



Investigation report

Investigation report: Electronic prescribing and medicines administration systems and safe discharge

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Theme:

Medication, Access to care

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A note of acknowledgement

We are grateful for the ongoing support and involvement of the family of Mrs Ann Midson, the patient whose experience is central to this report. Ann's name is used throughout this report at the family's request and her clinical details have been shared, with their consent.

Executive summary

Introduction

HSIB has identified a significant safety risk posed by the communication and transfer of information between secondary care, primary care and community pharmacy relating to medicines at the time of hospital discharge. A reference event was identified that resulted in a patient inadvertently receiving two anticoagulant medications at the same time, possibly causing an episode of gastrointestinal (digestive tract) bleeding.

Increasingly, healthcare facilities in primary and secondary care are introducing digital solutions (electronic prescribing and medicines administration (ePMA) systems) to improve medicines safety. However, analysis of the reference event identified how ePMA systems can create their own risks – risks that will need to be addressed as these systems become more widespread. Other risk factors relating to prescribing and the discharge of the patient, including medicines reconciliation, availability of pharmacy services and weekend working, were identified during the investigation.

The reference event

A 75-year-old woman, Mrs Ann Midson, was admitted to hospital during the early evening of a Friday in March 2018. Ann presented with a history of difficulty swallowing, vomiting and worsening shortness of breath; she had been diagnosed with incurable lung and kidney cancer in August 2017. In September 2017, she had commenced anticoagulant medication by self-administered injection (dalteparin) for atrial fibrillation(1) , which had been diagnosed several years earlier.

On the Sunday that same weekend in March 2018, Ann was discharged from hospital in the afternoon. While in hospital, her prescription for dalteparin was stopped on the Trust's ePMA system and she was prescribed an oral anticoagulant medicine (apixaban) instead; this was to avoid the need for a daily injection. The day after she was discharged from hospital, Ann received her regular repeat prescription of dalteparin; this was dispensed from her local pharmacy, following an order submitted the previous week. Ann continued to take both dalteparin and apixaban at home.

Following discharge, Ann had a further four interactions with healthcare professionals from primary and secondary care; however, it was not recognised that she was taking two anticoagulant medications. The error was detected 15 days after discharge by a hospice nurse who visited Ann at home. The GP visited on the same day and stopped both anticoagulant medications. Ann declined admission to hospital for a blood transfusion to treat a possible gastrointestinal bleed.

Two days later, Ann was admitted to a hospice because her health had deteriorated. Ann died the following day, 18 days after being discharged from hospital and three days after the anticoagulation medication had been stopped.

National investigation

Safety risk

The safety risk regarding the prescribing of high-risk medication using both electronic and paper systems, spanning primary and secondary care, was initially identified through routine review of the Strategic Executive Information System (StEIS)(2), along with intelligence shared with HSIB through referrals.

The reference event highlighted the risks to patients cared for by more than one healthcare provider, caused by errors in communication between providers if they use different systems for patient records and prescriptions.

The primary care medical practice (Health Centre) involved in the reference event highlighted the incident to the Acute Trust and carried out a local investigation. The Trust conducted its own investigation following the reference event's escalation to a Serious Incident(3) on to the StEIS. HSIB identified the incident through a StEIS review, gathered additional information and assessed the incident against its investigation criteria (see section 3.2). Consequently, the chief investigator authorised a national investigation.

The national investigation focused on:

1. the impact of ePMA systems on the safe discharge of patients, encapsulating the interface between primary and secondary care and communication with the patient/family
2. the influence of weekend working on patient safety in the context of the availability of support services and specialist input

(1) Atrial fibrillation is an abnormal heart rhythm.

(2) The StEIS is a national database that facilitates the reporting of serious patient safety incidents and the monitoring of investigations between NHS providers and commissioners.

(3) Serious Incidents include acts or omissions in care that result in; unexpected or avoidable death, unexpected or avoidable injury resulting in serious harm (<https://improvement.nhs.uk/documents/920/serious-incident-framework.pdf>)

The following work was carried out during the investigation:

- observation of other electronic prescribing systems being used by trusts
- engagement with developers of electronic prescribing systems
- identification of current best practice by observation visits to Global Digital Exemplar (GDE) trusts
- identification of NHS England's strategic objectives for digitisation
- observation of electronic prescribing systems currently used in primary care
- identification of points of interface/data exchange between systems
- review of the national standards for weekend working, including the timing and extent of implementation of these standards
- identification of which support services operate nationally in hospitals on a seven-day working system without a reduction of services, and which services operate a reduced service at weekends

- review of how medical care is organised at weekends to ensure that patients are reviewed by appropriate specialists in accordance with the primary (main) diagnosis.

The investigation identified opportunities and systemic remedies to reduce the risk of medication errors occurring when using ePMA systems. The investigation and the report focus primarily on the use of ePMA systems in the context of safe discharge from secondary to primary care. However, the findings, safety recommendations and safety observations may be helpful when considering the development of other national patient safety initiatives, particularly those relating to the introduction of new systems.

Findings

The investigation found:

1. The reference event could have occurred with or without the ePMA system, and a well-configured ePMA system could have prevented the error.
2. A single system of medicines administration that supports both hospital and self-administration is the optimal approach.
3. There was no standardised discharge process in place, incorporating a discharge summary that interfaced with the ePMA system and provided a synopsis of the patient's medication on discharge.
4. There was a lack of interoperability (the capacity to exchange, interpret and store data to common standards) between primary and secondary care electronic prescribing systems, between secondary care facilities, between secondary and tertiary care, and between secondary care and community pharmacy.
5. Within primary care, guidance on the design and implementation of electronic prescribing systems in respect of alerts (warnings) is variable.
6. There are many different types of ePMA system available in England – some bespoke, others commercial off-the-shelf systems – and they are provided by several different vendors.
7. There are opportunities for technological intervention specifically aimed at ePMA system improvements, as the roll-out in hospitals across England has been gradual.
8. The implementation of electronic prescribing is associated with a greater than 50% reduction in medication errors and possibly a similar reduction in patient adverse drug events.

9. There is limited knowledge and data relating to unintended consequences of introducing ePMA systems because of the varied nature of health IT products and the lack of common criteria against which to measure the impact.
10. Commercial ePMA systems reduced medication errors if the available functionality was switched on, used appropriately, integrated with other relevant IT systems and aligned with clinical workflows.
11. In the reference event, the medicines reconciliation process in primary care would have provided an opportunity to detect the continuation of the dalteparin after discharge from hospital.
12. Standardisation of clinical decision support (CDS) systems could benefit the prescriber in relation to drug–drug interaction alerting.
13. There are software design standards, including those for CDS systems, which are mandatory for all software suppliers.
14. Minimum rules would guarantee data interoperability and enable national open standards to be set for data and interoperability.
15. Transfer of care initiatives improve communication between care settings.
16. There is no standard discharge process built into ePMA systems to facilitate safe discharge.
17. Hospital ward pharmacy provision is not always available seven days a week to ensure there is: adequate checking for errors in prescribing; minimal transcription from paper systems into the ePMA by entering directly on to the system; and medicines reconciliation (see section 1.2) in accordance with national guidance.

HSIB makes the following safety recommendations:

Safety recommendation R/2019/050:

It is recommended that NHSX develops a process to recognise and act on digital issues reported from the Patient Safety Incident Management System.

Safety recommendation R/2019/051: It is recommended that NHSX supports the development of interoperability standards for medication messaging.

Safety recommendation R/2019/052:

It is recommended that NHSX continues its assessment of the ePRaSE pilot and considers making ePRaSE a mandatory annual reporting requirement for the assessment and assurance of electronic prescribing and medicines administration safety.

Safety recommendation R/2019/053:

It is recommended that the Department of Health and Social Care should consider how to prioritise the commissioning of research on human factors and clinical decision support systems; particularly in relation to the configuration of software system alerting and alert fatigue, to establish how best to maximise clinician response to high risk medication alerts.

Safety recommendation R/2019/054:

It is recommended that NHS England and NHS Improvement include in the Medication Safety Programme shared decision making and improved patient access to medication information across all sectors of care, to ensure a person-centred approach to safe and effective medicines use.

Safety recommendation R/2019/055:

It is recommended that NHSX produces guidance for configuring the electronic discharge process, and how electronic prescribing medicines and administration systems should be interfaced with such a process.

HSIB makes the following safety observations:

Safety observation O/2019/039:

The use of paper and electronic systems in parallel should be minimised to reduce the risk of error caused by multiple data entry/retrieval sources.

Safety observation O/2019/040:

The practice of documenting only newly prescribed medication on discharge summaries should be reviewed from a patient safety and medicines management perspective.

Safety observation O/2019/041:

Counselling of patients newly commenced on a direct oral anticoagulant is critical to the safe use of these medicines. It would be helpful if NHS trusts reviewed this practice paying particular consideration to the communication of changes in medication and the initiation of new medication

Safety observation O/2019/042:

There may be benefit for healthcare professionals to receive training in handover communications which should include integrating clinical information with full medicines information, and to share this information with patients and carers in writing and verbally.

Safety observation O/2019/043:

During the implementation of any new digital system, benefits may be realised by redesigning work practices to ensure the new system is fully embedded, with staff training/engagement to support this.

Safety observation O/2019/044:

It would be beneficial to the users of electronic prescribing medicines and administration systems if the system vendors raised awareness of the safety limitations of their products and had a system for collating safety feedback to inform future development and a mechanism for sharing feedback with other users.

HSIB notes the following safety action has been implemented

Safety action A/2019/017:

The National Academic Health Science Networks Medicines Optimisation Network has been commissioned by NHS England to support the roll-out of Transfers of Care Around Medicines across England.

1. Background and context

1.1 Electronic prescribing and medicines administration (ePMA) systems

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

1.1.2 In practical terms, an ePMA system supports the safe, effective, and cost-effective use of medicines from a patient's admission to hospital until their discharge. Figure 1 illustrates a well-defined, properly configured ePMA system, including 'closed loop medication management' (CLMM). A CLMM system is a fully electronic medication management process that integrates automated and intelligent systems to manage the process of prescription, dispensing and administration of medicines, and seamlessly document all the relevant information.

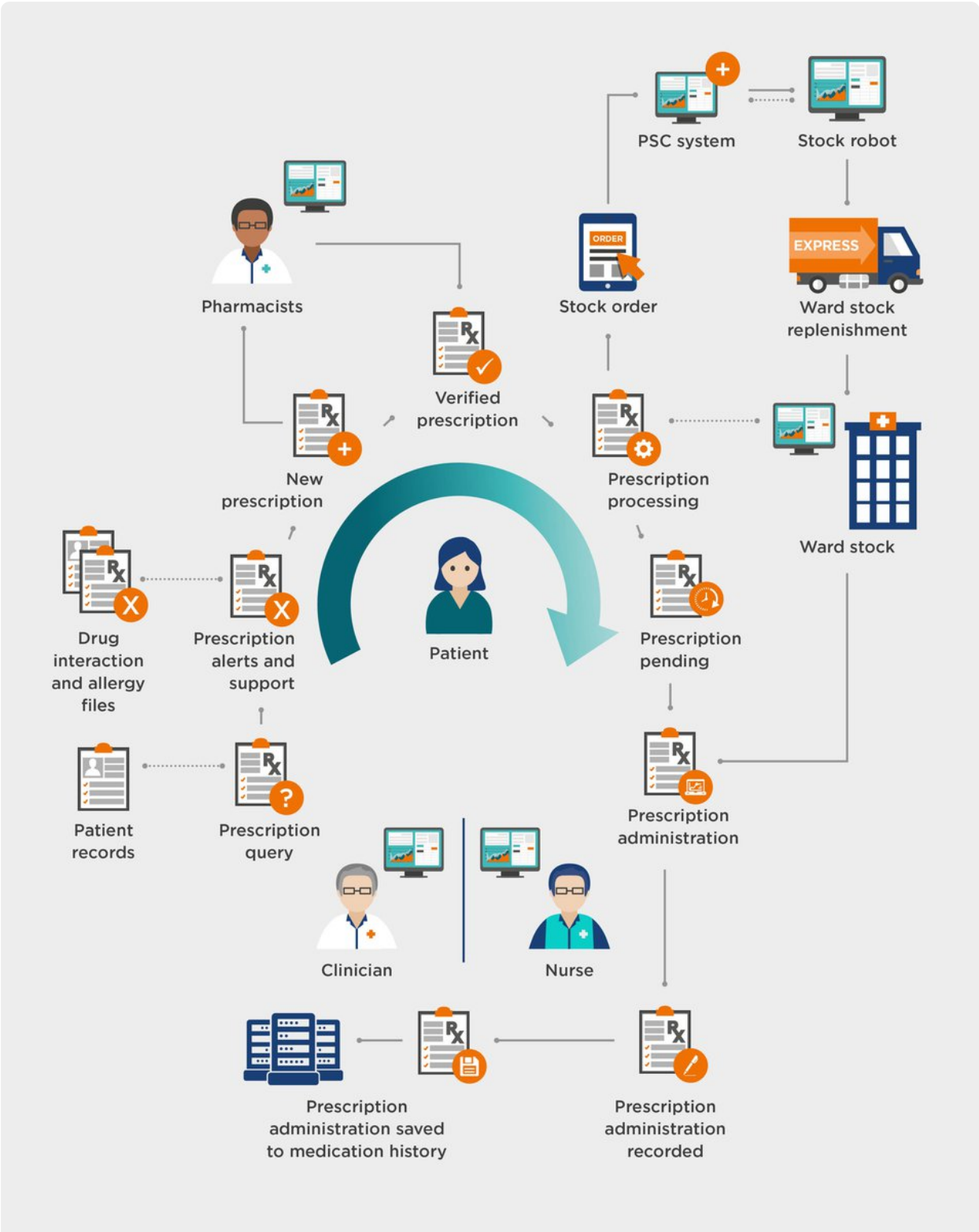


Fig 1 ePMA Process

1.1.3 In relation to terminology used in this report, see Appendix 1 for a detailed glossary. In general terms, throughout the report, electronic prescribing is referred to in the context of being an integral part of ePMA in the United Kingdom; in the United States it is referred to as a 'computerised provider order entry' (CPOE) system.

1.2 Medicines reconciliation

1.2.1 A guideline on the safe and effective use of medicines in health and social care has been issued (National Institute for Health and Care Excellence, 2015). The guideline aims to ensure that medicines provide the greatest possible benefit to people by encouraging medicines reconciliation (see 1.2.2), medication review(4), and the use of patient decision aids.

1.2.2 Medicines reconciliation, as defined by the Institute for Healthcare Improvement, is the process of identifying an accurate list of a person'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.

1.2.3 The medicines reconciliation process should be undertaken when a patient moves between care settings and will vary depending on the care setting that the person is moving from and to, for example, from primary care into hospital. 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 (National Institute for Health and Care Excellence, 2015). 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.

1.2.4 In relation to primary care, the National Institute for Health and Care Excellence (2015) states there is a need to 'ensure that systems are in place for people discharged from a care setting to have a reconciled list of their medicines in their GP record within one week of the GP practice receiving the information, and before a prescription or new supply of medicines is issued'.

1.2.5 In all care settings, organisations should ensure that a designated health professional has overall organisational responsibility for the medicines reconciliation process. The process should be determined locally and should include:

- organisational responsibilities
- responsibilities of health and social care practitioners involved in the process

- individual training and competency needs.

1.2.6 Organisations should ensure that medicines reconciliation is carried out by a trained and competent health professional, ideally a pharmacist, pharmacy technician, nurse or doctor.

They will have the necessary knowledge, skills and expertise including:

- effective communication skills
- technical knowledge of processes for managing medicines
- therapeutic knowledge of medicines use.

1.2.7 Patients and their family members or carers should be involved, whenever possible, in the medicines reconciliation process

(4) A structured medication review is a critical examination of a person's medicines (<https://www.nice.org.uk/guidance/QS120/chapter/Quality-statement-6-Structured-medication-review>).

1.3 Medicines optimisation

1.3.1 Medicines optimisation is defined as 'a person-centred approach to safe and effective medicines use, to ensure people obtain the best possible outcomes from their medicines' (National Institute for Health and Care Excellence, 2016).

1.3.2 Medicines optimisation looks at the value that medicines deliver, making sure they are clinically effective and cost effective. It is about ensuring people get the right choice of medicines, at the right time, and are engaged in the process by their clinical team (NHS England, 2019).

1.3.3 The Royal Pharmaceutical Society (2013) refers to four principles of medicines optimisation (Figure 2).

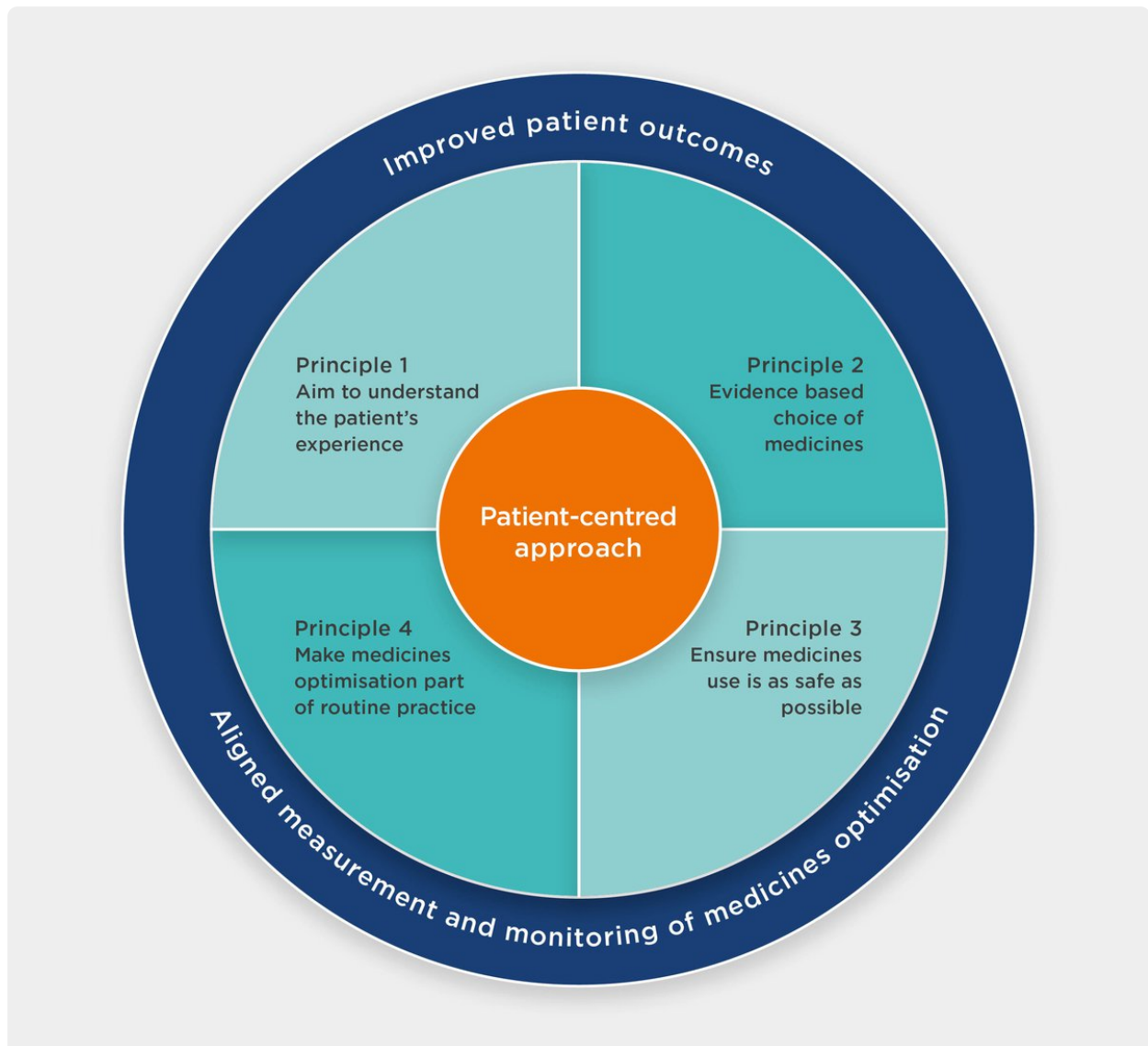


Fig 2 Summary of the four principles of medicines optimisation (The Royal Pharmaceutical Society, 2013)

1.4 Anticoagulant medication

1.4.1 Anticoagulants, commonly referred to as blood thinners, are medicines that prevent or reduce coagulation of blood, prolonging the time it takes for blood to clot. There are three main groups of anticoagulants: low molecular weight heparin (LMWH), warfarin and direct oral anticoagulants (DOAC).

1.4.2 Two of the medications discussed within this investigation are apixaban, which is a DOAC in tablet form and dalteparin, which is a LMWH and given by subcutaneous injection(5). There is currently no reliable way of reversing the effects of apixaban once it has been administered. For dalteparin, protamine sulphate can be given if there is evidence of haemorrhage (bleeding) or if very large amounts of

the medication have been injected, but anticoagulation will not be completely reversed (National Poisons Information Service, 2019). This is relevant for patients who are over-anticoagulated, as occurred in the reference event.

1.4.3 In 2014, the National Institute for Health and Care Excellence issued a guideline on the management of atrial fibrillation (National Institute for Health and Care Excellence, 2014). This guideline advocated the use of anticoagulant medication for the treatment of atrial fibrillation (AF) to prevent embolic stroke(6).

(5) An injection into the layer of fat under the skin.

(6) A stroke that occurs when a blood clot that has formed elsewhere in the body travels to the brain via the bloodstream and blocks the flow of blood to the brain

1.5 Drug interactions

1.5.1 There were several drug interactions noted in the reference event, the key ones being:

- The administration of the oral anticoagulant, apixaban, which the patient administered herself in addition to dalteparin. Taken together, these drugs can increase the risk of bleeding; this is graded as 'moderate' (amber) in the British National Formulary (BNF)(7) .
- The prescribing of amiodarone with crizotinib (anti-cancer drug). Amiodarone is an antiarrhythmic medication, used to treat and prevent a number of types of irregular heartbeat. The administration of both crizotinib and amiodarone increases the risk of bradycardia (low heart rate), with the severity of interaction graded as 'severe' (red) in the BNF(8).
- The prescribing of an increased dosage of bisoprolol (to treat high blood pressure) with crizotinib. The combined medicines increase the risk of bradycardia(9), with the severity of interaction graded as 'moderate' (amber) in the BNF.

(7) 'Moderate—the result could cause considerable distress or partially incapacitate a patient; they are unlikely to be life-threatening or result in long-term effects'. Accessed via: https://bnf.nice.org.uk/interaction/dalteparin.html#bnf_i1567199228225

(8) 'Severe—the result may be a life-threatening event or have a permanent detrimental effect'. Accessed via: https://bnf.nice.org.uk/interaction/crizotinib-2.html#bnf_i1567199226666

(9) https://bnf.nice.org.uk/interaction/crizotinib-2.html#bnf_i1567199226697

1.6 Organisational name changes

1.6.1 The Department is referred to as the Department of Health until January 2018, and the Department of Health and Social Care from January 2018 onwards.

1.6.2 NHS England and NHS Improvement are referred to in the report as separate entities until April 2019, and jointly as NHS England and NHS Improvement post April 2019.

1.6.3 There may be other organisations which are referred to following publication of this report that have subsequently changed their name; this report will not be updated.

2 The reference event

August 2017

2.1.1 The patient at the centre of the reference event was Mrs Ann Midson. Ann was 75-years-old at the time of the reference event (March 2018).

2.1.2 Ann was diagnosed with two types of cancer: stage 4 incurable lung adenocarcinoma and left renal carcinoma (both primary cancers). Her past medical history included spinal stenosis (narrowing of the spaces within the spine), hypertension (high blood pressure) and paroxysmal (intermittent) atrial fibrillation (AF). Ann was diagnosed with AF approximately 10 years previously when undergoing hip replacement surgery, but was not prescribed any medication for it at the time.

