



Health Services Safety
Investigations Body

Investigation report

Investigation report: The role of clinical pharmacy services in helping to identify and reduce high-risk prescribing errors in hospital

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Medication, Communication and decision making

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A note of acknowledgement

We would like to thank the patient's 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

Introduction

This investigation explores the role of ward-based clinical pharmacy services in helping to identify medication errors in hospital. As an example, which we refer to as the 'reference event', we considered the experience of the patient, a 79 year old man, who was admitted to hospital following a fall at home. Sadly, the patient died in hospital after he experienced a medication error that contributed to his death.

Medication safety is an important responsibility for every member of the hospital-based multidisciplinary team. Research has shown that ward-based clinical pharmacy services can play an important role in helping to support the multidisciplinary team to identify and reduce medication errors. However, ward-based clinical pharmacy provision in hospitals is often varied and its important role in helping to address medication errors may not be fully understood.

The reference event

The patient, who was 79 years of age, had a fall at home on day 1.

On day 3, he attended the emergency department at his local NHS Trust. The patient reported significant pain in his hip and a number of other medical conditions, including chronic kidney disease and high blood pressure. At the time of his admission the Trust was on Black Alert. This

is the highest level of operational alert for NHS trusts and means that pressure on the local health and social care system is at such a level that there is increased potential for patient care and safety to be compromised.

On day 4, the patient was transferred from the emergency department to a medical assessment unit. His family reported that he was alert and orientated at the time of his admission to the medical assessment unit.

While the patient was on the medical assessment unit, a medicines reconciliation was completed by a clinical pharmacist. Medicines reconciliation involves checking the medicines a patient is taking against those prescribed to ensure that the correct medicines are provided. This process confirmed that the patient was not prescribed or using warfarin, an anticoagulant medication used to thin the blood, at the time of his admission to hospital.

On day 5, the patient was transferred to the Trust's older people's ward at 04:06 hours. While on the ward, he was noted to be prescribed warfarin and a warfarin medication chart was present in his records. This was an error and it appears that one of the patient's identification stickers had been mistakenly attached to another patient's warfarin chart. This chart had then become part of the patient's medical records.

The patient received four or five doses of warfarin before the medication error was confirmed by a ward-based clinical pharmacist on day 11. The patient subsequently developed internal bleeding and his condition deteriorated due to a number of factors. The patient died on day 21. An inquest concluded that the bleeding he developed after being prescribed warfarin was a contributing factor in his death.

The national investigation

The Healthcare Safety Investigation Branch (HSIB) identified incidents relating to the incorrect prescribing of warfarin via ongoing monitoring of two national databases – the NHS National Incident Reporting and Learning System and the Strategic Executive Information System. The incidents highlighted the complexity associated with prescribing and administering medicines.

High-risk medicines are those which risk significant patient harm or death when used in error. When errors occur in prescribing high-risk medications (such as warfarin) for older patients with multiple medical problems there is a significant risk of serious harm. However, such errors are not limited to high-risk medications alone and may impact on the prescribing and administration of any medication.

The aim of resilient healthcare is to improve an organisation's ability to succeed under variable conditions, in order to improve the safety and performance of routine work. This requires staff and leaders to learn to recognise changing conditions, such as an increase the size or complexity of caseloads and know how to adjust procedures to match these working conditions while sustaining safety and performance.

The provision of ward-based clinical pharmacy services can be a significant component of a trust's healthcare resilience, as it can enhance the multidisciplinary team's ability to prevent and identify medication errors. The investigation has considered whether ward-based clinical pharmacy services are resilient to the challenges created by operational pressures and the additional complexity associated with caring for older people.

These considerations may be applicable to other staff groups presented with increased demand and patients with more complex needs when considering how such factors impact on the ability of staff to carry out their work.

Findings

Ward-based clinical pharmacy services can play an important role in helping the multidisciplinary team to identify and reduce high-risk medication errors.

- There is significant variation in how ward-based clinical pharmacy services are staffed, organised and developed.
- There is variation in the organisation and understanding of the role of ward-based clinical pharmacy services in the NHS between the point of initial medicines reconciliation and discharge.
- The impact of a complex patient caseload or operational pressures on the ability of ward-based clinical pharmacy services to operate and adapt effectively is not well studied.

There may be a gap between the expected standard of pharmacy care and the care pharmacy services are able to deliver within the constraints of current systems and pressures.

- Practical strategies should be developed to help address risks to the resilience of ward-based clinical pharmacy services to best use the pharmacy resources currently available within the NHS.
- There is a lack of evidence to support which models of pharmacy care are resilient and offer the most effective use of ward-based clinical pharmacy resources.
- There is not a consistent, shared understanding between NHS staff of medications that may be considered high risk or situations in which there is a higher risk of medication errors occurring.

- Pharmaceutical care of older people is a complex and increasingly demanding specialty that involves caring for patients at the greatest risk of medicine-related harm.

Recommendations and observations

HSIB makes the following safety recommendations

Safety recommendation R/2020/087:

It is recommended that NHS England and NHS Improvement carry out work to understand and further define the work of hospital clinical pharmacy teams, including the period between initial medicine reconciliation and discharge, in consultation with relevant stakeholders.

Safety recommendation R/2020/088:

It is recommended that the Royal Pharmaceutical Society, supported by NHS England and NHS Improvement, should provide guidance on models of hospital clinical pharmacy provision. The guidance should provide information on the models' ability to enhance safety and healthcare resilience and include consideration of the appropriate skill mix and experience within the clinical pharmacy team.

Safety recommendation R/2020/089:

It is recommended that the NHS Specialist Pharmacy Service should update its resource on the prioritisation of hospital clinical pharmacy services to facilitate the dissemination of developments in good practice and policy with respect to pharmacy prioritisation and the issues highlighted in this report.

HSIB makes the following safety observations

Safety observation O/2020/066:

Effective clinical pharmacy services have been evidenced to improve a range of measures linked to efficiency and patient safety in acute hospitals.

Safety observation O/2020/067:

Further integration of clinical pharmacy services within the MDT and within strategic decision making may improve a shared understanding of which medicines and situations place patients at greater risk of serious medication errors occurring.

Safety observation O/2020/068:

Clinical pharmacy services should consider using validated tools to assist in prioritising pharmacy care and identifying high-risk medicines and high-risk situations for medication error. Where electronic medical record systems are used, such tools could be integrated into these systems to aid prioritisation.

Safety observation O/2020/069:

Caring for older patients in hospital often presents a high-risk situation for medication errors occurring. Further efforts should be made to learn from technological developments and the organisation of pharmacy services in other high-risk areas of care that may improve system resilience in older persons care.

1 Background

1.1 Definition of medication errors

1.1.1 A medication error is an unintended failure in the drug treatment process that leads to, or has the potential to lead to, harm to the patient (European Medicines Agency, 2015a).

Examples of common medication errors include prescribing or dispensing errors, giving a medication to the wrong patient, giving the wrong dose of a medication to a patient, or forgetting to give a patient a medication that has been prescribed for them (European Medicines Agency, 2015b).

1.1.2 Many medication errors cause little or no harm, but they demonstrate failures in the system that have the potential to cause fatal errors, and so need to be corrected to protect patients. The report 'To err is human' (Institute of Medicine, 2000) highlighted medication error as the most frequent failure in care causing injury and death. Medication errors, irrespective of harm, carry human costs for the patient, their family and friends, and for the professionals concerned.

1.2 Prevalence of medication errors

1.2.1 Research published in February 2018 (Elliott et al., 2018) estimated that 237 million medication errors occur at some point in the medication process in England per year. Of these, the researchers estimated that 66 million accounted for potentially significant errors that led to patient harm.

1.2.2 Further research in 2020 (Elliott et al., 2020) estimated that medication errors cost the NHS over £98m annually and may directly cause 712 deaths per year and indirectly contribute to approximately 1,708 deaths per year.

1.3 World Health Organization targets and priorities

1.3.1 The World Health Organization (WHO) aims to co-ordinate, disseminate and accelerate improvements in patient safety worldwide.

1.3.2 In March 2017, the WHO announced its 3rd Global Safety Challenge – Medication Without Harm (World Health Organization, 2017). Medication Without Harm aims to reduce severe avoidable medication-related harm by 50% globally in the next five years.

1.3.3 In June 2019 the WHO published three technical reports (2019a; 2019b; 2019c) highlighting priority areas for action:

- medication safety in polypharmacy (the use of multiple medicines at the same time by one patient)
- medication safety in high-risk situations medication safety in transitions of care.

1.4 Care of older people

1.4.1 The WHO (2011) estimates that the global population of people aged over 65 years will double from 8% in 2010 to 16% in 2050. In the UK, the Office for National Statistics (2019) identified that in 2017 one in every five people (18.2%) in the UK was aged over 65 years. By 2037, this is projected to reach around one in every four people (24%).

1.4.2 National Institute for Health and Care Excellence (NICE) guidance (2018) recognises that: 'Older people are more likely to be admitted for medical emergencies, and to stay longer in hospital, than younger people. This is because there is more multi-morbidity, frailty and polypharmacy in older people.'

1.4.3 Multi-morbidity refers to patients who have two or more long-term conditions. Frailty is a distinctive health state related to the ageing process in which multiple body systems gradually lose their in-built reserves. Around 10% of people aged over 65 years live with frailty; this rises to between a quarter and a half of those aged over 85 years. Polypharmacy refers to the concurrent use of multiple medications by one patient. Patients aged 65 years or older

1.5 High-risk medicines

1.5.1 High-risk medicines are broadly understood to be those medicines that have a high risk of causing significant harm or death when used in error. This can identify medicines that may be fatal if administered incorrectly or where there is a narrow therapeutic range between effective treatment and harmful doses.

1.5.2 A systematic review of errors involving high-risk medicines in hospitals (Alanazi et al., 2016) showed that the prevalence of prescribing errors could be as low as 0.24 errors per 100 prescriptions or as high as 89.6 errors per 100 prescriptions. The study identified that this broad range of results may reflect the lack of a shared understanding of what constitutes a high-risk medicine, and the methods used, among the studies it reviewed.

1.6 Warfarin

1.6.1 Warfarin is an anticoagulant medication (a medication to stop blood clotting) and is the most common form of anticoagulant prescribed by the NHS (NHS, 2019a). Warfarin is an example of a medication commonly considered to be a high-risk medicine. Saedder et al (2014) identified that warfarin was one of seven medications that were involved in 47% of all serious medication errors.

1.6.2 Warfarin therapy is intended to decrease the blood's tendency to clot, but not to stop it clotting completely. Many factors affect the effectiveness of warfarin; however, the effects of warfarin may only manifest themselves up to a week after warfarin is taken, depending on the dose and specific patient factors. This requires warfarin doses to be closely supervised and regular blood tests to be performed to monitor the international normalised ratio (INR). This is a measure of how long it takes blood to clot; the longer it takes, the higher the INR reading.

1.6.3 Patients will have an identified therapeutic INR range for their condition. This is normally between 2.0 and 3.0 for most conditions for which warfarin is prescribed (British National Formulary, 2019). The amount of warfarin taken to ensure patients are within this range can vary on a daily basis. Patients not receiving warfarin therapy would normally be expected to have an INR reading of around 1.0.

1.6.4 Due to the complexity, associated risks and monitoring requirements of warfarin therapy, details of warfarin prescribing and administration may be contained within a dedicated warfarin medication chart. This is a separate document to the main medication chart where most other medications would be noted. Warfarin charting is considered further at Appendix B.

1.6.5 Warfarin may be more commonly prescribed in older patients due to its use in conditions more frequently identified in older patients, such as atrial fibrillation (a heart rhythm disorder) (British National Formulary, 2019; NHS, 2019b). The potential for errors in warfarin therapy may also increase in older patients (Khoury and Sheikh-Taha, 2014).

1.7 Medicines reconciliation

1.7.1 Medicines reconciliation is the process of identifying an accurate list of a patient's current medicines and comparing them with the list currently in use, recognising any discrepancies and documenting any changes. This process results in a complete list of medicines that can be accurately communicated.

1.7.2 The NICE guideline on the safe and effective use of medicines in health and social care (National Institute for Health and Care Excellence, 2015) covers medicines reconciliation. The guideline states that in an acute setting, a patient's medicines should be accurately listed, and medicines reconciliation should be carried out within 24 hours, or sooner if clinically necessary. Medicines reconciliation may need to be carried out more than once during a patient's hospital stay, for example, when the patient is admitted, transferred between wards or discharged.

1.8 Medication review

1.8.1 The NICE guideline (2015) identifies that the term medication review can have different interpretations, and that there are different types of medication review which vary in their quality and effectiveness. The investigation has focused on the role of medication review for inpatients in acute hospitals. NHS Specialist Pharmacy Service guidance (2011) identifies that the purpose of medication review for ward-based clinical pharmacy services in these settings is to review prescriptions written for inpatients to ensure that prescriptions are safe and appropriate.

1.9 NHS England Operational Pressures Escalations Levels (OPEL) alerting framework

1.9.1 The OPEL alerting framework was first introduced in 2016 (NHS England, 2019). It aimed to provide a consistent approach at times of increased pressure on the NHS, specifically by providing a nationally consistent set of escalation levels and responsibilities to maintain quality and patient safety. There are four levels of OPEL reporting:

OPEL 1: The local health and social care system capacity is such that organisations are able to maintain patient flow and are able to meet anticipated demand within available resources.

