Weight-based medication errors in children

Independent report by the Healthcare Safety Investigation Branch I2020/026

February 2022
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About HSIB

We conduct independent investigations of patient safety concerns in NHS-funded care across England. Most harm in healthcare results from problems within the systems and processes that determine how care is delivered. Our investigations identify the contributory factors that have led to harm or the potential for harm to patients. The safety recommendations we make aim to improve healthcare systems and processes, to reduce risk and improve safety.

We work closely with patients, families and healthcare staff affected by patient safety incidents, and we never attribute blame or liability.

Considerations in light of coronavirus (COVID-19)

A number of national investigations were in progress when the COVID-19 pandemic significantly affected the UK in 2020. Much of the work associated with developing the investigation reports necessarily ceased as HSIB’s response was redirected.

For this national report, while the learning described has not changed due to COVID-19, the processes HSIB used to engage with staff had to be adapted. This included fewer face-to-face interviews and interactions and an increased use of virtual interviewing. Owing to the nature of this investigation there was no need to visit clinical areas to observe work in practice.

A note of acknowledgement

We are grateful for the ongoing support and involvement of the family of Felicity, the patient whose experience is central to this report. We would also like to thank the healthcare staff who engaged with the investigation for their openness and willingness to support improvements in this area of care.
About Felicity

Felicity lives with her mum, step-dad, and brother. She is not independently mobile and is non-verbal, which causes her frustration at times. Despite these challenges, Felicity is learning to adapt and adjust with the help of a wheelchair/pushchair. Her ability to use an iPad to play games is being channelled into the development of a ‘communication board’ so that her voice can be heard.

Felicity is loving, affectionate and bubbly, and enjoys 80s music. She is now attending school, which she loves, especially the swimming pool.

About this report

This report is intended for healthcare organisations, policymakers, and the public to help improve patient safety in relation to the prescribing of medicines for children based on their weight. For readers less familiar with this area of healthcare, terminology and electronic prescribing and medicines administration (ePMA) systems are explained in the ‘Background and context’ section, and in explanatory text and graphics in sections 4 and 5.
Our investigations

Our investigators and analysts have diverse experience of healthcare and other safety-critical industries and are trained in human factors and safety science. We consult widely in England and internationally to ensure that our work is informed by appropriate clinical and other relevant expertise.

We undertake patient safety investigations through two programmes:

**National investigations**

Concerns about patient safety in any area of NHS-funded healthcare in England can be referred to us by any person, group or organisation. We review these concerns against our investigation criteria to decide whether to conduct a national investigation. National investigation reports are published on our website and include safety recommendations for specific organisations. These organisations are requested to respond to our safety recommendations within 90 days, and we publish their responses on our website.

**Maternity investigations**

We investigate incidents in NHS maternity services that meet criteria set out within one of the following national maternity healthcare programmes:

- Royal College of Obstetricians and Gynaecologists’ ‘Each Baby Counts’ report
- MBRRACE-UK ‘Saving Lives, Improving Mothers’ Care’ report.

Incidents are referred to us by the NHS trust where the incident took place, and, where an incident meets the criteria, our investigation replaces the trust’s own local investigation. Our investigation report is shared with the family and trust, and the trust is responsible for carrying out any safety recommendations made in the report.

In addition, we identify and examine recurring themes that arise from trust-level investigations in order to make safety recommendations to local and national organisations for system-level improvements in maternity services.

For full information on our national and maternity investigations please visit our website.
Executive Summary

This investigation explored patient safety issues that relate to prescribing, dispensing and administering medications to children. Studies show that prescribing errors are the most frequent type of medication error in children’s (paediatric) inpatient healthcare settings. Prescribing for children is complex, because prescriptions must be tailored to the individual child based on factors such as weight, age, gestation and body surface area. Prescribing errors can lead to unsafe doses of medications, potentially causing serious harm or death.

A real patient safety incident, referred to as ‘the reference event’, was used to examine issues around prescribing for children. The reference event involved Felicity, a girl who was given 10 times the intended dose of a medicine on several occasions during a stay in hospital.

The investigation also looked at the safety issues around prescribing for children in the context of national policy and guidance.

The reference event

Felicity was 4 years old at the time of the incident. She was admitted to a cardiology (heart) ward in mid-February. She was diagnosed with fluid on her lungs. This is a recognised and common complication of a complex heart procedure which Felicity had had 3 months previously.

During her stay in hospital, Felicity underwent a further complex heart procedure and was under the care of the paediatric cardio-respiratory team – a specialist team which looks after children with heart and lung problems. In March, she was diagnosed with a blood clot in her right leg, known as a deep vein thrombosis (DVT).

Doctors identified that there was a need to balance the risk between providing blood thinning medicine for Felicity’s heart condition and to treat the DVT, without increasing the possibility of a bleed on the brain. A multidisciplinary team agreed that Felicity should be prescribed 100 units/kg of dalteparin twice daily. This recommendation was in line with the British National Formulary for Children, which is the guide clinicians refer to when prescribing, dispensing and administering medication for children.

Felicity’s weight at the time of the prescription was 15.2kg, so the dose for administration was calculated manually by the prescriber as being 15.2 x 100 = 1,520 units twice daily, rounded down to 1,500 units twice daily. The dalteparin was then inadvertently prescribed at a dose of 15,000 units twice daily, using the Trust’s electronic prescribing and medicines administration system (ePMA), due to the prescriber not making the necessary manual alteration to the dose within
the system. The ePMA system itself and the subsequent processes for approval of the prescription and the dispensing, checking and administration of the medicine did not identify the incorrect prescription. This meant Felicity received 15,000 units of dalteparin (10 times the dose intended) on 5 occasions over one weekend. A subsequent CT scan showed that Felicity had a new right-sided bleed in the brain.

**Wider investigation**

The acute NHS trust where the reference event took place (referred to as ‘the Trust’) notified HSIB of the incident. The Trust also escalated the incident, reporting it on the Strategic Executive Information System (a database of serious patient safety incidents), and conducted a serious incident investigation. HSIB gathered additional information and assessed the incident against its investigation criteria. HSIB decided to progress to a national investigation.

The national investigation focused on:

- An exploration of the factors that both support and inhibit multidisciplinary co-ordination and decision-making, including communication of critical decisions in relation to weight-based medications in support of a child’s treatment.
- Understanding the factors which contribute to a reduction in the effectiveness of checking as a barrier to medication errors, including those that result in workarounds.
- The implementation of ‘off-the-shelf’ electronic prescribing systems in specific contexts, particularly paediatric prescribing.

**Findings**

**Multidisciplinary co-ordination and decision-making**

- Email discussions may be being used for discussion of critical decisions in relation to patient care, with limited dissemination to the wider team.
- There is limited standardisation of handovers, ward rounds (visits to each patient in a ward to review and discuss their care) and huddles (short, focused staff briefings), in terms of which members of the multidisciplinary team are involved, and how they are conducted for maximum effectiveness.
- There is limited national guidance on the management of ward rounds in paediatrics (as is available for adult care).
- There is variability in hospital clinical pharmacy provision. This reduces the availability of ward-based pharmacists and may result in a dispensary-based service only at weekends.
• Nursing staff perceived themselves to be the final barrier to prevent an incorrect dose prior to the administration of medication, resulting in them feeling accountable for the error.

Factors undermining the effectiveness of checking as a barrier

• Multiple cues influenced whether staff considered medication doses to be correct.

• Processes for the checking of medicines varied without evidence of what constituted the most effective process.

• The distinction between verification and checking was not explicit, that is, checking that the prepared medication correlated with the prescription versus verification that the prescription was appropriate against a standard.

• The environments within which staff prepared and checked medicines influenced their performance.

• Environmental layouts and limited resource resulted in workarounds.

Implementation of ‘off-the-shelf’ electronic prescribing systems in specific contexts

• There are no standards for what safety-critical functionality should be available in ePMA systems configured for use in paediatrics (for example, the use of weight-based dose bands, where individually calculated doses are rounded to a set of predefined doses).

• The use of free-text comment boxes in ePMA systems is not specified or standardised.

• The usability and functionality of ePMA systems need to be assessed through user-testing across a range of different settings.

• Local configuration of ePMA systems potentially introduces variability and risks if not undertaken with clear understanding of the potential hazards and their mitigations.

• Software could qualify as a medical device if it meets the definition, set out in the Medical Device Regulations 2002 (as amended).

• Local governance of ePMA systems is limited with evidence of gaps in training and an absence of safety cases (reports that provide a transparent, evidence-based argument for why a system is safe for use in a particular setting).
HSIB’s safety recommendations are directed to a specific organisation for action. They are based on information derived from the investigation or other sources, such as safety studies, and are made with the intention of preventing future, similar events.

The HSIB investigation focused on errors in the prescription of weight-based medication for children, in the context of electronic prescribing and medicines administration (ePMA) systems. The responsibility for ensuring the safety of medicines prescribing and administration is with individual trusts, with input from NHSX, NHS Digital and the Medicines and Healthcare products Regulatory Agency (MHRA). Therefore, safety recommendations made in this respect are directed towards those organisations. Different parts of the healthcare system have also been identified to address the other risks highlighted in this investigation relating to paediatric ward rounds and second-checking processes. Safety recommendations have been directed to them accordingly.