September 2017

2.1.3 Ann attended a hospital clinic appointment at which there was a discussion between an oncologist and a cardiologist⁽¹⁰⁾ regarding treatment for her AF. A letter from the oncologist stated that a decision was made at the clinic to commence an anticoagulant medication for AF, based on the diagnosis of background metastatic (secondary) lung cancer with an increased risk of a blood clot formation. Ann was started on low molecular weight heparin (LMWH) injections (dalteparin 15,000 units) after checking for drug interactions with the chemotherapy medication (crizotinib), which was started at the same time.

(10) An oncologist is a cancer specialist; a cardiologist is a heart specialist. 11 A restaging scan is undertaken to determine whether cancer has spread in the body or how cancer has responded to treatment.

Mid-February 2018

2.1.4 Ann and her husband moved to be near her family. Ann registered with a general practitioner (GP) at a local Health Centre.

Late February 2018

2.1.5 Ann was seen at the local acute hospital trust as an outpatient. The management plan was to continue chemotherapy (following five previous cycles) and to arrange a restaging computed tomography (CT) scan¹¹ of her chest, abdomen, pelvis and head. At this consultation the family mentioned that occasionally Ann could appear slightly confused.

2.1.6 Ann was self-administering several medications: crizotinib (chemotherapy) bisoprolol (to treat high blood pressure); pregabalin (for nerve pain); lansoprazole (for excess stomach acid); dalteparin (anticoagulant); salbutamol (which opens the airways into the lungs); and co-codamol (pain relief).

March 2018

2.1.7 The restaging CT scan was undertaken to determine the amount or spread of cancer in Ann's body after treatment. A CT scan of Ann's head was also carried out; this was the first time Ann had undergone this.

2.1.8 The following day, Ann was seen by a duty doctor at the Health Centre as she had had a cough for three days. Ann was diagnosed with a chest infection and prescribed a seven-day course of amoxicillin (an antibiotic).

Day 1: Friday at 15:46 hours

2.1.9 The Health Centre issued a repeat prescription for Ann's medicines. The medicines issued were: bisoprolol 2.5mg; lansoprazole 30mg; pregabalin 75mg; and a 30-day supply of dalteparin 15,000 units.

Day 1: Friday afternoon

2.1.10 Ann's daughter was concerned about Ann's persistent cough, so she phoned a Macmillan nurse who advised her to call an ambulance. Two paramedics attended at 17:36 hours. The history they obtained indicated that Ann had been suffering with a productive cough for five days (which was worse that day) and was short of breath with any exertion. An electrocardiogram (ECG) showed that Ann's heartbeat was very irregular, and the paramedics recorded the provisional diagnosis as

'cardiac' and specifically as 'atrial fibrillation'. They added: 'new onset atrial fibrillation? cause; prior chest infection – appears to be clearing up; PE?; pleural effusion?; progression of lung CA?'

2.1.11 The paramedics arranged for Ann to attend the local hospital for further review and within 16 minutes of arrival at her home, they were on the way to hospital.

Day 1: Friday at 18:45 hours

2.1.12 Ann arrived at the emergency department (ED) via ambulance. The clerking (admitting) doctor, an ED specialty trainee (ST4)(12), documented in the paper ED records that Ann had a two-week history of dysphagia (difficulty swallowing), vomiting and worsening shortness of breath. The primary diagnosis was recorded as AF with rapid ventricular response (fast heart rhythm). The secondary diagnosis was documented as decline in the previous two weeks, difficulty swallowing and nausea/vomiting, possibly related to cancer/ cancer treatment. Ann kept the medicines she was taking in a basket and this was brought to hospital with her, along with a yellow folder containing her clinical notes.

Day 1: Friday at 23:55 hours

2.1.13 Ann was transferred from the ED to the medical assessment unit (MAU).

Day 2: Saturday at 10:50 hours

2.1.14 Ann was seen on a ward round, and a consultant review was completed. It was confirmed that the diagnosis was:

“1. AF with FVR [fast ventricular response or rapid heartbeat] – rate controlled¹³ and 2. Progression of disease – L [left] lung collapse, bone mets [metastases, or secondary cancer growths], renal mass, cerebral mets [metastases]”.

2.1.15 A plan was made for Ann’s case to be reviewed by the acute oncology service, so that the CT scan findings could be discussed with her. Ann would be seen as an outpatient, as the acute oncology service only runs on weekdays. Ann was not aware of the progression of the cancer at this stage.

Day 2: Saturday at 11:50 hours

2.1.16 A Specialist Trainee in respiratory medicine reviewed the CT scan images and examined Ann. Their findings were consistent with the collapsed left lung evident from the CT scan, but it was considered unlikely that there was any significant drainable pleural effusion (fluid) on Ann's lungs(14), so no further interventions were undertaken.

Day 2: Saturday at 19:25 hours

2.1.17 Ann was transferred to a cardiac (heart) ward.

Day 3: Sunday at 08:10 hours

2.1.18 Ann was seen by a consultant cardiologist and Foundation Year Two (FY2)(15) trainee during a ward round. The doctors reviewed Ann's chest X-ray, which confirmed a 'white out of her left lung' (due to the lung being collapsed). They also looked at the results of the ECG that had been carried out when Ann was admitted, which confirmed fast AF.

2.1.19 The medication plan discussed during Ann's clinical review was to prescribe amiodarone (an antiarrhythmic agent) for the fast AF and to commence apixaban (an oral anticoagulant). The latter was intended as an alternative to the dalteparin injections, to remove the need for daily injections.

2.1.20 A decision was made to discharge Ann home.

Day 3: Sunday at 08:20 hours

2.1.21 Dalteparin was discontinued on the ePMA system by the FY2, following verbal communication during the ward round. However, there was no written documentation in Ann's medical records to note that the decision to stop dalteparin and start apixaban instead, had been discussed with her.

Day 3: Sunday at 08:32 hours

2.1.22 The 'To Take Away' (TTA) prescription for apixaban was created within the ePMA system in preparation for Ann taking this medication home with her. A care plan for the new medication was not generated from the ePMA system, to provide detailed individual medication information.

2.1.23 The 'pharmacy summary' (a workflow for dispensing only) was generated on the ePMA system by the FY2, which would alert the pharmacy to any changes in admission medications that may need to be dispensed. The pharmacy summary stated that Ann's admission medicines were unchanged. However, this was

incorrect as the bisoprolol dosage had been increased; dalteparin was not included in the 'stopped medication' section; and the apixaban had been added. The dalteparin was not in the 'stopped medication' section because the medicines Ann had been taking before admission had not been entered on the system.

(13) AF with fast ventricular response (rate controlled) means that the fast heart rhythm had been slowed down by the treatment given.

(14) Fluid can collect around the lungs in conditions like cancer and this fluid can be drained by the insertion of a small tube between the ribs.

(15) FY2 is a foundation year two junior doctor, in their second year since leaving medical school.

Day 3: Sunday up until discharge at 15:11 hours

2.1.24 Ann's husband and daughter went to the hospital to collect Ann and take her home. The family informed the investigation that they discovered her bed in the MAU to be empty and eventually found her on the cardiology ward, sitting on a chair. While waiting for the TTA and the discharge documentation, Ann and her husband decided to go to the hospital chapel together. Their daughter remained on the ward to receive the medicines.

2.1.25 Ann's daughter recalls that a nurse on the ward gave her a bag of medications, explaining that the dosage of one of these medications had increased. In the bag of medicines was apixaban, bisoprolol (the dosage of which had been increased to 3.75mg), pregabalin and lansoprazole. The amiodarone had been discontinued as the interaction with crizotinib was recognised (see 1.5.1), although there was no indication of bradycardia (low heart rate) on Ann's 'Adult Vital Signs Assessment' record, which would have indicated an adverse reaction.

2.1.26 At 14:00 hours the nurse who discharged Ann recorded in the medical records that Ann's medication was given as prescribed. The discharge summary included the new medications commenced (including apixaban) but did not record that dalteparin had been stopped. Ann and her husband returned to the ward to join their daughter and they left for home.

2.1.27 The discharge letter from the hospital was completed on day three at 13:47 hours and printed off. Ann's daughter cannot recollect whether it was given to her with the medicines.

Day 4: Monday at 10:21 hours

2.1.28 There was a telephone consultation with a duty doctor at the local Health Centre as Ann had a worsening cough and vomiting. The GP did not visit Ann at home, as it was noted there was an oncology follow-up planned for later that day.

2.1.29 The community pharmacy issued the dalteparin medication for Ann (along with bisoprolol, lansoprazole and pregabalin), using an existing repeat prescription issued by her GP prior to the hospital admission. The pharmacy had no record of Ann being on apixaban, as it had been dispensed by the hospital.

Day 4: Monday afternoon

2.1.30 Ann was seen by the acute oncology service clinic at the hospital. The findings of the CT scan from March 2018 were discussed. This included 'complete whiteout of the left lung and...some obstruction of the mid to lower oesophagus due to the lymph node disease in the mediastinum(16) which may be accounting for her dysphagia(17) The head scan shows at least two brain metastases'. A plan was made for a multidisciplinary team meeting to discuss the possibility of an oesophageal stent(18) or palliative radiotherapy to the mediastinum, to relieve some of Ann's symptoms. A medication history was not taken by the clinic on this occasion. However, Ann's daughter recalls one of the clinicians in the clinic asking, "What's this drug?", following which they surmised that perhaps it was just given in hospital. The family tried to follow this up afterwards with the clinic staff, but no one could recall what they were referring to.

(16) The region of the body located between the lungs.

(17) Dysphagia means difficulty swallowing.

(18) An oesophageal stent is a metal or plastic tube put into the food pipe (oesophagus). It keeps the food pipe open.

Day 5: Tuesday

2.1.31 The discharge document generated by the ePMA system in the hospital was transferred electronically to the Health Centre on day three and was forwarded through the electronic system to Ann's GP on day five. Medicines reconciliation did not occur as the Health Centre's pharmacist was on holiday for one week and although there were alternative arrangements in place to achieve medicines reconciliation in the practice pharmacist's absence, these were not carried out. The GP was expected to undertake medicines reconciliation however, on this occasion, a review of Ann's medicine was carried out during a face-to-face consultation rather than reconciliation (as outlined in 2.1.32).

Day 13: Wednesday at 17:06 hours

2.1.32 Ann was seen by her named GP during a brief emergency appointment, fitted in on the day. This was the first time she had met the GP in person after recently moving to the area. Ann had a cough and reported a low mood following the cancer progression.

2.1.33 The GP noted from the electronic health record (EHR) that Ann had scapula (shoulder bone) metastases from the CT scan undertaken in March 2018 (which Ann had been unaware of). The GP also found a lump in her breast, but Ann declined further investigation of these findings.

2.1.34 The medicine review was undertaken by the GP and she added apixaban to Ann's repeat medications. The GP did not see the drug interaction warning message on the electronic health record screen. The reason for this is explored in section 4.

Day 17: Sunday at 15:19 hours

2.1.35 Ann was seen by an out-of-hours GP as her condition had deteriorated during the previous three to four days. Ann's daughter had noticed dark staining on the bed linen. Ann was also vomiting and appeared to have blood in her urine (although she could not produce a sample for testing). She declined admission to hospital. During the consultation, the GP documented that the medication history was checked, but incorrectly documented that Ann was on warfarin.

Day 18: Monday at 09:58 hours

2.1.36 Following the contact initiated by the family over the weekend, there was a telephone conversation between a Hospice Specialist Nurse and the Care Co-ordinator at the Health Centre. Based on Ann's history, they agreed it sounded like there was blood in her urine and stools. It was again incorrectly noted in Ann's records that she was taking warfarin.

Day 18: Monday at 16:00 hours

2.1.37 Ann was visited by a Hospice Specialist Nurse who, during her assessment, discovered that Ann had been administering two anticoagulants. The family was advised to stop all medications until the nurse had discussed this discovery with the medical team. By this stage, a black, malodorous liquid (melaena) was leaking from Ann's bowel and there was a concern that this could be a sign of bleeding from the stomach or small intestines.

Day 18: Monday at 16:50 hours

2.1.38 The Hospice Specialist Nurse discussed the duplication of the anticoagulation medicines with a senior pharmacist at the hospital via a professional advice line. She was advised that the drugs should not be used together and the symptoms of blood in the stools and urine, and blood-streaked sputum (mucous from the airway), could be a consequence of excessive anticoagulation.

Day 18: Monday at 19:00 hours

2.1.39 Ann was visited by her usual GP and had a long discussion about the risks of being on two anticoagulants. The GP explained that the deterioration in her health could be caused by the gastrointestinal bleed or the progression of cancer. Ann declined admission to hospital and signed a Do Not Attempt Resuscitation order.

Day 20: Wednesday 2.1.40

Ann was admitted to a hospice.

Day 21: Thursday at 22:55 hours

2.1.41 Ann died. The anticoagulant medicines had been discontinued three days prior to her death. Subsequent examination found no evidence of a gastrointestinal bleed or of haemorrhage (bleeding), an infarction (obstruction of the blood supply causing tissue to die) or an infection in the central nervous system (brain), at the time of her death.

3 Involvement of the Healthcare Safety Investigation Branch

3.1 Referral of the reference event

3.1.1 The incident relating to the simultaneous prescription of two anticoagulation medications was identified by HSIB and a scoping investigation was initiated to determine the learning potential of a national investigation.

3.2 Decision to investigate

3.2.1 Following an initial scoping investigation, the chief investigator authorised a full investigation as the incident met HSIB's criteria:

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

The reference event highlighted some of the risks associated with prescribing medicines for patients during a stay in hospital and on discharge, particularly when patients are taking unusual medication treatments at home prior to admission. Such risks are exacerbated when patients move between wards and departments. In addition, support services may not be available seven days a week (NHS England, 2017) to perform tasks such as medicines reconciliation.

According to data published by NHS Improvement on 25 September 2019, 2,036,657 incidents were reported to the National Reporting and Learning System (NRLS) as occurring in England between April 2018 and March 2019. Of these, 216,154 were classified as medication incidents, with approximately 1% of the medication incidents reported as resulting in moderate harm, severe harm or death.

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

Medicines are prescribed across primary and secondary care using a mixture of electronic and paper systems, but with an increasing reliance on electronic systems.

The widespread use of anticoagulants to treat atrial fibrillation (AF) (Fitzpatrick et al, 2017) is supported by National Institute for Health and Care Excellence guideline CG180 (National Institute for Health and Care Excellence, 2014).

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

There were opportunities for HSIB to share learning on a national level to positively influence processes and practices to reduce prescribing and administrative errors when using ePMA systems, in the context of improving the safe discharge of patients from secondary to primary care.

3.3 Evidence gathering and methodology

3.3.1 The investigation interviewed frontline staff and managers within the Trust where the reference event occurred. The investigation reviewed Ann's clinical records, and Trust policies and national guidance, to understand what actions were taken and how these aligned with both the Trusts' and national expectations. The investigation identified factors relevant to Ann's care and treatment.

3.3.2 The findings of this report have been supplemented by insights from subject matter advisors (SMAs), academics and academic literature, in addition to expertise provided by colleagues in national organisations.

(19) Accessed via: <https://improvement.nhs.uk/resources/national-patient-safety-incident-reports-25-september-2019/>

(20) The National Reporting and Learning System (NRLS) is a primarily voluntary confidential reporting system for patient safety incidents. These can be reported by anyone, with most reported by NHS organisations across England and Wales via their local risk management systems. As the system is mainly voluntary, it is not a reflection of incidence, but can provide insight into the types of risks and incidents reported by NHS organisations, as well as patient safety reporting culture.

3.3.3 AcciMap method

The AcciMap model was used to analyse the reference event information and supports the direction of the national investigation. The AcciMap method (Svedung and Rasmussen, 2002) is an incident analysis method that identifies factors within the system that influenced the occurrence of an incident.

The analysis focuses on identifying relationships between the different levels of the system (Figure 3), which include government policy and budgeting; regulatory bodies and associations; local area management; physical processes and actor activities (what staff, people, organisations, systems did); and equipment and surroundings (Stanton et al, 2013).

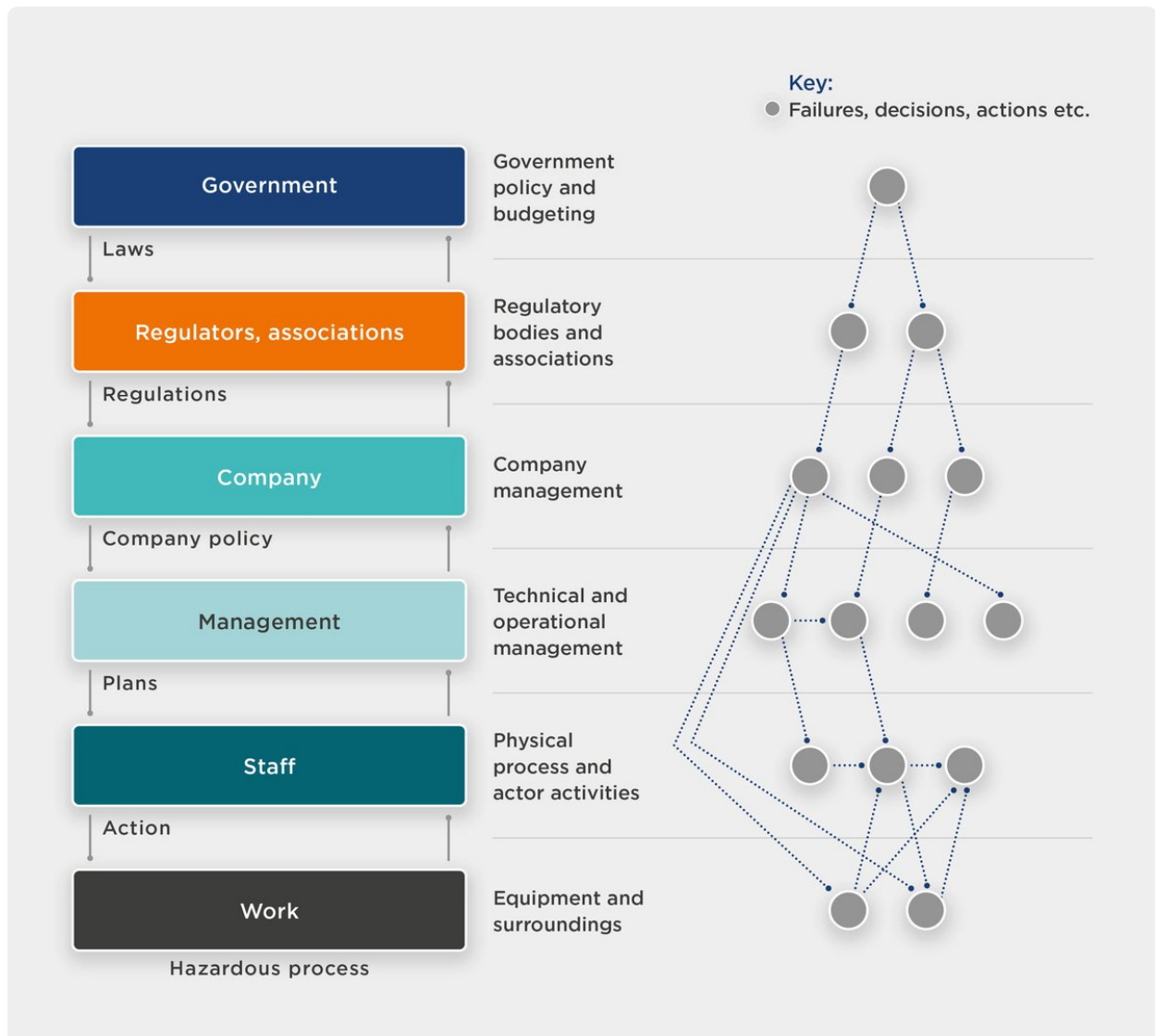


Fig 3 The AcciMap Method (Svedung and Rasmussen, 2002)

4. Findings and analysis of the reference event in relation to the national and local policy

Introduction

HSIB has identified a significant safety risk posed by the communication and transfer of information between secondary care, primary care and community pharmacy relating to medicines at the time of hospital discharge. A reference event was identified that resulted in a patient inadvertently receiving two anticoagulant medications at the same time, possibly causing an episode of gastrointestinal (digestive tract) bleeding. Increasingly, healthcare facilities in primary and secondary care are introducing digital solutions (electronic prescribing and

medicines administration (ePMA) systems) to improve medicines safety. However, analysis of the reference event identified how ePMA systems can create their own risks – risks that will need to be addressed as these systems become more widespread. Other risk factors relating to prescribing and the discharge of the patient, including medicines reconciliation(21), availability of pharmacy services and weekend working, were identified during the investigation.

(21) Medicines reconciliation, as defined by the Institute for Healthcare Improvement, is the process of identifying an accurate list of a person's current medicines and comparing them with the list currently in use, recognising any discrepancies and documenting any changes.

4.1 Electronic prescribing and medicines administration (ePMA) systems

National and local context

4.1.1 The investigation was advised by NHS England that, according to data from 2017, not all healthcare services were using ePMA systems and not all functionality was being used, even in the most digitally mature trusts. However, it is expected that the position has improved since then, particularly among the Global Digital Exemplar(22) sites with ePMA systems, and acknowledging that such systems require continuous optimisation beyond the initial baseline implementation.

(22) NHS England defines a Global Digital Exemplar as 'an internationally recognised NHS provider delivering improvements in the quality of care, through the world-class use of digital technologies and information'

4.1.2 In the Trust where the reference event occurred, an electronic health record (EHR) system had been in use since 2012. The ePMA elements of the system were chosen as they were an add-on module to the existing EHR system.

4.1.3 The Trust implemented the ePMA system in November 2017 using a 'big bang' approach (introducing it throughout the Trust at the same time), an approach that the investigation was advised had only been taken by three trusts in England. The remainder of trusts implemented ePMA systems via a phased implementation, at increasing rates as experience grows, adopting an incremental roll-out approach to a smaller number of services.

4.1.4 Prior to implementation of the ePMA system, the Trust drafted a deployment plan which stated that if the availability of resources (staff and finance) could fully support a big bang approach, then this would be the recommended roll-out method to minimise clinical risk. Ultimately, the roll-out resulted in not all services using the electronic system and not all of the system's functions being used. One of the

vendors for an ePMA system advised the investigation that implementation would be expected to take 12 months to two years. This highlights the relative infancy of the system at the time of the reference event.

4.1.5 It was not possible to see Ann's stay in hospital end to end using the Trust's EHR because of the way the system was configured. Instead, the admission was represented as individual workflows (processes), accessed via different screens in the system. This meant that each workflow had to be analysed separately to determine the sequence of events and error points.

4.1.6 Electronic reconciliation of medicines was enabled on the Trust's ePMA system from the outset and so was available at the time of the reference event. However, this function was primarily used only by pharmacy staff (pharmacists and medicine management technicians). Clinicians were not recording medicines on admission on the ePMA system at this time. Medicines reconciliation on discharge was also enabled as a function on the ePMA system from its introduction, and was carried out by pharmacists at the point of checking the 'To Take Away' (TTA) medication. However, its functionality was limited where no history of prior medication was completed, and therefore the medicines information was not included in patient discharge letters.

4.1.7 The Trust's electronic pharmacy stock-control system was separate from its EHR system. This adds to the complexity of systems and makes interoperability more challenging, although it did not impact on the reference event.

4.1.8 The drug chart, TTA medicines and the discharge summary were separate tasks within the ePMA system. The TTA process was as follows:

1. The TTA is created and signed electronically by a doctor.
2. A pop-up window prompts the prescriber to notify pharmacy to dispense the TTA.
3. Once notified, a task is added to the pharmacy patient task list prompting a pharmacist to complete the TTA prescription screen in the ePMA system.
4. Once the screening task is complete, a task is created on the dispensing tasks.
5. The task is completed when the TTA has been dispensed and checked.
6. The TTA is then ready for delivery to the ward.

