understood this was an escalation on clinical grounds, and this did not change when the CT scan took place.

3.1.42 There was no reference in the patient's records that anticoagulation formed part of the discussion around the scheduling of the patient's CT scan. This meant that the length of time the patient's anticoagulation was paused, and the increased risk this posed, may not have formed part of the decision making about the urgency of the scan.

Not restarting apixaban after the procedure

3.1.43 The respiratory doctor who undertook the pleural procedure documented a post procedure management plan in the patient's EPR. This did not include guidance on restarting the patient's apixaban.

3.1.44 The investigation identified that the documentation that clinicians were required to complete before a procedure included a number of blood clotting and medication related fields. However, in the documentation completed after a pleural procedure there were no cues to prompt consideration of anticoagulation.

3.1.45 This meant that the onus was on the doctor completing the paperwork after a procedure to remember to include consideration of anticoagulation within their management plan, without a prompt to do so. This is in the context of a number of other competing demands for their attention. The investigation discussed this with two respiratory consultants who thought such a prompt would be a useful addition and reflected learning from the safety event.

3.1.46 The day after the patient's procedure, the AGM medical team requested blood tests with a view to restarting his apixaban if the blood tests showed that it was safe to do so. Having reviewed the blood test results, mid-afternoon on a Friday, the resident AGM doctor planned to prescribe apixaban for the patient. However, this did not happen.

3.1.47 The investigation spoke with this resident doctor who said there were a number of possible reasons for this. They explained that their process for recording tasks they needed to do was to write them on the paper ward handover sheet. However, the handover sheet contained information about all the patients on the ward for the multidisciplinary team and was described as a "busy" document, which meant information could be missed.

3.1.48 The resident doctor explained there was an electronic system available to support task management, but this created individual printouts for each task, meaning that each patient may have many individual printouts. Staff said it was therefore “not a viable way” of managing tasks. This illustrates staff having to adapt due to limited functionality of the EPR system. The resident doctor explained that in addition the ward is busy, and that concerns had been raised to the ward consultant by all the resident doctors about the need for more senior medical input.

3.1.49 National best practice is that documentation of clinical care should happen contemporaneously (at the same time as care happens) (General Medical Council, 2024). The investigation was told that medical staff on the AGM ward were unable to review or amend the prescription chart or document patient reviews contemporaneously in the EPR due to a lack of mobile or portable computers. A resident doctor said that there used to be a ‘computer on wheels’ but it was no longer available. They therefore managed this by noting things down on paper and then transcribing it onto the ePMA/EPR system.

3.1.50 At weekends there was no routine medical review of patients on the AGM ward. The on-call medical team was available to review patients who were escalated to them and to carry out tasks that were allocated to them through the EPR system. In the patient safety event, because the patient was clinically stable after his procedure and no task had been left to prescribe the apixaban, he did not meet the criteria for on-call review. This meant that there was no opportunity for the medical team to review the patient’s electronic prescription and identify that the apixaban had not been restarted. In essence, there was no feedback mechanism in place to ensure that a planned action had taken place; this is an example of where the Trust’s organisational resilience could be strengthened.

Local-level learning prompts for acute hospitals

The following prompts are provided by HSSIB to help acute hospitals with improving the safety of patients undergoing procedures who require anticoagulation. These prompts may also be useful in other settings.

Anticoagulant prescribing

- How does your organisation support staff to identify and document decision making at critical decision points where anticoagulation should be reviewed?

- How does your patient record system support staff to document and clearly display the rationale behind any decision to pause anticoagulant medication?
- Does your organisation have systems and processes in place that support regular risk assessment of anticoagulants that have been paused?
- Does your organisation have a process for ensuring that guidelines that cross-refer to other relevant guidelines are reviewed together to ensure they provide consistent advice?
- How do you ensure that all members of the multidisciplinary team with relevant expertise are included in clinical guideline reviews?
- Does your organisation have processes in place to ensure that when new evidence on newer anticoagulants becomes available it is considered for inclusion in local guidance as soon as possible?
- How does your organisation support staff to find and readily access anticoagulation related guidelines?

Care processes supporting inpatients on anticoagulants

- Do your organisation’s bed management meetings include a review of patients who have been waiting more than 24 hours for transfer to a specialty ward?
- Does your organisation have effective processes in place to ensure inpatients accepted by a speciality, but awaiting a specialty bed, receive a specialty review on a regular basis?
- Does your organisation have a process in place for the prioritisation of inpatient transfer to specialty services?
- Does your organisation have a process in place for the prioritisation of inpatients who need investigations (including imaging) and procedures?
- Do your organisation’s post procedure processes include a prompt to review anticoagulation?