**HSIB makes the following safety recommendations**

### Safety recommendation R/2022/175:

HSIB recommends that the Royal College of Paediatrics and Child Health identifies the best practice principles for effective paediatric ward rounds in relation to medicines, and disseminates them to its members.

### Safety recommendation R/2022/176:

HSIB recommends that the National Institute for Health Research assesses the priority, feasibility and impact of future research on processes for second checking medication, and considers the most appropriate way of building up the evidence base on this topic.

### Safety recommendation R/2022/177:

HSIB recommends that the Medicines and Healthcare products Regulatory Agency works with the manufacturers of electronic prescribing and medicines administration systems to provide guidance on their obligations under the Medical Devices Regulations 2002 (as amended).

### Safety recommendation R/2022/178:

HSIB recommends that NHS Digital and NHSX promote the organisational requirements for digital clinical safety, including organisations’ responsibilities in terms of safety cases and clinical safety officers, to encompass system functionality and processes.

### Safety recommendation R/2022/179:

HSIB recommends that the Care Quality Commission (CQC) reviews whether a provider’s assurance of its compliance with the Clinical Risk Management standard specific to electronic prescribing and medicines administration systems in healthcare, can form part of the CQC’s developing regulatory model.
HSIB makes the following safety observations

**Safety observation O/2022/145:**
It may be beneficial if a standard format for multidisciplinary care reviews (including handovers and huddles) was adopted by healthcare organisations, with a shared understanding of the management plans for individual patients.

**Safety observation O/2022/146:**
It may be beneficial for trusts to consider creating the optimum environment and conditions to support medication checking processes, by reducing distractions and interruptions to a minimum.

**Safety observation O/2022/147:**
It may be beneficial for trusts to evaluate the use of the free-text fields in electronic prescribing and medicines administration systems and to define their purpose, to ensure they are used in the way intended and used consistently to prevent unintentional consequences.

**Safety observation O/2022/148:**
It would be beneficial if manufacturers of electronic prescribing and medicines administration systems conducted assessments of their products against the relevant regulation, to identify whether their systems meet the definition of a medical device and, if so, ensure associated regulatory requirements are met.

**Safety observation O/2022/149:**
It would be beneficial if those organisations procuring electronic prescribing and medicines administration systems ascertain whether the product they are procuring meets the definition of a medical device and, if so, whether the manufacturer meets the expected regulatory requirements and the product is either UKCA marked or CE marked to demonstrate conformity.

**Safety observation O/2022/150:**
It may be beneficial for healthcare organisations to ensure that any clinical staff responsible for the day-to-day management and configuration of electronic prescribing and medicines administration systems access clinical safety risk management training.

In addition, HSIB made the following safety observation in an interim bulletin (March 2021)

**Safety observation O/2021/097:**
It would be beneficial for trusts that have adult and paediatric prescribing supported through the same ePMA system to ensure they have adequately risk assessed the way in which the system supports the calculation of doses to ensure that adult doses do not require manipulation for paediatric patients.
1 Background and context

This section provides the background and context for the aspects of healthcare covered in this investigation. The investigation considered the care of a child in hospital who received medication prescribed via an electronic prescribing and medicines administration (ePMA) system (see 1.3).

1.1 Medication errors in paediatrics

1.1.1 The prescribing and administration of medicines are among the most common healthcare interventions. However, it is estimated that 237 million medication errors occur at some point in the medication process in England each year; 66 million are potentially clinically significant (Elliot et al, 2020). In paediatrics (children’s healthcare), 13% of prescriptions written for children contain errors (Ghaleb et al, 2010).

1.1.2 Medication errors can occur at the procurement (ordering) stage in addition to the prescribing, dispensing, administration and monitoring stages of the medication process. Specific factors complicate prescribing and administration of medicines for children and these factors can contribute to errors. Some of these factors are shown in figure 1 (Conn et al, 2019).
Figure 1 Factors leading to prescribing errors in paediatrics
(adapted from Conn et al, 2019) (In this figure, the term ‘off-licence prescribing’ refers to the use of medicines outside of the indications for which they are licensed by national regulatory bodies).

Children’s fundamental differences

Prescribing errors

Mechanisms

- Children’s fundamental differences
- Individualised dosing and calculations
- Off-licence prescribing
- Medication formulations
- Experience working with children
- Communication with children
1.1.3 The World Health Organization has previously highlighted the challenge of medication errors and in 2017 launched its third Global Patient Safety Challenge, ‘Medication Without Harm’ (World Health Organization, 2017). This aimed to reduce the global burden of severe and avoidable medication-related harm by 50% over 4 years. In response, the Medicines Safety Improvement Programme (NHS England and NHS Improvement, 2019) was established. The aim was to address the most common causes of severe harm related to medication by influencing safety culture, safety systems and high-risk medicines in common use. It is also supporting the development and implementation of ePMA systems as part of this programme of work.

1.2 Weight-based prescribing

1.2.1 Because children vary in terms of body size, weight, and their ability to process medications as their bodies develop, prescriptions for children must be individualised. Calculations are typically based on a child’s weight, age, gestation (the time between conception and birth) or body surface area. A child’s organ function (how efficiently their kidneys/liver are working) and underlying or new illnesses may also affect the dose calculation, which adds to the complexity.

1.2.2 A scoping review by Conn et al (2019) found that junior doctors frequently miscalculate doses, with tenfold errors (prescribing ten times the amount intended) mostly arising from decimal point inaccuracies. Only around half of doctors double-checked calculations.

1.2.3 In organisations where ePMA systems are used, calculations are often still undertaken manually. This is because not all systems have an automated calculation function, and some systems have an automated calculation but staff do not use it (Shah and Chui, 2019).

1.3 Electronic prescribing and medicines administration (ePMA) systems

1.3.1 An ePMA system is an electronic medication management system which replaces paper medication charts. It should support the end-to-end management of medication, from prescribing and dispensing, through to administration (this is known as ‘closed loop medicines management’). An ePMA system also supports medicines reconciliation and is linked to electronic patient records for clinical decision support functionality, for example, alerting.
1.3.2 As outlined in the report ‘Electronic prescribing and medicines administration systems and safe discharge’ (Healthcare Safety Investigation Branch, 2019), ePMA systems are able to reduce certain prescription errors. However, they have also created new types of errors (NHS Connecting for Health, 2009). The reduction in medication errors depends on optimising commercial ePMA 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).

1.3.3 A study by Puaar and Franklin (2018) found that 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. The study described three components of an ePMA system that may contribute to errors. These were ePMA system functionality and design; organisational decisions around ePMA system implementation and use; and different approaches to prescribing in the context of the electronic system.

1.3.4 In relation to terminology used in the report, the UKCA (UK Conformity Assessed) marking is a new UK product marking that is used for goods being placed on the market in Great Britain (Department for Business, Energy and Industrial Strategy, 2020). It covers most goods which previously required the CE marking. It came into effect on 1 January 2021.

1.4 Medication checking processes and terminology

1.4.1 Healthcare staff use various processes to check that they are giving the right medication to the right patient. In this report, the generic term used to describe these processes is ‘second checking’. However, as outlined later in the report, there are different terms and definitions used in relation to the checking processes prior to the administration of medication.

1.4.2 The second checking of medication prior to administration has been embedded in nursing practice for decades as an intervention to safeguard against errors and associated harm (Westbrook et al, 2020). In children’s health services, second checking is widely applied given the complexity of medication management, and the vulnerable nature of patients.

1.4.3 The second-checking process involves two registered healthcare professionals checking medication prior to administration. To prevent errors in administration, nurses are encouraged to check that they have the correct patient, medication, route (for example, by mouth or injection), time, and dose. This involves a step-by-step process which should be defined at an
organisational level, according to the Royal College of Nursing (2020). Because the process is defined by individual organisations, practice varies and there is no standardised approach.

1.4.4 In relation to terminology used in the report:

• ‘Double-checking’ is the more generic term used to describe some form of second check undertaken by a second individual.

• ‘Single-person double-checking’ is the term used to describe one person undertaking both checks.

• ‘Independent double-checking’ involves both the requesting and checking nurse separately performing a check without sharing information.

• ‘Primed double-checking’ involves two people either working together or influencing the checking process by suggesting what the checker should find.
2 The reference event

This investigation used the following patient safety incident, referred to as ‘the reference event’, to examine the issue of weight-based medication errors in children.

Background

2.1 Felicity was diagnosed at birth with a complex heart condition and associated health problems which required multiple operations and medical interventions. She also had developmental delay.

2.2 In the October before the reference event, Felicity underwent a heart procedure. Following this, Felicity had neurological symptoms (disorders of the brain and nervous system). A CT scan of her head (a scan which uses X-rays and a computer to create detailed images of the inside of the body) showed evidence of a lack of oxygen to her brain on the right side – that is, she had had a stroke. This had an impact on her functional ability (ability to perform activities of daily living) and confidence.