4.1.9 The ePMA TTA process was for dispensing purposes only and this information did not interface with the discharge summary. At the time of the reference event, the discharge summary was created as a clinical note within the EHR; this

contained sections for medications to be added to the 'summary' note and the TTA medications could be selected for inclusion in the note. However, this was a manual process and relied on the doctor selecting the correct medications (that is the TTAs, not inpatient prescriptions).

Analysis

4.1.10 It cannot be determined with certainty why medicines reconciliation did not occur in the reference event. However, the Trust has advised that the process is principally carried out by pharmacy staff (pharmacists and technicians) and there was no provision for this as a funded service on Saturdays and Sundays. This limited the number of patients who could receive a full medicines reconciliation over the weekend, the majority needing to wait until a weekday.

4.1.11 There was limited pharmacist cover (for two hours) on the Medical Assessment Unit (MAU) on Saturday, but Ann's medicines reconciliation was not undertaken during this time. At the weekend, junior doctors on wards were expected to input the medications on to the ePMA system, but again this did not occur, for reasons that could not be determined by the investigation. Aside from the omission, medicines reconciliation relies on staff entering data into the system. In addition, the process was hindered by interoperability issues, as the Trust's ePMA system was not linked to the electronic systems used in primary care.

4.1.12 The Foundation Year Two (FY2) trainee entered the prescription for the tablet form of anticoagulant (apixaban) on the ePMA system. Immediately prior to this, the anticoagulant injection (dalteparin) was discontinued by the FY2 trainee. The FY2 trainee completed the ePMA TTA medicines section at 08:34 hours so that pharmacy could prepare the medicines and Ann could be discharged.

4.1.13 Ann's medication history had not been put into the ePMA system, so when the TTA was generated from the 'Discharge reconciliation' screen it did not highlight on the drug chart whether any medication had been discontinued. If the medication history had been added to the ePMA, the history would have been visible on the screen and the medications documented as either continued or stopped

4.1.14 A care plan function was available on the ePMA system to provide detailed individual medication information. On Ann's record there was a care plan for dalteparin; however, the existing care plans for dalteparin had not been fully integrated into the system at the time of the reference event. There was no care plan for apixaban. The investigation was advised that the use of a care plan would guide the prescriber to the correct drug/ dose for a specific condition and prompt the entry of information, which then could be included in the discharge letter. In the

case of apixaban, the key piece of information would be the indication for commencing the medication, and this was required information on the TTA, both then and now.

4.1.15 The investigation was given a demonstration of the Trust's ePMA system, by the lead pharmacist for electronic prescribing and medicines administration, highlighting how a patient's existing medications could be recorded on the system. It was considered by the investigation that the prescription systems used in primary and secondary care should allow for or enable the importing and exporting of this data

Issues around prescribing, communication, and documentation of take-home medications, leading to over-anticoagulation.

Fig 4 Review by a consultant physician subject matter advisor

A subject matter advisor (a consultant physician) stated that the reference event

“highlights risks associated with prescribing for patients in hospital and on discharge, particularly when patients are taking unusual medication regimens at home prior to admission. Such risks are exacerbated when patients are moved between wards and teams, where documentation and handover become even more crucial.

Electronic prescribing plays an important part in ensuring accuracy of prescription but is not a failsafe system. Ward pharmacists have developed an important role in checking that errors in prescribing, and transcription of medication are minimised, with robust processes for medicines reconciliation being in place in many hospitals. However, as pharmacists are increasingly relied upon to ensure that systems are safe, it is essential that this provision is available seven days a week”.

4.2 Use of paper, electronic and combined systems

National and local context

4.2.1 The investigation was informed by several sources that the concurrent use of paper and electronic systems increases clinical risk. There is an increased risk of error in any transfer of care that requires transcription of medication lists, in this context from paper to ePMA. Therefore, minimising transcribing is the optimal approach, with all services using electronic systems.

4.2.2 The way that the ePMA system was designed, implemented and used at the time of the reference event meant that the electronic system was not implemented across all services. The paediatrics and critical care departments were still using paper records and the emergency department (ED) was using paper healthcare records, alongside ePMA for prescribing medicines administered in the department.

Analysis

4.2.3 When Ann went into hospital, she took a yellow folder containing her previous clinical notes and a basket containing the medications she was self-administering prior to admission (Figure 5).

Fig 5 Ann's basket of medicines



Fig 5 Ann's basket of medicines

4.2.4 A record of Ann's medicines was written in the ED paper records by the clerking (admitting) doctor. The ED notes were scanned digitally but also transferred as a hard copy with the patient to the wards when admitted, as per the Trust's normal process at the time.

4.2.5 The ED used the ePMA system for prescribing new medicines and prescribing could be viewed as the patient moved to other areas within the Trust. However, rather than all of the admission tasks being undertaken by the ED doctor, the clerking doctor in the reference event Trust was not expected to enter the patient's existing medicines on to the ePMA system, until they had been admitted to a ward. The existence of the ED paper record of Ann's drug history resulted in the information becoming dislocated from the electronic system used in other areas of the Trust.

Ann's medicines needed to be entered on the ePMA system so that the information could be correlated and for adverse drug interaction checks to be undertaken.

HSIB makes the following safety observation

Safety observation O/2019/039:

The use of paper and electronic systems in parallel should be minimised to reduce the risk of error caused by multiple data entry/retrieval sources

4.2.6 In addition to the anticoagulant medication issues already outlined, discrepancies were identified in relation to other medicines that Ann was prescribed.

4.2.7 Firstly, the investigation established that not all the medications Ann was self-administering at home were recorded in the paper ED records. The General Practice Summary, from the Health Centre indicates that Ann was prescribed salbutamol 100 micrograms/dose and amoxicillin 500 mg capsules (antibiotics) as a seven-day course, which should have been ongoing throughout her hospital stay. It is not known for certain why these two medicines were not recorded in the ED records. However, the family advised the investigation that Ann rarely administered the salbutamol, so it is likely she left this at home, and possibly the antibiotics too, since they did not appear to be in her basket of medicines (Figure 5).

4.2.8 Secondly, several discrepancies were identified regarding the prescription of medications following Ann's admission to hospital:

1. Amiodarone was prescribed during the ward round on the cardiology ward and Ann was given two doses before the medication was stopped by the FY2 trainee (following contact by the dispensing pharmacist). This was due to the contraindication with crizotinib (see 1.5.1).
2. The FY2 trainee prescribed 2.5mg apixaban to be administered twice a day, which was subsequently amended to 5mg twice a day by the dispensing pharmacist. The reason for this decision was that Ann did not have any of the risk factors necessitating a lower dose; however, increasing the dose increased the risk of bleeding.
3. The drug dosage of bisoprolol was increased in the discharge summary by the same FY2 trainee. The bisoprolol dose was modified on the TTA at 13:43 hours, but, following this, no notification was sent to alert the pharmacy of the amendment.
4. Not all the medicines that Ann was taking on admission and noted on to the ED paper record, were entered on the ePMA system, one example being crizotinib. Ann self-administered this drug from her own supply since the Trust's medicine code for oral chemotherapy drugs specified that only senior medical oncology staff could prescribe following review. Another example is pregabalin, which the investigation was unable to find out why it was not entered on the ePMA system, although it was issued as a TTA.

4.2.9 Thirdly, the evidence gathered by the investigation indicated that Ann was self-administering at least one medicine from her own supply of medications during her inpatient stay, in addition to being administered other medicines by the hospital. It was not clear to the investigation whether Ann's ability to self-administer was assessed and documented. A subject matter advisor (SMA) has advised that a patient should be able to self-administer their own medicines whilst in hospital, unless they are at risk, and providing the appropriate assessments have been undertaken and documented.

4.2.10 The investigation was advised that self-administration may lead to a dual system, which is difficult to maintain in an acute hospital, particularly in respect of ensuring self-administration matches the prescribed record. Unless a discontinued medication is removed from a patient's own supply, there is always the risk that they may be unaware that a prescription has been amended and/or discontinued and replaced with one for another drug. Unlike in the home environment where drug administration is consistent, treatment in hospital is unstable and subject to

adjustments, so potentially confusing for the patient. This is compounded by the fact that patients have limited access to electronic records, compared with paper systems such as the chart at the end of the bed.

4.3 Discharge process

National and local context

4.3.1 The design, implementation and use of the ePMA system used at the time of the incident meant that only approximately 80% of functionality had been rolled out, in terms of processes enabled. One example of functionality that was not enabled across the Trust was the specific discharge process(23). This process was considered by the reference event Trust to be the 'gold standard' in terms of discharge, and it included an electronic counselling checklist for the prescription of high-risk medications, including anticoagulants. However, the discharge process was only used in one division within the Trust at the time of the event. The Trust considered that using this discharge process would have improved prescribing and standardised information across secondary and primary care.

4.3.2 Using a standardised discharge process, that includes a discharge summary that can interface with ePMA, provides a synopsis of a patient's medication on discharge, including standardised sections detailing what medication was stopped, what new medication was started and what medication was unchanged (Figure 6). The Trust accelerated the roll-out of this functionality following the reference event.

Discharge Process

Allergies: Penicillin -class of antibiotic- Age: Sex: Male Loc: Inpatient [22/Aug/2018 13:43 - No - Discharge date-] Fin#:2002378902
 DOB: MRN: CCG: GP:Not Known , GP - UK Resident
 Phone: NHS:

Templates: Pharmacy Only

Discharge Patient

CLINICAL

Allergies: Penicillin -class of antibiotic- - Rash
 Weight: No measured or estimated weight recorded
 Height: No measured or estimated height recorded
 BSA: No measured or estimated BSA recorded

Admission Medication Stopped						
Medication	Route	Dose	Frequency	Pharmacy Use only		
amlODIPine tablet	oral	10 mg	ONCE a day			
Aspirin tablet, dispersible	oral	75 mg	ONCE a day			
Dalteparin injection	subCUTAN EOUS	10,000 units	ONCE a day			

Admission Medication Unchanged						
Medication	Route	Dose	Frequency	No. of Days Supplied	GP to continue	Pharmacy Use only
bisoPROLOL tablet	oral	2.5 mg	ONCE a day (evening)		-	

New Medication Prescribed Since Admission						
Medication	Route	Dose	Frequency	No. of Days Supplied	GP to continue	Pharmacy Use only
Apixaban tablet	oral	5 mg	TWICE a day		-	
Indication: Atrial Fibrillation						
Special Instructions: dalteparin stopped.						

Prescriber: Smartcard ID:

Pharmacy Use Only

Final check by:	Dispensed by:	Checked by:
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Fig 6 An example illustrating the specific discharge process (Source: Reference event Trust)

(23) The specific discharge process is a module within the electronic health record enabling a robust discharge process from hospital, which includes medication reconciliation.

4.3.3 The Standards for medicines management, published by the Nursing and Midwifery Council (2010), stated the registrant was responsible for ensuring that on discharge, the patient is 'aware of any changes to their medication, that is, new medicine, dose, brand, route'. The investigation could not verify that this was undertaken during the reference event.

4.3.4 Whilst the Medicines Management Standard (Nursing and Midwifery Council, 2010) was the national guidance in place at the time of the reference event in 2018, it has now been replaced with guidance from the Royal Pharmaceutical Society and the Royal College of Nursing (2019). However, the new guidance does not specifically mention nursing responsibility for handing TTAs over to the patient to administer out of hospital.

4.3.5 The Trust informed the investigation that whilst there is a discharge process that is followed, and was followed at the time of the event, the process did not form part of a Trust policy. The key aspects of the procedure which the Trust used when discharging patients from the ward are as follows:

- 'Discharge medications received on the ward and then checked against the drug chart on EPMA to ensure accuracy and all present.
- On [the clinical application] within the xxx system print off the discharge medication sheet found on the top toolbar - discharge medication. This can then be electronically signed to say the medications have been given to the patient after the process below.
- Discharge medication then taken to the patient and checked with them.

This involves:

1. Checking all the patient identifier detail is correct.
2. That any new medications are explained as to their use and any potential side-effects discussed.
3. Discussing any issues or concerns the patient may have are addressed and allayed'.
4. If the discharge medication includes any NOAC/DOAC the appropriate counselling form is completed and given to the patient with a copy in the notes
5. Document in the patient MDT notes actions taken.'

Analysis

4.3.6 The discharge summary was completed by the FY2 trainee at 08:49 hours, following the ward round. It included the following medications: apixaban 2.5mg oral tablet twice a day, lansoprazole 30mg once a day, bisoprolol 2.5mg (dose increased to 3.75mg later that day) once a day, and pregabalin 75mg once a day. The discharge summary therefore consisted of one new medication (apixaban) and three existing ones that were continuing (lansoprazole, bisoprolol and pregabalin). It made no reference to the dalteparin being discontinued.

4.3.7 If Ann's medicines had been entered on the ePMA system as part of a medication history, it would have been apparent when prescribing the medications for discharge that dalteparin had been discontinued and was not on the list of currently prescribed inpatient medications. This would be the case even without the use of the specific discharge process, as the mechanism and screens within which

the TTA is composed are the same. The benefit of the discharge process is that it ensures the discharge summary letter contains the most accurate and up to date information when the patient is discharged.

4.3.8 The record on the dispensing system indicates that apixaban was dispensed at 10:26 hours, with an A5-sized patient alert card (from the manufacturer), for Ann to retain and carry with her at all times²⁴. It is documented that a bottle of 56 tablets was dispensed and transferred to the ward in a sealable plastic bag.

4.3.9 The FY2 trainee stated it was normal practice (although not verified), to put only new medications on the discharge summary and not the medicines that had been stopped or were continuing. This practice resulted in the discharge summary and communication being unclear in respect of what medications had been stopped in hospital; it was not explicit in either the discharge summary or medical records that the apixaban had been prescribed to replace dalteparin.

(24) Apixaban patient alert card: <https://www.medicines.org.uk/emc/rmm/112/Document>

HSIB makes the following safety observation:

Safety observation O/2019/040:

The practice of documenting only newly prescribed medication on discharge summaries should be reviewed from a patient safety and medicines management perspective.

4.3.10 Ann was discharged home on day three at 15:11 hours. An entry in Ann's medical records, made at 14:00 hours by the discharging nurse, notes that medication was given as prescribed. However, there is no further information, other than the family's recollection of events and the knowledge that Ann was discharged with a supply of apixaban from the hospital pharmacy, in addition to the other three TTAs (as outlined in 4.3.6).

4.3.11 The nurse who discharged Ann at 14:00 hours was working a day shift. The staffing levels on the cardiac ward should be six registered nurses and three healthcare assistants. On the Sunday of Ann's discharge there were four registered nurses, four healthcare assistants and one agency nurse who was a registered mental healthcare nurse. This meant that there was a shortfall of one registered nurse, although there is no evidence to suggest that staffing levels contributed to the occurrence of the incident.

4.4 Communication with patient and family

National and local context

4.4.1 There was a checklist to be completed when counselling a patient on taking a direct oral anticoagulant (DOAC), which was available on the Trust's intranet. It was not used in the reference event and was considered to be a critical omission. The checklist includes information about anticoagulation, the patient's drug, taking the medication, consulting the general practitioner (GP) and other advice. The intention was for this to be completed by the healthcare professional providing counselling and signed by the patient/guardian. There was a note to the healthcare professional at the top of the checklist advising that if the patient had previously been on an alternative anticoagulant which had been or would be stopped at a certain point, then the patient/ carer should be made aware of the change.

4.4.2 The investigation received version 2.0 of the checklist, dated May 2018, which was after the reference event. The investigation was not provided with the version of the checklist that was in use at the time of the reference event.

Analysis

4.4.3 The consultant cardiologist recalled seeing Ann for the first time during a ward round at 08:10 hours on day three, for a consultation lasting five to 10 minutes. He told the investigation which bay Ann was in, how she was sitting and that she appeared to be "buoyant". He talked to Ann about her palpitations and the cardiac arrhythmia (abnormal heart rhythm), as the consultant cardiologist noted she had been 'admitted with atrial fibrillation'.

4.4.4 The consultant changed Ann's anticoagulant medication from dalteparin to apixaban to ease the self-administration requirements. The only reference to the change of medication in Ann's notes was 'apixaban 2.5mg BD'. The consultant cardiologist told the investigation there was one thing Ann mentioned to him, which was: "if I could stop these injections, that would be great". The consultant cardiologist said he responded in good faith by saying: "I can do something about that", believing he could improve her comfort by prescribing an oral anticoagulant. He also acknowledged that Ann had a life-limiting condition and so wanted to get her home as soon as possible.

4.4.5 Ann's family members were not present at the time of the ward round. However, their perception was that Ann did not have an issue with administering dalteparin every day and was accepting of the injections. Ann's daughter told the

investigation that Ann would administer the injection every night before she went to bed. She remembered asking her mother whether it was painful, and Ann's response was: "No, it's just something I've got to do, and I get on with it."

4.4.6 The consultant cardiologist's recollection of his conversation with Ann regarding the dalteparin injections was that she expressed frustration with having to inject the dalteparin, and he considered that he could prescribe an oral alternative. However, the documentation in the medical notes and discharge summary did not fully reflect the discussion between the consultant cardiologist and Ann in relation to this.

4.4.7 The consultant cardiologist and FY2 trainee informed the investigation that they were not aware of the Trust's counselling checklist for DOACs. The investigation did not establish how widely used the counselling checklist was within the Trust.

HSIB makes the following safety observation:

Safety observation O/2019/041:

Counselling of patients newly commenced on a direct oral anticoagulant is critical to the safe use of these medicines. It would be helpful if NHS trusts reviewed this practice paying particular consideration to the communication of changes in medication and the initiation of new medication

4.4.8 The consultant cardiologist informed the investigation of his usual process on ward rounds. He reviews the medical records, investigations undertaken and test results. The consultant cardiologist then talks to the patient whilst the more junior doctor is recording in the medical records at the bedside. Decisions are made and the more junior doctor follows up any subsequent actions afterwards. He said that simple tasks such as discontinuing medications might be undertaken immediately, using the nearest computer, whilst tasks such as writing up TTAs would be undertaken after the ward round.

4.4.9 At 14:00 hours on day three of the reference event, the following was documented in Ann's medical records: '...Patient gone home today, husband collect her. Discharge letter and medication given and explained all. Contact number'.

4.4.10 The family informed the investigation that around the time of her discharge, Ann was in the hospital chapel with her husband, whilst her daughter remained on the ward to receive the discharge documentation and a bag of medications. Ann's daughter did not recall the nurse opening the bag and going through the contents. She recollects being told that in the bag was apixaban, bisoprolol, pregabalin and lansoprazole, with the dosage of bisoprolol having been increased to 3.75mg.

4.4.11 When Ann returned home, she started taking the apixaban tablets as prescribed, but also continued administering the dalteparin injections.

4.4.12 There was limited evidence of the communication with the family in Ann's notes. The consultant ward round on the cardiology ward took place outside visiting hours at 08:10 hours, so no family members were present.

4.4.13 There was no documentation of direct communication regarding discharge medication with Ann or her family. The investigation identified that there was a discharge process in existence at the reference event Trust. However, the investigation found no evidence of medicines information being shared with Ann or her family, as part of their handover communications prior to discharge.

HSIB makes the following safety observation:

Safety observation O/2019/042:

There may be benefit for healthcare professionals to receive training in handover communications which should include integrating clinical information with full medicines information, and to share this information with patients and carers in writing and verbally.

4.5 Interface between primary care, secondary care, and community pharmacy

National and local context

4.5.1 A software vendor advised the investigation that if primary care settings use a 'Health Information Exchange' (HIE)²⁵ point, then data from the trust's EHR system could be automatically/systematically pushed to the primary care electronic patient record system. Once GP practices and trusts have signed up to share the information, the EHR systems will permit agreed data to be accessible. HIE is

important in aiding the right information to transfer across the patient pathway from primary to secondary care. The Summary Care Record (NHS Digital, 2019) will also provide the latest information about a person's medication from GP systems.

(25) Health Information Exchange enables care professionals to exchange and view patient data, based on an electronic health record system.

4.5.2 The primary care practice involved in the reference event used an electronic system widely employed in GP practices. There was limited interoperability (see 1.1.3) between the hospital's ePMA system and the primary care system, with no digital link from the ePMA system to the community pharmacy. Therefore, medication-related information from Ann's inpatient stay could not be readily transferred or accessed electronically across all systems.

4.5.3 Following Ann's discharge from hospital, there should have been a reconciled list of her medicines in her GP record within one week of the GP practice receiving the information, and before a prescription or new supply of medicines was issued (National Institute for Health and Care Excellence, 2015). The primary care medical practice employed a practice pharmacist, and part of her role was to undertake medicines reconciliation for hospital patients who had been discharged. However, the practice pharmacist was on holiday when Ann was discharged from hospital.

4.5.4 At the time of the reference event, the Health Centre did not have a policy for medicines reconciliation that set out detailed roles, responsibilities and timescales for completion. The investigation was advised it was "expected practice" that medicines reconciliation would be undertaken by a GP in the absence of a pharmacist, but there was no written policy or procedure to reflect this.

4.5.5 In some parts of the country, web-based platforms (for example, 'PharmOutcomes', 'Refer to Pharmacy') enable the electronic transmission of medicines-related information. When a patient is discharged from a local hospital, hospital staff will send a referral via the platform to the patient's pharmacy of choice.

4.5.6 PharmOutcomes was in use at the reference event Trust at the time of the event. However, it was only used to refer patients who required compliance aid devices in the community (which allow medicines to be packaged in individual compartments), to ensure these were in place following discharge.

4.5.7 In primary care, there was a system provided by the local clinical commissioning group that enabled patients to order repeat medications. The patient was required to call the service, following which the prescription would be available at their nominated pharmacy within four working days.

Analysis

4.5.8 Following analysis of the reference event, the investigation identified a lack of interoperability between primary and secondary care electronic prescribing systems and between secondary care and community pharmacies.

4.5.9 The hospital records indicate that a copy of the discharge letter was provided to Ann/ her family at the point of discharge on day three. The discharge summary was received electronically by the Health Centre on the same day (Sunday), reviewed by one of the practice staff the following day, and on day five sent electronically to the GP to action.

4.5.10 As a medicines reconciliation was not undertaken by the pharmacist based in the Health Centre, a medicines review was undertaken by the GP during a face-to-face consultation with Ann. However, this was not until 10 days after she had been discharged.

4.5.11 During the consultation with Ann, the GP added apixaban to her 'repeat' medications. When entering this into the electronic system, the GP did not notice an alert notification in respect of dual anticoagulant administration.

4.5.12 Primary care prescribing systems differ in the extent, design, and capabilities of their clinical decision support, and alerts for drug interactions are also different on every system. In the reference event, the primary care electronic system displayed multiple, recurring alerts when the prescribing function was being used. The investigation observed the GP's computer screen in the Health Centre while elements of the system were demonstrated.

4.5.13 In relation to the drug warnings generated by the primary care system, the investigation was advised there would have been organisation-level control over the way in which the patient-specific warnings are ordered and their visibility (Figure 7). There was a similar control for the individual user, so there was an alternative to adopting the organisational preference. The individual user, in this case the GP, could preview the settings and filter the drug warnings so that all warnings, particular ones or none at all would be displayed.