OPEL 2: The local health and social care system is starting to show signs of pressure.

OPEL 3: The local health and social care system is experiencing major pressures compromising patient flow, and these pressures continue to increase.

OPEL 4: This is the highest level of operational alert and means that pressure on the local health and social care system is at such a level that there is increased potential for patient care and safety to be compromised and organisations are unable to deliver comprehensive care. OPEL 4 is commonly referred to in the NHS as 'Black Alert'.

1.9.2 Parliamentary reports (Baker, 2017) identified that a quarter of NHS trusts in England experienced a Black Alert on at least one day of winter in 2016/2017. The reporting of operational pressure escalation levels during winter 2017/2018 was not made available to the public. However, a further report (Baker, 2018) acknowledges that there was an increase in ambulance attendances to hospital, four-hour waiting times, bed occupancy and a decrease in available beds compared to the previous winter. This would represent even greater strain on the NHS and its ability to meet demand in this period.

2 The reference event

2.1 Day 1 – Monday

2.1.1 The patient, a retired civil servant aged 79 years, suffered a fall at home. Immediately after the fall, the patient reported some hip pain to his son, but he did not wish to attend hospital at this point. The patient's son told the investigation that his father enjoyed horse racing and did not want to miss the Cheltenham horse racing festival, which was due to be shown on television.

2.2 Day 3 – Wednesday

2.2.1 The patient's pain had increased and he called an ambulance. The patient attended the Trust's emergency department at approximately 12:30 hours, when the Trust was on Operational Pressures Escalation Level (OPEL) 4, or Black Alert.

2.2.2 The patient was experiencing hip pain and reduced mobility. His medical history was taken, and this included: chronic anaemia [1], chronic obstructive pulmonary disease [2], high blood pressure, stage four kidney disease [3], and vitamin D deficiency [4]. At the time of his admission, the patient was taking 12 different medications and supplements at home.

2.2.3 An X-ray of the patient's hip did not clearly show a fracture. Medical staff decided that the patient did not immediately require an operation but that he would be admitted to hospital. He would require an MRI scan and further medical treatment to confirm whether his hip was fractured and to address his ongoing pain and mobility problems.

2.3 Day 4 – Thursday

2.3.1 The patient was transferred to a medical assessment unit (the Unit) at around 04:00 hours. The Unit had an enhanced pharmacy provision, with a clinical pharmacist available from 08:00 hours to 20:00 hours, 365 days per year.

2.3.2 The Trust used a mainly paper-based medical records system and did not have an electronic prescribing and medicines administration system. Instead, the Trust used paper-based medicine charts.

2.3.3 A pharmacist completed the patient's medicines reconciliation at 13:30 hours. At this time, the patient was noted to be receiving all his usual medications.

2.4 Day 5 – Friday

2.4.1 The patient was transferred to one of the Trust's older people's wards (the Ward) at 04:06 hours. Ward admission documentation was completed by staff and recorded that the patient had been prescribed warfarin.

2.4.2 The investigation found that at this point, the patient had not been prescribed warfarin by Trust staff and this was not one of his usual medications noted by his medicines reconciliation. Instead, a patient identification sticker containing the patient's details was attached to another patient's (Patient B's) warfarin medication chart in error.

2.4.3 This sticker included the patient's name, date of birth, hospital and NHS number, and address. The chart was included in the patient's medical notes and recorded one dose of warfarin as having been administered on day 3. This was likely administered to Patient B prior to the patient's details being added to the warfarin medication chart. However, the investigation cannot discount that this dose may have been the first dose provided to the patient.

2.4.4 From this point on, the warfarin medication chart formed part of the patient's medical record during his time on the Ward. The circumstances in which this error may have occurred are explored in Appendix A. The patient was subsequently prescribed a 3 milligram (mg) dose of warfarin by a member of the medical team, but an error meant that this dose was not given to the patient.

2.5 Day 6 – Saturday

2.5.1 The patient's international normalised ratio (INR) range (see 1.6.2 to 1.6.3) was tested and the blood test showed a reading of 1.0. This was below the therapeutic range noted on the warfarin medication chart. The patient's medical record suggests that nursing staff noted that the warfarin dose planned for day 5 had not been given. However, the warfarin was prescribed on the warfarin medication chart and the investigation cannot confirm if it was given to the patient. This would have been his first or second dose. A plan was noted to check the patient's INR reading on day 7 and re-dose the warfarin accordingly.

2.6 Day 7 – Sunday

2.6.1 The patient's INR was again recorded as 1.0 and he received a 4.5mg dose of warfarin. This was the second or third dose of warfarin he received.

2.7 Day 8 – Monday

2.7.1 The patient was again given a 4.5mg dose of warfarin. This was the third or fourth dose of warfarin he received.

2.8 Day 9 – Tuesday

2.8.1 The patient's INR was recorded as 1.5 and he was given 6mg of warfarin. This was the fourth or fifth, and last, dose of warfarin that the patient received.

2.8.2 The ward-based clinical pharmacist reviewed the patient's medications at 13:46 hours. The pharmacist identified that the patient had a separate warfarin medication chart in his records, that the indication noted for warfarin on the chart was atrial fibrillation (an irregular heartbeat), and that the reason for admission had been listed as 'acute delirium'.

2.8.3 The pharmacist noted that the warfarin medication chart had not been indicated on the patient's main medication chart. In response to this, the pharmacist ticked a box on the main medication chart indicating that a separate warfarin medication chart was in use. They wrote 'warfarin' on the main medication chart together with a note saying: 'As per chart: see anticoagulation chart.'

2.9 Day 10 – Wednesday

2.9.1 Nursing staff noted that the patient was more confused and drowsy. His kidney function decreased and his case was reviewed by members of the specialist medical team. They advised that the confusion was likely due to an infection and his existing co-morbidities.

2.9.2 At 18:50 hours, the patient was seen by the hospital at night team [5] due to decreased consciousness and a suspected seizure. A CT scan [6] of the patient's brain was requested to rule out a bleed on his brain. A note was then entered by the hospital at night team to ask that nursing staff 'hold warfarin until CT reviewed'.

2.10 Day 11 – Thursday

2.10.1 The clinical pharmacist reviewed the patient's medications in detail. The pharmacist entered a note into the medical record to confirm that they had checked the patient's past medical history in more detail and that he did not have atrial fibrillation or a history of being prescribed warfarin.

2.11 Day 12 – Friday

2.11.1 Medical staff contacted the patient's GP surgery to confirm whether the patient was routinely taking warfarin while at home. The GP surgery confirmed that the patient had not been prescribed warfarin and a plan was noted in the medical records to stop warfarin as it was not indicated in the patient's care.

2.12 Day 14 – Sunday

2.12.1 The patient developed a large internal bleed and was given five units of blood. A blood test showed his INR as 4.9 indicating his blood would take longer to clot. The patient received vitamin K to counteract the effects of the warfarin; however, he continued to bleed from his rectum over the following days and acquired pneumonia (a swelling of the tissue in the lungs).

2.12.2 As the patient's condition continued to deteriorate, staff discussed the patient's condition with his family and they agreed that he would receive palliative care.

2.13 Day 21 – Sunday

2.13.1 The patient died in hospital. His primary cause of death was noted as bronchopneumonia, with a retroperitoneal bleed (a bleed behind the abdominal membrane) also being noted on the death certificate.

2.13.2 A subsequent Coroner's inquest found that the unnecessary warfarin treatment contributed to the patient's death

3 Involvement of the Healthcare Safety Investigation Branch

3.1 HSIB identified incidents relating to the incorrect prescribing of warfarin (an anticoagulant) via ongoing monitoring of the NHS National Reporting and Learning System and Strategic Executive Information System. The incidents highlighted the complexity associated with prescribing medicines.

3.2 When errors occur in prescribing high-risk medications (such as warfarin) for older patients with multiple medical problems there is a significant risk of serious harm.

3.3 The incidents also identified the need for the healthcare system to proactively identify risks. Although the role of ward-based clinical pharmacists is traditionally viewed as a 'safety net', they can also improve capacity to proactively monitor patients with complex medical needs who are receiving medicines that are known to be high risk.

3.4 Following a detailed scoping investigation, HSIB's Chief Investigator authorised a full investigation as the safety issue met the following criteria:

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

3.5 People in England are living longer and the number of older people in England is growing significantly. Risks associated with medicine prescription are present in all care settings where medicines are prescribed to older people.

3.6 The average age of patients admitted to hospital is increasing (NHS Digital, 2018). Operational and clinical pressures within acute hospital care may create additional factors that lead to drug errors not being identified in older patients. Multimorbidity and medicines taken by older people increases the complexity of medication prescription and the risk of patient harm when medication errors occur.

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

3.7 Information from NHS England (2014) suggests that medicine prescribing errors in hospital occur in around 7% of all prescriptions issued. Most drug prescribing errors are identified by clinical staff. However, this requires resources that may be degraded by other clinical and operational activities. The increased complexity of medicine use in older people can further stretch these resources and increase the risks that these errors may be missed.

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

3.8 There is a need to understand how the risks of incorrect drug prescribing are mitigated by staff and the systems in which care is provided to older people. There is the potential for an HSIB investigation to provide further insight into the specific risks and needs associated with the care of older people in hospital and identify appropriate interventions.

3.9 The initial investigation considered that there may be a specific risk related to the administration of high-risk medicines to older patients in hospital. Further investigation has identified specific risks associated with medication prescription and that these risks are not limited to the prescription of high-risk medications in isolation.

Investigation methodology

3.10 The concept of resilient healthcare stems from the field of safety science and has been proposed as necessary to improve safety in complex systems (Hollnagel et al., 2017). The aim of resilient healthcare is to understand and improve an organisation's ability to succeed under variable conditions, in order to improve the safety and performance of routine work. This requires staff and leaders to learn to recognise changing conditions and know how to adjust procedures accordingly.

3.11 The investigation has considered the resilience of the design of current ward-based clinical pharmacy provision by examining the challenges posed by caring for older people and increased operational pressures. These considerations may be applicable to other staff groups presented with increased demand and patients with complex needs when assessing how these factors impact on staff's ability to carry out their work and maintain patient safety.

3.12 The reference event consisted of a complex set of interactions, each of which contributed to the outcome for the patient. They included, among other elements:

- the work environment in the medical assessment unit
- medical prescribing
- nursing and medical staffing
- seven-day working
- electronic and paper-based medical record systems.

3.13 The investigation could not reasonably consider all these factors at a national level. Some of these factors have already been considered as broader patient safety risks in other HSIB investigation reports. For example:

- electronic medical record systems and weekend working were considered in 'Electronic prescribing and medicines administration systems and safe discharge' (Healthcare Safety Investigation Branch, 2019a)
- medical prescribing was considered in 'Inadvertent administration of an oral liquid medicine into a vein' (Healthcare Safety Investigation Branch, 2019b).

3.14 Other factors that were identified in the reference event have been referred internally to the HSIB Intelligence Unit for consideration as safety risks that may require specific focus in future national investigations. These include, for example:

- patient transitions in hospital care
- the wider impact of Black Alert on hospital systems work systems in medical assessment units.

3.15 The investigation adopted an adapted 'bowtie' methodology (a diagrammatic method for identifying, visualising and analysing the risks and barriers associated with adverse events) (Chartered Institute of Ergonomics and Human Factors, 2016) to consider the processes in place to identify a medication error occurring.

3.16 The bowtie approach can provide a visual summary of scenarios that may exist in relation to a hazard (in this case a medication error occurring) (see figure 1). Once a 'hazard' is released by the 'top event' the bowtie helps to identify what control measures are in place to help identify or mitigate the hazard and what may impact on these measures being successful.

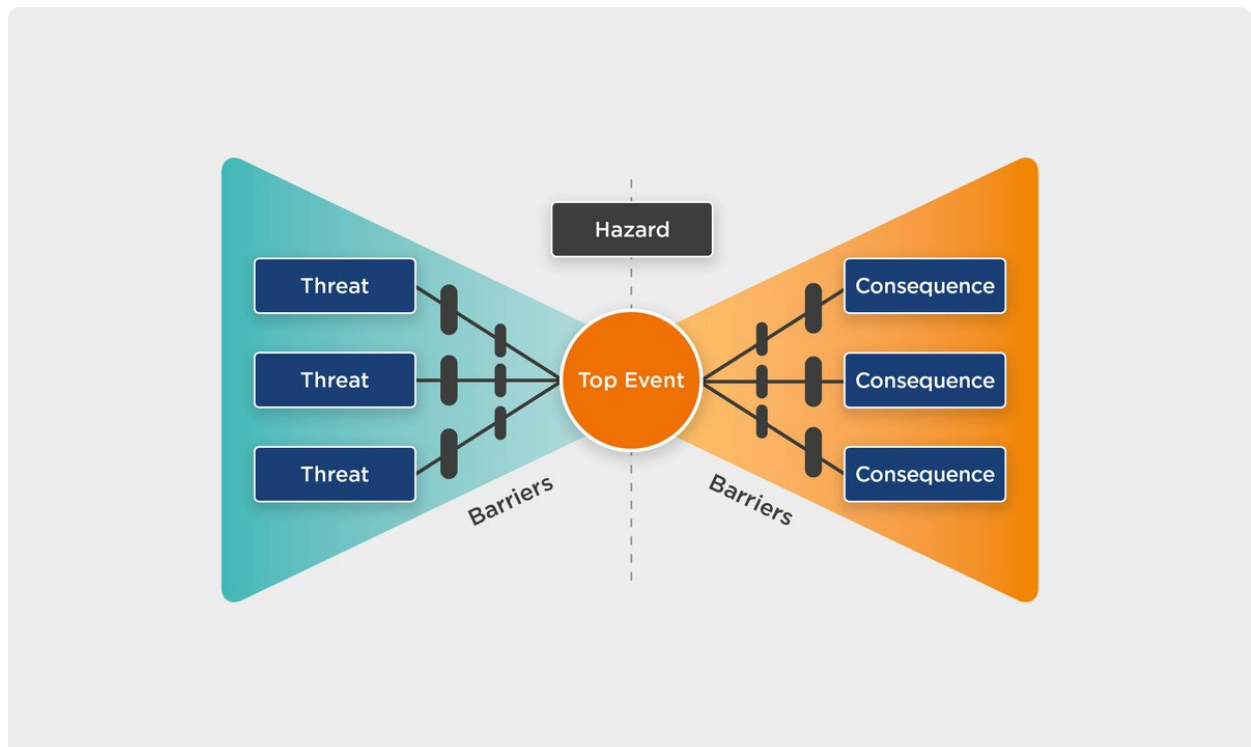


Fig 1 Example bowtie diagram

3.17 For example, in the reference case the bowtie highlighted the various professionals and systems that existed prior to the medication error occurring and the systems in place to identify this error once the hazard was released.