Before the reference event: February to March

2.3 Felicity was transferred from her local hospital to a regional centre for treatment of a large right-sided pleural effusion (fluid on the lungs). This is a recognised and common complication of the heart procedures she had undergone. She was on warfarin (an anticoagulant medication to thin her blood) following the surgical procedure in the October prior to the reference event.

2.4 Felicity was diagnosed with a suspected lower respiratory tract infection, excess fluid in her lungs and possible further complications arising from her previous heart surgery. She had a right-sided chest drain inserted (a tube to drain off the fluid from her lung) and was transferred to the paediatric intensive care unit (PICU).

2.5 PICU provides high dependency and intensive care. A child would be admitted to the PICU if intubated (having their breathing supported), or if one-to-one nursing care was essential until their condition could be stabilised and it was considered appropriate for them to receive routine ward-based care.
2.6 Felicity was transferred from PICU to a children’s cardiology ward. This 17-bedded ward provided specialist care for children with heart conditions and was a ‘step-down’ area for those who had sufficiently recovered from heart surgery to not require intensive care. This was the only children’s ward in the Trust using an electronic prescribing and medicines administration (ePMA) system at the time of the reference event.

2.7 The parents raised concerns to the ward staff that Felicity had experienced increased episodes of unresponsiveness and eye rolling over the preceding weeks. An electroencephalogram (EEG) (a test used to find problems related to electrical activity of the brain) was undertaken, and the results were found to be within the expected ranges.

2.8 A meeting of the different healthcare professionals involved in Felicity’s hospital care (known as a multidisciplinary team meeting) was held to discuss Felicity’s condition and it was decided that she should have a further heart procedure in view of her prolonged pleural effusion. Her warfarin medication was stopped and she was started on heparin (another anticoagulant) in preparation for the procedure.

2.9 The procedure was undertaken in the catheter laboratory and took approximately 12 hours. During this time, Felicity had a 40-second cardiac arrest (her heart stopped) and significant bleeding, needing blood transfusions. Because of these complications, Felicity was transferred to PICU after the procedure.

2.10 On PICU, Felicity’s sedation was reduced and as she became more active, it was noted that she had developed weakness in her limbs on her right side. A CT scan showed changes in the brain that were the result of a further stroke and bleeding in the brain.

2.11 A subsequent MRI scan (which produces detailed images of the organs and tissues in the body), showed an extensive middle cerebral artery stroke (a stroke in a specific area of the brain) with subsequent bleeding in the brain. Felicity was started on medication to prevent seizures because she was at increased risk of convulsions.

2.12 Following the MRI scan, the multidisciplinary team considered Felicity’s anticoagulant (to help prevent blood clots) medication. A decision was made to continue the intravenous heparin for one week, and then to consider changing to low molecular weight heparin (LMWH).

2.13 Felicity had a seizure and was given medication to treat this. A CT scan of her head was undertaken and this showed that the bleeding in the brain had extended. She was transferred back to PICU.
2.14 Felicity’s condition was discussed with the neurosurgery team at a regional specialist centre, who advised a non-surgical approach to treatment. The team also advised stopping the anticoagulation treatment, so the intravenous heparin was discontinued.

2.15 At this point Felicity was very unwell. The family recall there was a discussion with the organ donation team, in anticipation of her condition deteriorating further, potentially leading to a withdrawal of active treatment and the need for end-of-life care. Felicity was blessed by the chaplain in accordance with her parents’ wishes.

2.16 Felicity’s condition then stabilised, and she was transferred back to the cardiology ward.

**Events leading up to and following the medication error**

**9 March**

2.17 A consultant paediatric neurologist (specialist in brain and nervous system) and a consultant haematologist (specialist in blood and bone marrow) discussed plans for Felicity’s care, due to the improvement in her condition and the need to make longer-term treatment plans. A decision was made to put Felicity on a medication to prevent a blood clot (clopidogrel) for 2 weeks, starting from 12 March.

**10 March**

2.18 Two days before starting the clopidogrel treatment, it was noted that Felicity had swelling in her right leg. A bedside scan at 15:40 hours confirmed a right-sided deep vein thrombosis (DVT) (a blood clot in her leg).

**11 March**

2.19 Following identification of the DVT, the consultant paediatric neurologist and the consultant haematologist discussed treatment options. Felicity was given one dose of clopidogrel during the evening.

**Friday 13 March at 09:47 hours**

2.20 The consultant paediatric neurologist sent a plan for Felicity’s treatment by email to the consultant paediatric neurologist, consultant haematologist, neurosurgeon (specialist in surgery on the brain and spinal cord), cardiology registrar and Consultant Paediatric Cardiologist 1 (specialist in heart and blood vessels). The plan was to start Felicity on anticoagulant
medication (dalteparin), starting from 13 March 2020, at a dose of 100 units/kg/twice a day. This was in accordance with the British National Formulary for Children (BNFC), which provides guidance on best practice, and enables safe medication use in children.

2.21 The email stated that the first dose should be given immediately (10:00 hours) and subsequent doses from 18:00 hours onwards every 12 hours. It also included a plan for an Anti-Xa level (a blood test to check the efficacy of the dalteparin) to be taken on 16 March 2020 at 09:00 hours.

11:48 hours

2.22 A specialist trainee 2 doctor (ST2) prescribed dalteparin following a request by Consultant Paediatric Cardiologist 1, who was part of the email correspondence. The ST2 checked the BNFC, confirmed the dose and calculated 1,520 units, which he then rounded down to 1,500 units for ease of administration.

2.23 The ST2 completed the prescription on the electronic prescribing and medicines administration (ePMA) system. He then selected 15,000 units of dalteparin which comes in a pre-filled syringe. He intended to amend the dose to 1,500 units twice daily, but omitted to do so. The ST2 typed ‘as per discussion with haematology’ in the comment box, to reflect the multidisciplinary team discussions. The prescription was then completed, with the 10 times intended dose of the medication remaining uncorrected.

2.24 A specialist pharmacist (SPI) checked the dose of dalteparin on the ePMA system. She initially thought the dose was high and checked with the BNFC. She noted the 15, not recognising that the prescription stated 15,000 rather than 1,500, and completed the pharmacy checking of the dalteparin.

2.25 A pharmacy technician prepared the dalteparin for dispensing, after the generation of a worksheet from the ePMA system. A manual check did not identify any concerns with the dose and dalteparin 15,000 units was dispensed in prefilled syringes.

2.26 Following the ward round, a briefing took place with the multidisciplinary team. Nurse 1 told the investigation that pharmacy had rung the ward. She said someone from pharmacy had telephoned to confirm receipt of the dalteparin prescription, recognising the dose was high, but that it was approved and the ward staff need not be concerned about it. This telephone call was undocumented. Pharmacy staff did not speak directly to Nurse 1.
19:08 hours

2.27 Nurse 1 prepared the dalteparin injection using the ePMA system and described checking the medicines guide. Nurse 1 selected a preloaded 15,000 unit syringe and checked the dose with Nurse 2 before administration. Nurse 2 questioned the large dose, but Nurse 1 confirmed it had been discussed with pharmacy. It was also noted by Nurse 2 that haematology had approved the dose (via a note in the free-text box on the ePMA system) and she confirmed with a second check that it was the correct dose to administer.

2.28 Nurse 1 administered all of the content of the preloaded syringe via subcutaneous injection (an injection under the skin), in line with the pharmacy label instructions on the box, which included Felicity’s details.

Saturday, 14 March at 06:35 hours

2.29 Nurse 3 prepared the next dose of dalteparin and checked with Nurse 4, who commented on the very high dose. Nurse 3 confirmed it was a high dose, but said it had been discussed with haematology and the annotations were noted in the ePMA system.

10:10 hours

2.30 Consultant Paediatric Cardiologist 2 saw Felicity on the ward round. There were no new neurological concerns and her chest was clear. The consultant discussed Felicity's medications during the ward round, but did not directly access the ePMA system prescription on this occasion.

22:00 hours

2.31 The dalteparin dose due at 18:00 hours had not been given, so Nurse 3 (who was on a night shift) got the dalteparin syringe from the box with Felicity’s name on it. Nurse 5 (another night shift nurse) provided a second check and challenged the “whacking” dose. Nurse 3 was assured by the dose prescribed on ePMA, noting the comment regarding haematology on the system and also the check by pharmacy. Nurse 5 checked the BNFC and noted the dalteparin was a very high dose. However, in their experience poorly patients sometimes received medications outside the BNFC parameters. The dalteparin was given.
Sunday, 15 March at 06:18 hours

2.32 Nurse 3 prepared the next dose of dalteparin and checked the medication with Nurse 5 before administering it to Felicity.

Approximately 07:30 hours

2.33 During the nursing handover, the ePMA system was reviewed and Nurse 6 questioned Nurse 3 on the very high dose of dalteparin. Nurse 3 explained that they knew it was high but that it had been verified by doctors, pharmacy, and haematology.

09:50 hours

2.34 A ward round was undertaken by a specialist registrar (SpR) in paediatric cardiology. Alongside the entry in the medical records is a list of medications including dalteparin. It is unclear whether the handwritten documentation says 1000/kg/bd or 100U/kg/bd (namely, either zero or U for ‘unit’ after 100). It is not clear whether a medication review was undertaken.