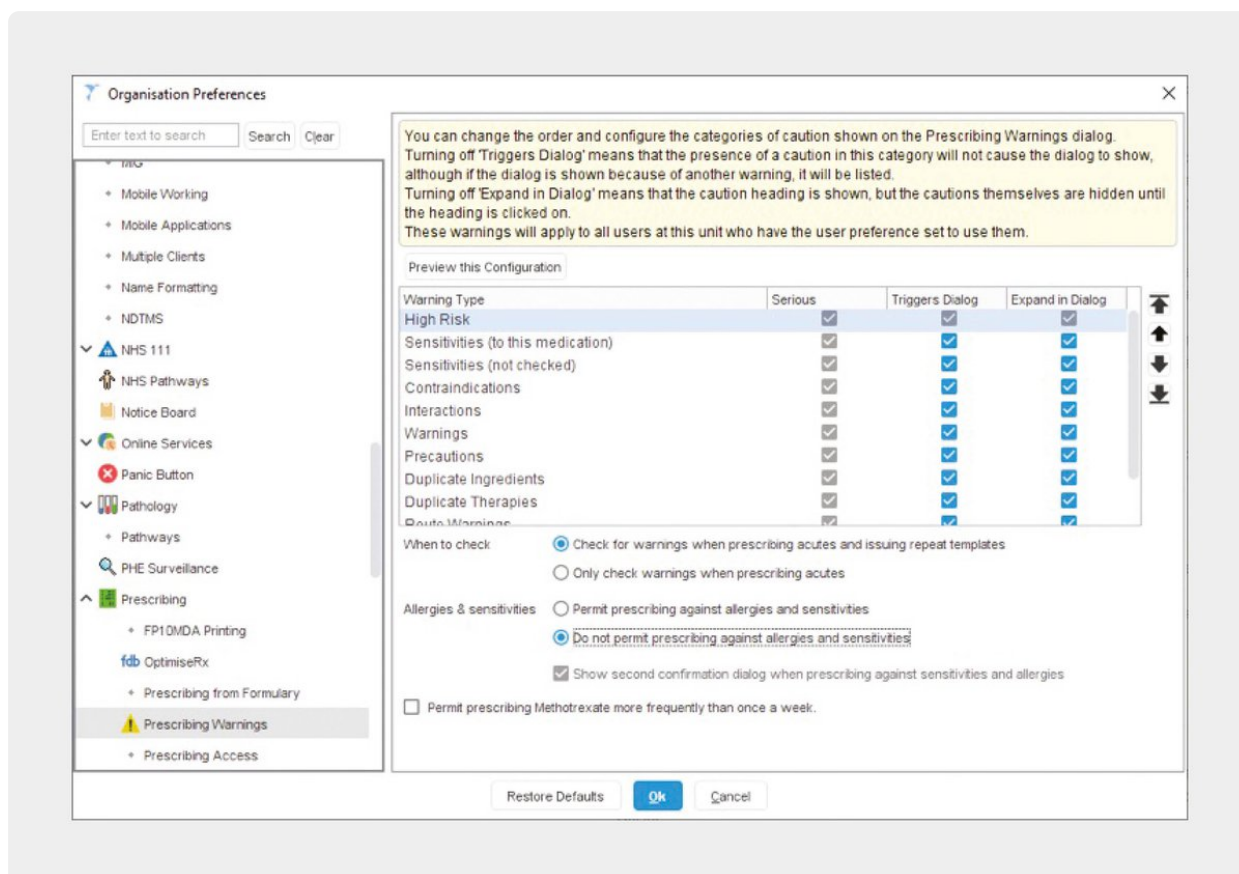


Fig 7 Primary care system drug warnings (Source: TPP)

4.5.14 When a new repeat medication was created on the primary care system, the system would automatically cross-check against the patient’s pre-existing medicines. If there were contraindications, interactions or precautions identified, between the new medicine and a pre-existing one, a patient specific warning would appear on the GP’s computer screen. In the reference event, when the GP added the apixaban to the existing prescription on the electronic system, an interaction warning would have been triggered regarding the dalteparin, as illustrated in Figure 8.

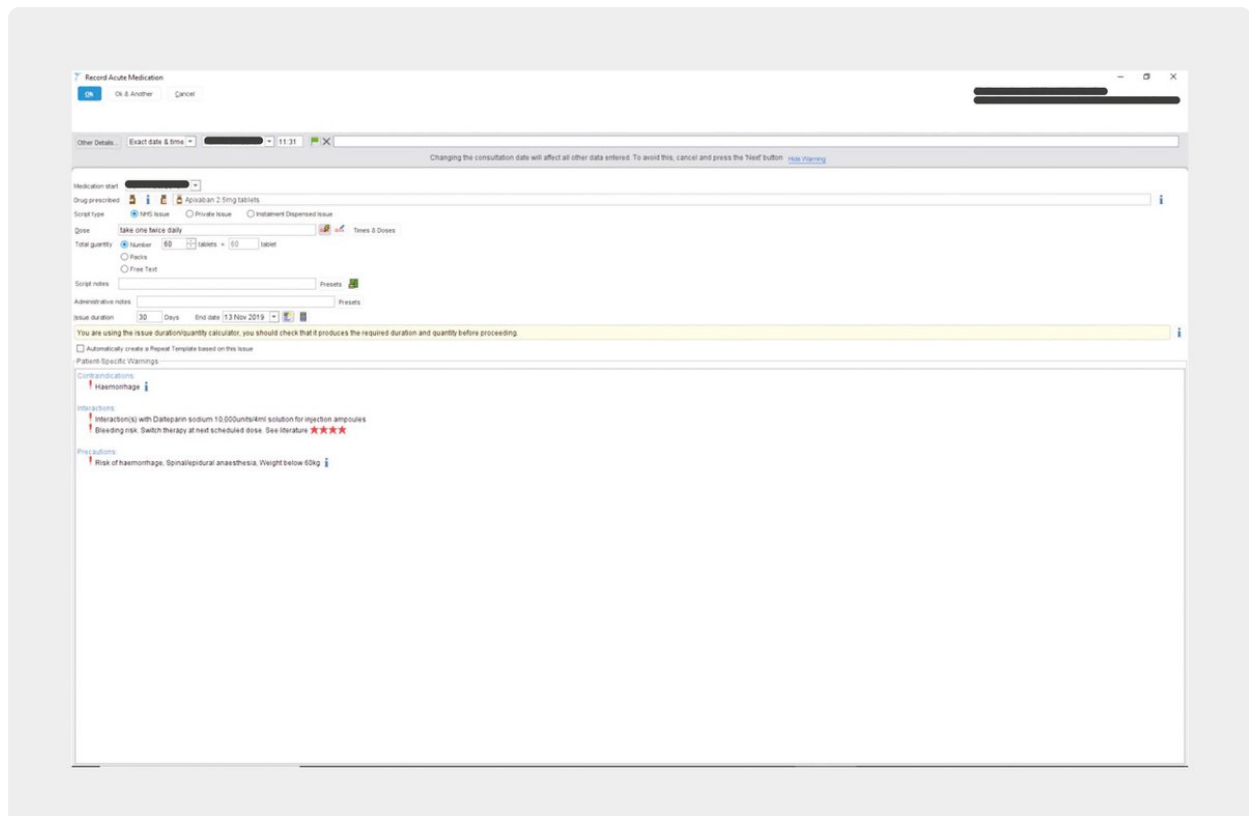


Fig 8 System warnings when new repeat anticoagulant medication is added to an existing prescription (Source: TPP)

4.5.15 At the reference event Trust, PharmOutcomes was not used to electronically transmit medicines-related information to community pharmacies. Therefore, when Ann was discharged, a referral was not sent to her community pharmacy and this contributed to the delayed detection of the error relating to the anticoagulants.

4.5.16 The community pharmacy was not aware that apixaban had been prescribed by the hospital, because the patient went home with a TTA supplied by the hospital pharmacy and there was no direct electronic link from the hospital to the community pharmacy. If a direct link had been in place, the community pharmacy would have been alerted to the issuing of dalteparin to Ann, as a 'repeat', following her discharge from hospital.

4.5.17 When the GP added apixaban to the repeat medications, no apixaban prescription was written and no apixaban tablets were dispensed by the community pharmacy, as Ann still had an adequate supply at home from the 56 tablets she had been issued in hospital.

4.6 Clinical decision making

National and local context

4.6.1 Ann was diagnosed with paroxysmal atrial fibrillation (AF) (an irregular/fast heartbeat) when undergoing hip replacement surgery approximately 10 years prior to the reference event. However, it was only in September 2017, one month after the diagnosis of two cancers (stage 4 incurable lung adenocarcinoma and left renal carcinoma), that she was commenced on an anticoagulant for her AF. The National Institute for Health and Care Excellence (NICE) guideline on atrial fibrillation management was only issued in 2014, so the treatment regime was different when Ann was first diagnosed with AF. The 2014 guidance states that new-onset AF patients should be offered low molecular weight heparin (LMWH) at initial presentation.

Analysis

4.6.2 Ann attended a clinic appointment in September 2017, at which an oncologist and a cardiologist discussed the treatment of her AF. During the consultation with Ann a decision was made to commence an anticoagulant, based on the diagnosis of background metastatic lung cancer (cancer that had spread from another part of her body to her lungs) with the increased risk of a thromboembolic condition (stroke). LMWH injections in the form of dalteparin 15,000 units was prescribed, after checking contraindications.

4.6.3 When the consultant cardiologist saw Ann during a ward round on the cardiac ward on day three, it was the first time he had seen her. The evidence appears to indicate that the focus of the consultation was Ann's AF and its treatment, which generally consists of heart rate control (or rhythm control) and blood clot prevention.

4.6.4 At the point when the consultant cardiologist changed the anticoagulant medication to apixaban, it was recognised that direct oral anticoagulants (DOACs) are used infrequently in patients with cancer. However, the consultant said that he wanted to help Ann and make "her life a little better" in this respect. It appears that the consultant cardiologist was focused on what would be the most convenient anticoagulant for Ann and not whether any coagulant would be beneficial, or whether apixaban would be as effective as dalteparin. The risks and potential benefits of prescribing an anticoagulant changed after the first decision to prescribe, due to a deterioration in her clinical condition. However, there is no documentary evidence to suggest that the potential benefits and harms of anticoagulation were reassessed when the apixaban was prescribed.

4.6.5 A consultant physician advised the investigation that the decision to prescribe DOACs in patients with advanced cancer needs to be considered carefully. Cancer patients have not been involved in clinical trials of these drugs and the risk of bleeding may be greater in patients with advanced cancer, particularly in those with cerebral (brain) metastases.

Fig 9 Review by a consultant physician subject matter advisor

Decision-making in relation to anticoagulant medication for a patient with atrial fibrillation and cancer

“There is good evidence to support the use of oral anticoagulant drugs for prevention of thromboembolic stroke in patients with atrial fibrillation. Patients with cancer are at higher risk of venous thromboembolism than the general population, due in part to increased clotting; it is likely that this risk also extends to the arterial thromboembolism seen in atrial fibrillation, although there is no direct trial data to support this. The risk-scoring tools utilised in assessing the benefit of anticoagulation in patients with atrial fibrillation do not include cancer as a risk factor, and patients with cancer were excluded from many of the trials of anticoagulant medication in atrial fibrillation”.

Furthermore, patients with cancer are likely to be at higher risk of bleeding when given anticoagulant medication, due in part to the direct effect of the tumour itself, and in part to the unpredictable metabolism of the drugs. The shortened life expectancy of some patients with cancer also needs to be considered when anticoagulation decisions are taken, as the benefit of the drug in stroke prevention is cumulative, such that patients with a shorter life span will be less likely to experience a stroke and therefore derive less benefit from anticoagulation. Decisions on anticoagulation in this group need to be highly individualised, weighing up the perceived risk of bleeding, life expectation and quality of life against the risk of ischaemic stroke. Patient preferences may also need to be considered, as for some patients the fear of a disabling stroke may be greater than the fear of bleeding, while for others the thought of dying from a massive haemorrhage may outweigh this. After initiation of anticoagulation, the decision will also need to be revised as the disease process progresses, as risk of bleeding as well as the relevance of stroke prevention will inevitably change over time”.

Admission to hospital or an outpatient clinic review should be an opportunity to review appropriateness of prescribing of 'preventative' medications such as anticoagulants. This case highlights this important issue and equally applies to a variety of other medications, such as lipid lowering agents [to lower high cholesterol], antihypertensives [to treat high blood pressure] and anti-diabetic medications, whose importance reduces as patients near the end of their lives."

4.6.6 The investigation considered the reference event in relation to decision making regarding the safety of anticoagulant medications in patients with high-risk, complex conditions. A computed tomography (CT) scan undertaken in March 2018 showed that Ann's cancer had spread to her brain. One of the major risk factors for bleeding and contraindications to anticoagulation is structural brain disease (Kearnon et al, 2016). Therefore, Ann was at risk of complications due to being on the therapeutic anticoagulant, namely a cerebral bleed (bleed on the brain) (although there is no evidence of this from the clinical findings). It is not apparent that this was considered by the Trust or the doctors who reviewed her case following the CT scan, which included an outpatient review by the acute oncology service. However, the investigation was advised that this service did not routinely review medications due to time pressure, as it is an acute service with rapid throughput.

4.7 Weekend working/weekend service provision

National and local context

4.7.1 The National Institute for Health and Care Excellence (2016) states pharmacists should undertake medicines reconciliation. However, this did not occur in Ann's case for the following reasons:

- The reference event Trust had not kept up with the increase in demand for services and there was limited pharmacy cover at weekends. It was a weekend and there was limited pharmacy provision. This resulted in a focus on covering dispensing activities, rather than ward-based work.
- The FY2 trainee did not have time to complete medicines reconciliation on the ward.

4.7.2 Some of the Trust's services operated at weekends, but this was not universal and there was limited staffing of support services to enact medical decisions and facilitate discharge. Analysis

4.7.3 Ann was in hospital over a weekend, from Friday evening (day one) until Sunday (day three). Ann's basket of medicines was transferred with her as she moved from the ED to the MAU and finally to the cardiac ward, (although this was only noted in the medical records in the ED and MAU, and not the cardiac ward). As it was a weekend, Ann was not seen by a pharmacist or pharmacy technician and no medicines reconciliation process was completed. The only input from pharmacy was at the dispensing level. Consequently, there was no electronic documentation of the medications that Ann was receiving prior to her admission.

4.7.4 Staffing in the pharmacy dispensary on Sunday (day three) comprised three pharmacists who worked in the morning and one pharmacist who worked all day. The usual support services from pharmacy were not available as ward pharmacists predominately work Monday to Friday. During the week, the ward pharmacists undertake medicines reconciliation.

4.7.5 The investigation was advised by the reference event Trust that the provision of pharmacy services from 09:00 to 17:00 hours on Saturdays and Sundays was significantly reduced compared to those available from Monday to Friday. The service had been unable to keep pace with the 24-hour, seven-days-a-week medical service and increasing numbers of patients discharged during weekends.

4.7.6 The Trust advised the investigation that, whilst pharmacy cover seven days per week would be desirable, the reality is that there is a national shortage of pharmacists, making recruitment to existing vacancies challenging. If the Trust moved to seven-day working, there would be an additional requirement to recruit to the new posts that would be required. Many pharmacists are leaving secondary care for roles in primary care to avoid weekend and on-call working.

4.7.7 The consequence of a reduced weekend pharmacy service in the reference event Trust was that junior doctors, who were already under pressure with an increased workload, had to enter patients' medication history into the ePMA system. The role of the junior doctor in this context was to document in the medical notes, generate prescriptions on the ePMA and write discharge summaries.

4.7.8 There was no palliative care service or acute oncology service available at the weekend at the Trust where the reference event occurred, so the earliest Ann would have been seen by those services as an inpatient would have been day four. However, she already had an outpatient appointment to attend the acute oncology service on day four and so attended this appointment post discharge. Ideally, Ann should have been reviewed while she was in hospital, which would have been an

opportunity to stop her anticoagulants. If her hospital admission had not been over a weekend period, she might have been reviewed by the acute oncology service as an inpatient.

4.7.9 The investigation was advised that weekends were usually the time when clinical teams were most stretched and pressure to discharge patients was often at its greatest, leading to a greater potential for errors. The investigation was also advised that due to workload and staffing at weekends, there was a time pressure on ward rounds.

This was substantiated by a staff member who outlined that a typical weekend workload was as follows:

- The ward round commences at approximately 07:45 hours to 08:00 hours on the coronary care unit (CCU), where there are typically eight patients (the review of the CCU patients on a Sunday tends to be brief if they are stable, as they have been seen on the Saturday too).
- The ward round will then review all new admissions on the cardiac ward (average being five to six new patients).
- Following the ward round, the FY2 trainee would be expected to carry out the jobs and be on call covering half of the hospital's medical wards and medical outliers for the remainder of the day.
- The consultant cardiologist would go to the cardiac catheterisation suite to do a list there, which the consultant said he would try to start as soon as possible after the ward round.

4.8 Organisation of medical care and services

National and local context

4.9.1 A subject matter advisor (SMA) advised the investigation that most UK hospitals now operate systems whereby medical patients who cannot safely be discharged from the ED are initially admitted to an acute medical unit (AMU) or medical assessment unit (MAU). A proportion of patients will be discharged directly from the AMU/MAU, but those who require ongoing treatment in hospital will be moved to other ward areas.

4.9.2 According to recommendations from the Royal College of Physicians (2013), the ward area selected for transfer should be determined by the patient's main clinical problem. Therefore, a patient whose primary problem is AF may be deemed suitable for transfer to a cardiac ward, while a patient with lung cancer may be

more appropriately managed on an oncology ward or respiratory unit. Challenges arise where patients have combinations of problems affecting more than one body system; this was the situation in the reference event.

Analysis

4.9.3 Upon initial assessment by the Specialist Trainee 4 (ST4) in the ED, the notes listed two diagnoses:

1. 'AF with fast ventricular rate
2. Decline in last 2 weeks with difficulty swallowing and had nausea/vomiting possibly related to cancer/cancer treatment.'

Review by a consultant physician subject matter advisor: Generic issues related to the organisation of medical care within hospital

An issue identified by a subject matter advisor who is a consultant physician in acute and general medicine was the organisation of medical care and services, especially at weekends. He considered that there needed to be a system in place to ensure that patients are seen by the most appropriate specialists in accordance with their clinical issues/ problems. It is essential that a patient's ward location is determined by the primary problem with which the patient presents, which will often require careful consideration by a senior and experienced clinician. Increasingly, junior doctors are being encouraged to document a clear diagnostic category for patients admitted to hospital, rather than problem lists and 'differential' diagnoses, to meet the rules for clinical coding.

This will be an increasing problem as medical notes become more electronic with 'drop-down' menus for diagnoses rather than free text boxes. In this way, it is easy to see how a patient with a complex series of symptoms relating to advancing cancer could be categorised by just one of these problems, in this case fast atrial fibrillation. This can have unintended consequences if the transfer of their care to an inappropriate speciality team changes the focus of their ongoing care. It is essential that the decision to move a patient is primarily driven by senior clinicians; documentation at the time of first senior

clinical review should include a clear recommendation for the area of the hospital where the patient should receive their ongoing care, whether that be to remain on the AMU or be transferred to a specified speciality ward.

4.9.4 AF was listed as the primary diagnosis when Ann was clerked by the doctor in the ED. However, her symptoms (difficulty swallowing, nausea and vomiting) did not correlate with the primary diagnosis. It appears that subsequent decision making and specialty referrals were made on the basis of this primary diagnosis.

4.9.5 Ann was reviewed by the medical team; she was seen by the respiratory registrar and by a cardiology consultant with the support of the FY2 trainee. Ann was transferred from the MAU to cardiology (because of the diagnosis of AF). The SMA considered that respiratory medicine would have been a more appropriate specialty for Ann to have been referred to, as it was clear she had advanced cancer.

4.9.6 Ann was seen by a respiratory registrar following the ward round on the MAU and then by a consultant cardiologist prior to discharge. However, she was not seen in hospital by clinicians in oncology or palliative medicine to address her other significant health issues.

4.9.7 Ann was seen in the acute oncology service outpatient clinic at the hospital following discharge, to discuss the findings from a recent CT scan and to relieve distressing symptoms such as difficulty swallowing. The short appointment time meant there was no opportunity to undertake a medicines review. A medicines review would have provided an opportunity to detect the administration error and possibly to question whether Ann needed to remain on anticoagulants at all, given the progression of her cancer.

4.9.8 In summary, the administration of two anticoagulant medicines was not detected until 15 days post discharge from hospital. The opportunity to intervene to prevent harm from the medication error was missed during two contacts with an out-of-hours GP, an appointment with the patient's own GP and an outpatient visit to an oncology service (Figure 10).

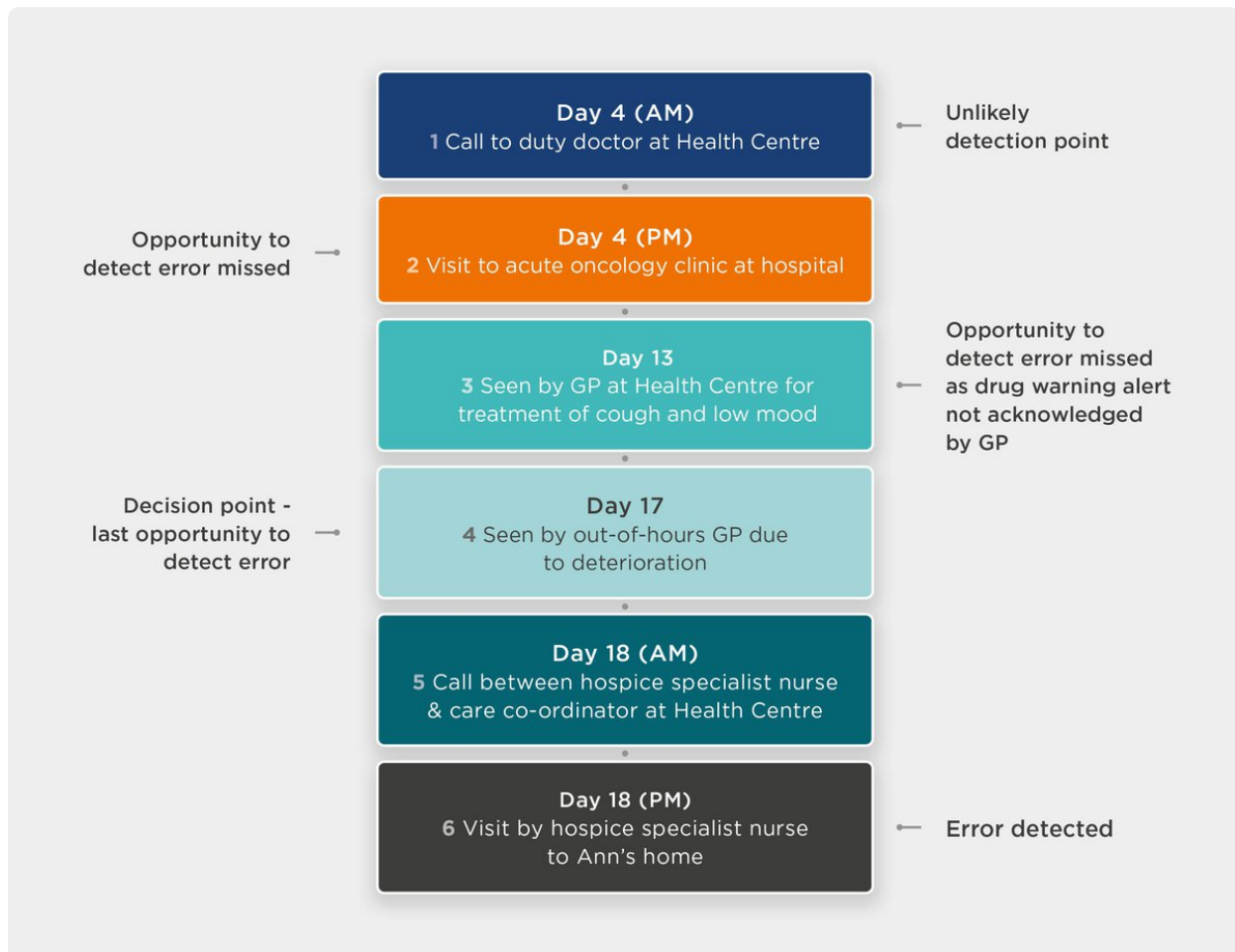


Fig 10 Ann's interactions with healthcare professionals after her discharge on day 3

5. Findings and analysis from the wider investigation

5.1 Opportunities for technological intervention and unintended consequences of embracing technology

National and international perspective on digitising the secondary care system

5.1.1 The National Programme for IT (NPfIT) aimed to introduce a single electronic health record (EHR), including electronic prescribing, connecting all general practices and hospitals in England. The NPfIT was set up by NHS Connecting for Health (Department of Health, 2005) in 2002 and the UK government announced the dismantling of this NPfIT in September 2011. Consequently, trusts started making their own technology procurement decisions.