3.18 Although the specific medication error in the reference event was induced by a chart labelling error, the investigation considered that a medication error could be induced in a number of different ways. Given this, the investigation focused on how medication errors in general may be identified (the right of the bowtie), regardless of how they may have been induced.

3.19 The investigation interviewed frontline nursing, medical and pharmacy staff and managers within the Trust where the reference event occurred. The investigation also carried out observations in clinical areas and reviewed the patient's clinical records, Trust policies and national guidance.

3.20 The findings of this report have been supplemented by reference site visits to other NHS trusts, insights from subject matter advisors, academics and academic literature, in addition to expertise provided by colleagues in national organisations.

3.21 The evidence collated by the investigation indicated that ward-based clinical pharmacy services were an area for further investigation. Although medication safety is a key responsibility for all members of the multidisciplinary team (MDT), pharmacy services were perceived to act as a key component in assisting the MDT to identify medication errors, owing to their role as medication specialists. These findings have been supported by the subject matter advisors and national bodies that have engaged with the investigation.

4 Analysis and findings from the local investigation

4.1 Ward-based clinical pharmacy services

4.1.1 The investigation identified that a range of measures in place between the members of the multidisciplinary team (MDT) to help capture medication errors had not been effective in identifying the medication error in the patient's care.

4.1.2 Typically, the mechanisms on the left-hand side of a bowtie (to mitigate the chance of errors occurring) will be different to the mechanisms on the right-hand side of the bowtie (to capture and mitigate an error once it has occurred).

4.1.3 With regard to identifying medication errors, the investigation observed that many of these processes were the same on both sides of the bowtie; the same processes were in place on the Unit and the Ward to assist in identifying medication errors.

4.1.4 However, the medication review conducted by the ward-based clinical pharmacy service provided a new barrier to capturing errors once the patient was admitted to the Ward. The review went beyond medicines reconciliation and provided a more holistic view of the patient's medication history.

4.1.5 This was an example of where a service assisted the MDT in identifying a high-risk medication error. In the reference event, it happened too late to avoid the patient from suffering the adverse effects of a medication error. However, a greater understanding of the role and importance of ward-based clinical pharmacy services may have facilitated the MDT to identify the medication error at an earlier stage and could be important in enhancing the resilience of the healthcare system.

4.1.6 Both medical and nursing staff groups stressed that they considered pharmacy to be a "safety layer" that provided a specific insight into any medication-related concerns. Medical and nursing staff highlighted that it was routinely pharmacy staff that would alert them to any medicines-related issues and that they would rely on the pharmacy team to help in resolving any medication-related issues that were brought to their attention.

4.1.7 The nature of comments from medical and nursing staff framed pharmacy as a service that would act to “catch” any errors (the right hand side of the bowtie) that had occurred in the medical or nursing care and then alert these to the medical or nursing team to be resolved.

4.1.8 The responsibility for medication safety is shared among the MDT and no single role is exclusively responsible for medication safety. Pharmacy staff felt that resourcing and the challenges they faced caring for older patients and during Black Alert meant that they could not provide the comprehensive service that other staff understood was in place on the Ward. Pharmacy staff told the investigation that they often felt it was “their job” to identify medication errors but that they were limited in their ability to be proactive in seeking to identify and address medication errors.

4.1.9 The investigation identified the important role that the ward-based clinical pharmacy service played in identifying the medication error in the reference event. The investigation considered whether ward-based clinical pharmacy services were organised and operated in a way that allowed them to be resilient to the pressures faced by the healthcare system. This was with a view to considering whether a greater understanding of the role of ward-based pharmacy services would further assist in supporting the MDT in the identification and mitigation of medication errors.

4.2 Organisation of Trust pharmacy services

4.2.1 Pharmacy services in the Trust operated under service-level agreements with the main clinical directorates. Directorates would agree a level of pharmacy provision and contract with pharmacy services to provide this level of care based on an assessed level of need. The Trust used paper-based medication charts to record prescribing and administration of medicines. The Trust did not use an electronic prescribing and administration system or a full electronic patient record.

Pharmacy provision on the Unit

4.2.2 On the Unit, pharmacy services had been contracted to provide a service for 12 hours a day (08:00 hours to 20:00 hours), 365 days a year. The service model provided that up to four pharmacists were present on the Unit from Monday to Friday between 08:00 hours and 12:00 hours, with at least one pharmacist present at all other times. This allowed a focus on reviewing evening and overnight admissions to the Unit so that timely medicines reconciliation could take place, irrespective of hospital alert status.

4.2.3 A pharmacy technician [7] was also available on the Unit from Monday to Friday between 08:30 hours and 17:00 hours to assist pharmacists in carrying out their duties.

4.2.4 The model of pharmacy care on the Unit had been developed in response to challenges in recruiting medical staff. This model of service aimed to enhance the resilience in the system by accommodating regular peaks in workload associated with medicines reconciliation.

4.2.5 The focus on medicines reconciliation and pharmacy intervention within the first 24 hours of a patient's admission meant that staff were confident that any errors would be captured before patients were admitted to the Ward. However, as is obvious, medicines reconciliation within 24 hours cannot act to capture medication errors that may be made after the medicines reconciliation has taken place.

Pharmacy provision on the Ward

4.2.6 Clinical pharmacy staff were available on the Ward. The service-level agreement in place with the pharmacy team meant that one pharmacist would work from 09:00 hours to 17:30 hours, Monday to Friday. Out-of-hours and weekend services were then provided by an on-call pharmacy team.

4.2.7 Older people's wards were a level two priority for the Trust pharmacy services, meaning 50% of patient medication charts were due to be screened by a clinical pharmacist every day.

4.2.8 The service-level agreement in place between pharmacy and the clinical directorate at the time of the reference event was approximately 10 years old and had not been subject to a review. Staff commented to the investigation that the increased complexity encountered in older people's care was not reflected in this service-level agreement.

4.2.9 The ward-based clinical pharmacist on duty was expected to cover 56 patients across two wards. The expectation was that half of the patients on each ward would be seen every day, Monday to Friday, by a pharmacist. During Black Alert the Trust had created an additional bed space within each ward to respond to the increased demand on services. This meant that at the time of the patient's admission, the pharmacist was caring for 58 patients across two wards.

4.2.10 The ward-based clinical pharmacist on duty during the patient's admission was a band six staff member (a junior pharmacist), approximately six months into their first year in post. They had access to a band seven senior clinical pharmacist as a mentor and for management support.

4.2.11 In addition to the ward-based clinical pharmacy staff, the Trust had made provision for pharmacy technicians to support the care of patients in the older people's wards. However, pharmacy staff and staffing data highlighted that there were several vacancies for pharmacy technicians within the service and that often pharmacists would operate alone, without this support.

4.2.12 At the time of the patient's admission, the Trust confirmed that one pharmacy technician was covering three wards in total (including the Ward) and could not confirm what (if any) time the technician would have been able to dedicate to the Ward. This meant that ward-based clinical pharmacists were also carrying out duties that would have routinely been delegated to pharmacy technicians (for example, transcribing new medication charts or assisting in ordering medications).

4.3 Pharmacy work prioritisation

4.3.1 An electronic pharmacy handover tool was available to document an overview of clinical information to assist ward-based clinical pharmacists in planning and delivering care. This was perceived to enhance system resilience by allowing clinical pharmacists to prioritise services in times of high demand.

4.3.2 The relevant part of the handover tool regarding medications involved two yes-or-no questions, which asked:

- whether a medicines reconciliation had been completed
- whether a full medicines history had been taken.

4.3.3 In the reference event, the answer to both these questions had been 'yes', to show that these tasks had been completed on the Unit prior to the patient's admission to the Ward.

4.3.4 Staff told the investigation that prioritisation of patients was often based on a range of clinical and operational needs. The following hierarchy reflected the patients perceived to be of greatest pharmaceutical priority on the Ward:

- patients who had not had their medicines reconciled
- patients that were due to be discharged
- patients whose early warning scores may be elevated (which could suggest that their condition was deteriorating).

4.3.5 When the patient was admitted to the Ward, the ward-based clinical pharmacist was able to refer to the electronic handover tool and note that the patient's medicines had been reconciled and a full medicines history had been taken. This influenced their perception of how urgently the patient required pharmacy intervention.

4.3.6 The approach to prioritisation was also reflected in the Trust's internal investigation report. It commented that: 'Usual practice...is that only patients who are new to the ward over the weekend have their medication charts screened as a priority by the ward pharmacist on the Monday. These screenings take place following the processing of...prescriptions to support

patient discharges. If the pharmacist has the capacity in their work schedule they will also screen any charts of other ward inpatients with the aim of reviewing any other patient charts within the next 48 hours.'

4.3.7 The ward-based clinical pharmacist explained that there was limited time to focus on other patients whose needs did not fall within the stated priorities for pharmacy care. They provided an example from their working week, describing that on a Monday morning, four patients had required their medicines to be reconciled on the Ward as this had not been completed prior to admission. The pharmacist estimated that this had taken at least 45 minutes per patient. This meant that nearly half of their working day had been spent on four of the 29 patients they had been expected to see that day.

4.3.8 The ward-based clinical pharmacist told the investigation that this was a relatively common workload as the Ward primarily admitted patients from two separate medical assessment units: the Unit from which the patient was admitted and another medical assessment unit within the hospital.

Most patients admitted to the Ward from the Unit had undergone medicines reconciliation. However, the other medical assessment unit in the hospital did not have an enhanced pharmacy provision. Instead it operated a pharmacy service from Monday to Friday, 09:00 hours to 17:30 hours. This meant that patients admitted to the Ward via this route out of hours or over the weekend would routinely require medicines reconciliation on the Ward.

4.4 Identification of the warfarin prescribing error

4.4.1 The ward-based clinical pharmacist explained that they would try to review all patient medication charts as soon as possible. However, it was only later in the working week that admissions and discharges appeared to slow, and with more time available and a more manageable workload, it was possible to carry out a more detailed medication review for non-priority patients.

4.4.2 The patient was first seen by the ward-based clinical pharmacist when they completed a medicines review at 13:46 hours on day 9, five days following his admission. The pharmacist identified that this was the first opportunity they had to review the patient's medication chart owing to their workload that week.

4.4.3 Data from the Trust supports this recollection, with day 5 being the first day of the patient's admission to the Ward (Friday). The data shows the increased number of patients being admitted and requiring discharge on Friday and Monday, with this demand slowly reducing during the week (see figure 2).