17:50 hours

2.35 The next dose of dalteparin was due to be given by Nurse 6, with Nurse 7 as second checker. The BNFC was checked and it was noted that the 15,000 dose was out of range. The ePMA system was reviewed and it was noted that the dose had been seen by doctors, pharmacy, and haematology. Nurse 6 gave Felicity the dalteparin.

22:00 hours

2.36 While preparing dalteparin for another patient (from a different box of the medicine with an orange banner), Nurse 8 noticed the box of dalteparin for Felicity with a purple banner. She thought this was unusual as it was a dose of dalteparin (adult dose) not routinely stocked on the children’s ward.

22:20 hours

2.37 Felicity was being fed through a nasogastric tube - a tube that goes through the nose directly into the stomach. The ST2 reviewed Felicity because she had blood in her nasogastric tube aspirate (fluid in the tube from her stomach), which was thought to be caused by irritation/trauma of the lining of her stomach. The plan was for further review if needed.
Monday 16 March at 03:00 to 03:30 hours

2.38 Felicity's feed was briefly discontinued due to a large vomit with blood present.

2.39 During her break, Nurse 8 reflected on Felicity's purple bannered box that she had seen earlier in the night shift, combined with the bloodstained vomit, and felt she needed to investigate this further. Nurse 8 checked on the ePMA system and calculated the dose against the BNFC, following which she identified the overdose. Nurse 8 discussed this with the PICU SpR, who informed the nurses to withhold the morning dalteparin and await a review by the day team.

06:28 hours

2.40 The dalteparin was not given to Felicity pending a clinical review, due to the query identified by Nurse 8. It was highlighted at this point that Felicity had received 10 times the intended dose of dalteparin on 5 occasions over a period of 3 days.

08:14 hours

2.41 The ST2 was made aware of the error and immediately cancelled the dalteparin prescription. It was noted that Felicity was unsettled, she had facial droop on the left side of her face, was unable to weight bear and had experienced a short seizure. An urgent CT scan was undertaken, which showed a new right-sided bleed in the brain.

21:45 hours

2.42 The SpR and consultant haematologist discussed giving Felicity protamine sulfate (an antidote to reverse the activity of heparin). This was given, following which Felicity had an allergic reaction, requiring medication to improve her symptoms.

Day 5: Tuesday 17 March

2.43 Felicity was transferred to PICU for neuroprotective measures (protecting the nervous system from injury and damage).

Day 11 onwards

2.44 Felicity was transferred back to the cardiology ward, where she was noted to have right-sided weakness. She was discharged home on 10 June.

2.45 The investigation heard from Felicity's family that she has been unable to walk or speak since this inpatient episode, which she was able to do beforehand. She attends hospital on a regular basis, as an outpatient and an inpatient.
3 Involvement of the Healthcare Safety Investigation Branch

This section outlines the evidence and methods used in the investigation process.

3.1 Method

The investigation was completed between August 2020 and October 2021.

3.1.1 Investigative approach

HSIB adopts a no-blame approach to all investigations. It considers the healthcare system in its entirety to identify the factors that have contributed to the patient safety incident.

This investigation used the Systems Engineering Initiative for Patient Safety (SEIPS) and the Functional Resonance Analysis Method (FRAM), (see 3.1.7).

3.1.2 Investigation team

The HSIB investigation team was multidisciplinary:

- In relation to the skills and knowledge that the investigation team applied, it had expertise associated with clinical domains and safety science.

- The team was supported by a subject matter advisor (SMA), who is a Fellow of the Chartered Institute of Ergonomics and Human Factors. Excerpts from the SMA’s human factors report are included as figures throughout the report, to support the analysis carried out by the investigation.

3.1.3 Reference event investigation

The reference event investigation required visits to the Acute NHS Trust where the patient’s care was provided.

Engagement (reference event)

Felicity’s family was contacted and interviewed to establish their perspective on the reference event. The staff directly involved in the reference event were interviewed and included:
• eight members of the nursing team from the cardiology ward
• two consultant paediatric cardiologists
• the specialist registrar (paediatric cardiology)
• the specialist trainee 2 doctor (paediatrics)
• two specialist pharmacists.

3.1.4 National investigation

HSIB launched an investigation to explore the implementation of safety improvements for reducing the number of weight-based medication errors in children. The goal of the healthcare system is to ensure that the appropriate dose of a medicine is prescribed and administered for a patient’s weight or other characteristics (see 1.2.1). The safety risk is that this does not occur and that the system does not support healthcare providers to prescribe, dispense and administer medicines safely. The safety risk is focused on paediatric care, but may be applicable to other groups of patients where medicine dose calculations are required.

Findings from the scoping investigation led to a decision to broaden the investigation and identify healthcare settings to collect further data to understand the national context.

Information was gathered from three further hospital trusts, as outlined in table 1.

Table 1 Details of further hospital trusts (national investigation)

<table>
<thead>
<tr>
<th>Healthcare setting</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children's Hospital 1</td>
<td>This comparison site was selected due to its ‘high digital maturity’ rating</td>
</tr>
<tr>
<td>Teaching hospitals NHS trust with an integral children's hospital</td>
<td>This comparison site was selected as it used the same type of ePMA system as the reference event Trust</td>
</tr>
<tr>
<td>Children's Hospital 2</td>
<td>This comparison site was selected due to its ‘very high rating of digital maturity’</td>
</tr>
</tbody>
</table>
Engagement (national investigation)

Stakeholders across the healthcare system were contacted and interviewed to establish their perspective on the national context. In addition, there was engagement with:

- contacts across the UK
- secondary care organisations in regions across England
- software manufacturers for electronic prescribing and medicines administration (ePMA) systems in healthcare.

Limitations to engagement or access to information (national investigation)

Observation visits to hospitals necessarily ceased during 2020/21 when the COVID-19 pandemic significantly affected the UK. For this investigation, even though not all of the planned observations and visits were completed, it was thought that the findings and safety recommendations were supported by the evidence gathered and analysed by the investigation.

3.1.5 Evidence gathering

Multiple sources of evidence were gathered and reviewed by the investigation, including:

- Felicity’s clinical records
- Trust policies, procedures, and practice
- the findings of the Trust’s internal incident investigation report
- relevant incidents reported to the two national patient safety incident databases: the Strategic Executive Information System and the National Reporting and Learning System
- national guidelines and standards
- literature relevant to the identified safety risks.

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

- An interview plan was developed to gather information on safety risks
- Observations were conducted and a thematic analysis was performed on the fieldnotes
- Virtual meetings were held with a number of software manufacturers.

### 3.1.6 Analysis

The analysis process had the following aims:

- To generate findings through group discussions after evidence gathering, analysis days, multi-disciplinary team working, reflections on what evidence was missing or inadequate.
- To develop visualisations of the system involved in the patient’s pathway and a timeline of the events. This assisted in recognising communications, interactions and decision making.
- To develop a comprehensive understanding of the healthcare system so that safety recommendations could be identified, and their potential impact on the system could be considered.

### 3.1.7 Analysis methods used in the investigation

Analysis methods were used to consider local and national practices, and practices evidenced in research literature. This enabled a detailed analysis of how the healthcare system influenced the reference event and allowed potential recommendations for improvement to be considered.

To help understand the healthcare system, the investigation used two methods:

1. **The Systems Engineering Initiative for Patient Safety** (Holden et al, 2013; Carayon et al, 2006). SEIPS is a framework for understanding structures, processes and outcomes and the relationships between them. SEIPS is explained in more detail in appendix 1.

2. **The Functional Resonance Analysis Method (FRAM)** (Hollnagel, 2012). FRAM aims to reflect risks within complex systems, by describing variability relative to the functions within the system and potentially modelling what is needed for everyday performance to go right. It is explained in more detail in appendix 2.
3.1.8 Verification of findings

The findings were shared with Felicity’s family, the healthcare organisations involved in the reference event, and with key stakeholders within the healthcare system. This enabled checking for factual accuracy and overall sense-checking.
4 Analysis and findings – the reference event

This section sets out the investigation’s findings in relation to the reference event. The findings are structured under headings which correspond with the Systems Engineering Initiative for Patient Safety (SEIPS) framework described in section 3 and appendix 2. SEIPS was used to define the processes of care underpinning the events that contributed to the outcomes of interest. For each process, the investigation considered the ‘work system’ factors (section 3 and appendix 2) that contributed to these processes progressing as intended or not.

Processes of interest

The medication error with dalteparin ultimately contributed to excess thinning of Felicity’s blood which then contributed to a haemorrhage (bleed) on the right side of her brain. As a result, she developed right-sided weakness and a facial droop. The investigation identified several processes, which contributed to the safety event and the outcome for Felicity (see figure 2). The investigation looked at each of the processes and identified four cross-cutting themes:

• multi-disciplinary teamworking and communication
• technology for weight-based prescribing in paediatrics
• implementation of the electronic prescribing and medicines administration (ePMA) system
• confirmation and challenge of the dose.