5.1.2 The European Commission (2009) investigated the socio-economic impact of interoperable EHR and ePrescribing systems. General findings were that EHR and ePrescribing were beneficial investments in healthcare: the gains to society from such systems exceeded the costs. However, the study found that it typically takes up to nine years before initiatives produce their first positive annual socio-economic return. The study highlighted interoperability as a key contributor to the benefits produced from EHR and electronic prescribing systems.

5.1.3 The National Information Board (2014), established by the Department of Health, stated that all patient and care records would be digital, real-time and interoperable by 2020. In the NHS Long Term Plan, NHS England outlined plans to connect electronic records across primary, secondary and social care by 2024 (NHS England, 2019). Planning for electronic records was managed by NHS England, the National Information Board and the Health and Social Care Information Centre. The three bodies were developing national standards, but local areas could choose their own systems. Challenges to implementation were stated as including interoperability (there were over 100 commercially available electronic record systems), installation and staff training.

5.1.4 In late 2015, the National Advisory Group on Health Information Technology was formed to advise the Department of Health and NHS England on digitising the secondary care system (Wachter, 2016). The advisory group concluded that:

- the NHS should digitise secondary care in stages, so that trusts who were not ready were encouraged and supported to build capacity
- a new digital strategy was needed to achieve a balance between local/regional control and engagement versus centralisation
- systems should be designed with the user in mind, since poorly designed and implemented systems could create opportunities for errors and user dissatisfaction
- national standards for interoperability should be developed and enforced
- all trusts should have a high degree of digital maturity by 2023.

5.1.5 In September 2016, the first 12 Global Digital Exemplar (GDE) acute trusts were announced. GDEs are part of the NHS England's flagship programme of NHS trusts who are leading the transformation of healthcare technology. The blueprints they develop (structured information and methodologies to help other trusts develop digital capabilities) aim to make it quicker and cheaper for others to reach the same standard (Department of Health and Social Care, 2018a). According to

Next Steps on the NHS Five Year Forward View (NHS England, 2017), the intention was that hospitals would choose a GDE to partner with, implementing 80% of the same system and changing 20% to adapt to local needs (NHS England, 2017).

5.1.6 The Nuffield Trust report (Castle-Clarke and Hutchings, 2019) describes how the national policy for digitisation is working from the perspective of acute trusts. The report states that an important role for national bodies is setting digital standards, particularly standards to support access to data across the system, although the national strategy for implementation is often lacking. In relation to the GDE programme specifically, positive feedback was received, particularly regarding the collaborative environment it promoted, which focused on sharing best practice and learning. This was in direct contrast to trusts working 'in silos' (on their own), outside the GDE programme (Castle-Clarke and Hutchings, 2019). However, those involved in the programme reported challenges with the reporting requirements.

5.1.7 One of the recommendations arising from the Nuffield Trust report relates to looking beyond blueprints to share best practice, which is a reflection on the GDE and 'Fast Follower'(26) programme. Significantly, the report says the digital exemplar trusts have had limited success in spreading their expertise to other providers and alternative mechanisms should be considered. However, the report data was gathered in 2018, at which point there were no blueprints and the Fast Follower programme was not established.

5.1.8 NHS England commissioned the University of Edinburgh to independently evaluate the GDE programme. The first-year report (Williams et al, 2018) shows that 'the GDE Programme has helped to accelerate and focus local efforts of digital transformation in the NHS'. The independent GDE evaluation programme is reviewing both this and the 18-month report, which is now available, and is starting to see some evidence that spread is working in terms of digitisation. The next milestone is the two-year report, which is due in January 2020.

Intended consequences of electronic prescribing and medicines administration (ePMA) systems

5.1.9 There is an international impetus to reduce medication errors, and to implement patient care information systems (PCISs(27)) as a potential means to do so (Ash et al, 2004). Similarly, Shemilt et al (2016) state that ePMA was promoted to reduce prescribing errors (particularly those caused by illegibility) and supported the efficient management of medicines for both patient and trust. Key findings from the Institute of Medicine (2012) also support the concept that health information

technology (IT) can improve patient safety (Figure 11) and Mulherin et al (2013) state that electronic prescribing systems are considered a key technology for the prevention of adverse medication events caused by errors.

Fig 11 Interdependent activities for building a safer system for health IT (Institute of Medicine, 2012)

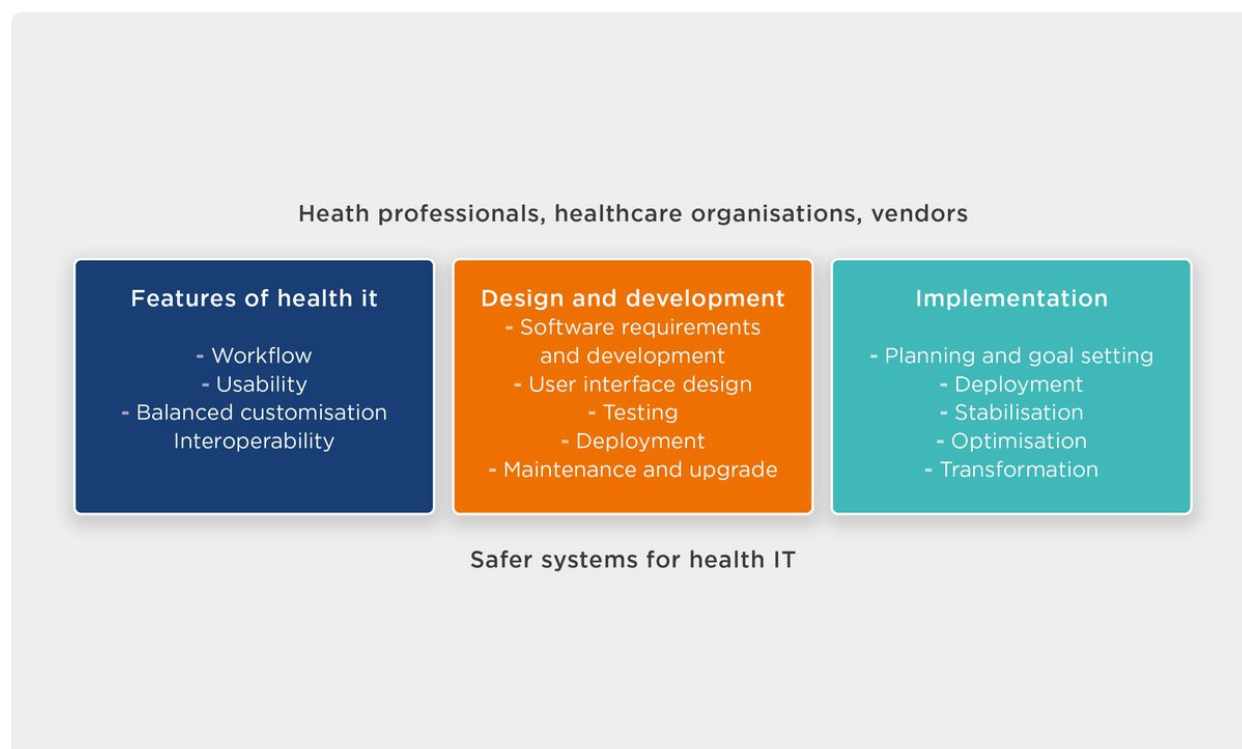


Fig 11 Interdependent activities for building a safer system for health IT (Institute of Medicine, 2012)

5.1.10 The World Health Organisation's (WHO's) third global challenge to reduce medication error is a key national programme of work. Electronic prescribing is seen as a key enabler for this and is an NHS England priority (NHS England, 2018). NHS England has now developed a simulation tool, known as the ePrescribing Risk and Safety Evaluation (ePRaSE). A pilot began in mid-2019, and the tool was launched on 2 September 2019. According to ePRaSE, implementing ePrescribing is associated with a greater than 50% reduction in patient adverse drug events and medication errors.

Introduction of new types of error associated with ePMA systems

5.1.11 However, the complexity of implementation encompassing multiple work processes and cultural factors affects the adoption and use of ePMA systems, causing both intended and unintended consequences (Westbrook et al, 2012). NHS Connecting for Health recognised that although ePMA systems were able to reduce certain prescription errors, they had introduced new types of error.

(26) Fast Followers are trusts that have partnered with GDEs.

(27) PCISs are broadly defined as applications that support the healthcare process by allowing healthcare professionals or patients direct access to systems such as ePMA (Ash et al, 2004)

5.1.12 The extent of the problem is uncertain, however, as there is limited data available relating to the unintended consequences of ePrescribing. In the US, the degree of harm and impact of systems on quality and safety is not well known because of the varied nature of health IT products (Institute of Medicine, 2012), and the lack of a uniform measurement to assess the impact. The position in the UK is similar (Ahmed et al, 2016), with the main problem being that there is no systematic way of collecting and cataloguing incidences of harm caused by ePrescribing. The Department of Health and Social Care policy research group has commissioned a study on optimising ePrescribing in hospitals to address the knowledge gap regarding medication error reduction.

5.1.13 Westbrook et al (2012) say that whilst their study provides persuasive evidence of the current and potential value of commercial e-prescribing systems to significantly and substantially reduce prescribing errors in hospitals, success in achieving this outcome depends on many contextual and organisational factors. Multi-method studies are of great value to understand the mechanisms by which electronic prescribing systems affect prescribing behaviours. Campbell et al (2006) say that in order to ensure clinicians will accept and use a new system, it needs to balance required new work with system-based reductions in the workload associated with old ways of working.

5.1.14 Ash et al (2004) describe that, in practice, prescriptions for medicines are initiated during ward rounds, during discussions among senior and junior doctors and nurses. 'A case is discussed, a suggestion is made and elaborated on, and it becomes an order [that is, a prescription]. It can also be transformed, renegotiated, or ignored.' Relevant to the reference event, Ash et al (2004) indicate that the entering of prescriptions on to an ePMA system is the task of the junior doctor, who often undertakes this task alone at a computer, after the patient rounds. The researchers reflect that the junior doctor may enter a series of prescriptions for several patients, copying from the notes made during ward rounds. In such a

setting, outside of the actual context in which the patient's case was discussed, and away from those who could correct any misinterpretations, the researchers state that prescription entry can be prone to errors.

5.1.15 From the UK perspective, the observation of users entering information in batches has more recently been confirmed by Cresswell et al (2017b): '...some users recorded patient medication data on paper and entered them into the system in batches'. This information included the prescription of medicines by doctors, as evident in the reference event. The research paper also refers to the delegation of this task to junior doctors, who may not be the decision makers but nevertheless are expected to enter the information on to the system. Both these practices have the potential to create errors in prescribing and are do not reflect the intended contemporaneous use of ePMA systems.

5.1.16 It is evident that implementing ePrescribing is associated with a reduction in prescribing errors, but there are caveats. The reduction in medication errors depends on optimising commercial systems so that the available functionality is switched on, appropriately used, integrated with other relevant IT systems and aligned with clinical workflows (National Institute for Healthcare Research, 2018).

HSIB makes the following safety observation:

Safety observation O/2019/043:

During the implementation of any new digital system, benefits may be realised by redesigning work practices to ensure the new system is fully embedded, with staff training/engagement to support this.

Categories of error types

5.1.17 Campbell et al (2006) identify that health care organisations in the US often implement ePMA systems as part of their approach to improve medication safety and reduce health care costs. However, the researchers support what others have said about the creation of errors and refer to unintended adverse consequences (UACs) resulting from ePMA system implementation and maintenance. The paper refers to nine major categories of UAC, which were devised as part of a study that focused on US hospitals:

- More/new work for clinicians. ePMA systems may create additional work for clinicians and slow the rate at which they can carry out the clinical

documentation and ordering processes (although this loss of efficiency often recovers over time).

- Unfavourable healthcare workflow issues caused by clinical computer technology integration and adjustment.
- Ongoing system requirements. The system must be adjusted, upgraded, tested, interfaced with other systems, and backed up regularly. All employees must be trained in system use and retrained after substantive system changes.
- Electronic medical record systems trend toward 'going paperless', whereas in healthcare organisations there remains 'paper persistence and proliferation in all areas of patient care'.
- Untoward changes in clinical communication patterns and practices. For example, clinicians reported that clinical systems like ePMA may reduce face-to-face communications regarding patient care. This has the potential to increase the likelihood of errors and so requires modifications of computer-based communication systems.
- Negative emotions. This may be helped by training and open communication, to promote better understanding.
- Generation of new kinds of errors. This may be partially overcome by optimising human/ computer interface design.
- Unexpected changes in the organisational structure.
- Overdependence on the technology.

5.1.18 Few studies have applied a systems approach to understanding the causes of specific prescribing errors in the context of hospital electronic prescribing (Puaar and Franklin, 2017), particularly in the UK. A study by Puaar and Franklin (2018), which reviewed how ePrescribing gives rise to new types of error, described three broad groups of latent conditions:

- ePrescribing system functionality and design
- organisational decisions around ePrescribing implementation and use
- prescribing behaviours in the context of ePrescribing.

5.1.19 A further study describing how hospital ePrescribing systems can introduce new areas of risk in addition to offering patient safety benefits, outlined a taxonomy of factors underlying unintended safety risks (Mozaffar et al, 2017):

- Suboptimal system design, including: lack of support for complex medication administration regimens; lack of effective integration between different

systems; and lack of effective automated decision support tools. Enhancements in system design by suppliers were considered to be the key enablers of improved patient safety outcomes. These enhancements included better interface designs, and improved integration and transferability of data between systems. The researchers suggest that hospitals need to understand and communicate the safety benefits of ePrescribing as well as unintended consequences and safety threats.

- Inappropriate use of systems (workarounds). Cresswell et al (2017a) define workarounds as behavioural/technological strategies that users of technology employ to overcome issues that hinder them in completing a task. They often arise in the context of changed workflows initiated by the new technologies. Workarounds can create new risks and present new opportunities for improvement in system design and integration.
- Suboptimal implementation strategies, resulting from partial roll-outs/dual systems and lack of appropriate training.

Mitigating risk factors

5.1.20 The causes of errors arising following the introduction of ePrescribing systems are often subtle but potentially serious. Mozaffar et al (2017) highlight the importance of understanding the causes of unintended safety consequences so that the existing and new problems in the development and use of the systems can be addressed. The study demonstrates that the unintended risks that occur in English hospitals are similar to those that occur in the US, although some of the underlying causes are different because of the diversity of systems and greater reliance on overseas suppliers in England.

5.1.21 Puaar and Franklin (2017) found that errors were associated with the design of ePMA systems and integration within the healthcare environment. Their findings suggested that system vendors should focus on revolutionising interface design and usability issues, considering the wider healthcare context in which such software is used. The study also stated that healthcare organisations should draw upon human factors principles when implementing ePrescribing. Consideration of work environment, infrastructure, training, prescribing responsibilities and behaviours should be considered to address local issues identified.

5.1.22 Following the completion of their study in UK hospitals, Mozaffar et al (2017) recommended the creation of technological and organisational strategies, to be implemented by hospitals and the system vendors. To achieve patient safety while using complex technologies means that strategies must be considered that can be

used by adopters, implementers and suppliers of health technologies. Work has been undertaken to provide guidelines for best practice in how to create medication prescriptions on electronic systems to mitigate risk (Mozaffar et al, 2017).

HSIB makes the following safety observation:

Safety observation O/2019/044:

It would be beneficial to the users of electronic prescribing and medicines administration systems if the system vendors raised awareness of the safety limitations of their products and had a system for collating safety feedback to inform future development and a mechanism for sharing feedback with other users.

Learning from ePMA system issues

5.1.23 In the HSIB investigation report Design and safe use of portable oxygen systems(28), the 'Yellow Card' system was discussed (see section 5.4). This system offers vendors a viable way to collect and respond to end-users' findings, thus informing future development. The investigation noted that the 'Yellow Card' system was an underused reporting mechanism and is an appropriate reporting method for ePMA systems as they are medical devices.

(28) www.hsib.org.uk

5.1.24 Lichtner et al (2017) state that health information technology is often involved in patient safety incidents, such as incidents involving medication. A sample of reported incidents from the National Reporting and Learning System (NRLS) showed that a variety of digital systems presented common usability problems, problems in data configuration, software coding and supporting infrastructure. The study noted the absence of an effective system at national level to address common issues and enable learning.

5.1.25 The investigation has been advised that the NRLS has been challenging to use in this respect for the collation and IT data aggregation for learning, as there is no taxonomy around IT-related events.

5.1.26 NHS England and NHS Improvement advised the investigation that its project, Development of the Patient Safety Incident Management System (DPSIMS), provided an opportunity to capture technology-related issues, so enhancing

learning and the delivery of safe care. Although it is still in the testing phase and may be amended following feedback from users, the DPSIMS will give IT systems and software more prominence than they received in the NRLS. It is possible that aspects of the PSIMS taxonomy will change to allow better classification and identification of IT-related incidents and/or a new category will be created.

5.1.27 Live roll-out of DPSIMS is anticipated to begin during mid-2020. PSIMS will enable better classification and identification of incidents relating to IT systems and software than the NRLS, and the extraction of data about such incidents. However, due to the agile nature of the development of this system, the specific tools that will allow this to happen have not yet been fully developed.

HSIB makes the following safety recommendation:

Safety recommendation R/2019/050:

It is recommended that NHSX develops a process to recognise and act on digital issues reported from the Patient Safety Incident Management System.

Lack of standardisation and wide variety of ePMA systems

5.1.28 Mozaffar (2019) describes 18 suppliers of 19 different ePrescribing systems available in hospitals in England (not including specialist oncology and critical care systems). Approximately half of the products were designed and developed by UK based suppliers; the remaining half originated from various other countries, predominately the US. Most of the international systems were designed to cater for the practice needs of their countries of origin and then adapted for the UK. Some systems were developed by trusts as bespoke products; others were commercial 'off the shelf' systems and some were a hybrid of both. However, even when the same commercial system has been employed by trusts, some have adapted and configured them differently, negating standardisation and introducing variability. This diversity in the background of the products has resulted in a range of different pre-defined processes, tasks and workflows in the system.

5.1.29 Challenges facing trusts include variable procurement options and a wide range of products with different interoperability and varying functionality. Because of these challenges, Mozaffar et al (2014) reinforce the requirement for further guidance in relation to system selection strategy.

5.1.30 Figure 12 illustrates the main system types used by trusts.

System Type	Description	Example
Type 1: Bespoke Systems	Home-grown systems developed to meet the particular requirements of a single hospital. During the design process of these systems the user and vendor are directly connected and the aim is to solve the particular needs of the user organisation.	PICS
Type 2: Packaged Application	Applications designed with the aim of catering for the needs of various organisations. They tend to cover the 'generic' needs of adopter hospitals. Hence a standard system is designed to be implemented in different hospitals. These systems are configured (or parameterised) to meet particular needs of each hospital.	
Type 2a: Standalone systems	In this case the ePrescribing system is a separate application, not connected to wider hospital information system. Particular interfaces are required to link such applications to other systems.	JAC
Type 2b: Modules within an integrated system	A single module that performs various functionalities required for prescribing and administration of medicine and works as a part of a larger health information system. In such cases the ePrescribing module can be implemented as a whole unit at different points of time. Integrated systems tend to have more advanced decision support functionalities.	Cerner, Lorenzo
Type 2c: Functionalities spread over several modules	Similar to the above case, this type of system also integrates into a larger health information system. However it differs from 2b in that the ePrescribing functionalities are not compiled into a single module; rather they are performed by multiple integrated modules. Hence to have the entire functionalities, various modules must be implemented. Integrated systems tend to have more advanced decision support functionalities.	Magic, EpicCare
Type 2d: Specialty systems	These systems are designed to meet the particular needs of a specialty in health care. Similar to the above cases they are designed as standard packages, but with special features to cater for the particularities of that specialty care. The specialty systems may be designed as standalone applications or modules within an integrated system.	ChemoCare, ARIA Oncology

doi:10.1371/journal.pone.0092516.t005

Fig 12 Types of ePrescribing systems (Mozaffar et al, 2014)

5.1.31 The wide variation in systems and how they are used creates challenges for healthcare professionals who may have to use multiple systems in any given organisation. This is compounded by the need for clinicians to learn and understand new systems if they move between organisations (Barber, 2013). The investigation has been informed that the Royal College of Physicians (RCP) Patient Safety Committee had discussed the need for a standard human-computer interface, so that doctors moving from one trust to another do not have to learn new systems. The RCP Safer Prescribing report highlighted that junior doctors and other prescribers need to be familiar with the functionality of the system and be aware of the potential sources of error in ePrescribing.

HSIB makes the following safety recommendation:

Safety recommendation R/2019/051:

It is recommended that NHSX supports the development of interoperability standards for medication messaging

Implementation of ePMA systems

5.1.32 According to the European Commission (2009), there is no single, theoretically correct strategy for implementing interoperable EHRs and ePrescribing systems. It states that decisions to invest in such systems should adopt strategies which fit local settings, adding they are designed to succeed by meeting clearly identified, measurable needs. They identify the use of EHRs and ePrescribing as an essential component of successful change in clinical and working practices, to improve health service delivery and performance.

5.1.33 The primary care sector began digitising in the 1980s, and by the mid-2000s was nearly 100% digital (Wachter, 2016). In 2004, it was recognised that greater use of electronic prescribing in hospitals, bar-coding technology and robotic dispensing had the potential to further reduce the risk of medication errors (Department of Health, 2004). However, full implementation of ePMA systems in secondary care has not yet been achieved (Digital Health, 2017).

5.1.34 IT initiatives are often politically rather than clinically motivated (Cresswell and Sheikh, 2009) which disengages healthcare professionals and other key stakeholders from the outset. The European Commission (2009) adds that EHR and ePrescribing should be approached as a clinical venture, not as an IT project, recognising the significant strategic gains of such systems for healthcare. According to Cresswell and Sheikh (2009), previous research has shown that top-down implementations can contribute to user resistance and subsequently carry a high risk of failure.

5.1.35 Experience has shown that embedding systems into everyday practice is a long-term project. Importantly, the results highlight the need to continually monitor and refine the design of these systems to increase their capacity to improve both the safety and appropriateness of medication use in hospitals (Westbrook et al, 2012). The consequence is that trusts require IT departments with sufficient resources to monitor and adapt systems to local needs, while submitting to external audit and quality control.

5.1.36 The investigation considered the opportunities for improved technological interventions, specifically ePMA systems. The adoption of ePMA systems in hospitals across England (and internationally) has been slow. Data from November 2017 shows that 35% of acute trusts had ePMA supported inpatient prescribing and less than 12% of mental health organisations had an ePMA system (Department of Health and Social Care, February 2018a). Figure 13 illustrates inpatient ePrescribing data from NHS England for acute and mental health/ community trusts from January 2016 and November 2017.