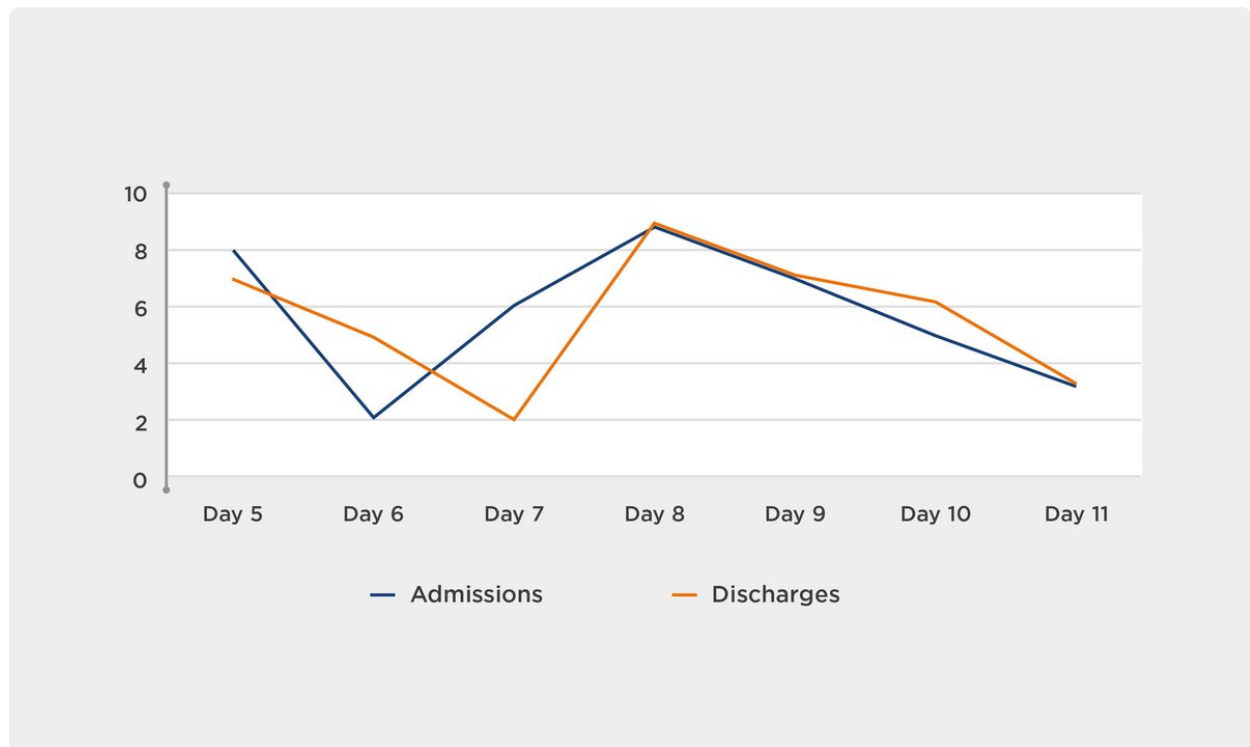


Fig 2 Admissions and discharges from the two wards covered by the clinical pharmacist

4.4.4 When carrying out a medicines review on day 9 the ward based clinical pharmacist had identified that the patient was prescribed warfarin and that he had a separate warfarin chart in his medical records. This had not been indicated on his main medication chart, so the pharmacist ticked the anticoagulant box on the front of the medication chart and also wrote 'warfarin' on it with a note saying: 'As per chart: see anticoagulation chart.' They noted that the indication for warfarin was atrial fibrillation, in line with the information contained on the warfarin medication chart. They also wrote a query asking why acute delirium had been noted as the reason for the patient's admission on the warfarin medication chart, given he had been admitted for a suspected fracture.

4.4.5 The ward-based clinical pharmacist told the investigation that they would have had limited time to review the patient's medication chart in detail due to the need to prioritise other patients. They had noted the warfarin medication chart on the main medication chart to ensure that this did not get overlooked by ward staff and understood that the patient's medicines reconciliation would have resolved any medication issues prior to the patient's admission to the Ward.

4.4.6 The ward-based clinical pharmacist explained to the investigation that it was only when they had more time to review the patient's medical records on day 11 that they were able to confirm the warfarin prescribing error. This was following a further, more detailed examination of the patient's medical records.

4.5 Systems and processes to identify prescribing errors

4.5.1 There were a number of other systems and processes in place to underpin prescribing and administration of medications that could have assisted in identifying the medication error before day 11. The investigation has considered some factors that were relevant in the reference event:

- handover to the ward team
- consultant and junior medical review
- administration of warfarin by nursing staff
- multidisciplinary team.

Handover to the ward

4.5.2 The patient was transferred to the Ward at 04:06 hours on day 5. Staff told the investigation that they would routinely not seek to transfer older patients at night, or before around 06:00 hours, as this could cause increased confusion and often meant disturbing patients from sleep. However, at the time of the reference event the Trust was operating a “green for go” policy due to the Black Alert status.

4.5.3 Staff explained that, due to the demand on the system, once a bed space became available it was marked green on the hospital bed management system and patients were transferred immediately to increase the patient flow from the emergency department and assessment units.

4.5.4 Nursing staff explained that during this period they would not always receive a complete verbal handover from the assessment units and it was possible for patients to “just appear” on wards with their accompanying medical records.

4.5.5 A telephone handover is documented in the patient’s medical records. However, the entry does not indicate what was communicated to nursing staff at this time or whether handover was conducted using the SBAR [8] process (NHS Improvement, 2018).

4.5.6 Nursing staff told the investigation that typically a handover would focus on the medical complaint for which the patient was being admitted to the Ward and their planned treatment. It would be unlikely that it would be possible or expected that all medications and comorbidities may be communicated in the case of an older patient, owing to the complexities of their care and the time available to staff for the handover of information. This meant that handover information alone was not an effective barrier to capture the medication error.

4.5.7 When the patient was transferred from the Unit it was expected that he would have been accompanied by any medications he had brought with him to the hospital. In addition, patients on warfarin therapy were issued with a 'yellow book' by the Trust that is used in anticoagulation clinic to monitor international normalised ratio (INR) readings (see 1.6.2 to 1.6.3). This would also have been expected to travel with the patient to the Ward.

4.5.8 However, staff explained that it was relatively common for medications to go missing into a "black hole" between the assessment units and the Ward when patients were transferred, particularly in times of peak demand. In addition, staff identified that it was common for patients not to have their yellow book with them when they arrived at hospital, particularly where there had been an emergency or ambulance transfer. Absent or incomplete patient medications and information had become normalised to staff and meant that there was limited opportunity for this barrier to be effective.

Consultant and junior medical review

4.5.9 When the patient was admitted to the Ward his name was added to a consultant's patient list so that he could receive a consultant review. The consultant explained that the purpose of their medical review was to focus their attention on the patient's presenting complaint and form a plan of care to treat it and allow the patient to be discharged home as soon as possible.

4.5.10 Medical staff commented that, as in the patient's case, patients admitted to the Ward often had several comorbidities, were on a wide range of medications, were at increased risk of hospital acquired infection and injury (such as falls or pressure ulcers) and may have problems with their capacity to consent to and understand treatment.

4.5.11 The consultant first saw the patient on the Ward on day 5 during a routine ward round. The consultant recalled that the patient had been admitted following a fall and a suspected fracture. At the time, the consultant stated that their primary concern was the pain the patient was reporting from his hip and his limited mobility.

4.5.12 The consultant told the investigation that it would be part of their routine practice to review the medications a patient was taking to ensure that they matched the medical history and to ensure that effective medical treatment was being provided. However, medical staff explained that it was not always possible to easily obtain a full medical history for older patients with complex cases.

4.5.13 Obtaining a full medical history often required staff to access multiple sources of information. Staff had access to patient's summary care records but reported that these were not always up to date. Staff could also access clinical correspondence and scanned PDF copies of medical notes from previous admissions. Staff again reported that these may also be incomplete or contradictory.

4.5.14 When the patient was admitted to the Trust he was already taking 12 medications and was then prescribed more medications and supplements to address his medical needs. By day 9 the patient was receiving 16 different medications and staff explained that this was common in the care of older people.

4.5.15 The consultant explained that warfarin was a common medication to see prescribed to older patients; this fact was repeated by a member of the junior medical team. They explained that warfarin was a commonly prescribed medication in the Ward's patient group and was unlikely to be highlighted as a concern to senior medical colleagues without a specific reason to do so.

4.5.16 The consultant explained that "unless [medication] issues are flagged up, it becomes difficult to identify" if they are not associated with a patient's presenting medical issue. Where there was no obvious indication that an important element of a medical history had been omitted, it would not always be possible to check this due to a range of time and clinical pressures linked to caring for older patients and in a Black Alert scenario.

4.5.17 The consultant explained that, owing to the complexity of the patient's case and their limited ability to gather a full medical history, they believed the indication for warfarin of atrial fibrillation on the warfarin medication chart was likely to be accurate. The consultant felt it was possible that this could have been missed from documentation when the patient's medical history was taken in the emergency department. The consultant felt the indication was also supported because the patient was taking another medication (bisoprolol) that would routinely be used in a patient diagnosed with atrial fibrillation.

4.5.18 As warfarin was considered to be appropriately prescribed to the patient, it was dosed in accordance to the information available to junior medical staff from the warfarin medication chart and the patient's blood test results. When blood test results were returned these showed that his INR reading was between 1 and 1.5. On this basis, medical staff took steps to increase his warfarin dose. This would have been with the intention of bringing the patient's INR into the therapeutic range staff understood they were aiming to achieve.

4.5.19 The limited time available for clinical staff to review the patient's medical history and medications would have been under further pressure due to the efficiency required to manage Black Alert status. These pressures are explored in more detail in section 5. The additional time pressure would have further impacted on the ability of staff to identify the medication error, particularly in the context of the complex medical and pharmaceutical care the patient required.

Administration of warfarin by nursing staff

4.5.20 Nursing staff were responsible for the administration of warfarin medication in line with the dosage prescribed by medical staff and noted on the warfarin medication chart.

4.5.21 There was a shortage of qualified nursing staff on the ward at the time of the patient's admission. Data provided by the Trust showed that the Ward was below planned nurse staffing levels on four of the five day shifts and one of the five night shifts between the patient's admission and the final warfarin dose being provided.

4.5.22 In addition, during this period on average nearly 40% of staff on duty had been drawn from the Trust's internal bank. This also has the potential to create additional challenges if bank staff are not familiar with the Ward and require additional support to orientate and familiarise themselves with the environment and usual Ward practice.

4.5.23 The patient was given an identity wrist band in line with the Trust medication policy. The policy required staff to use the medication chart as the point of reference from which to cross-check patient information. For example, the medication chart would be the reference point against which the wrist band would be checked to confirm that the patient's name and date of birth matched the details on the medication chart.

4.5.24 As the patient's details had been attached to the warfarin medication chart, the identity checks required in the Trust policy would not have been effective in identifying the prescription error. Instead, these checks would have confirmed that the patient was the intended recipient of the medications listed on the warfarin medication chart.

4.5.25 Nursing staff explained that the warfarin medication chart appeared to have been completed for the patient and the warfarin dose had been calculated by a member of the medical team. Nursing staff told the investigation that they saw no reason to question why warfarin was being administered: "right chart, right dose, right patient, INR OK, and it goes through a process". Nursing staff did not have a reason or the operational capacity to question the prescription of warfarin. This barrier was not effective in capturing the error.

4.5.26 The Trust medication policy also set out that nursing staff were expected to engage with patients to discuss medications. This included seeking confirmation and consent from the patient that the patient was receiving their appropriate medications. The patient was increasingly confused and drowsy during his time on the Ward. This would have further inhibited the patient's ability to communicate with staff about his medications, and thus reduced the effectiveness of this barrier.

Multidisciplinary team

4.5.27 The investigation observed that a range of communication between ward-based clinical pharmacy staff and other clinical staff was not conducted face to face. Instead, a pharmacist would write notes in the medical records and on the medication charts to flag any concerns to the wider MDT. Similarly, other ward-based staff would write notes for pharmacy staff in a ward book or on medication charts.

4.5.28 Staff explained that ward-based clinical pharmacists did not attend the morning board round [9] at 09:00 hours or accompany medical staff on ward rounds [10]. Pharmacy staff told the investigation that they were “too busy” to attend these meetings or accompany staff on ward rounds. This was because pharmacy staff were required to cover two wards; they could not attend both meetings. Staff told the investigation that if pharmacists were required to attend board rounds and accompany medical staff on the ward round then “discharges would grind to a halt”.

4.5.29 At the time of the reference event, there was an increased focus on discharge and freeing up bed spaces because of the Trust’s Black Alert status. The team at board rounds included a discharge co-ordinator and a social worker to help facilitate the discharge process.

4.5.30 Staff reflected that the absence of pharmacy staff at the board round or on ward rounds meant that the opportunity for pharmacy to proactively contribute to an MDT discussion, and potentially assist in identifying medication discrepancies prior to errors occurring, was missed.

5 Analysis and findings from the national investigation

5.1 Prescribing error rates are seen to be higher in hospitalised patients (Dornan et al., 2009) than in other settings. The Council of Europe (2006) identified that up to 12.9% of hospital patients have suffered at least one adverse medication error in hospital with up to 38.7% of these medication errors being avoidable.

5.2 On average, a patient in hospital may be subject to at least one medication error per day (Institute of Medicine, 2006). One older study identifies that errors causing an adverse drug reaction account for 4% of the hospital bed capacity in England (Pirmohamed et al., 2004). A 2020 study identified that hospital-based medication errors lead to longer hospital stays, costing the NHS £14.8m per year and causing or contributing to 1,081 deaths (Elliot et al., 2020).

5.3 Medication errors can be hard to identify. Medicines safety is a multidisciplinary team (MDT) responsibility. No single member of the MDT has sole responsibility for identifying medication errors. The role of the MDT and various professional groups in medicines safety training was considered in the HSIB investigation report ‘Inadvertent administration of an oral liquid medicine into a vein’ (Healthcare Safety Investigation Branch, 2019b).

5.4 Members of the MDT have varying skill sets that are complementary to providing patient care. The reference event demonstrates how a variety of processes designed to identify medication errors by the MDT may be eroded by a range of factors.

5.5 The investigation, literature and subject matter advisors all supported the important role that ward-based clinical pharmacy services play as the 'clinical medicines specialist' in helping the MDT to identify and respond to medication errors and in improving the quality and safety of patient care.

5.6 Lombardi et al (2018) identified a range of interventions that were routinely carried out by ward-based clinical pharmacists. These included responding to prescription writing errors, amending dosages, and providing education to other staff. Over 23% of the interventions made by pharmacists were seen to have a major clinical significance. Bullock et al (2019) found that ward-based clinical pharmacy services improved communication about medicines and improved medication appropriateness.