These themes are examined in the following sections.
Figure 2 Timeline of events (blue text indicates the focus of the investigation)

- **01** 13/2 Felicity admitted to reference Hospital
- **02** 13/3 Decision for Felicity to receive dalteparin
  - 1 Doctor prescribed Felicity dalteparin
  - 2 Pharmacy checking and dispensing of dalteparin
  - 3 Administration of dalteparin to Felicity (dose 1)
- **03** 7/3 DVT identified
- **04** 14/3 1 Administration of dalteparin to Felicity (dose 2)
  - 2 Consultant ward round
- **05** 15/3 1 Registrar ward round followed by handover ‘huddle’ with Consultant
  - 2 Administration of dalteparin to Felicity (doses 4 and 5)
- **06** 16/3 Identification of the overdose of dalteparin
- **07** 17/3 Felicity admitted to Paediatric Intensive Care Unit
- **08** 10/6 Felicity discharged home
4.1 Multidisciplinary teamworking and communication

Communication of management plans

4.1.1 The multi-specialty medical team’s discussion by email concluded that dalteparin should be prescribed at the treatment dose of 100 units/kg/dose twice a day. There was evidence of joint decision making and the communication of plans regarding the intended dose of dalteparin. However, teamworking in this context did not include the specialist pharmacy and nursing teams on the cardiology ward. The medical staff told the investigation that all professional groups were invited. However, this was at variance with the perception of other staff groups who reflected that they would not be told information on the ward round or during a ‘huddle’ (short, focused staff briefings). Some staff considered that they were not part of the discussions at all: “Emails float around and [name of professional group] are the last to hear.”

4.1.2 Correspondence by email appeared to be common practice in cardiology to facilitate discussion across different medical specialties and to generate a written record. The intention was then for these emails to be filed in the medical records. This was supported by a junior doctor who told the investigation that patient plans were either agreed on the telephone or by email, and they were not always part of these discussions. However, they would be updated separately (verbally) by the consultants to ensure they were aware of the plans.

4.1.3 Consultant Paediatric Cardiologist 1 advised the investigation that the email plan had been forwarded to more junior members of the medical team, with a request for it to be added to Felicity’s medical records. A high-level, weight-based plan was made by the consultant team for dalteparin, with the expectation that the ward doctors would undertake the calculation and prescribe a specific dose. The specialist trainee 2 doctor (ST2) inadvertently prescribed dalteparin via the ePMA system at a dose of 1,000 units/kg/dose twice a day, rather than the intended 100 units/kg/dose twice a day.

4.1.4 A free-text box on the ePMA system was completed to say, ‘as per discussion with haematology’. This was intended to reflect the multidisciplinary team discussion involving the haematology. However, it instead later served to falsely reassure the dispensing pharmacist and the nursing staff administering the medicine that there was a rationale for the unusually high dose.

4.1.5 The ST2 told the investigation that while it was not mandatory to use the free-text field for annotations, he did so frequently because nurses often queried doses. At times when a doctor may not be present on the ward (at night-time for example), comments in the free-text box provided additional information about a prescription for the nursing team.
4.1.6 In relation to pharmacy team working and communication, checking of the dalteparin prescription was undertaken by a specialist paediatric pharmacist (Specialist Pharmacist 1 (SP1)) and subsequently dispensed by a pharmacy technician. On Friday 13 March, the SP1 was covering the paediatric cardiology ward for the day. The ward normally sits under the remit of a senior advanced specialist pharmacist (Specialist Pharmacist 2 (SP2)). SP1 was covering the ward because SP2 was on leave the previous day and SP1 had covered the ward then, so SP1 provided cover for the ward on the Friday too for continuity.

4.1.7 SP1 told the investigation about a non-work issue that took place on the morning of the dalteparin dispensing, which caused her distress and meant she was away from work for a short time. The unplanned absence from her pharmacy duties created additional pressure for her, as she attempted to make up the lost time. Additionally, the pharmacy workload was described as being generally more intense on Fridays due to weekend leave, replenishing stock, and preparing discharge medicines. On this day, a third specialist pharmacist was on leave which, together with the other factors, compounded the workload pressure for the pharmacists still further.
A ‘professional check’ would be undertaken, to assess for clinical suitability and safety. This was a check that could only be performed by a pharmacist. On the ePMA system, this would generate a green tick and the annotation ‘reviewed’, alongside the pharmacist’s name.

The printed worksheet would be booked into the ‘Prescription Tracking System’ (PTS) manually by the receptionist (the PTS is not linked to the ePMA system). It would then be put into a ‘first in, first out’ pile for dispensing.

The dispenser would place the generated label on the medicines packaging, provide ancillary items (bags, spoons etc.), if required and leave the completed item(s) in its own dispensing tray within the checking area.

A ‘pharmacy checker’ would then complete a final visual accuracy check of the product, label, and expiry date.

In relation to pharmacy processes, dispensing required a number of steps and different systems:
4.1.9 In the reference event, the only communication between pharmacy and the ward was the alleged phone call from pharmacy following the dispensing of the dalteparin, to reassure staff regarding the dose. The pharmacist’s professional check would normally have been undertaken in the clinical environment, particularly for newly prescribed medicines. In the case of the reference event, SP1 undertook the professional check for Felicity’s dalteparin prescription remotely, while she was in the pharmacy department. This was due to the non-work issue alluded to in 4.1.7.

4.1.10 SP1 recalled seeing the ‘15’ and ‘as per discussion with haematology’. She was unaware of the plan to commence dalteparin, as she had not been updated from the previous day when the intention had been to start Felicity on clopidogrel. Normal practice for SP1 would have been to undertake a manual calculation to check the dose was correct. On this occasion, the calculation was not made. SP1 thought that potential factors that contributed to this omission were time constraints and being aware of previous delays regarding Felicity’s medication. Pharmacist checking is undertaken to assess for clinical suitability and the safety of medicines, which is essentially verification of the prescription (see subject matter advisor’s analysis 4 on page 58). The investigation heard that this is a common task, but requires manual calculations.

4.1.11 In relation to the dalteparin, SP1 described the choice of anticoagulant as being unusual, since a different type of anticoagulant, ‘unfractionated heparin’, was more commonly prescribed on the paediatric cardiology ward than dalteparin. The investigation heard from SP1 that dalteparin could be prescribed as a treatment (therapeutic) or preventative (prophylactic) dose. SP1 noted that the dose was unusual because it was at a therapeutic (rather than prophylactic) level. The SP1 told the investigation of her initial concerns around how the nurses were going to prepare that dose for administration. The preparation would normally involve withdrawing the prescribed dose from a vial and diluting it to provide a sufficient volume to be given. SP1 then realised that 15,000 units was available via a pre-filled syringe, which avoided the need for a vial and diluting agent.

4.1.12 SP1 was in the pharmacy office when she checked the dalteparin prescription. The investigation observed the working environment to be potentially distracting because of the busy, confined space and elevated levels of noise from other members of staff, bleeps and phones.

4.1.13 The investigation was informed that a phone call was made to the ward by someone from pharmacy, informing the ward of the large dose for dispensing. This was after the pharmacy check and prior to the dalteparin reaching the
ward, but further detail could not be ascertained by the investigation. A pharmacy technician informed the investigation that they would regularly contact the ward about medicines being ready for collection. This differed from a specialist pharmacist’s account, who said that a ward would not be routinely contacted in this way.

4.1.14 Following the dispensing of the dalteparin, the next interaction with a pharmacist was 3 days later. This was because the dalteparin was issued on a Friday afternoon and pharmacy provision was reduced to a dispensary-based service only at the weekend, since the Trust did not have 7-day ward pharmacist cover. During the week, the cardiology ward had a higher level of pharmacy service. This included a daily review of every patient’s medication chart, and pharmacist presence on the ward, both of which would have provided an opportunity to verify the dose. The SP2 confirmed this by reflecting to the investigation that: “If it had have happened on a Monday, I feel pretty sure that it wouldn’t have got past Tuesday morning.”

Handovers

4.1.15 Weekend handover from Consultant Paediatric Cardiologist 1 (Consultant 1) to Consultant Paediatric Cardiologist 2 (Consultant 2) occurred at 17:00 hours on Friday 13 March. Consultant 1 informed his colleague of the discussions he had earlier in the day with the neurology team about Felicity’s anticoagulation management. He informed Consultant 2 that he had copied him into the relevant email correspondence confirming the decision to start the dalteparin, along with the recommended dose of 100 units/kg twice a day.

4.1.16 The investigation heard from Consultant Paediatric Cardiologist 2 that it might have been more appropriate for the handover to occur during the Friday morning ward round to allow for increased familiarity with the patients. That said, Felicity was known to most of the medical team, as well as the nursing and pharmacy team, due to the number of times she had visited hospital and the length of her stay on both the cardiology ward and the paediatric intensive care unit (PICU).