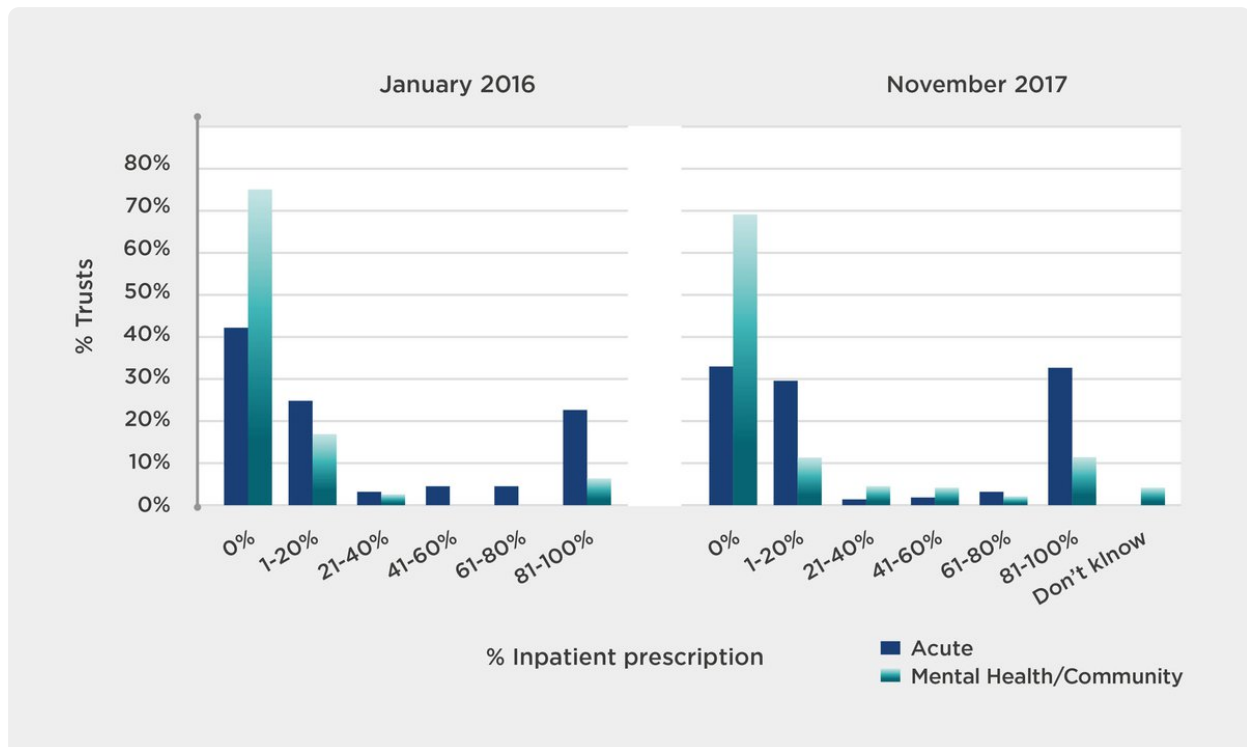


Fig 13 Inpatient ePrescribing data from 2016 and 2017 (NHS England, 2019)

5.1.37 The various ePMA systems are technically complex and the environments in which they have been employed are equally complex and various, with different systems offering different capabilities and functionalities. Successful implementation requires considerable change to working practices across medicine, nursing and pharmacy. These challenges mean that implementing systems can take years rather than months. There is variability in the effectiveness of ePrescribing, which may be attributable to the different systems, interventions or implementation factors (Nuckols et al, 2014).

5.1.38 The wide range of systems available with different interoperability and varying functionality reinforce the requirement for further guidance to help trusts select and implement systems.

5.1.39 In England, multiple electronic and paper systems present significant challenges to the design of systems interfaces, training of the workforce, and the design of safe systems of working (Ahmed et al, 2013, Digital Health, 2017).

5.1.40 The Report of the Short Life Working Group on Reducing Medication-Related Harm (Department of Health and Social Care, 2018a) states that ePMA systems can provide patients with improved information, particularly when patients are transferring between care settings. However, a consequence of patients not being

able to view a paper drug chart in hospital is that conversations with healthcare professionals about their medication might be more challenging. One of the key priorities outlined by the Working Group is to improve access to inpatient medication information, particularly in digitised systems.

5.1.41 An ePMA research team funded by the National Institute of Healthcare Research (NIHR) developed an ePrescribing toolkit. This toolkit has been commissioned by NHS England and will continue to support organisations looking to procure and implement an ePMA system. It brings together learning and experience from trusts who have implemented ePMA systems.

Medicines reconciliation and ePMA systems

5.1.42 The Special Report: E-prescribing (Digital Health, 2018) recognises that reconciling the medicine a patient is on when they come into hospital with what they are given whilst in hospital is a significant safety issue. It states:

‘What becomes really powerful is when you link that [ePrescribing] with other systems. Whether that be other systems within the hospital or linking with GP prescribing.’

5.1.43 The guideline NG5 (National Institute for Health and Care Excellence, 2015), states that 95% of medicines reconciliation should be conducted within 24 hours. The investigation was advised that no organisation in England was meeting this standard. This is supported by Safety Thermometer data (Figure 14) which illustrates that in the six year period from October 2013 to (but not including) October 2019, the proportion of patients with medicines reconciliation started within 24 hours of admission has consistently been below the target of 95%. Figure 14 also highlights variability in the proportion achieving the median average of 74.5%, with a decline in performance overall for 2019.

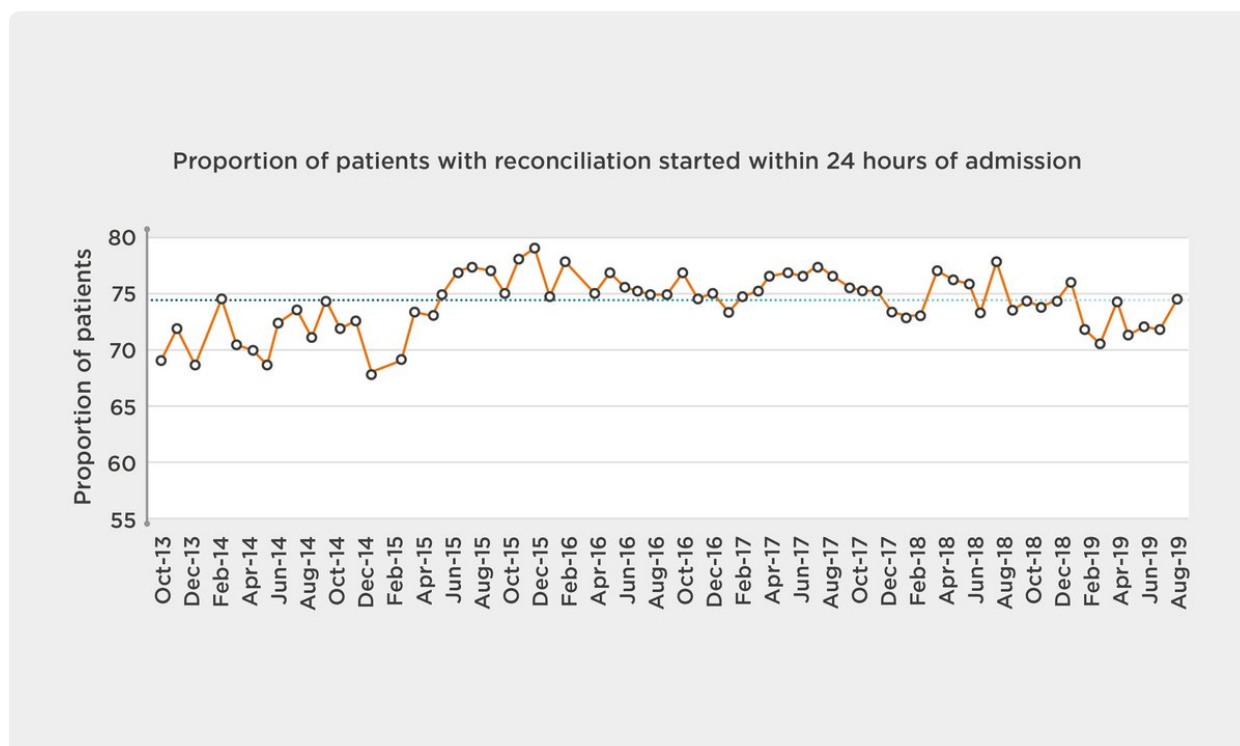


Fig 14 Safety Thermometer data for medicines reconciliation standard (acute organisations only) Copyright © NHS Improvement 2013(29)

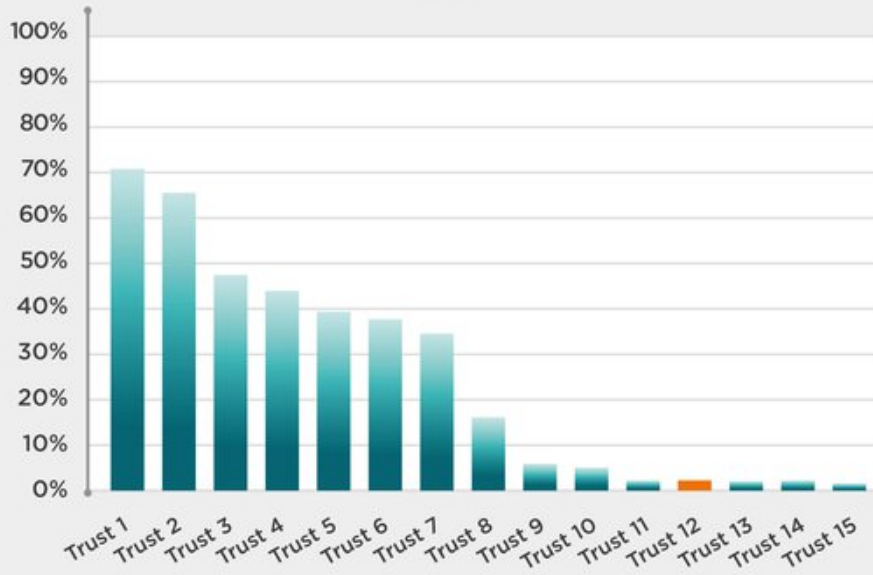
5.1.44 One of the GDE trusts visited informed the investigation that it was achieving 100% of medicines reconciliation on the medical admissions unit, frequently within 14 hours, and approximately 80% trust wide within 24 hours. This was achieved by having an integrated medicines management service encompassing electronic prescribing and medicines administration, electronic care plans and access to the Summary Care Record.

Systems optimisation

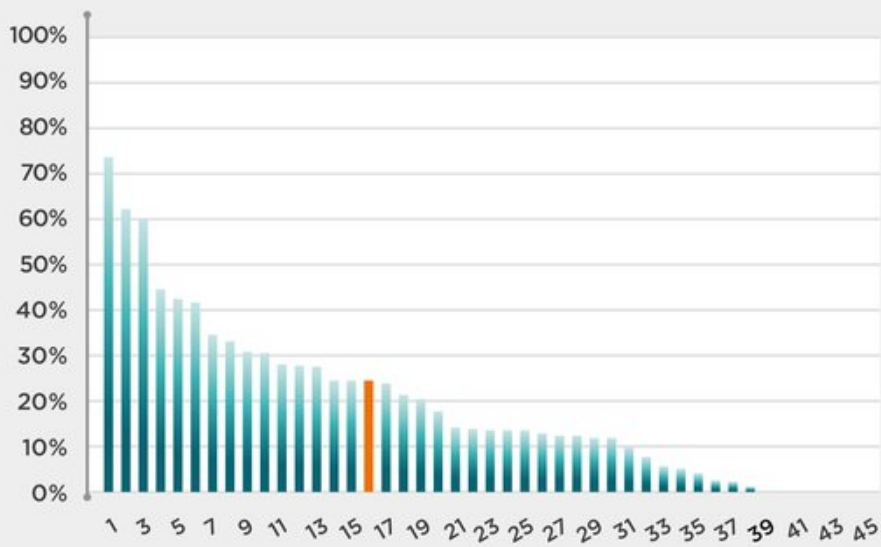
5.1.45 In the report Ten key considerations for the successful optimisation of large-scale health information technology, Cresswell et al (2017c) state that optimisation strategies should be 'continuous organisational efforts to improve HIT [health information technology] systems and the ways they are used'. Further, these efforts might involve the enhancement of functionalities such as decision support systems; the development of data analytic functionalities; and creating robust mechanisms to manage emerging problems, some of which may have been introduced by the HIT. It was anticipated that this will 'help healthcare organisations in their continuing journey of refining HIT systems to maximise benefits' (Cresswell et al, 2017c).

5.1.46 The investigation reviewed data about levels of IT adoption within trusts and the use of the available functions offered by IT systems. Three national digital maturity assessments have been undertaken by NHS England in 2015, 2016 and 2017 across all system types (Figure 15). The latest assessment in 2017 found that digital maturity around ePrescribing across trusts ranged from 0% to 71%, with the average being 21%. The information demonstrates that the uptake of systems and the functionality has increased over this period, however, full utilisation of available functionality has still not been completely achieved.

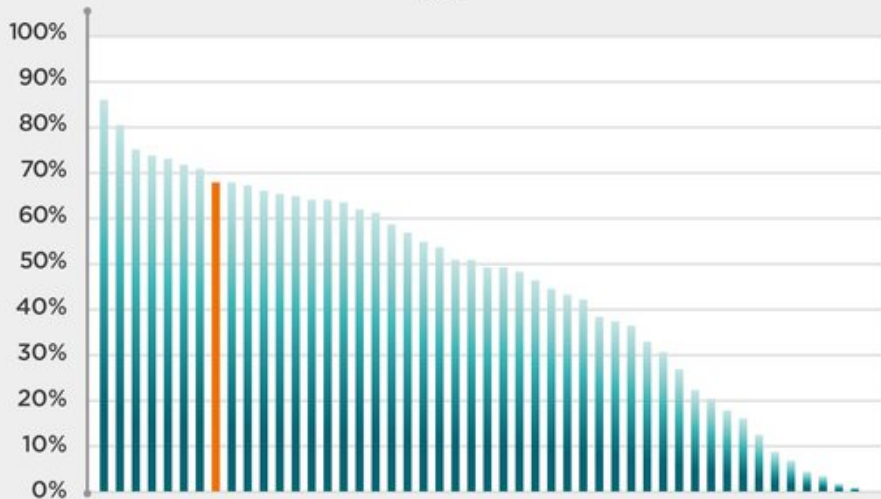
2015



2016



2017



KEY:

The horizontal axis represents individual trusts, and the vertical axis represents the level of maturity (with figures closest to 100% being the most mature).

Fig 15 Digital maturity self-assessment by trusts 2015-2017 (NHS England, 2017)

5.1.47 Digital maturity was self-assessed by individual organisations. The aim of the work was to identify how ready trusts were to implement and maintain ePMA systems; identify the available functional and mature capabilities; and find out to what extent these were being utilised. The measures were developed in collaboration with system users and a number of experts in the field and revisited over three years as the initial acceleration of ePMA took place following the distribution of technology funds.

5.1.48 The Report of the Short Life Working Group on Reducing Medication-Related Harm (Department of Health and Social Care, 2018a) finds that systems optimisation remains a challenge. The report states,

‘It is clear from work undertaken by NIHR, and the national digital e-prescribing and medicines administration maturity information, that there are significant challenges and delays with sites optimising systems once they have been implemented.’

Problems with systems optimisation are leading to delays in reaping the benefits of ePMA systems, particularly in relation to medication safety and the oversight of system-generated errors. The challenges are attributable to the technically complex systems, which require considerable change to working practices across medicine, nursing and pharmacy if implementation is to be successful.

5.1.49 NHS England has advised the investigation that whilst it is fully aware of the challenges faced by secondary care when attempting to introduce ePMA systems, until the introduction of ePRaSE, there was no means of evaluating how these challenges were being addressed at a local level. The ePRaSE tool evaluates and supports improvements relating to hospitals’ use of local configuration and clinical decision support (CDS) (see 5.2.8) in ePMA. The aim is to reduce harm caused by adverse drug events and to improve medication and patient safety; the focus being on learning and sharing information to drive optimisation more quickly. If ePRaSE had been in existence at the time of the reference event, the potential for error would have been reduced, by enabling organisational assessment of how well the system had been locally configured.

5.1.50 In summary, attempts to introduce ePrescribing into secondary care have resulted in intended and unintended consequences. There is evidence that ePMAs reduce prescribing errors and improve medicines reconciliation. However,

ePrescribing introduces new forms of risk and error. Such risks are compounded by a lack of standardisation in terms of implementation strategies, the wide variety of ePMA systems and inadequate interoperability between systems. Additionally, systems optimisation is hampered by the lack of robust mechanisms to capture, act on and test issues and improvements relating to digital technologies in healthcare.

HSIB makes the following safety recommendation

Safety recommendation R/2019/052:

It is recommended that NHSX continues its assessment of the ePRaSE pilot and considers making ePRaSE a mandatory annual reporting requirement for the assessment and assurance of electronic prescribing and medicines administration safety

5.2 Electronic prescribing systems in primary care

Medicines reconciliation in primary care

5.2.1 At a strategic level, 'In primary care, clinical pharmacists are now a key part of the general practice team in primary care networks, working alongside GPs and nurses, seeing patients and using their expertise to get the best health outcomes for people from medicines' (NHS England, 2019).

5.2.2 At an operational level, the deployment of clinical pharmacists in general practice was launched as a pilot scheme in 2015 (NHS England, 2019). Eighty-nine GP federations were successful in applying for funding from the pilot scheme, which enabled them to recruit more than 490 pharmacists (over 450 whole time equivalent (WTE)) to work across 658 GP practices.

5.2.3 The NHS Long Term Plan (NHS England, 2019) commits to substantially increasing the number of clinical pharmacists working in primary care over the coming years. The Plan states that NHS England will work with government to make more use of community pharmacists' skills and the opportunities to engage patients.

5.2.4 GPs have usually undertaken the task of medicines reconciliation. However, in recent years some health centres have employed a dedicated practice pharmacist for this task. This is not universal and practice pharmacists are often used for a wide variety of tasks. A subject matter advisor has advised the investigation that the process for medicines reconciliation in primary care is variable.

HSIB makes the following safety observation:

Safety observation O/2019/045:

The processes for medicines reconciliation in the community would benefit from being reviewed, taking into account the intent for practice-based pharmacists outlined in NHS England's Long Term Plan (NHS England, 2019).

Summary Care Records

5.2.5 Summary Care Records (SCRs) (NHS Digital, 2019) are electronic records of patient information created from GP medical records. Among other information, the SCR holds information about current medication. SCRs can be viewed by authorised staff in other areas of the health and care system involved in the patient's direct care. Viewing has also been rolled out to community pharmacies.

5.2.6 Access to SCR information means that care in other settings is safer, reducing the risk of prescribing errors (NHS Digital, 2019). However, acute trusts can currently only view the SCR; they cannot update the information or add their own data. The investigation has been advised by NHSX that there are currently no plans to change the SCR or the SCRa (which is the viewing platform for SCR). The Local Health and Care Records programme will be looking to hold this information in the future and NHS England are investing in a number of exemplars to progress the work. This will enable the safe and secure sharing of an individual's health and care information as they move between different parts of the NHS and social care. It will also enable information to be created and potentially edited by care settings, including secondary care.

5.2.7 This element was not explored further in HSIB's national investigation. There was no evidence to suggest the inability of the Trust to update or add to Ann's SCR was an issue in the reference event. It was also evident that work is ongoing at a national level in this area.

Clinical decision support systems: types and functionality

5.2.8 Health IT (2019) defines clinical decision support as follows:

‘Clinical decision support (CDS) provides clinicians, staff, patients or other individuals with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care. CDS encompasses a variety of tools to enhance decision-making in the clinical workflow. These tools include computerized alerts and reminders to care providers and patients; clinical guidelines; condition-specific order sets; focused patient data reports and summaries; documentation templates; diagnostic support, and contextually relevant reference information, among other tools.’

5.2.9 There are a variety of CDS systems available to guide prescribers when they are clinically managing a patient’s condition. In the context of the reference event, the primary care CDS system generated alerts and drug-drug interaction checks. This included an alert warning the prescriber of an interaction between apixaban and dalteparin.

5.2.10 The investigation undertook direct observation of the electronic system in primary care, by viewing the GP’s computer screen in the Health Centre. In relation to secondary care, evidence was analysed from the literature regarding CDS systems. During field work and observational visits, the investigation heard a wide variety of opinions from clinicians on the usefulness of CDS. The issue was also discussed with stakeholders, academics, and specialist advisors. Both the observational evidence and literature are considered in this section.

5.2.11 Kesselheim et al (2011) highlight that simple CDS systems can provide medication-specific information to users based on a stored repository of clinical information; this repository of clinical information is the knowledge base underlying the CDS system. There are different options for supporting clinical decision making; the most prevalent method is synchronous ‘pop-up’ alerts (alerts that appear immediately when the user selects a field or inputs data) (Mulherin et al, 2013).

5.2.12 The Health Centre involved in the reference event used an electronic system in which all the alerts appeared to be activated. However, other organisations advised their alerts were filtered or turned off altogether.

Alert fatigue

5.2.13 Ash et al (2004) state that decision support overload – the triggering of numerous reminders, alerts, or warning messages – may constantly interrupt the user. Alerts often contain trivial, redundant, or already known information (Campbell et al, 2006). Additionally, alerts present a major workflow process issue, adding to the steps required to enter a prescription. This is supported by Mozaffar et al (2017) who state that ‘the consequent proliferation of alerts, many of which highlighted matters that did not have serious consequences, impaired the usability of the system, as the need to acknowledge these made it harder to complete tasks’.

5.2.14 Campbell et al (2006) state that building and maintaining an appropriate set of alerts for electronic prescribing systems based on current evidence is an onerous, never-ending task, and one that involves calculating specificity versus sensitivity. Mulherin et al (2013) say that for a CDS system to be effective, the ease of using it to provide clinical information and alerts must be balanced with the risk of over-alerting system users. Too many alerts may lead to users paying less attention to them. This is commonly referred to as ‘alert fatigue’.

5.2.15 Alert fatigue is widely agreed to be responsible for high override⁽³⁰⁾ rates in CDS systems and EHRs; however, the concept itself is not well defined. A 2017 retrospective cohort study found that alert fatigue occurred as a result of cognitive overload⁽³¹⁾. Uninformative alerts act as ‘false alarms’, reducing overall responsiveness to alerts, and high numbers of alerts also reduced clinicians’ acceptance of these alerts (Ancker et al, 2017).

(30) In this context, if an alert is overridden, the warning is not acknowledged and is dismissed without any action being taken.

(31) Cognitive overload occurs when a large quantity of information is given in insufficient time and without sufficient cognitive resources to distinguish relevant from irrelevant information.

5.2.16 According to Kesselheim et al (2011), CDS systems are sometimes criticised for issuing too many alerts about possible drug interactions that are of limited clinical usefulness. Users (at departmental/practice level) are often unable to set up the system so that it displays fewer, more specific or more tailored alerts, partly because of the fear of legal consequences if alerts are disabled and harm to a patient ensues. When CDS systems issue excessive alerts about possible drug interactions that are of limited clinical use, this results in 49% to 96% of all alerts being ignored or overridden (Kesselheim et al, 2011)

5.2.17 Campbell et al (2006), Kesselheim et al (2011) and Ancker et al (2017) identify that if clinically appropriate alerts are inadvertently ignored due to alert fatigue, systems' effectiveness will be diminished, possibly leading to a disproportionately large number (over 25%) of errors and serious adverse consequences for patients.

5.2.18 From a communication perspective, Ash et al (2004) suggest data overload is not the only potential impact of such alerts. The user may experience negative emotions as a result of being constantly interrupted. This is supported by Campbell et al (2006), who state that clinicians report inappropriate alerts as 'highly frustrating nuisances'. Consequently, healthcare professionals disregard the messages, click them away without looking at the information or turn the warning systems off when they have an opportunity. This was supported by Mozaffar et al (2017), who found that some users created workarounds by switching alerts off, or clicking through them without reading them.

Drug-drug interaction alerts

5.2.19 Phansalkar et al (2012) say that the problem of alert fatigue associated with the use of CDS systems is particularly profound in relation to drug-drug interaction (DDI) alerts. Studies have reported override rates of approximately 90% for DDI alerts. Cho et al (2018) found that alerts relating to potentially harmful DDIs are only moderately effective at preventing harm due to high override rates.

5.2.20 The researchers found that to address the issue of alert overriding, alerts need to be made more specific. This could be achieved by focusing on high-priority DDIs, tiering DDIs according to severity, considering patient factors and co-medications to suppress insignificant alerts, or a combination of these approaches (Cho et al, 2018). Phansalkar et al (2012) concluded that the creation of a standardised list of low-priority DDIs may help to reduce alert fatigue. Despite all this research, override rates remain high and inconsistent across organisations.

5.2.21 The effectiveness of CDS systems was evaluated in US hospitals using simulated prescriptions. The systems detected only 53% of potentially fatal prescriptions and 10% to 82% of prescriptions that would have caused serious adverse drug events (Metzger et al, 2010). The study suggested an increase in national and international collaboration among vendors, implementers, and regulators was required for the co-ordination and oversight of CDS system software.