5.7 NHS Providers (2016) and Gray et al (2017) reported on work to integrate ward-based clinical pharmacy services into the MDT and ward rounds at an NHS hospital. This resulted in reduced length of stay, reduced readmission rates, improved discharge processes, and reduced expenditure on medicines.

5.8 These studies suggest that ward-based clinical pharmacy services can play an important role in supporting the MDT to identify and address medication errors and improve the efficiency of the healthcare system. This in turn may help the healthcare system to be more resilient.

HSIB makes the following safety observation

Safety observation O/2020/066:

Effective clinical pharmacy services have been evidenced to improve a range of measures linked to efficiency and patient safety in acute hospitals.

5.9 Resilient healthcare

5.9.1 As described by Hollnagel et al (2015), resilient healthcare involves understanding and improving an organisation's ability to succeed under variable conditions, to improve safety and routine work performance.

5.9.2 Hollnagel et al (2017) describe four properties of a resilient healthcare system:

- the potential to respond
- the potential to monitor
- the potential to learn
- the potential to anticipate.

5.9.3 How well an organisation responds to variable conditions, while sustaining its level of performance and safety, will depend on factors such as:

- an understanding of how to respond and adjust procedures to accommodate working conditions
- an ability to recognise and anticipate levels of demand
- an ability to monitor indicators of increased demand and learn from practices that may improve system resilience.

5.9.4 The investigation considered the extent to which ward-based clinical pharmacy services may be resilient in the light of current practice and additional challenges posed by caring for older patients and increased demand for services.

5.10 Current challenges in NHS clinical pharmacy provision

5.10.1 The Carter review (Department of Health, 2016) encouraged pharmacy services to spend the majority of their time carrying out direct clinical functions to support medicines optimisation and the clinical care of patients. Local hospital pharmacy transformation plans were expected to be developed by NHS trusts to achieve this goal, with a view to 80% of pharmacy time being dedicated to clinical activities (Royal Pharmaceutical Society, 2017a). However, the Carter review did not suggest ways in which to determine demand and capacity for pharmacy services in any given hospital.

5.10.2 The Royal Pharmaceutical Society (RPS) (2017b) sets professional 38 standards for hospital pharmacy services which describe what a good hospital pharmacy service looks like. The eight standards are directed toward chief pharmacists, providing a consistent set of standards by which pharmacy services can be measured and improved. Standard eight covers the development, planning and quality assurance of the local pharmacy workforce. This includes broad principles to assist in the planning and development of a pharmacy team that can support quality, productivity and safety.

5.10.3 The guidance available from the RPS allows for pharmacy services to be developed in line with the requirements of the chief pharmacist in each NHS trust. However, whereas guidance is available in some areas where clinical pharmacists may be closely involved in patient care (specifically, medicines reconciliation and discharge) there is no specific guidance highlighting in more detail the role of ward-based clinical pharmacy services on an acute ward between medicines reconciliation taking place (typically on admission) and a patient being discharged.

5.11 Understanding the role of the ward-based clinical pharmacist

5.11.1 The investigation observed that pharmacy services were often viewed by colleagues as a “safety net” to help identify and address medication errors in the period between medicines reconciliation and discharge. The investigation sought to understand the extent to which the role of ward-based clinical pharmacists was understood by the system, whether they were able to operate as the safety net often envisaged by staff, and whether this was an appropriate role.

5.11.2 A resilient healthcare system should be able to anticipate challenges in the provision of clinical pharmacy services. The Care Quality Commission (2019) highlighted that insufficient pharmacy resource was a concern for both NHS and independent hospitals. Turnover in pharmacy staff in acute NHS hospitals stands at around 14% (NHS Benchmarking, 2019).

5.11.3 Some challenges associated with weekend pharmacy provision are considered in HSIB’s investigation report ‘Electronic prescribing and medicines administration systems and safe discharge’ (Healthcare Safety Investigation Branch, 2019a).

5.11.4 The NHS Specialist Pharmacy Service (NHS SPS) was previously organised within NHS regions. However, since 2015 they have been commissioned nationally by NHS England and NHS Improvement.

5.11.5 NHS SPS guidance from the South East region, which has subsequently been taken forward by the national NHS SPS, comments that ‘pharmacy services are often not clearly understood by senior members of the organisation or seen only in terms of supply of medicines. This makes the role of clinical services particularly vulnerable, especially as they often involve large numbers of expensive staff’ (NHS Specialist Pharmacy Service, 2011).

5.11.6 The lack of a clear understanding of the scope of ward-based clinical pharmacy services may hinder the ability of the healthcare system to anticipate the demands placed on pharmacy staff and the ability of the pharmacy service to respond to challenges.

5.12 Ward-based clinical pharmacist workload

5.12.1 The investigation sought to understand whether the current demands placed on ward-based clinical pharmacy services were understood.

5.12.2 In other industries the concept of workload and workload management is considered of interest to organisations and their regulators (Health and Safety Executive, 2019). Typically, workload research or investigations in other industries (Matthews et al., 2015; Young et al., 2015) will seek to understand the nature of the work being carried out by staff (for example, the physical or mental requirements of a task or an understanding of the complexity or compatibility of tasks).

5.12.3 For any job role where performance influences the safety of others, this depth of knowledge is required to assist in the proactive management of any potential degradation of staff or organisational performance that may impact on safety.

5.12.4 The investigation identified a small range of time and motion studies [11] that sought to describe the activities and tasks undertaken by ward-based clinical pharmacists. These studies are helpful in describing the amount of time clinical pharmacists spend on day-to-day tasks and considering the time available to them to complete these tasks.

5.12.5 De Clifford et al (2015) considered the tasks performed by pharmacists to determine how they spent their working day. Clinical activities were seen to account for 56% of the total time clinical pharmacists spent at work. This included professional communication (20%), medication chart review (9.6%), medication history interview (9.5%), clinical review (9.1%), providing information to patients/carers (5.5%), ascertaining discharge drugs required (1.6%), and obtaining drug information (0.5%).

5.12.6 Non-clinical activities were seen to account for 44% of their total time. Of note, on average each pharmacist was able to review only 21 of a possible 38 medication charts (55%) they were tasked to review.

5.12.7 A study undertaken in Canada (Meguerditchian et al., 2013) considered the time taken to complete medicines reconciliation on admission and discharge for a sample of patients admitted to and discharged from older people's, medical and surgical units. The study identified that medicines reconciliation in older patients took the most time to complete at admission (a mean time of 92.2 minutes per patient) and discharge (a mean time of 29.0 minutes per patient).

5.12.8 An American study (Nguyen et al., 2017) considered the time taken for pharmacists to carry out admission medication histories for patients at high risk of medication errors. The study found that pharmacists required a mean time of 58.5 minutes to complete this task.

5.12.9 These studies provide an insight into the work of clinical pharmacists. Considered in the context of the reference event, they show how the demands placed on clinical pharmacists may not be aligned to the current knowledge of how these services operate, or the time available to pharmacy staff to complete the range of tasks they perform.

For example:

The reference event involved a single clinical pharmacist. They worked a 7.5 hour (450 minute) shift. The service-level agreement in place indicated that they should see 28 of 56 patients per day to review their medicines.

Figure 3 demonstrates the difference between the perceived time available for medication review per patient by the clinical pharmacist in the reference event, compared to an estimate of the actual time available per patient when a range of factors impacting on their time is accounted for.

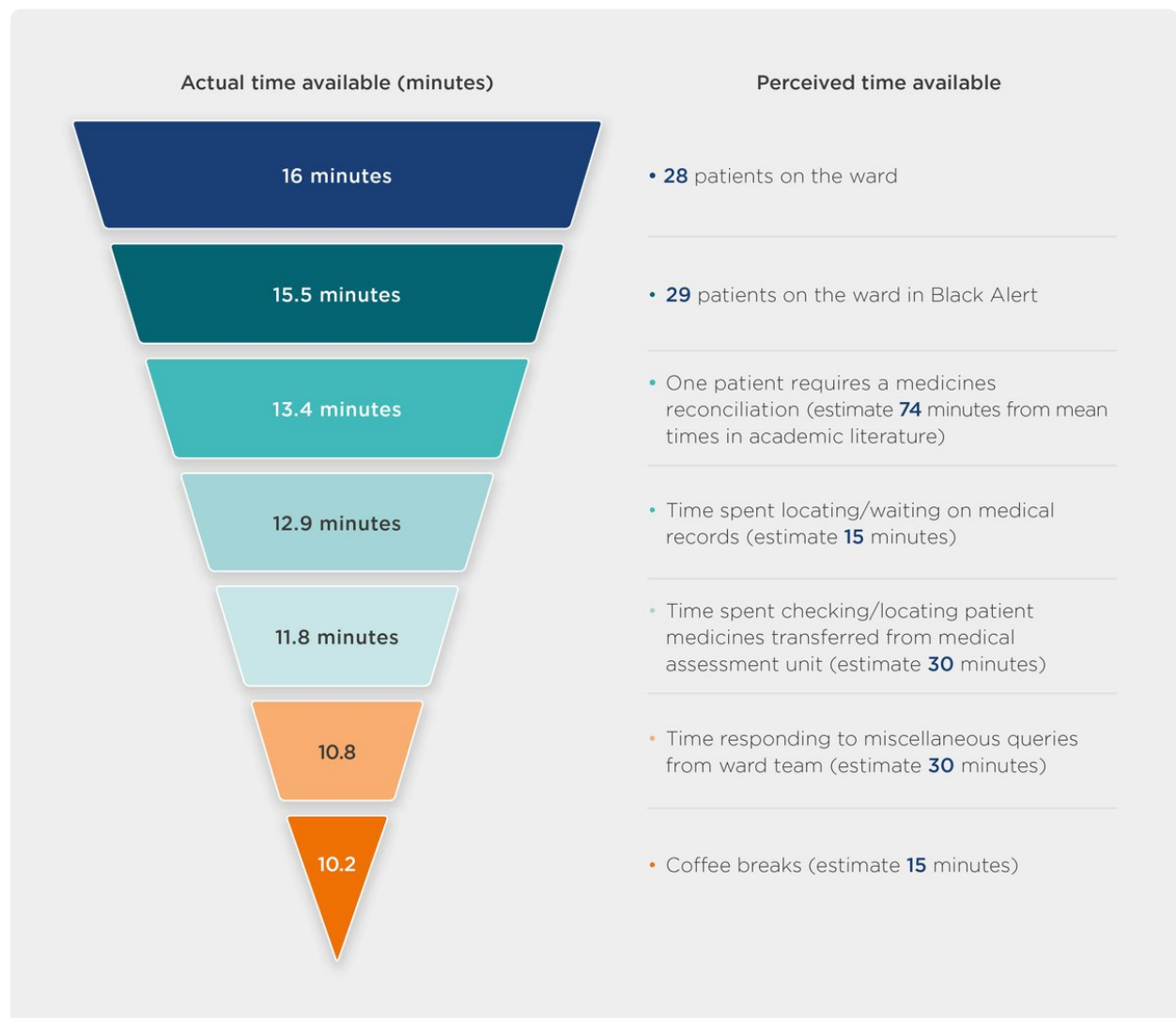


Fig 3 Representation of clinical pharmacist time per patient

5.12.10 The investigation found that there is a need for a better understanding of ward-based clinical pharmacy services by those planning services to enable the proactive management of any potential degradation of staff or organisational performance that may impact on safety. In this instance, there is a need to ensure that the provision of pharmacy services reflects the challenges faced by pharmacists and accounts for the time taken to complete their work under 'real world' working conditions.

5.12.11 The varieties of human work are described by Shorrock (2016). 'Work as imagined' refers to assumptions that may be made about how work is carried out by staff. However, people making these assumptions may be removed in time and space from the 'frontline' and therefore unable to observe work being carried out in the workplace (Hollnagel et al., 2015).

5.12.12 The imagined way in which people work becomes 'work as prescribed' when it is set out in policy or processes that frontline staff are asked to follow and adhere to. This is often assumed to be the safest way to work (Shorrock, 2016).

5.12.13 'Work as done' refers to how people actually carry out their work. Understanding 'work as done' requires a practical focus on understanding and observing work in the environment in which it takes place in order to inform ideas about how work should be planned and managed. Catchpole and Jeffcott (2017) identified that direct observation of staff within healthcare usually reveals a difference between what is disclosed and how work is done in practice.

5.12.14 The HSIB investigation report 'Wrong patient details on blood sample' (Healthcare Safety Investigation Branch, 2019c) highlights the need for services to understand 'work as done' by staff in order to ensure that policies and procedures reflect the day-to-day realities of clinical work.

5.12.15 This approach has yet to be considered in detail in many aspects of healthcare research (Longo, 2016). Without the ability to understand and monitor the work required of clinical pharmacy staff, the healthcare system may not be able to anticipate the additional challenges they face at times of peak demand.

5.12.16 A greater appreciation of the factors that may impact on pharmacists' workload would enable an accurate understanding of how an organisation needs to plan services, adapt and respond to demand. This would help ward-based clinical pharmacy services to operate effectively and maximise the opportunity for them to be further integrated in supporting the MDT in identifying medication errors.

5.12.17 Current guidance and work planning for ward-based clinical pharmacists may benefit from a greater insight into 'work as done' by clinical pharmacists and the typical adjustments perceived as necessary to sustain efficiency and safety.