3.2 EPR/ePMA systems and inpatient anticoagulation medication

Anticoagulation

3.2.1 The process of using the ePMA system to prescribe apixaban and pause the apixaban once it had been prescribed was demonstrated to the investigation. Several staff interviewed said they thought that when a medication was paused, this showed clearly on the ePMA. However, the ePMA pharmacist highlighted two “weaknesses” with the current process:

- there is no prompt to the medical team to review a paused medication
- it would be useful to include how long the medication was planned to be paused for.

3.2.2 The suggestion above of including a prompt within the ePMA to re-review paused anticoagulation acknowledges the uncertainty and variation in patient care; therefore enabling decision making to be revisited. The ePMA pharmacist demonstrated a new report that pharmacy staff could run on the ePMA system to identify paused medication, which could be filtered to focus on high-risk medication. They said that there are many possibilities that could be considered to optimise medication but were at the start of fully exploring these. The Trust was keen to share its learning from these new reports with other hospitals to allow them to consider if they may be helpful.

System usability

3.2.3 The Trust used one supplier’s digital system for most adult patient care. This consisted of a number of different, interconnected modules with different purposes and functionality, including the patient specialty referral, ePMA module and EPR. The system was not bespoke but was configured to meet the Trust’s needs. Although other trusts in England use the same system, the user experience will be different because of version control, upgrades and local configuration. In addition, other suppliers’ digital systems were in use for specific areas of patient care at the Trust, such as imaging, which staff had to log into to use.

3.2.4 Staff told the investigation that logging in was time consuming because the computers were old. One consultant suggested that it would be helpful if information could automatically populate data fields across the different systems instead of staff needing to manually sign in and transfer information across. This manual process also introduced the risk of transcription error.

3.2.5 The investigation identified that there may be opportunities where technology could improve timely access to key patient information, such as the patient’s stroke and bleeding risk assessment. This is known as ‘surfacing of information’, where information is presented in such a way that it comes to the fore without onerous or

frustrating warnings or notifications. Surfacing of information has previously been considered in the HSSIB investigation ‘Continuity of care: delayed diagnosis in GP practices’ (Health Services Safety Investigations Body, 2023). This would remove sole reliance on the patient, family or carer being able to communicate key information.

Local-level learning prompts for acute hospitals

The following prompts are provided by HSSIB to help acute hospitals with improving the safety of patients undergoing procedures who require anticoagulation. These prompts may also be useful in other settings.

EPR/ePMA supporting anticoagulation

- Does your organisation ensure it is easy for staff to access information in patients’ records relevant to decision making about anticoagulant medication?
- Does your ePMA system identify patients with paused time-critical medication that may warrant a review?
- How does your organisation consider factors relating to equipment which may affect the successful implementation of EPR/ePMA systems?

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5. Appendix: Investigation approach

A review of patient safety insights suggested a theme of medication-related harm. The investigation reviewed:

- reports to prevent future deaths
- reports to the Strategic Executive Information System (StEIS)
- reports made directly to HSSIB by the public
- previous Healthcare Safety Investigation Branch reports related to medication
- discussions with stakeholders to identify areas of concern.

Once a decision was made to proceed to investigation, further stakeholder discussions were held to identify more specific areas of concern and to understand the current patient safety landscape in relation to medication-related harm. Analysis of all the information obtained suggested a theme of medication not given, with three topic areas:

1. time-critical medication in the emergency department
2. anticoagulants before and after a procedure

3. discharge to a nursing home.

A further theme emerged regarding electronic prescribing and medicines administration (ePMA) systems.

HSSIB's Chief Investigator authorised an investigation into each of these topics.

Evidence gathering and verification of findings

A local investigation was undertaken. This meant identifying and investigating a single patient safety event that involved missed anticoagulant medication before and after a procedure. The investigation visited the Trust where the patient safety event took place. Meetings and interviews were held with staff involved in the patient safety event and key staff in the management of patient flow, medication safety and respiratory medicine. The investigation also observed practice on the acute general medicine ward and the use of digital systems. The following practices were observed:

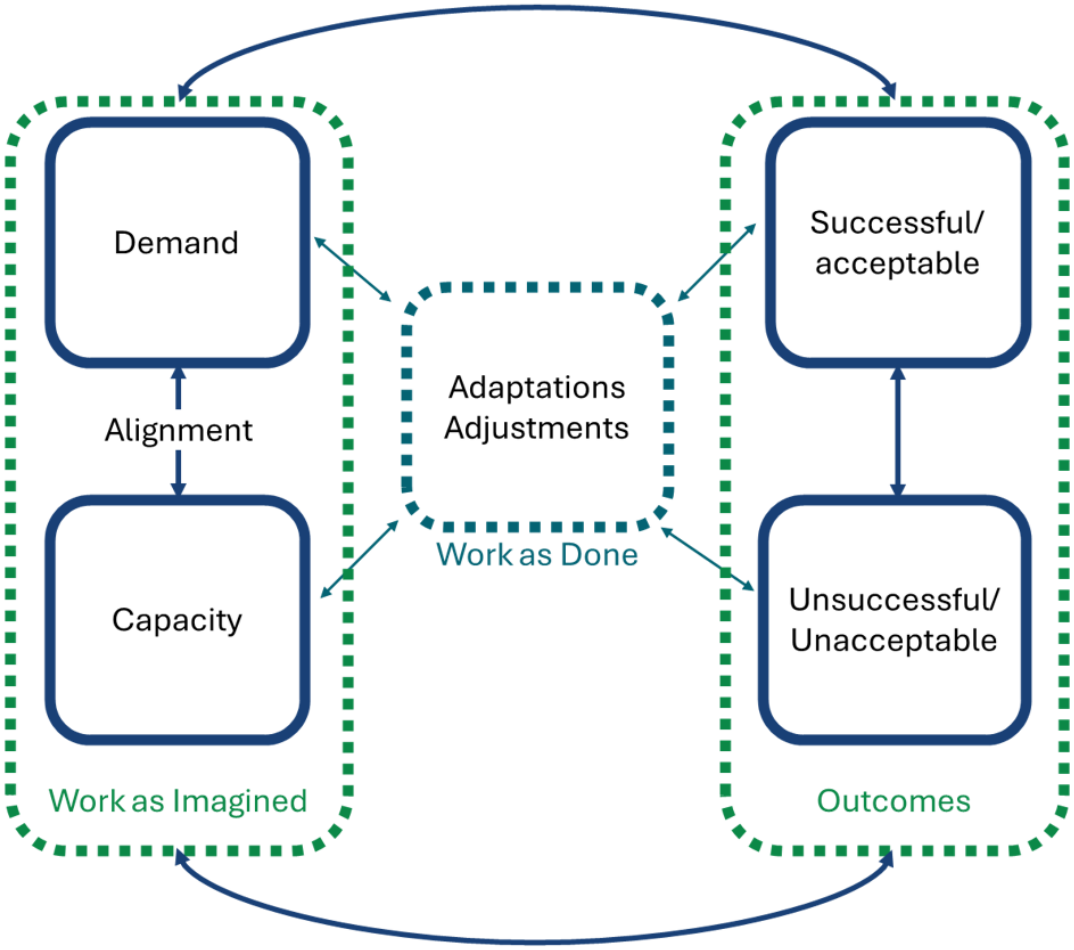
- a board round (where patients are discussed by the multidisciplinary team)
- the process for prescribing medication using the ePMA
- a nursing medication administration round using the ePMA.

The investigation contacted the patient's family who decided not to input into the investigation.

Evidence gathering took place between September 2024 and December 2024.

The investigation used the CARe model (see figure A) to identify adaptations and adjustments that staff had made to bridge the misalignments between unforeseen and/or anticipated demands and capacity (Anderson and Ross, 2020). Using the resilient healthcare approach helped identify opportunities where the Trust may support the use of adaptations by staff, within safe limits, to cope with these challenges. Such supported adaptations enable the dynamic management of pressures and challenges in a safe way (Anderson and Ross, 2020).

Figure A The CARe model



Stakeholder engagement and consultation

The investigation engaged with national organisations to gather evidence at the beginning of the investigation, to determine the scope of work across the theme of medications not given.

The local investigation then engaged with a range of organisations and staff involved in the patient safety event. Local stakeholders and key national organisations were consulted on the local investigation, including the British Thoracic Society and British Society of Haematology. This also enabled checking for factual accuracy and overall sense-checking.

Investigation stakeholders

Local organisations	Staff	National organisations linked to the local investigation	National organisations
Acute NHS Trust where the patient safety event took place	Two respiratory consultants Acute general medicine (AGM) consultant	British Thoracic Society	Medicines and Healthcare products Regulatory Agency
	AGM resident doctor	British Society of Haematology	NHS England
	VTE prevention lead		Independent Health Providers Network
	Matron – acute medicine Lead nurse – AGM ward		Community Pharmacy Patient Safety Group
	Five ward nurses		The Patients Association
	Ward clerk		Academics
	Deputy service manager		Care Quality Commission
	Nurse manager patient flow		Healthwatch
	Two clinical governance staff		Royal Pharmaceutical Society
	Medication safety officer ePMA lead pharmacist		National Institute for Health and Care Excellence