5.2.22 Ancker et al (2017) found that primary care clinicians became less likely to accept alerts as the numbers increased, particularly more repeated alerts. Complexity of patients' health conditions was also a factor. Findings were consistent

with alert fatigue caused by a high proportion of uninformative alerts combined with complex work, making it challenging to distinguish relevant from irrelevant alerts.

Measures to reduce alert fatigue

5.2.23 To ease alert fatigue, Kesselheim et al (2011) recommend more bespoke or fewer warnings, to include those of the highest importance. However, as mentioned previously, this requires time, expertise, and a continuing commitment.

5.2.24 A study by Kesselheim et al (2011) found that designers, vendors and local organisations limit the ability to modify alerts because of the legal implications of removing a warning that could have prevented a harmful prescribing error. The study identified the solution to be increased national and international collaboration among vendors, implementers, and regulators. It also recommended stronger government regulation of CDS systems and the development of international practice guidelines.

HSIB makes the following safety observation:

Safety observation O/2019/046:

National, peer-reviewed, standardised lists of alerts for clinical decision support systems should be the gold standard, to enable consistency of approach and to promote evidence-based safety improvements.

Decision support systems in sectors other than healthcare

5.2.25 There do not appear to be any studies that demonstrate the occurrence of alert fatigue in healthcare. However, other sectors, such as transport, have well-developed systems. The Rail Safety and Standards Board (2009) states that good design of alarms and alerts ensures that operators can detect, understand and respond to them appropriately.

5.2.26 Within the aviation industry, the Federal Aviation Administration (FAA) published the Human Factors Team Report on the Interfaces Between Flight Crews and Modern Flight Deck Systems (Federal Aviation Administration, 1996). The FAA's human factors working group reported in 2004 that, 'Human factors design guidelines already existing within aircraft certification are somewhat fragmented and do not present a unified, coherent approach to the human factors engineering

of the modern flight deck.’ Subsequent updates and amendments to the international Certification Specification 25.130232 aim to address human factors and engineering usability of installed equipment on the flight deck, to reduce design-related errors.

5.2.27 Frequently repeated alerts are likely to cause an operator to become familiar with the alert signal, resulting in a reduced response to that alert (known colloquially as the ‘cry wolf effect’), and slower responses in cases where a response is made (cited in Dalton et al, 2018). Dalton et al also discuss the involvement of higher-level cognitive factors. For instance, there is evidence that the ‘cry wolf effect’ may become more obvious in situations of high workload. It has also been demonstrated that being informed that an alert is more reliable is enough to increase the response rates to that alert. Additionally, there is evidence that response rates to an alert increase if other nearby alerts are also active, even if these alerts relate to completely different issues. Collectively, the evidence points to operators using their previous experience of alert reliability, and of their current assessment of the situation, to decide whether to respond. Consequently, in sectors such as aviation, the false alert rate is considered to be a critical factor in the design and evaluation of alerting systems (Dalton et al, 2018).

Development of standards

5.2.28 CDS software sold in the US is subject to oversight by the Food and Drug Administration as medical devices. This body has the authority to ensure systems adhere to general development standards, including engineering usability and human factors evaluation (cited in Kesselheim et al, 2011).

5.2.29 The Australian Commission on Safety and Quality in Healthcare (2016) refers to the country’s national guidelines for on-screen display of clinical medicines information. These guidelines comprise recommendations for clear, unambiguous, standardised on-screen display of medicines information in clinical information systems. The guidelines are intended for those developing, assessing, procuring and implementing IT systems for medication management and electronic prescribing, helping them to understand how design contributes to patient safety, amongst other factors.

5.2.30 In the UK, similar guidelines drafted by the National Patient Safety Agency in 2010 are still in use. The Department of Health and Social Care has already developed software design standards, including standards for CDS systems, which are mandatory for all software suppliers (NHS Digital, 2018).

5.2.31 There is an abundance of literature outlining CDS-related issues, along with initiatives to try and address these issues, by balancing specificity versus sensitivity. However, there are no evidence-based standards for the configuration of software system alerting to ensure users to acknowledge and respond appropriately, using a tiered alert system to determine the type of intervention required (Phansalkar et al, 2012).

(32) Certification specification 25.1302 addresses the design and approval of installed equipment intended for flight crewmembers to use from their normally seated positions on the flight deck, encompassing the design and evaluation of controls, displays, system behaviour, and system integration, as well as design guidance for error management.

HSIB makes the following safety recommendation:

Safety recommendation R/2019/053:

It is recommended that the Department of Health and Social Care should consider how to prioritise the commissioning of research on human factors and clinical decision support systems; particularly in relation to the configuration of software system alerting and alert fatigue, to establish how best to maximise clinician response to high risk medication alerts.

5.3 Sharing of data between primary care, secondary care and community pharmacies

National vision for interoperability and standards

5.3.1 The technology landscape is varied and diverse. This introduces poor interoperability, leading to delays in the transmission of data from one system to another (National Information Board, 2014).

5.3.2 Interoperability in healthcare is defined as ‘the ability to exchange, understand and act on patient and other health information and knowledge, among linguistically and culturally disparate clinicians, patients and other actors, within and across jurisdictions [regions], in a collaborative manner’ (European Commission, 2009). In the context of the reference event, this would include creating a more efficient handover between primary and secondary care, to ensure GPs have the data they need and that they feel able to challenge and change prescribing decisions made in hospitals.

5.3.3 Many systems in hospitals, primary care and the community are not linked electronically (Department of Health and Social Care, 2018b). This is attributable to the contracts in place between trusts and IT suppliers, which do not adequately specify the standards of interoperability, usability and continual improvement. To address this, the Department of Health and Social Care sets out mandatory IT standards for NHS trusts and NHS IT suppliers, and issues a recommendation that NHS data and IT systems should be moved on to public cloud services(33).

5.3.4 According to the Department of Health and Social Care (2018b), open standards(34) and interoperability are two of the conditions considered to be critical to the safe and successful use of technology, ensuring that systems in different healthcare sectors connect electronically and the right data gets to the right place at the right time.

5.3.5 In relation to standards, the vision states that digital transformation across a large set of organisations requires clear standards to be set centrally so that organisations can make decisions that meet their own local needs. The Department of Health and Social Care (2018b) will set the minimum rules needed to guarantee data interoperability and will set national open standards for data and interoperability.

5.3.6 Alongside the vision document, NHS Digital (2018) has published a new draft NHS digital, data and technology standards framework, which sets out early thinking and expectations for the use of data, interoperability, design, and IT commercial standards within the NHS.

5.3.7 A standard has been developed (Professional Records Standards Body, 2019) which defines the full prescription such that all relevant component parts can be coded, not just the medicine name. A Dictionary of Medicines and Devices is used for this purpose(35) and a supporting application has been developed to assist in using the dictionary to build a drugs catalogue on ePMA systems.

(33) Computing services offered by third-party providers over the public Internet

(34) Open standards facilitate interoperability and data exchange among different products or services and are intended for widespread adoption.

(35) The Dictionary of Medicines and Devices is a dictionary of descriptions and codes representing medicines and devices used across the NHS.

5.3.8 The publication Digital Medication Information Assurance (Professional Records Standards Body, 2019) states that NHS Digital and NHS England teams have developed draft implementation guidance to allow medication dose and timing information to be machine readable (read by computers), so it can be shared in a standardised way between different systems. The publication states that this will create numerous opportunities to optimise the ways in which care is delivered and streamline working practices, and is supported by non-technical guidance for healthcare professionals. The benefits to patients and the system in terms of improved safety and efficiency of transmission of medicines information are potentially significant and the project has been identified as the top priority of the NHS England interoperability programme.

Information and technology interfacing

5.3.9 Cresswell et al (2017b) state that to achieve co-ordinated care, systems need to be connected to allow exchange of clinical and other related data. One of the ways of achieving this is by interfacing. Interfacing is a strategy that involves linking standalone systems which have been developed separately by different suppliers for different purposes. Cresswell et al (2017b) also explored the social and technical challenges relating to integrated electronic prescribing systems.

5.3.10 Research by Cresswell et al (2017b) found that integration and interfacing issues in both standalone and multimodular systems could increase user workload, create possibilities for errors and delay the healthcare provided. These issues were caused partly by users having to manage multiple log-ins and by a lack of data coherence across modules. The research stated that multimodular systems were easier to use; however, standalone systems provided greater flexibility and opportunity for innovation.

5.3.11 The study discusses a lack of national standards for joining up systems, that would allow ePrescribing systems to connect with wider organisational processes and information held in related systems. The researchers proposed that more flexible interfacing, for example between ePrescribing and specialty systems, should also be considered by system developers (Cresswell et al, 2017b) and designed a conceptual multimodular electronic prescribing system that interfaced with other care settings (Figure 17).

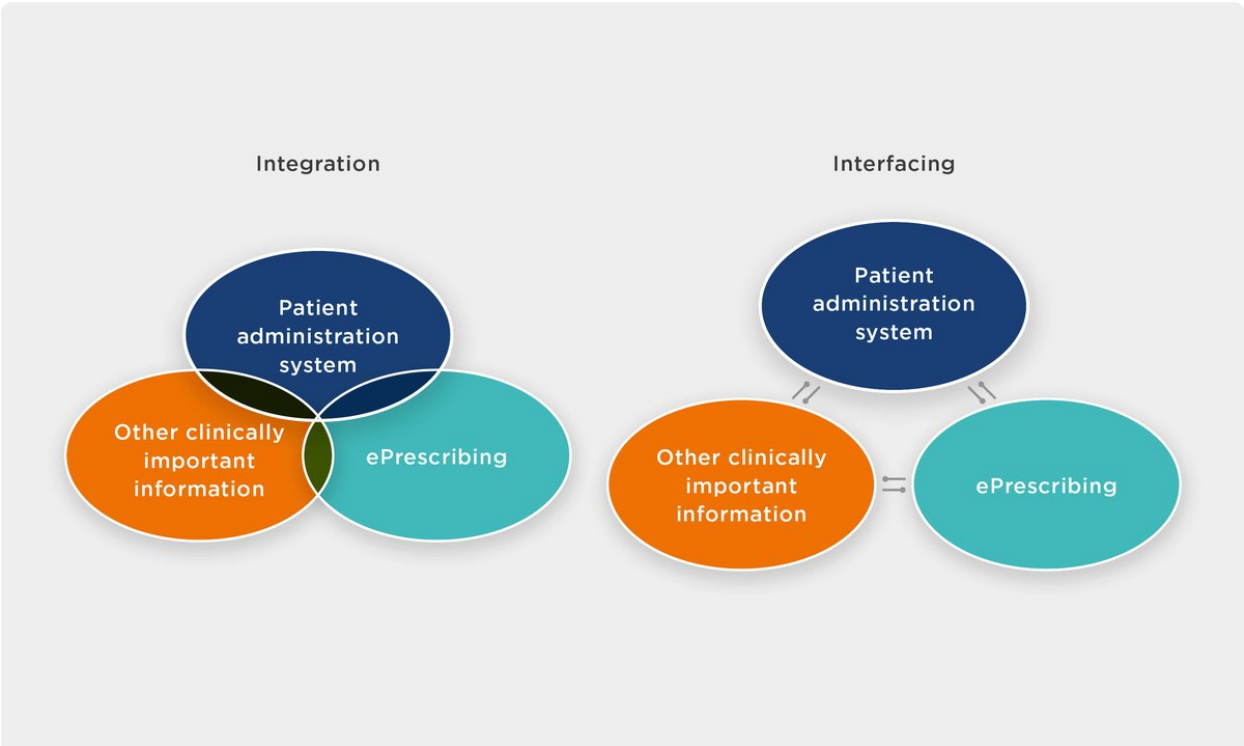


Fig 16 Illustrating the difference between integration of information within systems and interfacing to allow information exchange across systems (Cresswell et al, 2017b).

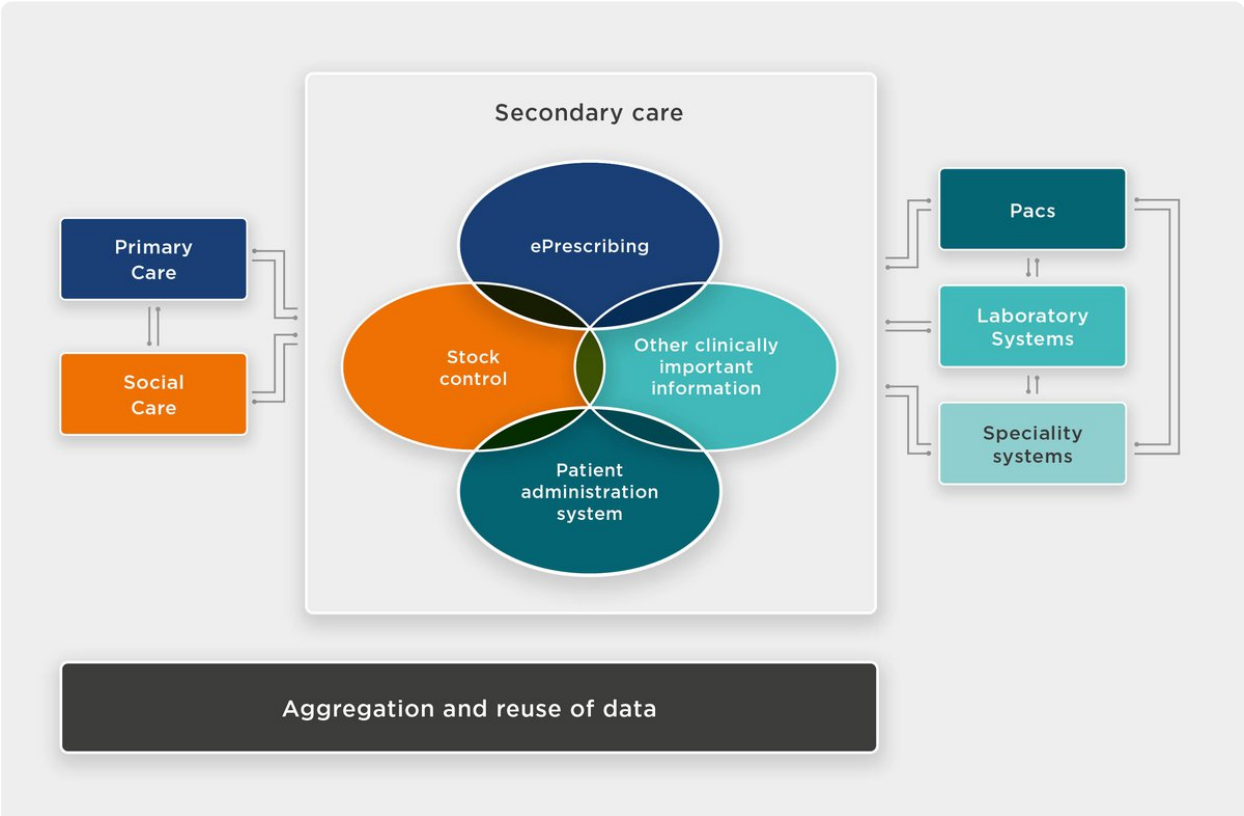


Fig 17 A visualisation of an idealised multimodular electronic prescribing (ePrescribing) system interfacing with other care settings and specialty systems. Picture Archiving and Communication System (PACS)(36) (Cresswell et al, 2017b).

(36) PACS is a system that enables medical staff to view X-rays/diagnostic images.

Communication of medication-related information across care settings

5.3.12 As cited in Shemilt et al (2016), 'The prescribing of medicines is the most common form of therapeutic intervention in healthcare.' The individualised patient prescription chart, either paper or electronic, is an integral part of communication between healthcare professionals. Garfield et al (2016) stated that greater involvement of inpatients with their medication has not been widely studied. They explored patients' involvement with medication safety-related behaviours, enablers and barriers to this involvement, and the impact of electronic prescribing.

5.3.13 Garfield et al (2016) found that patients were more likely to see paper-based medication records than electronic equivalents; only 2% of patients saw either type of record. The findings suggest that to develop interventions to increase patient engagement, the following factors need to be considered:

- the hospital environment
- the healthcare team and organisational culture
- factors relating to individual patients, healthcare professionals and tasks.

5.3.14 Allen and Sequist (2012) state that although the process of initiating medication prescriptions has been improved to ensure both patient safety and efficiency, less attention has been paid to the process of discontinuing medications. The authors reflect that patient harm is possible if pharmacies dispense medications to patients after the clinician has discontinued them for a clinically important reason, as occurred in the reference event. They highlight the opportunity offered by EHRs to track when a clinician discontinues a medication, and to transmit details of the discontinuation electronically to the community pharmacy.

5.3.15 The Department of Health and Social Care, (2018a) identified shared decision-making to be important in improving medication safety in this context. It concluded that patients and their carers should be encouraged and supported to play a more active role in medicines management, including when to stop previously prescribed medication.

Similarly, Allen and Sequist (2012) considered that further work should focus on evaluating methods of improving communication between providers and pharmacies to reconcile medicines, as well as to explore strategies to improve patients' knowledge and awareness of their medicines.

5.3.16 The Care Quality Commission (2009) undertook a study focusing on the management of patients' medicines post discharge from hospital, part of which covered the importance of primary care clinicians updating medication records (medicines reconciliation). Almost a decade later, NHS England (2018) states that good organisation of care across the interface between primary and secondary/tertiary care is crucial in ensuring that patients receive high-quality care.

5.3.17 The guideline NG5 (National Institute for Health and Care Excellence, 2015) specifies that relevant information about medicines should be shared with patients and family members (where appropriate), and between health and social care practitioners when a person moves from one care setting to another.

This information should include:

- details of the medication the patient is taking
- changes to medicines started or stopped in hospital
- dosage changes
- reasons for changes to medication
- information that has been given to the person and family members.

5.3.18 There are specific requirements regarding the sharing of patient information between current and new care providers. NG5 stipulates that complete and accurate information about medicines should be shared, ideally within 24 hours of the person being transferred, 'in the most effective and secure way, such as by secure electronic communication' (National Institute for Health and Care Excellence, 2015).

5.3.19 The NICE guideline encompasses the safe and effective use of medicines in health and social care for people taking one or more than one medicine. It aims to ensure that medicines provide the greatest possible benefit by encouraging medicines reconciliation, medication review, and the use of decision aids for patients. The guideline acknowledged that at points where patient care is transferred, such as admission or discharge, there is a higher risk of unintended changes to medicines.

5.3.20 The transfer of care process is associated with an increased risk of adverse effects. However, those patients most at risk of medication errors, including those recently discharged from hospital, may not be highlighted to community pharmacies. The National Institute for Health and Care Excellence (2015) identifies that between 30% and 70% of patients experience an error or unintentional medication change because of a lack of communication or miscommunication, as they move from one care setting to another. Similarly, Hesselink et al (2012) state that 20% of patients have experienced adverse events within three weeks of discharge, 60% of which could have been avoided.

5.3.21 There is evidently a great deal of guidance on how to ensure that medication-related information is communicated safely across care settings, but errors still occur. The investigation carefully considered the factors that contribute to these errors, aside from the lack of communication or miscommunication identified by the National Institute for Health and Care Excellence (2015). Factors that contribute to the risks of medication error around the time of transfer include understaffing on the ward, competing priorities for junior doctors, and the lack of interoperability between systems (which is alluded to elsewhere in this report). These issues extend beyond secondary care level and developing solutions would require a wider, more strategic approach.

5.3.22 The NICE guideline NG5 (National Institute for Health and Care Excellence, 2015) includes the instruction to send a patient's medicines discharge information to their nominated community pharmacy, when possible and in agreement with the patient. It also suggests organisations should consider arranging additional support for certain groups of people on discharge, such as those taking multiple medicines. The support suggested includes pharmacist counselling, telephone follow-up, and GP or nurse home visits. Resources that could support safe medicines management in the community include Medicines Use Reviews (MUR) and the New Medicines Service (NHS Employers, 2019 and NHS, 2019). MURs aim to improve patients' adherence and experience of using their medication(s), maximise the benefits of medication and reduce waste due to unused medicines (NHS Employers, 2019).

5.3.23 An initiative called, pharmacist-led information technology intervention (PINCER), described in The Report of the Short Life Working Group on Reducing Medication-Related Harm (Department of Health and Social Care, 2018a), involves searching GP computer systems to identify groups of patients who are at risk from what is referred to as 'hazardous prescribing'. Once such patients are identified, specially trained pharmacists can work with each general practice to develop an action plan to address the prescribing issues. Trial data has demonstrated the effectiveness of the intervention in reducing incidences of clinically significant

errors in general practice prescribing. PINCER has now been incorporated into national guidelines to support medicines optimisation by both NICE and NHS England (Department of Health and Social Care, 2018a). The following target relating to PINCER is outlined in The NHS Patient Safety Strategy (NHS England and NHS Improvement, 2019): ‘AHSN [Academic Health Science Network]-supported national roll-out will reach at least 40% of GP practices by 2020.’

Transfer of care service (ToC) to community pharmacy

5.3.24 In 2012, the Royal Pharmaceutical Society (RPS) issued professional guidance in its publication, Keeping patients safe when they transfer between care providers – getting the medicines right. The guidance related to the core principles that underpin the safe transfer of medicines-related information for a patient transferring between care providers. Following publication of the RPS professional guidance, early indications suggested that patients referred from hospital, who received a follow-up consultation with their community pharmacist, had lower rates of readmission and shorter hospital stays (Nazar et al, 2016). As reflected by Wilcock et al (2019), community pharmacists are well placed to counsel patients on new/changed medicines in a community setting and to provide an additional medicines reconciliation.

5.3.25 The NHS Digital Transfer of Care initiative is part of a wider interoperability programme run between NHS England and NHS Digital. Its primary purpose is to ensure the establishment and uptake of consistent professional and technical data standards across the health sector, particularly the patient documentation which follows a patient’s transfer of care between provider organisations.

5.3.26 The investigation has been advised of a Transfers of Care Around Medicines (TCAM) project. TCAM was developed by the national Academic Health Science Networks (AHSN) Medicines Optimisation programme, supporting the roll-out of the project nationally, as part of the NHS England commissioned activity. The AHSNs have worked with trusts and local Pharmaceutical Committees to help set up a secure electronic interface between hospital IT systems and community pharmacies in their area. This results in data being provided promptly to the community pharmacist. A draft Implementation Toolkit for Clinical Handover to Pharmacists in the Community was shared with the investigation. Once signed off, this will be a guide for commissioners, managers and providers reviewing the planning, reviewing and implementation of local clinical handover services from hospital to pharmacists in the community.

5.3.27 As one subject matter advisor informed the investigation, changing behaviours and practice is challenging but needs to be considered alongside technological intervention. The National Institute for Health and Care Excellence (2017) feature a project on their shared learning database which includes the consideration of behavioural changes, at both hospital and community pharmacy level. This project relates to the introduction of a pharmacy service that comprises one pharmacist delivering pharmaceutical care to one ward, to help implement a range of innovations in the field. A hospital-to-community pharmacy electronic referral system is central to this, alerting community pharmacists to a patient's hospital admission and subsequent discharge, and a copy of their discharge letter is provided.

The Clinical Services Lead Pharmacist responsible for implementing the project, summarised their achievements, by saying:

'With the current economic climate in the NHS, there will be obstacles, but we can persistently implement small-scale changes and use data to demonstrate the benefits we provide as a profession; we have changed practice, attitudes and mind-sets within our trust'.

HSIB notes the following action has been implemented:

Safety action A/2019/017:

The National Academic Health Science Networks Medicines Optimisation Network has been commissioned by NHS England to support the roll-out of Transfers of Care Around Medicines across England.

5.4 Safe discharge - best practice and strategic objectives nationally

Discharge standards and processes

5.4.1 Discharge is a key point of interface between secondary care, primary care and community pharmacy. However, while the investigation identified over 400 elements (tools, resources and information) in the ePrescribing Toolkit for NHS Hospitals, it was identified that there is minimal focus on integration into safe discharge and/or the interface across primary and secondary care.