5.13 Organisational and patient-related factors

5.13.1 This section considers the additional organisational and patient factors that may impact on the resilience of ward-based clinical pharmacy services – the complexities inherent in the care of older patients, and operational pressures caused by a high demand for services.

Impact of caring for older patients

5.13.2 The World Health Organization (WHO) (2019b) has identified high-risk situations that are more commonly associated with medication errors occurring. These include specific patient-related factors that were identified as contributing to high-risk situations. Patients are at greater risk of being affected by a medication error if they:

- are taking high-risk medications (see 5.14.32)
- are taking multiple medications (polypharmacy)
- have more than one health condition (multimorbidity)
- have a high-risk condition (such as kidney, liver or heart dysfunction).

5.13.3 The high-risk situations identified by the WHO report describe a range of patient groups within the NHS that may have complex care needs. However, the investigation found that these correspond to the common challenges that can be identified and anticipated in the care of older people. The investigation has considered these challenges in the context of older people's care, but they should also be considered in relation to other areas of care that present similar high-risk situations.

5.13.4 The importance of adequate pharmacy support to help address the challenges faced in medicines management for older people is reflected in National Institute for Health and Care Excellence (NICE) guidance (2018):

'Currently medical wards in the UK do have access to a pharmacist. However, the pharmacist may be responsible for covering several areas concurrently; limiting the level of detail they can bring to medicines reconciliation and patient and staff communication. This is particularly important for an ageing population with multiple co-morbidities for whom polypharmacy adds complexity and may indeed be the cause of the acute admission. In this situation the pharmacist plays a vital role advising the medical team regarding the interactions of drugs and how to prescribe treatment optimally.'

5.13.5 Polypharmacy (when a patient is prescribed a number of medication treat a range of conditions) is expected to rise due to the ageing population (World Health Organization, 2019a) with studies (Gallagher et al., 2011) identifying that many older patients in hospital would be expected to be prescribed between four and nine medications. Around a third of patients aged 65 years or older may be prescribed high risk medications as part of their treatment (Ble et al., 2015).

5.13.6 Because of the increasingly complex medical needs of older patients admitted to hospital, the likelihood that an older patient will be discharged receiving the same medicines that they were admitted with is less than 10% (NHS England, 2016). As medications are added to and removed from older patients' prescriptions during their hospital stay there are increased opportunities for errors to occur. The incidence of medication errors has been seen to increase with the number of medications that a patient is prescribed (Sears et al., 2012).

5.13.7 Studies have suggested that there is potentially a high rate of inappropriate prescribing in older patient groups (Gallagher et al., 2011) and older patients are subject to greater numbers of medication errors occurring in hospital (Elliot et al., 2018).

5.13.8 Studies have also identified that the risk of multi morbidity increases with age; Barnett et al (2012) found that 65% of patients aged between 65 and 84 years were multimorbid and 81% of patients aged 85 years or older were multimorbid. Projections (Kingston et al., 2018) show that in the next 20 years the prevalence of patients with multi morbidity will increase, particularly in regard to complex multi morbidity (where a patient may have four or more medical conditions). Caring for patients with multi morbidity is more complex as their conditions and their treatments may interact in multiple ways.

5.13.9 The prevalence of medical conditions such as chronic liver disease is increasing in the older population (Frith et al., 2009). Diseases such as chronic kidney disease (NHS, 2019c) and heart failure (NHS, 2019d) are more commonly seen in older patients. This can be seen in the reference event, as the patient was already diagnosed with chronic kidney disease and hypertension (high blood pressure) prior to his admission to the Trust.

5.13.10 Around a quarter of NHS beds in use by patients over 65 years old are occupied by patients with dementia (Alzheimer's Society, 2009) who may have additional care needs. This can create additional challenges and complexities for those ensuring these patients receive the correct and appropriate care.

5.13.11 There is significant potential to learn from the increasing number of studies identifying the additional challenges posed in caring for older people. This can help a healthcare system anticipate and develop potential responses to these challenges. The investigation found that older people's care was a significant example of the situation identified by the WHO report (2019b) (see 5.13.2) in which patients were at an increased risk of medication errors.

5.13.12 The complexity associated with the specific needs of older patients, such as the prevalence of polypharmacy and multi morbidity, implies a likely source of variability in the workload of ward-based clinical pharmacists caring for older people. This may impact on the resilience of ward-based clinical pharmacy services operating within these areas.

Impact of operational demand

5.13.13 The WHO report (2019b) identifies factors such as a shortage of suitably qualified staff, fatigue and strains on resource as factors that may contribute to high-risk situations.

5.13.14 The reference event showed how externally driven system factors may dictate and impact on how ward-based clinical pharmacy services operated. In the reference event, emphasis was placed on 24-hour medicines reconciliation and the need to prioritise patients for discharge due to the pressure to free up beds. These are common considerations within pharmacy services in the NHS. Such conflicts in service goals will typically produce a trade-off between the quality and efficiency of the service provision (Hollnagel, 2009).

5.13.15 Prioritisation of patient care due to externally driven factors (for example, medicines reconciliation targets and discharge) is identified by the NHS SPS (2011) as one way in which patient care may need to be prioritised by hospital pharmacy services.

5.13.16 Observations by the investigation in other NHS trusts identified a similar approach, with medicines reconciliation often being seen as the key driver to pharmacy prioritisation in line with NICE guidance (2015). Coupled with increasing bed pressures on the NHS (The King's Fund, 2017), this meant that emphasis was often placed on ensuring patients received appropriate pharmacy input at discharge, to ensure that discharge could take place and maximise the movement of patients into and out of the hospital.

5.13.17 The risk of a patient suffering an adverse medication incident is not static and cannot rely on an assessment of risk taken at only one given moment of a patient's hospital stay (for example, at medicines reconciliation or at discharge). The risk of an adverse medication event (or any patient safety incident) occurring is fluid and may change depending on the various ongoing interventions, clinical developments and interactions between staff and the patient.

5.13.18 The reference event demonstrated the range of duties that a ward-based clinical pharmacist may be expected to perform. In addition, they would be placed under additional pressure due to the complex medical needs of the older patients being cared for on the Ward and the pressures of Black Alert.

The duties included:

- medicines reconciliation
- checking medicines on discharge
- ordering medicines
- resolving ad hoc medicine queries
- creating medicine charts and transposing medicines onto the new chart
- responding to staff requests for assistance

- reviewing patient medications
- attending ward and pharmacy department meetings.

5.13.19 Black Alert may lead to other additional pressures on the system and other staff groups. In the reference event these pressures included:

- crowding in the emergency department and a need to prioritise discharges from acute wards
- cancellation of non-emergency procedures
- 'green for go' out-of-hours bed moves (see 4.5.2 to 4.5.3) and the associated impact on patient handover
- additional patients being placed on wards and an additional strain on staff to care for extra patients due to increased patient throughput
- clinical staff who would routinely not work clinically (for example, staff in clinical management positions) being asked to work clinically or support clinical colleagues to maintain patient flow.

5.13.20 The Black Alert status of a hospital reflects a high patient caseload and a focus on patient discharges to increase the availability of bed spaces. The potential impact on safety to the wider system is anticipated in the OPEL reporting framework (see 1.9.1) and the need for the healthcare system to adapt to meet this demand is identified.

5.13.21 Black Alert may also increase the specific duties and task focus for individual staff (for example, increased involvement in discharge planning). This may reduce the time available to staff to carry out their other work and create competing demands on their time. In this scenario, a clinical pharmacist is likely to play a critical role in processing the medications of patients to be discharged. Any delay has implications for the admission of new patients and the flow of patients from the emergency department to the wards.

5.13.22 This emphasis on discharge may compromise the range of other duties the clinical pharmacist is able to undertake, such as completing planned medication reviews. This creates variations from the work a clinical pharmacist is able to complete during 'normal' conditions and their capacity to act as a 'safety net' during times of increased demand.

5.14 Strategies to improve resilience

5.14.1 The reference event demonstrated a scenario in which several separate factors, each of which carry a significant risk of serious medication errors occurring, all contributed to the medication error the patient experienced.

These factors included:

- the age of the patient
- polypharmacy
- multi-morbidity
- use of high-risk medicines • operational pressures.

5.14.2 The ability of a healthcare organisation to adapt to high caseloads, while sustaining safety and performance, requires staff and system leaders to learn to recognise changes in working conditions and know how to adjust procedures accordingly.

5.14.3 Increased system resilience could reduce the risks associated with the complexity and uncertainty of healthcare (Hollnagel et al., 2015). This requires a proactive approach that looks at how healthcare systems currently function and succeed, while considering how they might fail (Spurgeon et al., 2019).

5.14.4 Amalberti and Vincent (2019) acknowledge that there may be a gap between the expected standard of care for patients and the care it is possible to deliver within the constraints of current systems and pressures. This is demonstrated by the increased pressures placed on trusts due to the lack of pharmacy resource, the specific complexities of caring for an older patient group, and the additional pressures created by Black Alert status.

5.14.5 Amalberti and Vincent (2019) suggest that in the face of increasing complexity in healthcare, alongside the need for increased recognition of threats to patient safety, practical strategies need to be developed to address these risks to make best use of the resources available.

5.14.6 The investigation has considered some strategies that may be available to improve the resilience of ward-based clinical pharmacy services, and the broader healthcare system, in enabling the prevention and/or identification of medication errors.

Pharmacy workforce

5.14.7 The investigation found significant variations in how the pharmacy workforce is organised and operates across NHS trusts. The RPS (2017b) recognises a need to focus on where pharmacy resource and add value to clinical services. However, the investigation found local variation in the number of pharmacists deployed per patient group, the experience of pharmacists on the ward, and the use and availability of pharmacy technicians.

5.14.8 In some trusts visited by the investigation, pharmacy provision was contracted to individual clinical directorates to provide a specific, individual service. This provided certainty to directorates with regard to the pharmacy provision they would expect to receive, and may provide specialist knowledge. However, where this was the case, pharmacy staff could not routinely be brought in from other clinical directorates to provide cover or assist in times of increased demand due to the need to fulfil obligations in the service-level contract with the other directorates.

5.14.9 The investigation also visited trusts where pharmacy provision was centrally controlled and organised. This meant that clinical directorates did not have a dedicated pharmacy provision. However, this arrangement provided the flexibility for central pharmacy teams to deploy staff to clinical areas based on perceived risk and demand for the service.

5.14.10 NHS Providers (2016) and Gray et al (2017) reported on work completed at an NHS hospital to provide a dedicated clinical pharmacist to every ward. The investigation visited the Trust to consider how services had developed and organised since the pilot phase. Dedicated clinical pharmacists were available to each ward (with some wards having more than one pharmacist if they were particularly large or served a patient group with complex needs). Pharmacy services were centrally funded and organised and the Trust reported that the initiative resulted in significant health benefits to patients and cost savings.

5.14.11 The investigation heard from senior medical staff who said that they had not realised the value that dedicated pharmacy services could bring. They told the investigation that they now “could not be without” a pharmacist due to the value they added to patient care and the “professional and different approach” pharmacy brought to the MDT.

5.14.12 The investigation also found variation in the way pharmacy teams were constituted. Many services incorporated pharmacy technicians into their service model. Use of pharmacy technicians has been seen to have broader benefits in regard to reducing delayed or omitted medication dosages (El-Fahimi et al., 2019) and may assist in allowing clinical pharmacists to focus their time on completing more clinical duties. The investigation did not consider the role of pharmacy technicians in detail. However, comments from ward-based clinical pharmacy staff made clear the important role technicians play in medicines safety and allowing clinical pharmacy staff time to focus on clinical duties.

5.14.13 Comments received by the investigation from stakeholders and the investigation's pharmacy subject matter advisor reflected the fact that there is no single approach that is backed by evidence which offers the best way to organise pharmacy services. However, there is a need to ensure that services can be responsive and adapt to change at times of high demand. Strategies to consider how pharmacy services can monitor and respond to demand would enhance resilience within the system.

5.14.14 Any further consideration of how the organisation of pharmacy services may be optimised would benefit from ensuring that appropriate models of pharmacy provision are explored, tested and evaluated to consider which models help to increase organisational resilience. This would enhance the ability of the healthcare system to adjust its procedures to accommodate working conditions.

5.14.15 This approach to enhancing system resilience implies a need for organisations to understand how the work of a clinical pharmacy team and patient safety are currently achieved. This applies to everyday work, as well as how work is carried out under additional pressures such as Black Alert or caring for older patients.

HSIB makes the following safety recommendations

Safety recommendation R/2020/087:

It is recommended that NHS England and NHS Improvement carry out work to understand and further define the work of hospital clinical pharmacy teams, including the period between initial medicine reconciliation and discharge, in consultation with relevant stakeholders.

Safety recommendation R/2020/088:

It is recommended that the Royal Pharmaceutical Society, supported by NHS England and NHS Improvement, should provide guidance on models of hospital clinical pharmacy provision. The guidance should provide information on the models' ability to enhance safety and healthcare resilience and include consideration of the appropriate skill mix and experience within the clinical pharmacy team.

Pharmacy prioritisation

5.14.16 A recognised benefit of clinical prioritisation is that it allows pharmacy services to focus on areas where the need is greatest and where services can have the greatest impact on patient outcomes (NHS England, 2016). Prioritisation may be considered to help identify patients who are at highest risk of medication errors in scenarios involving patients with complex medical needs and increased demand on the pharmacy services.