4.1.17 The decision to start Felicity on dalteparin was made at 09:47 on Friday 13 March, which would have been after a morning handover had taken place. In relation to subsequent nursing handovers on Saturday and Sunday, the investigation heard that general aspects of care would have been considered during these handovers. This may have included the new dalteparin prescription, but specific information (such as the dose) would not have been discussed. The nursing handover would have been unlikely to detect the error since the purpose was to convey information from one nurse to another about a child’s condition during the shift.
Ward rounds and huddles

4.1.18 The investigation heard that in general terms, the ward round was more about a strategic view from the consultant’s perspective (at the reference event Trust). The consultant said: “My main role at that stage is to see what is keeping the patient in hospital, how can I think about sending her home.” From the ST2’s perspective, their role was more of an operational one, with the expectation that they prepare information about the patients for discussion during the ward round.

4.1.19 The investigation heard that the nurse in charge was supposed to join the ward round, but could only do so on approximately 10% of occasions, due to their own patient workload. Pharmacists and individual nursing staff who were looking after the patients joined the ward round infrequently, if at all.

4.1.20 In terms of the culture of weekend ward rounds, they were conducted differently than on weekdays, with different expectations (custom and practice – practice that has developed over a period of time). The investigation heard that over a weekend period, ward round reviews consisted of a summary of each patient and updates of significant events. Clinicians would usually aim to make decisions for children requiring changes in therapy or discharge decisions. For more patients with long-term, more complex health problems, the aim would be to ensure their condition was stable throughout the weekend.

4.1.21 The ward rounds would be led by a consultant or specialist registrar, depending on the seniority of the registrar. If the ward round was led by a specialist registrar, the on-call consultant, junior doctors, and the nurse in charge would usually be briefed in a post ward round huddle. The ward round would be discussed at the huddle and plans amended and made for the day ahead.

4.1.22 In the reference event, Consultant Paediatric Cardiologist 2 led the Saturday ward round. The investigation was told that he would normally look at the bedside paper prescription charts during a ward round. However, Consultant 2’s lack of familiarity with the ePMA system meant that prescription information was not accessed and Felicity’s prescription was not viewed electronically. Instead, the medications were verbally discussed in terms of the doses of medications by weight (but not the individualised doses prescribed). This was in line with the routine practice of not second checking prescriptions generally. In Felicity’s case, Consultant Paediatric Cardiologist 2 considered that, as per the plan outlined in the email trail, the recommended dose of dalteparin was clear and there was no reason to second check.
4.1.23 The investigation heard that checking of medication during a ward round tended to be undertaken by exception, if medical staff were asked to do so, or if concerns were raised about a particular medicine. The investigation heard that sometimes dose adjustments (increases or decreases) were discussed and documented on the ward round plan by the junior doctors. However, generally, a review of medication would only include starting or stopping medicines, rather than checking individual doses. Medical staff told the investigation that they assumed that a pharmacist would have checked the dose.

4.1.24 The Sunday ward round was led by the Specialist Registrar. Felicity was noted to be on dalteparin, and the medical notes recorded the dose correctly as 1,500 units. The investigation was told that the ePMA system was not checked as the consultants and specialist registrars relied on junior doctors to use the ePMA system. Consultant staff described not being confident using the electronic system, partly because they were unfamiliar with it.

4.1.25 A consultant told the investigation that now everything was electronic, he missed looking through paper charts, partly because of ease of access. The investigation heard that: “Since the introduction of electronic prescription, we don’t have time. It is easy to flip to a [paper] medicine chart and see what it is and then close it, rather than logging into … different systems.”

4.1.26 A huddle followed each ward round, on weekdays and at the weekend. It would involve a specialist registrar or a more junior doctor going through the patient’s condition and the plan for the day. The huddle would not discuss the detail of medications (including doses) unless a query had been raised, though the introduction of a new medication or a dose change would normally be highlighted.

4.1.27 Most of the time, a consultant would be present at the huddle, especially if they had not been on the ward round. The nurse in charge joined the huddle if they had not been on the ward round. They would convey the relevant information to the nurse looking after the patient; this nurse then received the information third hand.

4.1.28 The investigation heard that the role of pharmacy staff was considered to be invaluable by the medical and nursing staff. However, pharmacy staff were rarely present during ward rounds or in huddles. The variability in pharmacy attendance at huddles was because they did not take place at set times and often conflicted with other commitments. The pharmacists instead worked independently on the ward, undertaking pharmacy tasks and responding to queries, mainly from the nursing team.
4.1.29 The investigation heard perceptions that the nursing staff were not always part of multidisciplinary team discussions. This was evidenced by the nursing staff not always being involved in email communication, handovers, ward rounds and huddles. The nursing staff told the investigation that these factors may have influenced the incorrect dose of dalteparin not being detected by the clinical staff over the weekend.

**Learning and accountability**

4.1.30 As part of the Trust’s serious incident investigation, a review of the error was undertaken from the prescribing, dispensing and administration perspectives. This was carried out to identify ‘where things went wrong and identify areas for action/improvement’. The outcome of the review regarding the administration process was ‘confirmation bias’, in that the dose was appropriate in line with the ePMA annotation. The nursing team felt that, despite this, they were ultimately responsible for the medication error since they were responsible for checking and giving the medicines. Nursing staff told the investigation that they perceived themselves to be the final barrier, and the last opportunity to prevent an incorrect dose from reaching the patient. The investigation witnessed the distress the event had caused them personally and professionally.

4.1.31 In relation to the prescribing stage, concerns about the suitability of the ePMA system for paediatrics was noted by the reference event Trust as being a ‘root cause’. The learning from this was used by the Trust to positively influence quality improvement:

‘The doctor was offered the opportunity to work with our e-medication team, who are working with [new ePMA system] in the development of the paediatric section of the e-medication application, and he is extremely enthusiastic about this opportunity.’

4.1.32 In respect of the culture of the medical team, the investigation heard concerns that consultants made high-level plans, and expected junior doctors to implement them. These plans may not have included guidance on the actual doses of medicines to be prescribed. The investigation team saw evidence of this in practice.

4.1.33 Conversely, members of the medical team told the investigation that consultants would generally state the dose to junior staff for high-risk medications, although it would not always be written in the patient’s notes. In the reference event, the ST2 considered the communication to be clear. The investigation heard that in view of the complex and highly specialised
nature of the work in children’s cardiology, junior doctors would check every decision with either the registrar or consultant. This included the doses of certain medicines. The ST2 said “I find in paediatrics it’s generally a very open culture”, adding that “I can ask a dose three times and no one will mind because they know I’m just doing it so that I can get the right dose for the right patient in the right way”.

4.1.34 In relation to nursing staff questioning decisions/medication doses, the investigation heard differing perspectives. The majority of nursing staff told the investigation that it was not uncommon to administer medicines where the prescription did not match the dosage recommended in the British National Formulary for Children (BNFC). Therefore, it may not be second checked or challenged if there appeared to be reasonable justification, which made it difficult to recognise an unintentional deviation. The investigation heard: “We all knew it [the dose] was high, but had a legitimate reason for it.”

4.1.35 A nurse told the investigation that the culture on the cardiology ward was such that she felt able to challenge her colleagues when required. For example, she felt able to ask colleagues to be quiet when she was preparing medicines. Another member of the nursing team told the investigation that when a prescription was outside of the BNFC guidance, and something did not seem right, she would question it: “I will ask if I don’t know.” The nurse said she would feel confident in challenging other staff until she received a satisfactory response.

4.1.36 The dalteparin medication error was detected by Nurse 8 after seeing the unfamiliar box of dalteparin (a purple bannered box) in the medicines cupboard while preparing dalteparin for her patient. It was during her break that she reflected on the unexpected box of dalteparin and afterwards she checked the dose, noting the 15,000 units. The nurse knew the dose of dalteparin from memory and her knowledge of normal doses combined with the unfamiliar packaging, in the context of a bloodstained vomit, triggered her to question and take action. She checked Felicity’s paper medical records for the dose (which Nurses 1 to 7 appeared not to do), and recalled seeing the email in the records summarising the multidisciplinary team decision. Following this, she checked the BNFC and the error was reported. Further doses were then withheld pending a medical review and the incident was reported.
Subject matter advisor’s analysis 1

Performance shaping factors (elements that impact on human performance) in relation to communication and hierarchies

In reviewing the recordings and transcripts of interviews, no evidence was found of poor communication between staff or unwillingness to challenge others. The human factors analysis attributes the reference case to the circumstances that staff found themselves in and not to the behaviour or disposition of the staff. Staff felt able to challenge the consultants and others, although concerns were expressed about the time-consuming nature of checking and challenging, delaying the delivery of treatment that the patient might need.

Communication in organisations, and the willingness to communicate, is strongly influenced by the roles and responsibilities of those concerned. It is these that determine the requirements for communication and define how and when care is delivered and by whom. In the reference event, there are plenty of references to checking and challenging within perceived limits of one’s role. For example, during one of the interviews with the nursing team, the investigation was told “it wouldn’t be common practice to speak to or challenge the haematologist … we’re staff nurses, we’re trained to deliver the care plan, we’re not trained to do that”. One nurse said: “If it was on the [ePMA] system, it would have been checked by a paediatric pharmacist.”

Several comments were made about problems with communication. For example, the nursing team said that “there is no standard for reporting drug details in huddles – sometimes they give the dose sometimes they don’t”. In such cases the nursing staff would obtain the details of the dose from the medication chart. Additionally, nurses were not always included in email correspondence between doctors and could not always attend ward rounds.