5.4.2 The Academy of Medical Royal Colleges (2013) published standards for the clinical structure and content of patient records, including discharge summaries. The publication put forward a strong case for the development and use of standardised electronic health records, in which data is recorded consistently across all contexts. Relevant to the reference event, the Academy of Medical Royal Colleges (2013) stated that the implementation of national standards for the clinical structure and content of electronic health records would enable interoperability between locations and contexts.

5.4.3 Following on from the Academy of Medical Royal Colleges report, the Professional Record Standards Body (2019) produced an eDischarge Summary Standard containing common standards for the information recorded in discharge summaries. The eDischarge standard allows hospitals to transfer standardised clinical information and coded data (SNOMED CT(37) and dm+d(38)) directly into GP IT systems. It ensures all relevant information on diagnoses, medications, procedures and allergies is shared with GPs, to improve quality and consistency of care. Spencer et al (2019) emphasise the importance of the document by stating that correct processing of discharge summaries is essential to ensure patients experience a safe transition of care and not just a hospital discharge.

5.4.4 To enable professionals to deliver the eDischarge standard, the Royal College of Physicians Health Informatics Unit has produced and evaluated a learning package (Royal College of Physicians, 2019). This emphasises the need for complete medication information to be passed on at transfer, and that information should be linked to clinical narrative, as including only new medications is not safe practice.

5.4.5 The Royal Pharmaceutical Society (2012) outlines four core principles for healthcare professionals:

- 'When transferring a patient, ensure all necessary information about medicines is accurately recorded and transferred with the patient, and that responsibility for ongoing prescribing is clear.
- When taking over care of a patient, check that information about medicines has been accurately received, recorded, and acted upon.
- Encourage patients as active partners in managing medicines when they move, knowing in plain terms why, when and what medicines they are taking.
- Information about medicines should be communicated in a way that is clear, timely, legible and unambiguous – ideally generated and/or transferred electronically.' There are also three key responsibilities for organisations

providing care, which include having safe systems that define roles and responsibilities, ensuring the healthcare professionals are supported to transfer information relating to medicines accurately.

5.4.6 A national Medication Safety Programme was initiated by NHS Improvement in response to the WHO Third Global Patient Safety Challenge: Medication Without Harm. A programme board and general outline of workstreams has been established across four domains, medicines; healthcare professionals; systems and practices; and patients.

HSIB makes the following safety recommendation:

Safety recommendation R/2019/054:

It is recommended that NHS England and NHS Improvement include in the Medication Safety Programme shared decision making and improved patient access to medication information across all sectors of care, to ensure a person-centred approach to safe and effective medicines use

5.4.7 Evidence from the reference event analysis indicates that the discharge process needs to be built into the functionality of ePMA systems from the outset to facilitate safe discharge. In theory each ePMA system could be configured to include the discharge process; however, there is currently no standard to stipulate how the system should be configured, resulting in variation across organisations.

HSIB makes the following safety recommendation:

Safety recommendation R/2019/055:

It is recommended that NHSX produces guidance for configuring the electronic discharge process, and how electronic prescribing and medicines administration systems should be interfaced with such a process.

5.5 Seven-day services across the NHS

Clinical standards for seven-day services in hospitals

5.5.1 NHS England's NHS Services, Seven Days a Week Forum was established in 2013 to consider how NHS services could be improved to provide safer, more responsive and patient-focused services across the seven-day week. The Forum concluded that there was significant variation in outcomes for patients admitted to hospitals at weekends, in terms of mortality rates, patient experience, length of stay and readmission rates (NHS England, 2013; British Medical Association, 2013).

(37) SNOMED CT is a structured clinical vocabulary for use in an electronic health record.

(38) The dm+d is a dictionary of descriptions and codes which represent medicines and devices in use across the NHS.

5.5.2 More recently, a systematic review and meta-analysis has revealed that 'the weekend effect is unlikely to have a single cause, or to be a reliable indicator of care quality at weekends' (Chen et al, 2019). This study found that evidence regarding the 'weekend effect' was weak and inconsistent in terms of adverse events and length of stay, and was limited on patient satisfaction. Regarding mortality, Chen et al (2019) reported that weekend admissions were associated with a 16% increase; however, the quality of evidence was low and the causes largely attributable to case-mix (type of patients treated) and contextual factors surrounding admissions.

5.5.3 The work of the Seven Day Services Forum (NHS England, 2013) led to the development of 10 clinical standards for seven-day services in hospitals (NHS England, 2017). The standards define what seven-day services should achieve, regardless of when or where patients are admitted.

The four priority standards are:

- time to first consultant review
- diagnostics
- intervention/key services
- ongoing review.

5.5.4 Pharmacy is not one of the priority standards and is part of another standard – the MDT review. This states: 'All emergency inpatients must be assessed for complex or on-going needs within 14 hours by a multi-professional team, overseen by a competent decision-maker, unless deemed unnecessary by the responsible consultant. An integrated management plan with estimated discharge date and physiological and functional criteria for discharge must be in place along with completed medicines reconciliation within 24 hours.'

5.5.5 The Seven Day Services Clinical Standards (NHS England, 2017) state that 'support services, both in the hospital and in primary, community and mental health settings must be available seven days a week to ensure that the next steps in the patient's care pathway, as determined by the daily consultant-led review, can be taken'. Pharmacy is explicitly mentioned in these standards.

5.5.6 In the Seven Day Services Forum (NHS England, 2013), four key themes emerged to support implementation of seven-day services, supporting the statement that: 'Pharmacy is the golden thread in seven-day services':

- joining up hospital and community pharmacy services
- pharmacy workforce and ways of working
- targeting where to deliver seven-day services
- affordability and building a case at an organisational level.

5.5.7 One of the supplementary drivers for the change towards the seven-day service was both the clinical and workload support for junior medical staff. The outcome led to a significant shift in work from medical to pharmaceutical staff for the provision of weekend discharge medication. This is one of the benefits of the integrated medicines management service, which the investigation heard about during a visit to a Global Digital Exemplar trust, where pharmacists carry out 98% of all medication requested discharges, seven days per week.

5.5.8 The Deputy Chief Pharmaceutical Officer at NHS Improvement advised the investigation that challenges to the progress of seven-day clinical pharmacy services include ongoing historical service challenges, including issues around the supply of medicines; a lack of service investment; workforce issues; and limitations of digital systems. Agenda for Change contracts (NHS grading and pay system), result in the cost of running services at weekends being significantly higher, particularly on Sundays. This is a significant issue for trusts, which have to balance risk and cost.

5.5.9 During an observation visit to a GDE trust, the investigation was informed about the impact of this variability on the consistency of care provided outside normal working hours. The GDE trust advised that pharmaceutical interventions were being delivered later in the patient pathway and this resulted in reduced rates of medicine reconciliation, delayed discharge and errors.

5.5.10 In most hospitals, support services (including pharmacy) do not match the hospital activity pattern, instead operating Monday to Friday, 09:00 to 17:00 hours. Outside these hours, services are reduced, emergency-only, or absent, with most

routine services closing at the point when demand from emergency admissions is at its highest (British Medical Journal, 2016). This finding was supported by Gordon (2017), who said that whilst there was 72% support for the concept of full seven-day services, for this to be properly enacted there must be increased provision and support across the whole hospital. The paper discusses the variable range of support services available out-of-hours and at weekends. Most hospitals reported emergency availability for endoscopy (85%), surgery (82%) anaesthetics (80%) and radiology (77%). However, there were fewer non-medical disciplines available, although pharmacy was one of the exceptions (73%), as there have been established services in hospitals for some years.

5.5.11 According to research by NHS England (2016), limited availability of patient-facing, out-of-hours hospital pharmacy services can lead to lack of support for junior medical and nursing staff, low levels of medicines reconciliation, and poor support for patients at the point of discharge. The paper emphasises that seven-day clinical pharmacy services in hospitals are important to:

- enhance patient experience by allowing patients to discuss medication-related aspects of their care and supporting progress through care pathways
- reduce variation in quality of care by embedding medicines optimisation principles into routine practice, seven days a week
- improve clinical efficiency and patient safety through increased pharmacy staff, able to focus on optimal use of medicines
- address clinical workforce demands by utilising staff such as pharmacist prescribers (Baqir et al, 2014).

5.5.12 The Deputy Chief Pharmaceutical Officer at NHS Improvement agreed that services are stretched due to limited staff numbers. He advised the investigation that consequently there was a need to work differently, for example by allocating more resource at the end of the day when workload tends to be greater. This was a point also made by a director of pharmacy at a GDE trust. During an observation visit, he advised the investigation that it was important to consider workforce efficiency rather than purely focusing on staff numbers. The medical profession has similarly needed to support flexible working to retain consultants in the later stages of their career, in an attempt to 'stem the drain of expertise and skills from the profession' (Royal College of Physicians, 2017).

5.5.13 A second GDE trust reported increased efficiency when an integrated medicines management (IMM) service was in place. The integrated management of medication provides a service to the patient from the point of admission to the

point of discharge. Integral to its success was the availability of clinical pharmacy services seven days a week, supported by ePMA, electronic care plans and access to the GP system.

5.5.14 To deliver seven-day services, trusts will need to consider a combination of approaches. NHS England (2016) states that planning should include:

- a practical, staged approach to redesigning clinical pharmacy services involving optimal use of technology, workforce and infrastructure
- the provision of targeted services to high-risk patients
- better integration of clinical pharmacists into multidisciplinary teams
- learning and shared practice from exemplar hospitals.

5.5.15 To increase efficiency while maintaining patient safety, an evidence-based clinical prioritisation tool, the Medicines Optimisation Assessment Tool (MOAT), has been developed (Geeson et al, 2019). The tool was developed to target inpatients most in need of pharmacists' input at two hospitals in England. Data on medication-related problems was collected by pharmacists and information was obtained regarding potential risk factors, such as comorbidities and use of high-risk medicines. Geeson et al (2019) concluded that MOAT has the potential to guide decision making by predicting those patients most at risk of adverse, preventable medication-related outcomes. However, while external validation and further research is required before MOAT is adopted more widely, it has the potential to help trusts to achieve the seven-day service standard. Medicines prioritisation will be explored further in HSIB's investigation report: 'I2018/019: Identifying and reducing high-risk prescribing errors in hospital', which will be published in 2020. Issues relating to the lack of seven-day pharmacy cover.

5.5.16 The Royal Pharmaceutical Society (2014) states that whilst hospital pharmacy teams deliver effective pharmaceutical care and ensure patients use medicines in an optimal way outside normal working hours, there is still variation in the consistency of this care. Limited availability of hospital pharmacy services in some trusts, particularly at weekends, has resulted in a number of reported issues. The two issues relevant to this investigation are prescription errors and the lack of medicines reconciliation.

5.5.17 In relation to addressing medication errors, a large research study (Scullin et al, 2007) identified that pharmaceutical implementation of the integrated medicines management (IMM) pathway reduced errors by an average of 4.2 per patient. In addition, there was a reduction in the length of stay by almost four days for medical

admissions and reduced readmission rates. The data also showed faster medication rounds, and timelier and significantly more accurate discharges with a five-fold to eight-fold return on investment.

5.5.18 The second issue relating to the lack of medicines reconciliation has been addressed by one of the GDE trusts visited by the investigation. The trust employs advanced practitioner pharmacists, whose role is to improve patient care and flow at admission and discharge. Additionally, their intervention includes discussions with patients to enhance shared decision making. The wider IMM service is delivered by clinical pharmacists and pharmacy technicians, who undertake medicines reconciliation, verification of medication and clinical review. In the first 18 months following implementation of the seven-day IMM service, there was a demonstrable improvement in the medicines reconciliation rate from 36% in less than 24 hours pre-implementation to around 80% post-implementation.

5.5.19 As previously stated, the medicines reconciliation rate is a significant measure because medicines-related patient safety incidents are more likely to occur when medicines reconciliation is undertaken more than 24 hours after a person is admitted to an acute setting (National Institute for Health and Care Excellence, 2016). Undertaking medicines reconciliation within 24 hours of admission to an acute setting (or sooner if clinically necessary) enables early action to be taken when discrepancies between lists of medicines are identified. This supports seven day working for the pharmacy service.

HSIB makes the following safety observation:

Safety observation O/2019/047:

In acute trusts where digital systems are in place, the prioritisation of medicines reconciliation and medication reviews supports the consistent delivery of these core functions, across seven-day services.

6 Summary of HSIB findings, safety recommendations, safety observations and safety actions

Findings

The investigation found:

1. The reference event could have occurred with or without the ePMA system, and a well-configured ePMA system could have prevented the error.
2. A single system of medicines administration that supports both hospital and self-administration is the optimal approach.
3. There was no standardised discharge process in place, incorporating a discharge summary that interfaced with the ePMA system and provided a synopsis of the patient's medication on discharge.
4. There was a lack of interoperability (the capacity to exchange, interpret and store data to common standards) between primary and secondary care electronic prescribing systems, between secondary care facilities, between secondary and tertiary care, and between secondary care and community pharmacy.
5. Within primary care, guidance on the design and implementation of electronic prescribing systems in respect of alerts (warnings) is variable.
6. There are many different types of ePMA system available in England – some bespoke, others commercial off-the-shelf systems – and they are provided by several different vendors.
7. There are opportunities for technological intervention specifically aimed at ePMA system improvements, as the roll-out in hospitals across England has been gradual.
8. The implementation of electronic prescribing is associated with a greater than 50% reduction in medication errors and possibly a similar reduction in patient adverse drug events.
9. There is limited knowledge and data relating to unintended consequences of introducing ePMA systems because of the varied nature of health IT products and the lack of common criteria against which to measure the impact.
10. Commercial ePMA systems reduced medication errors if the available functionality was switched on, used appropriately, integrated with other relevant IT systems and aligned with clinical workflows.
11. In the reference event, the medicines reconciliation process in primary care would have provided an opportunity to detect the continuation of the dalteparin after discharge from hospital.
12. Standardisation of clinical decision support (CDS) systems could benefit the prescriber in relation to drug-drug interaction alerting.

13. There are software design standards, including those for CDS systems, which are mandatory for all software suppliers.
14. Minimum rules would guarantee data interoperability and enable national open standards to be set for data and interoperability.
15. Transfer of care initiatives improve communication between care settings.
16. There is no standard discharge process built into ePMA systems to facilitate safe discharge.
17. Hospital ward pharmacy provision is not always available seven days a week to ensure there is: adequate checking for errors in prescribing; minimal transcription from paper systems into the ePMA by entering directly on to the system; and medicines reconciliation (see section 1.2) in accordance with national guidance.

HSIB makes the following safety recommendations:

Safety recommendation R/2019/050:

It is recommended that NHSX develops a process to recognise and act on digital issues reported from the Patient Safety Incident Management System.

Safety recommendation R/2019/051:

It is recommended that NHSX supports the development of interoperability standards for medication messaging.

Safety recommendation R/2019/052:

It is recommended that NHSX continues its assessment of the ePRaSE pilot and considers making ePRaSE a mandatory annual reporting requirement for the assessment and assurance of electronic prescribing and medicines administration safety.

Safety recommendation R/2019/053:

It is recommended that the Department of Health and Social Care should consider how to prioritise the commissioning of research on human factors and clinical decision support systems; particularly in relation to the configuration of software system alerting and alert fatigue, to establish how best to maximise clinician response to high risk medication alerts.

Safety recommendation R/2019/054:

It is recommended that NHS England and NHS Improvement include in the Medication Safety Programme shared decision making and improved patient access to medication information across all sectors of care, to ensure a person-centred approach to safe and effective medicines use.

Safety recommendation R/2019/055:

It is recommended that NHSX produces guidance for configuring the electronic discharge process, and how electronic prescribing and medicines administration systems should be interfaced with such a process

HSIB makes the following safety observations:

Safety observation O/2019/039:

The use of paper and electronic systems in parallel should be minimised to reduce the risk of error caused by multiple data entry/retrieval sources.

Safety observation O/2019/040:

The practice of documenting only newly prescribed medication on discharge summaries should be reviewed from a patient safety and medicines management perspective.

Safety observation O/2019/041:

Counselling of patients newly commenced on a direct oral anticoagulant is critical to the safe use of these medicines. It would be helpful if NHS trusts reviewed this practice paying particular consideration to the communication of changes in medication and the initiation of new medications.

Safety observation O/2019/042:

There may be benefit for healthcare professionals to receive training in handover communications which should include integrating clinical information with full medicines information, and to share this information with patients and carers in writing and verbally.

Safety observation O/2019/043:

During the implementation of any new digital system, benefits may be realised by redesigning work practices to ensure the new system is fully embedded, with staff training/engagement to support this.

Safety observation O/2019/044:

It would be beneficial to the users of electronic prescribing and medicines administration systems if the system vendors raised awareness of the safety limitations of their products and had a system for collating safety feedback to inform future development and a mechanism for sharing feedback with other users.

Safety observation O/2019/045:

The processes for medicines reconciliation in the community would benefit from being reviewed, taking into account the intent for practice-based pharmacists outlined in NHS England's Long Term Plan (NHS England, 2019).

Safety observation O/2019/046:

National, peer-reviewed, standardised lists of alerts for clinical decision support systems should be the gold standard, to enable consistency of approach and to promote evidence-based safety improvements.

Safety observation O/2019/047:

In acute trusts where digital systems are in place, the prioritisation of medicines reconciliation and medication reviews supports the consistent delivery of these core functions, across seven-day services.

HSIB notes the following safety action has been implemented:

Safety action A/2019/017:

The National Academic Health Science Networks Medicines Optimisation Network has been commissioned by NHS England to support the roll-out of Transfers of Care Around Medicines across England.

7. Appendix 1: Glossary

Glossary

Academic Health Science Network (AHSN)	The 15 Academic Health Science Networks were established by NHS England in 2013 to spread innovation at pace and scale, improving health and generating economic growth.
Acute medical unit (AMU)	Also known as an acute admissions unit or medical assessment unit, this is a short-stay department in some hospitals, that may be linked to the emergency department, but functions as a separate department.
Acute oncology	Refers to the management of the unexpected care needs of the patient with cancer, including emergency situations and the acutely unwell patient.
Alert fatigue	This is a condition caused by over-alerting electronic system users resulting in them paying less attention to warnings.
Anticoagulant	Anticoagulants, commonly referred to as blood thinners, are medicines that prevent or reduce coagulation of blood, prolonging the time it takes for blood to clot.
Atrial fibrillation	An abnormal heart rhythm.
Cardiac catheterisation suite	An examination room in a hospital or clinic with imaging equipment used to visualise the heart and treat any abnormality found.
Cardiac/cardiology ward	This ward looks after patients who have a problem with their heart.
Clerking	Taking a patient's complete history, performing an examination, recording all in the patient's notes, and writing a problem list and a care plan.
Clinical decision support (CDS) systems	Provide knowledge and person-specific information, intelligently filtered or presented at appropriate times. Tools include computerised alerts and reminders.
Closed loop medication management (CLMM)	A CLMM system is a fully electronic medication management process that integrates automated and intelligent systems to manage the process of prescription, dispensing and administration of medicines, and seamlessly document all the relevant information.
Community pharmacy	Local pharmacies in the community.

Computerised provider order entry (CPOE) system	Electronic prescribing system in the United States.
Computed tomography (CT) scan	Refers to a computerised x-ray imaging procedure, used to create detailed images of the inside of the body.
Coronary care unit (CCU)	A hospital ward specialising in the care of patients with various types of heart conditions that require continuous monitoring and treatment.
Development of the Patient safety incident management system (DPSIMS)	An ongoing project to upgrade the systems used to record and learn from incidents in NHS care.
Digital maturity assessment	Measures how well secondary care providers in England are making use of digital technology, to achieve a health and care system that is paper-free at the point of care.
Direct oral anticoagulants (DOAC)	A group of anticoagulants (blood thinners), given by mouth, in tablet form.
Dm+d	A dictionary of descriptions and codes which represent medicines and devices in use across the NHS.
Electrocardiogram (ECG)	A simple test used to check the heart's rhythm and electrical activity.
	Diane phoned the crisis team reporting she was feeling overwhelmed and felt she was having an anxiety attack.
Electronic health record (EHR)	An electronic health record is the systematised collection of electronically-stored health information for a patient, which can be shared across different health care settings.
Electronic prescribing and medicines administration (ePMA) system	The use of electronic systems to enable and improve the communication of prescriptions, aiding the choice, administration and supply of a medicine, and to provide an audit trail of the entire process.
ePRaSE	A simulation tool that will enable organisational assessment of how well systems have been locally configured.
Global digital exemplar (GDE) trusts	An NHS provider delivering improvements in the quality of care, through the use of digital technologies and information.
Health information exchange (HIE)	

	Enables care professionals to exchange and view patient data, based on an electronic health record system.
	1330hrs - ED Doctors assessment. ParvoLax infusion prescribed.
Health Information Technology (HIT)	The application of information technology to the collection, storage, processing, retrieval, and communication of information relevant to patient care within a health care system.
Interfacing	A strategy that involves linking standalone systems which have been developed separately by different suppliers for different purposes.
Interoperability	The capacity to exchange, interpret and store data to common standards.
Low molecular weight heparin (LMWH)	A group of anticoagulants (blood thinners), given by injection.
Medical assessment unit (MAU)	Also known as an acute medical unit or an acute admissions unit, this is a short-stay department in some hospitals, that may be linked to the emergency department, but functions as a separate department.
Medicines optimisation	A person-centred approach to safe and effective medicines use, to ensure people obtain the best possible outcomes from their medicines.
Medicines reconciliation	Defined by the Institute for Healthcare Improvement as the process of identifying an accurate list of a person's current medicines and comparing them with the list currently in use, recognising any discrepancies and documenting any changes.
	Ambulance called as Diane had been drinking and there was a suspicion she had taken an overdose which proved unfounded.
Medicines use reviews (MUR)	A planned face-to-face consultation between a pharmacist and a patient to discuss their medicines.
Multimodular systems	Multiple modules in one system, for example electronic prescribing linked with stock control, a patient administration system and other clinically important information.
New medicines service (NMS)	A scheme for patients who are newly prescribed a medicine to treat a long-term condition, whereby a local

	pharmacist provides additional help and advice about the medicine.
NHS Long Term Plan	A document published by NHS England on 7 January 2019, which sets out the priorities for healthcare over the next 10 years.
NHSX	A government body established to drive digital transformation and lead IT policy across the NHS by bringing together teams from the Department of Health and Social Care (DHSC), NHS England and NHS Improvement into one central unit.
Over the counter (OTC) medicines	Medicines that can be bought without a prescription from a healthcare professional.
Palliative care	Treatment, care and support for people with a life-limiting illness.
Prescribed medicines	Medicines prescribed for an individual person/patient by a healthcare professional.
Primary care	Healthcare provided in the community for people making an initial approach to a medical practitioner or clinic for advice or treatment.
Repeat medications	A prescription for a medicine that you have taken before or that you use regularly.
Respiratory medicine	Concerned with the diagnosis and treatment of a wide variety of diseases of the airway and lungs, their linings and blood vessels, and the muscles and nerves required for breathing
Safety Thermometer	A measurement tool for improvement in health care, which focuses on the most common harms to patients.
Secondary care	Sometimes referred to as 'hospital and community care', it can either be planned (elective) care, or urgent and emergency care.
SNOMED CT	A structured clinical vocabulary for use in an electronic health record.
Summary care record (SCR)	Electronic records of patient information created from GP medical records.
Taxonomy	A scheme of classification.
Tertiary care	Refers to highly specialised treatment, including cancer management.

To take away (TTA) medication	Medicines given to the patient to take home, on discharge from hospital.
Transfer of care around medicines (TCAM)	A secure electronic interface between hospital IT systems and community pharmacies resulting in data being provided promptly to the community pharmacist.
Vendor	Supplier (in this context, a commercial organisation who develop software to sell to the end user).
Workflow	Sequence of processes within a system through which work passes from initiation to completion.

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