5.14.17 Examples of prioritisation are shared by NHS SPS (2011); these include prioritisation of pharmacy resource by drug (for example, medicines identified as high risk) or by complexity of patients' medical needs (for example, polypharmacy).

5.14.18 An understanding of how ward-based clinical pharmacists prioritise all work tasks in situations of high demand could help organisations understand why, and in what circumstances, procedures become unachievable. The factors influencing the demand for clinical pharmacy tasks should be identified and monitored to recognise shifts in demand, and an appropriate response planned to sustain performance.

5.14.19 A literature review by NHS SPS (2019) identified a range of published prioritisation tools from the UK, New Zealand and Australia. A range of work has already taken place in a variety of local settings to develop further local prioritisation tools. These assist ward-based clinical pharmacy staff in identifying patients that may require an enhanced level of pharmacy support (Hickson et al., 2017; Saxby et al., 2017). They include both paper-based and electronic systems (Flynn et al., 2018).

5.14.20 NICE (2015) encourages the use of computerised clinical decision support systems to aid clinical decision making and many tools identified by the investigation included provision for the identification of medicines identified as being high-risk. The investigation observed two electronic pharmacy prioritisation tools in use across three acute trusts and found variations in how these systems operated.

5.14.21 One system required medication details to be entered manually by pharmacy staff. Once the medications were in the system, a pharmacist could allocate a provisional score to a patient to indicate the frequency by which they required pharmacy review. This score was generated with reference to a paper-based scoring policy that had been locally developed. Staff explained that the score allocated to patients could vary based on the experience and clinical judgement of the pharmacist allocating the score.

5.14.22 Such a system allows pharmacists to use their own clinical judgement when considering prioritisation (Onatade et al., 2018). However, creates the potential for variability and for patients to receive different scores (Hickson et al., 2017), depending on the level of expertise of the pharmacist calculating the score (Onatade et al., 2018).

5.14.23 Another system observed by the investigation was integrated into an electronic record system. This used data about the patient's care from a range of parameters to develop an automatically calculated score indicating the pharmacy priority of the patient. The range of variables used (for example, age, sex and comorbidities) could be adjusted locally, with different weighting applied to different data.

5.14.24 Such a system may remove any potential variability in scoring based on individual pharmacist experience. However, studies have identified significant variation in the factors used by these tools to calculate the pharmacy prioritisation (Flynn et al., 2018). In addition, individual clinical judgement has been seen to override scores produced by such systems (Saxby et al., 2017).

5.14.25 Due to the way in which these systems have developed they have often been subject to only limited evaluation and testing. Prioritisation tools in use within one NHS trust may be different from a tool used in another NHS trust, both in design and the factors they use to generate a pharmacy prioritisation score.

5.14.26 Work by Geeson et al (2017) and Lewis (2017) focused on developing an evidence-based clinical prioritisation tool that will be subject to further testing and validation on a larger scale. The intention is for the tool to provide a clinically credible model that can support pharmacists to make decisions about the level of intervention a patient may require. This may allow for increased sensitivity and the ability to assist in the prioritisation of patient care at times of increased demand on the system.

5.14.27 A validated model to aid pharmacy decision making may be beneficial in developing a shared understanding of factors that may lead to pharmacy prioritisation. This has been achieved in other areas of clinical care such as the NHS National Early Warning Scores (Royal College of Physicians, 2017). However, the use of any such tool requires the appropriate infrastructure, careful design, and appropriate training on their use (Saxby et al., 2017).

5.14.28 Such a validated model may be beneficial in helping to identify patients whose presentation represents a high-risk situation in line with findings from the WHO (2019c). The ability to target and prioritise patients in need of greater pharmacy support may also help to save pharmacy time and generate increased pharmacy resource (Onatade et al., 2018). This would support the healthcare system in recognising patients at increased risk of adverse medication events and help to anticipate the potential levels of demand on pharmacy services required to assist in caring for these patients.

5.14.29 The NHS SPS told the investigation that it was in the process of updating and reviewing its resource on prioritisation of pharmaceutical care (NHS Specialist Pharmacy Service, 2011). This work would assist in helping pharmacy services to identify priorities for pharmaceutical care and allow for updated research and evidence to be presented in order to support best practice pharmacy prioritisation tools.

5.14.30 This work should take into account the principles of resilient healthcare by considering how the guidance may assist staff to anticipate and respond to changing demands on the service. This should ensure that evidence-based decisions are made about the prioritisation of patients at greatest risk of medication-related harm.

HSIB makes the following safety recommendation

Safety recommendation R/2020/089:

It is recommended that the NHS Specialist Pharmacy Service should update its resource on the prioritisation of hospital clinical pharmacy services to facilitate the dissemination of developments in good practice and policy with respect to pharmacy prioritisation and the issues highlighted in this report.

High-risk medicines and situations

5.14.31 Understanding the implications of the impact individual medications and situations may have on patient safety is important. The classification of certain medications and situations as 'high risk' is intended to help direct focus towards patients at the greatest risk of serious harm.

5.14.32 The WHO (2019b) defines high-risk medications as drugs that have a heightened risk of causing significant patient harm when they are used in error. A review of the literature in this area by Suggett (2017) identified that the four most commonly named groups of 'high-risk' medicines identified in healthcare literature were antimicrobials, anticoagulants (such as warfarin) and thrombolytics (stroke medications), cardiovascular drugs and drugs acting on the central nervous system.

5.14.33 A systematic review of errors involving high-risk medicines in hospitals (Alanzani et al., 2016) showed that the prevalence of prescribing errors could be extremely high, ranging from 0.24 to 89.6 errors per 100 prescriptions. The use of different definitions of high risk medications by different academic studies was considered to be a potential cause of this large range of results.

5.14.34 The investigation's pharmacy subject matter advisor and medical subject matter advisor identified that medicines identified as being high risk may vary between care settings to reflect the specific medicines and circumstances most commonly encountered in each specialty. However, the availability of guidance around high-risk medicines varied between the NHS trusts the investigation visited. The investigation could not identify a common definition of what constitutes a high-risk medicine within the NHS in England.

5.14.35 The WHO (2019b) supports a shared definition of the main medication groups that may be considered high-risk. A range of academic work is referenced in the WHO report to provide an overview of the medication groups most commonly identified as high risk.

5.14.36 The definition included in the WHO report was initially adopted in Australia (Clinical Excellence Commission, 2015) and uses the acronym **A PINCH**:

A: Anti-infective amphotericin aminoglycosides

P: Potassium and other electrolytes

I: Insulin

N: Narcotics (opioids)

C: Chemotherapeutic agents

H: Heparin and anticoagulants (including warfarin)

5.14.37 The WHO acknowledges that such lists need to be developed locally by countries to help reflect the medications commonly associated with medication error and adverse drug events in their local healthcare settings.

5.14.38 A shared understanding of the main medication groups that may constitute high-risk medicines may help NHS organisations to develop approaches to assist in the prioritisation of patients receiving these medications who may also be in a high-risk situation.

5.14.39 The investigation's pharmacy subject matter advisor highlighted that many hospital inpatients may be on one or more high-risk medication at any one time (for example, surgical patients receiving opioid pain relief or medical patients on antibiotics). In this situation, prioritisation based on high-risk medicine use alone may not be effective in enabling ward-based clinical pharmacy services to prioritise their workload.

5.14.40 The WHO (2019a; 2019b; 2019c) supports a broader understanding of high-risk situations that are more commonly associated with medication errors occurring. As well as the medication factors highlighted above, these also include specific patient factors that were identified as contributing to high-risk situations (see 5.13.2).

5.14.41 As part of the NHS Patient Safety Strategy (NHS England and NHS Improvement, 2019) the NHS England and NHS Improvement medicines safety improvement programme is focused on reducing medication-related harms in the NHS. This piece of work will include some consideration of high-risk drugs, situations and vulnerable patients.

5.14.42 A greater shared understanding between NHS staff of medications and situations that should be considered high-risk may be beneficial. This may help to ensure that staff take a consistent approach toward patients in these situations and help to influence strategic decisions with regard to the use and allocation of resources.

HSIB makes the following safety observation

Safety observation O/2020/067:

Further integration of clinical pharmacy services within the MDT and within strategic decision making may improve a shared understanding of which medicines and situations place patients at greater risk of serious medication errors occurring.

5.14.43 The HSIB investigation report 'Electronic prescribing and medicines administration systems and safe discharge' (Healthcare Safety Investigation Branch, 2019a) dealt in detail with electronic prescribing systems and the benefits and challenges of using these systems effectively. The investigation identified potential benefits of electronic systems in assisting in the prioritisation of medicines reconciliation and alerting staff to potential medication errors.

5.14.44 The use of electronic systems to facilitate the implementation of guidance and tools for pharmacy prioritisation, and for the identification of high-risk medications and situations for medication errors, would also be beneficial. This may allow for a more consistent approach to be developed than may be possible with the use of paper-based tools alone.

HSIB makes the following safety observation

Safety observation O/2020/068:

Clinical pharmacy services should consider using validated tools to assist in prioritising pharmacy care and identifying high-risk medicines and high-risk situations for medication error. Where electronic medical record systems are used, such tools could be integrated into these systems to aid prioritisation.

Patient factors in older people's care

5.14.45 NICE guidance (2018) recognises that: 'Older people are more likely to be admitted for medical emergencies, and to stay longer in hospital, than younger people. This is because of multi morbidity, frailty and polypharmacy in older people.'

5.14.46 This investigation report has highlighted a range of additional challenges placed on clinical pharmacy services in older people's care. The investigation was told by staff that current pharmacy prioritisation tools in local use within the NHS may not be as effective in assisting pharmacy prioritisation in older patient groups. This was because the complex needs of older patients resulted in the majority of older patients being prioritised as being at high risk.

5.14.47 The reference event involved a pharmacy service that had been commissioned approximately 10 years ago and which may not have reflected the changes in older people's care that had occurred since. The investigation was told by a range of sources that older patient pharmacy care had traditionally been viewed as a "Cinderella service" (a service that is undervalued or neglected). Because of this, junior pharmacy staff and lower levels of pharmacy resource had traditionally been allocated to older people's wards.

5.14.48 The NHS SPS (2011) recognises that junior staff are commonly at the frontline of clinical ward pharmacy work and may spend the majority of their time working alone and without pharmacy technician support. The investigation observed that it was often more junior pharmacy staff that were providing day-to-day care on specialist older people's wards.

5.14.49 The NHS SPS (2011) recognised that although all wards and units can care for patients with very complex cases, some wards by definition are more likely to have more patients with complex cases. These wards may require a pharmacy team with specialised knowledge and capability to deliver an adequate service.

5.14.50 In some other complex medical specialities, further specific professional guidance is in place to outline staffing and service requirements. In each case the guidance is intended to reflect the complexity of the medical needs of patients being cared for in these specialties or the high risk of harm occurring from medication errors. The guidance acts to identify and address the need for further specific pharmacy input for these patient groups.

5.14.51 Guidance for critical care units (Faculty of Intensive Care Medicine and The Intensive Care Society, 2013) contains specific directions for competency requirements, number of pharmacists per patient, pharmacy support requirements, and the role of the pharmacist in the MDT.

5.14.52 Guidance for cancer treatment (British Oncology Pharmacy Association, 2015) includes recommended pharmacy staffing numbers per patient.

5.14.53 Guidance for neonatal care (Department of Health, 2009) provides for pharmacists to have dedicated time and expertise to support the service.

5.14.54 NICE (2015) identifies that organisations should consider an MDT approach to improve outcomes for people who have long-term conditions and who take multiple medicines. The investigation observed MDT meetings in admitting medical units and critical care units where pharmacy staff were integrated into the MDT. This allowed pharmacy staff to take an active role in discussions about patient care.

5.14.55 Innovative workforce approaches are encouraged by NHS England to ensure there is an appropriate skill mix of clinical pharmacists, clinical pharmacy technicians and other staff help to support high-quality care and maximise efficiency (NHS England, 2016). However, the investigation found that in older people's care, the approach to incorporating pharmacy within the MDT was often limited to models of care provided in admitting medical units (as seen in the reference event).

5.14.56 When pharmacy staff are integrated into clinical teams they are a greater resource to nurses, doctors and other staff. Clinical pharmacists have been shown to reduce medication errors and shorten length of hospital stay (NHS Specialist Pharmacy Service, 2015). Better integration of ward-based clinical pharmacy professionals into the multi-professional team has recognised benefits (NHS England, 2016).

5.14.57 Miller et al (2011) found that ward-based clinical pharmacists who attend consultant-led ward rounds as well as undertaking ward pharmacist visits make significantly more interventions per patient to address medicines issues than pharmacists who only undertake ward pharmacist visits. However, staff explained that in many trusts there would not usually be sufficient time or pharmacy staff available to allow this approach to be adopted.

5.14.58 The investigation observed innovative approaches to clinical pharmacy work facilitated by electronic prescribing systems. For example, in one dedicated pharmacy service in a critical care unit pharmacists routinely reviewed medicines information remotely. This allowed pharmacists to review information contained within electronic medical records in a controlled environment away from other distractions and demands. Any suggestions, queries or concerns were then presented in person by a pharmacist at the daily critical care MDT meeting.

5.14.59 There is significant opportunity to learn from technological developments and the organisation of ward-based pharmacy services in other high-risk areas of care to further understand practices that may improve system resilience in older people's care.