Two consultants commented on the checking of prescriptions and doses as alluded to above and did not consider it their role to check. Further, with the electronic systems in place, checking was reported to be difficult.

In summary, the two issues evident from the analysis of this aspect of the reference event relate to routinely reviewing medication doses and reviewing a medication chart on each ward round.
4.2 Introduction of technology for weight-based prescribing and medicines administration in paediatrics

Prescribing

4.2.1 The ePMA system was being used by the reference event Trust on adult wards on three separate hospital sites. While ePMA systems had been used in adult areas for 8 years prior to the reference event, an ePMA system had only been introduced into paediatrics 10 months before the incident. The usability and functionality of the ePMA system was raised as an issue across the multidisciplinary team in paediatrics.

4.2.2 The ePMA system used by the reference event Trust was configured to encourage prescribing for both adults and children via ‘dose sentences’ where possible. Dose sentences are inbuilt prescriptions within the ePMA system that generate pre-populated doses meaning the prescriber does not need to enter a dose. In the Trust’s ePMA system, dose sentences could be accessed via a ‘quick list’ for adults and through a ‘protocol function’ for children. The dose sentences for adults and children were intentionally separated.

4.2.3 The investigation heard about the challenges in developing some dose sentences in children because doses will vary for each medicine according to the child’s weight (newborn to 100kg or greater) and other characteristics (see 1.2.1). SP2 told the investigation that the system lacked:

‘… the human element when it comes to rounding up or rounding down critical doses, so we were unable to really sign off the dalteparin protocol because we couldn’t get the system to make that human decision point when something sits in the middle of two doses.’

4.2.4 The intention was for prescribers to use the standard ‘prescribe’ function instead, which allowed them to select the required medication in the most appropriate strength, which might come in either a pre-filled syringe or vial. SP2 advised the investigation that this was not always possible because “on the list of the options to pick from, our preferred product was always greyed out, so it wasn’t intuitive to pick”. The system had been pre-set to encourage the selection of the preferred strengths for adults.

4.2.5 The introduction of the ePMA system in paediatrics was described as being time pressured by some staff groups, compounded by additional configuration requirements reflecting the complexity of prescribing in paediatrics. The investigation was told that in order to transfer the medication prescriptions and protocols from the test system to the live system, the
system had to be rebuilt and tested again. Not all of the planned and tested features were then transferred to the live system, resulting in the system being rolled out to paediatrics in an incomplete state.

4.2.6 In the reference event, the ST2 was able to select an adult dalteparin ‘quick list’ and the dose defaulted to the syringe size intended for adults. The system then relied on the doctor manually entering the correct dose, replacing the dose information that had been automatically entered by the system. The investigation was advised by a software manufacturer that if a trust was using adult protocols in a paediatric environment, the expectation would be that this would be written into a safety case. Safety cases are used to demonstrate that patient safety risks have been addressed rigorously and proactively. The risk would then be mitigated by the local organisation through appropriate controls. The investigation found no evidence of this.

4.2.7 The need for manual alteration of a default dose was at variance with prescriber expectations of the ePMA system, one of whom said: “… you put weight, you put a dose and the system should say this doesn’t add up, but that wasn’t the case.” The clinicians’ perceptions were that the ePMA system would support their clinical decision-making and protect them from entering wrong doses. The investigation also heard that, while the system might alleviate some errors, it could not be assumed it would prevent all. The investigation found that it was not widely recognised by the clinical staff that the ‘alert’ functionality, which flags up potential errors, depended on the Trust’s configuration of the ePMA system.

4.2.8 In relation to available functionality, the ePMA system had an integrated calculator function. The software manufacturer advised this should have been a key functionality of an ePMA system used in paediatrics, where all medication doses are prescribed by a weight-based calculation. It was a manual function, which auto-populated the patient’s weight and prompted the prescriber to enter the dose required. The recommended dose from the calculator would then be transcribed back into the system. If a weight had not been entered (as occurred in the reference event), then this functionality could not be used. The investigation was told that some staff at the trust were concerned about the validity of the calculator and training did not appear to adequately prepare the prescriber to use it. The ST2 told the investigation that he had never used the calculator function. He said: “There is a built-in calculator that you can use just to, like, double-check your prescription, but … I’ve never heard of anyone using it.”
The process of prescribing the dalteparin

4.2.9 Following confirmation from Consultant Paediatric Cardiologist 1, combined with consultation of the BNFC and the medical records, the ST2 calculated the dose manually, using Felicity’s weight and the dose of 100 units/kg twice daily. The ST2 then accessed the ePMA system.

4.2.10 The prescribing of the dalteparin was described by the doctor as being straightforward. It was undertaken at the ward nurses’ station, using a laptop. The doctor described the environment as quiet and he was undisturbed during the task. No personal factors were noted on the day.

4.2.11 The following steps were undertaken as part of the prescribing process:

1. The doctor typed in the name of the medicine in the ‘Name’ box in top left corner of the screen, and a set of formulations appeared on the right of the screen. Anything which is greyed out was not in the Trust’s formulary.

2. The doctor selected dalteparin sodium 15000/0.6ml injection from the drop down ‘Adult A-Z, Quick List’ (see figure 3).
### Allergies: Allergy status unknown

<table>
<thead>
<tr>
<th>Name</th>
<th>Quick list orders</th>
<th>Medication search</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Single ingredient</strong></td>
<td><strong>Healthcare setting</strong></td>
<td><strong>Medication</strong></td>
</tr>
<tr>
<td>dalteparin sodium</td>
<td>Adult A-Z</td>
<td>dalteparin sodium 2500units/0.2ml injection</td>
</tr>
<tr>
<td></td>
<td>Adult A-Z</td>
<td>dalteparin sodium 5000units/0.2ml injection</td>
</tr>
<tr>
<td></td>
<td>Adult A-Z</td>
<td>dalteparin sodium 7500units/0.3ml injection</td>
</tr>
<tr>
<td></td>
<td>Adult A-Z</td>
<td>dalteparin sodium 10000units/0.4ml injection</td>
</tr>
<tr>
<td></td>
<td>Adult A-Z</td>
<td>dalteparin sodium 10000units/1ml injection</td>
</tr>
<tr>
<td></td>
<td>Adult A-Z</td>
<td>dalteparin sodium 12500units/0.5ml injection</td>
</tr>
<tr>
<td></td>
<td>Adult A-Z</td>
<td>dalteparin sodium 15000units/0.6ml injection</td>
</tr>
<tr>
<td></td>
<td>Adult A-Z</td>
<td>dalteparin sodium 18000units/0.72ml injection</td>
</tr>
</tbody>
</table>

**dalteparin sodium**

<table>
<thead>
<tr>
<th>Form</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescribe without strength or from</td>
<td></td>
</tr>
<tr>
<td>Injection</td>
<td>dalteparin sodium 5000units/0.2ml injection</td>
</tr>
<tr>
<td></td>
<td>dalteparin sodium 7500units/0.3ml injection</td>
</tr>
<tr>
<td></td>
<td>dalteparin sodium 10000units/0.4ml injection</td>
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<td></td>
<td>dalteparin sodium 10000units/1ml injection</td>
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<td></td>
<td>dalteparin sodium 18000units/0.72ml injection</td>
</tr>
</tbody>
</table>
3 On a second screen, 15000 was auto-populated in the dose field (see figure 4), which the doctor planned to manually alter to 1500 (but either did not do this or entered the number incorrectly).

4 On a third (final) screen, there was a requirement to ‘update’ the prescription, to finalise the process.

**Figure 4 Auto-population of dalteparin dose**

On a second screen, 15000 was auto-populated in the dose field (see figure 4), which the doctor planned to manually alter to 1500 (but either did not do this or entered the number incorrectly).

On a third (final) screen, there was a requirement to ‘update’ the prescription, to finalise the process.
4.2.12 The prescription of dalteparin then underwent a pharmacy check by SP1 on the ePMA system before being transferred electronically to the pharmacy department. There were three different electronic systems in pharmacy used for the checking and dispensing of medicines (the ePMA system, a prescription tracking system and a dispensing system), with limited interconnectivity. Once the dalteparin had been dispensed, the nursing staff were required to administer it. They used tablet computers for accessing the ePMA system, which they also used for recording observations via a different application.

**Administration**

4.2.13 The investigation was told that the Wi-Fi at the hospital site was “temperamental”. At the medicines administration stage, this presented a risk for nursing staff to mitigate, because a drop in the Wi-Fi could result in a medication not being signed for. This potentially could prompt a second dose to be given in error. The investigation saw evidence of this where a dose of dalteparin had been given, but it had not registered on the system because the Wi-Fi had dropped out. The nursing staff then needed to sign in later when the Wi-Fi was available to retrospectively sign off the dose.