HSIB makes the following safety observation

Safety observation O/2020/069:

Caring for older patients in hospital often presents a high-risk situation for medication errors occurring. Further efforts should be made to learn from technological developments and the organisation of pharmacy services in other high-risk areas of care that may improve system resilience in older persons care.

6 Summary of findings, safety recommendations and safety observations

Findings

- Ward-based clinical pharmacy services can play an important role in helping the multidisciplinary team to identify and reduce high risk medication errors.
- There is significant variation in how ward-based clinical pharmacy services are staffed, organised and developed.
- There is variation in the organisation and understanding of the role of ward-based clinical pharmacy services in the NHS between the point of initial medicines reconciliation and discharge.
- The impact of a complex patient caseload or operational pressures on the ability of ward-based clinical pharmacy services to operate and adapt effectively is not well studied.
- There may be a gap between the expected standard of pharmacy care and the care pharmacy services are able to deliver within the constraints of current systems and pressures.
- Practical strategies should be developed to help address risks to the resilience of ward-based clinical pharmacy services to best use the pharmacy resources currently available within the NHS.
- There is a lack of evidence to support which models of pharmacy care are resilient and offer the most effective use of ward-based clinical pharmacy resources.
- There is not a consistent, shared understanding between NHS staff of medications that may be considered high risk or situations in which there is a higher risk of medication errors occurring.
- Pharmaceutical care of older people is a complex and increasingly demanding specialty that involves caring for patients at the greatest risk of medicine-related harm.

Recommendations and observations

HSIB makes the following safety recommendations

Safety recommendation R/2020/087:

It is recommended that NHS England and NHS Improvement carry out work to understand and further define the work of hospital clinical pharmacy teams, including the period between initial medicine reconciliation and discharge, in consultation with relevant stakeholders.

Safety recommendation R/2020/088:

It is recommended that the Royal Pharmaceutical Society, supported by NHS England and NHS Improvement, should provide guidance on models of hospital clinical pharmacy provision. The guidance should provide information on the models' ability to enhance safety and healthcare resilience and include consideration of the appropriate skill mix and experience within the clinical pharmacy team.

Safety recommendation R/2020/089:

It is recommended that the NHS Specialist Pharmacy Service should update its resource on the prioritisation of hospital clinical pharmacy services to facilitate the dissemination of developments in good practice and policy with respect to pharmacy prioritisation and the issues highlighted in this report.

HSIB makes the following safety observations:**Safety observation O/2020/066:**

Effective clinical pharmacy services have been evidenced to improve a range of measures linked to efficiency and patient safety in acute hospitals.

Safety observation O/2020/067:

Further integration of clinical pharmacy services within the MDT and within strategic decision making may improve a shared understanding of which medicines and situations place patients at greater risk of serious medication errors occurring.

Safety observation O/2020/068:

Clinical pharmacy services should consider using validated tools to assist in prioritising pharmacy care and identifying high-risk medicines and high-risk situations for medication error. Where electronic medical record systems are used, such tools could be integrated into these systems to aid prioritisation.

Safety observation O/2020/069:

Caring for older patients in hospital often presents a high-risk situation for medication errors occurring. Further efforts should be made to learn from technological developments and the organisation of pharmacy services in other high-risk areas of care that may improve system resilience in older persons care.

7 Appendix A

Incorrect labelling of the warfarin medication chart

7.1 The patient was admitted to the Unit on day 4. He was reviewed by a junior doctor at 04:00 hours who noted the patient's presenting medical complaint. At the time, the patient was noted to routinely be prescribed 12 different medications at home. The patient was not prescribed warfarin, and at this time no mention of warfarin is contained within his medical records.

7.2 The patient was seen by a senior clinical pharmacist for his medicines to be reconciled at 09:10 hours and again at 13:30 hours on day 4. The pharmacist could recall the patient's admission and explained that his medicines reconciliation had taken some time to complete due to the need to query stock levels of certain medications. On the two occasions the senior clinical pharmacist saw the patient they recalled that he was not prescribed warfarin and that this medication did not appear on his medication chart. This is supported by the available medical records.

7.3 Patient B had been admitted to the Unit at 20:02 hours on day 3 with acute delirium. When the patient was admitted he shared a bay with Patient B, with the patient occupying bed space five and Patient B occupying bed space four.

7.4 Patient B was known to have atrial fibrillation (an irregular heartbeat) and was prescribed warfarin. A separate warfarin medication chart is noted as having been started for Patient B in their medical records. At 10:48 hours on day 4, Patient B was sent to the discharge lounge from the Unit to be transported home. The investigation understands that Patient B did not suffer any harm as a result of this incident.

7.5 The warfarin chart contained within the patient's medical records appears to correspond with Patient B's medical history. The relevant indication for warfarin, reason for admission, INR reading (see 1.6.2 to 1.6.3 in the main report), and dosing regimen all correspond with Patient B's care. The Trust has reviewed Patient B's medical records as part of its own serious incident investigation and cannot locate the contemporaneous warfarin medication chart that had been noted as being part of Patient B's medical records.

7.6 Patient identity stickers were routinely printed when a patient was admitted to the Unit and a sheet of the stickers was contained within the medical records for staff to affix to relevant paperwork. From the available evidence, it appears that one of the patient's identity sticker was inadvertently affixed to Patient B's warfarin medication chart. This was likely to have occurred at some point between the patient undergoing a pharmacy review at 13:30 hours on day 4 and his admission to the Ward on day 5.

7.7 The HSIB investigation could not determine the exact circumstances that led to the patient's identity sticker being affixed to Patient B's warfarin medication chart. In order to understand how the error may have occurred, the investigation observed practice on the Unit to understand the process staff followed to affix patient identity stickers to medical records. Based on these observations, the investigation has offered comment on two possibilities that could arise as a result of the way paper-based medical records were handled and organised.

Records handling at the nurses' station

7.8 The Trust operated a paper-based medical records system. Each patient bay had a nurses' station where medical and nursing records were stored. Medical records were contained in a red folder, with nursing and pharmacy records in a blue folder. The investigation observed that several nursing records would be open on the nurses' station at any one time, with staff multi-tasking and switching between records as required.

7.9 An example of how an error could occur was observed by the investigation. A staff member approached the nurses' station with a separate drug chart for a patient taking insulin. The staff member began a discussion with a colleague about the patient, before leaving the drug chart on the nurses' station to attend to another task and taking their colleague with them. A third member of staff then approached the nurses' station and saw the drug chart unattended on the desk. This staff member used the name on the chart to insert it in the correct patient paper record at the nurses' station. A short time later, the initial staff member approached to ask where the drug chart was and was told it had been filed in the patient's records.

7.10 In this instance the patient's name had been added to the drug chart, allowing the chart to be filed in the patient record. In the case of the reference event, if some of the details on Patient B's medication chart were missing it would be possible for the chart to be lost or misfiled, especially given the close proximity of the patient and Patient B's beds and medical records.

Records on transfer

7.11 When patients were admitted to a ward from the Unit their red medical record folder came with them. Notes from the Unit's blue nursing and pharmacy records folder were taken from the folder and inserted as loose pages into the red medical record folder on transfer. Then, once the patient arrived at a ward, these notes would be refiled in one of the ward's own blue nursing and pharmacy records folders.

7.12 The investigation observed that this meant there was a period when nursing and pharmacy records were stored loosely on the nurses' station and in the red medical record folder, where additional paperwork could easily become attached.

7.13 Staff described a scenario where Patient B's medication chart could have been on the nurses' station when the patient's loose-leaf nursing notes were placed down. These could then have been gathered up together and put in the patient's red medical record folder when he transferred to the Ward. A member of staff told the investigation that they were "surprised this didn't happen more often".

7.14 Warfarin medication charts were not physically attached to the main medication chart. They were on a separate piece of paper that was filed with the medication chart in the blue records folder.

7.15 The main medication chart included a tick box to indicate whether a patient also had a separate warfarin medication chart. In addition, some staff also chose to write 'warfarin' as a medication in the main medication chart with a note to 'see separate chart'.

7.16 Staff explained that there was no consistent practice in how warfarin was noted on the main medication chart. Some medical staff told the investigation they would tick the box, whereas other medical staff said that they would enter a note in the records. Nursing staff told the investigation that it was not uncommon to find neither a completed tick box nor a note on the main medication chart to indicate that a separate warfarin chart was present.

7.17 The investigation asked nursing staff what they were likely to do if presented with a warfarin medication chart in a patient record that did not contain a patient identity sticker and did not correspond to details on the main medication chart.

7.18 Some staff explained that they would discard the drug chart and start a new chart to ensure that the correct patient chart was contained in the medical records. However, they acknowledged that this would require a new drug chart to be created and that this could take some time to complete.

7.19 Other staff explained that they would likely try to ensure that a patient identity label was attached to the medication chart to ensure that it did not go missing and to avoid any further errors. Staff explained that if they found a completed medication chart in a patient's medical records that broadly fit their expectations of the care being provided to that patient, they may not question whether this chart was included in error.

7.20 The Trust has identified that the warfarin chart to which the patient's identity sticker was affixed does not appear to have contained an identity sticker for Patient B or any handwritten personal identification. However, it did contain all the relevant clinical information concerning Patient B's use of warfarin.

7.21 The investigation believes that a member of staff on the Unit, or on the patient's admission to the Ward, may have seen that a completed warfarin medication chart was included in the patient's records without an identity sticker being attached. At this point, it is likely that one of the patient's identity stickers was attached to the warfarin medication chart in the mistaken belief that it belonged to the patient.

7.22 When paperwork was completed to record the patient's admission to the Ward he was noted to be on warfarin medication. From this point forward Patient B's medication chart and the associated warfarin regimen became part of the patient's medical record.

7.23 As a result of this investigation, concerns about how paper medical records are handled and stored have been referred to the HSIB Intelligence Unit for further consideration.

8 Appendix B

Warfarin charting

8.1 The complexity of warfarin therapy has meant that dosages and international normalised ratio (INR) ranges (see 1.6.2 to 1.6.3 in the main report) have traditionally been recorded on a separate medication chart. This is due to the potential need to calculate a patient's required warfarin dosage on a day-by-day basis, subject to the result of daily blood tests. Even where patients are stable on warfarin therapy their daily medication dose may change from day to day, as demonstrated by Patient B's medication chart in the reference event.

8.2 Internationally, work has been completed to allow warfarin to be reflected on the main medication chart (Australian Commission on Safety and Quality in Healthcare, 2012). However, a national prescription chart developed by the Royal College of Physicians (2015) and intended for use in the NHS in England maintains the need for warfarin to be charted separately.

8.3 The majority of inpatient prescribing in the NHS was once completed on paper-based systems (Shemilt et al., 2017). However, NHS trusts are increasingly moving to electronic prescribing systems. Electronic prescribing is likely to improve patient safety and potentially provide financial benefits (NHS Specialist Pharmacy Service, 2015).

8.4 In 2017, 35% of acute trusts were identified as using electronic systems where more than 80% of inpatient prescriptions were issued digitally (Department of Health and Social Care, 2018a). An additional £78m in government funding was made available in 2018 to support trusts to adopt electronic prescribing systems (Department of Health and Social Care, 2018b). Even where electronic prescribing systems have been implemented, many trusts have retained supplementary paper drug charts for certain medications (Shemilt et al., 2017).

8.5 The investigation observed staff using electronic prescribing systems in place in NHS trusts. The systems in place at the Trust where the reference event occurred did not link electronically to primary care records and staff had to input medicines into the hospital system manually. This meant that it was still possible for staff to enter an incorrect drug onto a patient prescription. Transcribing errors are identified as a common cause of medication incidents (Care Quality Commission, 2019).

8.6 The investigation observed pharmacy staff performing medicines reconciliation using electronic prescribing systems, where such errors were identified. However, as demonstrated by the reference event, this process cannot work to identify errors made after medicines reconciliation takes place.

8.7 A detailed consideration of the use of electronic prescribing systems can be found in the HSIB investigation report 'Electronic prescribing and medicines administration systems and safe discharge' (Healthcare Safety Investigation Branch, 2019a).

9 Endnotes

[1] Chronic anaemia is a condition in which patients do not have enough red blood cells or haemoglobin to meet their body's needs.

[2] Chronic obstructive pulmonary disease is an inflammatory lung disease that causes obstructed airflow from the lungs.

[3] A person with stage 4 kidney disease has advanced damage to their kidneys.

[4] Low vitamin D levels can lead to a range of problems, especially relating to the bones and muscles.

[5] The hospital at night team is a multi-professional, multispecialty approach to delivering care at night and out of hours, with the aim of improving patient safety.

[6] A CT (computed tomography) scan is a test that uses X-rays and a computer to create detailed pictures of the inside of the body.

[7] Pharmacy technicians work under the supervision of a registered pharmacist and assist in a range of duties, including managing and preparing the supply of medicines. They are a professional group of staff that require registration with the General Pharmaceutical Council.

[8] SBAR stands for Situation, Background, Assessment, Recommendation. It is a structured form of communication that enables information to be transferred accurately between individuals.

[9] A board round involves a summary discussion of patients' needs and the care that is required for that day.

[10] Ward rounds are an opportunity for senior medical staff and the wider clinical team to review each patient's case.

[11] A time and motion study seeks to analyse working practices and efficiency through the observation and timing of tasks.

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