4.2.14 The ePMA system was described by the nursing, medical and pharmacy teams as being suboptimal in terms of its functionality and usability. The investigation was told that the ePMA system was rigid, and did not allow for manipulation of the functionality to support safe practice. This included limited safety features such as limited alerting functionality and functions to prevent the user from taking an action. Regarding usability, while the investigation did not undertake a specific usability assessment, staff feedback was considered in relation to Nielsen’s principles for user interface design *(see table 2)* (Nielsen and Molich,1990). Not all of these principles were found to be contributory to the reference event.
Table 2 Nielsen’s principles for user interface design (Nielsen and Molich, 1990)

<table>
<thead>
<tr>
<th>Nielsen’s principles</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visibility of system status</td>
<td>The last dose to be given was not visible in the system without searching for it.</td>
</tr>
<tr>
<td>Consistency and standards</td>
<td>The free text function left users considering the meaning of what had been written. There was no expectation or standardisation around how this was used.</td>
</tr>
<tr>
<td>Error prevention</td>
<td>Design of the system had not eliminated recognised errors that occur with prescribing, such as a 10 times overdose.</td>
</tr>
<tr>
<td></td>
<td>There were not error prevention systems such as forced stops when prescribing an unacceptable dose based on a child’s weight. This included not calculating doses and relying on the person doing the prescribing or administration to calculate correctly.</td>
</tr>
<tr>
<td>Recognition rather than recall</td>
<td>The layout of available preparations made recognition easy; however, they preparations were for adult patients and so required recall to ensure the right formulation was selected.</td>
</tr>
<tr>
<td>Flexibility and efficiency of use</td>
<td>The system was considered to be inflexible in that it forced fixed times to give medicines.</td>
</tr>
<tr>
<td>Recognise, diagnosis and recover from errors</td>
<td>While some alerts existed in the ePMA, there was an absence of alerts that would have prevented the medicine error. This included alerts for abnormal doses, high-risk medicines, and the need to review doses regularly in relation to a patient’s weight.</td>
</tr>
<tr>
<td>Help and documentation</td>
<td>Staff described limited training focused on the actual functions of the system. There was an absence of links in the system to direct users to sources of help, such as the BNFC.</td>
</tr>
</tbody>
</table>

4.2.15 Following the reference event (but not as a direct consequence), paediatrics was withdrawn from the ePMA system implementation programme. This was pending a different digital system, which was in the process of being rolled out in the Trust at the time of the investigation’s site visit.
Performance shaping factors in relation to the ePMA system

Performance shaping factors are not necessarily causes, but they do influence the way that a series of events unfolds.

In the case of the reference event, a number of interviewees commented on the ePMA system, saying that there were a variety of electronic systems not connected to each other. System optimisation did not appear to have been undertaken during the implementation in a paediatric setting.

Consultant 2 commented that he missed the old ward round where he could pick up a folder and see everything in 5 minutes. He also doubted whether he would be able to prescribe on the electronic system, as this task was usually delegated to junior doctors. Cultural influences appeared to result in consultants being separated from tasks such as electronic prescribing. Consultant 2 could not recall directly checking the medicines via the ePMA system during the weekend ward round. He considered that, as per the plan outlined in the email trail, the recommended dose of dalteparin was clear.

Consultant 1 had expressed similar views about the system:

“I think that people are involved and everything but I think physically, yes, for certain children we go through and dissect everything but since the introduction of electronic prescription we don’t have time. It is easy to flip to a drug chart and see what it is and then close it, rather than logging into three different systems.”

Further, Consultant 1 commented:

“The model for e-prescription is primarily for first of all junior doctors who use it on a day-to-day basis. I think if there is a real need and if I can’t do e-prescription then we default back to a paper copy, that is what we always have done.”

Further comments about the usability of the system were made by interviewees. In particular, the nursing team reflected that it was “Not easy to use, doesn’t look like a paper drug chart, looks busy”. The usability of new systems is strongly influenced by the extent to which prior knowledge (of the system being replaced) can be used in the new system. This is known as ‘positive transfer’, which appears to be lacking in the system used in the reference event. The way in which the ePMA system was introduced and implemented (including the buy-in of staff and approach to it) may have distanced consultants from the prescribing process.
A number of interviewees commented on the training/induction provided to learn the electronic system. “Training was needed but was not good enough and was on the job while you have to multitask” (nursing team) and also that the system was not intuitive. Staff reported that most of the training was “on-the-job” and there was no competency framework or tests of competency. A number of interviewees made such comments about the system. Specialist Pharmacist 2 (SP2) said:

“I don’t feel it was intuitive. There were too many clicks. There were too many things popping up. It didn’t really make you want to use it. I was in paediatrics at the time but I did have some experience of it, but I never found it intuitive. I think once you got used to it, then started to feel okay, but I don’t think it ever really was …”

Although the system offered three modes for prescribing, the ‘protocol’ function was not available for prescribing dalteparin to children. SP2 said:

“… they had to use the prescribe function, but on the list of the options to pick from, our preferred product was always greyed out, so it wasn’t intuitive to pick our product. It might be that the doctor in this case saw a ‘15’, which would have been 15,000 units in 0.6ml injection, saw ‘15’, picked the product and then carried that 15,000 through.”

In effect, the system prompted the specialist trainee 2 doctor (ST2) to select the wrong dose.

In the light of these statements, the decision by the ST2 to select the 15,000 units option can be seen as a ‘workaround’. Workarounds are practical methods in the workplace for overcoming a problem or limitation in a procedure or system, which are a reflection of system limitations rather than human limitations.

According to SP2:

“… and dalteparin is a particularly difficult one for us just because of what’s available, and they’ll tell you about how you get medicines into children when you’re using small doses when the products aren’t designed for them?”

The ST2 put it this way:

“My plan was that a 10th of that amount, the syringe could be then given to give 1,500 units. Instead of writing 1,500, which was my intention, I wrote 15,000.”

In effect, the ST2 forgot to edit the dose, although that was his intention.

However, he was prompted to select the wrong dose in the first place due to the fact that he was using an adult dose sentence.
4.3 Implementation of the ePMA system

4.3.1 The ePMA system was introduced into the Trust in 2012 for adult patients. The investigation was told that three clinical safety officers were in post (who were professionally medical and nursing staff), to oversee the initial implementation of the system in the clinical environment. The three clinical safety officers were trained and there was a clinical safety assessment for the first deployment of the ePMA system, in accordance with the national standard (DCB0160) (NHS Digital, 2018) (see ‘Clinical risk management standards’ below). The investigation was unable to determine whether the Trust went through a further clinical safety assessment process ahead of the implementation of the ePMA system on the paediatric cardiology ward in May 2019, which was the first paediatric area to use the system. Expectations for clinical safety assessment are outlined in ‘Clinical risk management standards’ below.

Clinical risk management standards

Information standards underpin national healthcare initiatives and provide the mechanism for introducing requirements to which the NHS must conform.

Compliance with the two standards that relate to clinical safety (DCB0129 and DCB0160) is mandatory under the Health and Social care Act 2012.

DCB0129 – Clinical Risk Management: its application in the manufacture of health IT systems.

This standard sets clinical risk management requirements for manufacturers of health IT systems. In the case of the reference event, the manufacturer told the investigation that it had consistently fulfilled the requirements of DCB0129 and that safety cases were issued for each release.

DCB0160 – Clinical Risk Management: its application in the deployment and use of health IT systems.

This standard requires a health organisation to establish a framework within which the clinical risks associated with the deployment and implementation of a new or modified health IT system are managed.

Any release is backed by a safety case which adopts a risk-based approach using a hazard register. For any changes in the scope of use, for example, changing from use in an adult to a paediatric setting, the clinical risk management standard should be complied with, which includes training (NHS Digital, 2018).
4.3.2 The investigation heard that general system configuration of an ePMA is governed by the software manufacturer, which retains responsibility for any changes that a Trust may request. The local configuration specific to a trust is governed by the trust, which has responsibility and ownership. Examples of local configuration include the development of quick lists (to organise medicines into folders for selection), dispensing practice, dose range checking order sets/guidance and restrictions. Dose range checking is required to prevent overdosing of medicines and can be set up by Trusts via an alert mechanism.

4.3.3 The investigation was told by a software manufacturer that there appeared to be limitations in the way the quick list had been set up by the reference event Trust. This was because there appeared to be no rule or alert set up for dalteparin to prevent overdosing. The Trust told the investigation that this could be challenging to set up because of other decisions that needed to be made in terms of recording a patient’s weight in the ePMA system. The Trust’s expectation was that if there was not a paediatric quick list, the prescriber should have been able to select from a generic formulary item. However, only the adult quick list was visible in the reference event and the ST2 was unable to select a generic item.

4.3.4 The investigation was told by another trust that was using the same ePMA system as the reference event Trust that it was not possible to safely separate quick lists for adults from quick lists for paediatrics. They stated that quick lists could be organised into folders, so allowing for segregation when users went into the ‘quick list’ function. However, on the prescribing search screen, quick lists for a given medicine were all listed on the same screen. This increased the amount of information that paediatric prescribers had to scroll through and did not support the separation of quick lists for adults and children across the same organisation. This trust does not use the quick lists for children, but rather medication ‘protocols’ for prescribing.

4.3.5 The investigation was told by the clinical staff involved in the reference event that they had concerns about the implementation of the ePMA system. These concerns related to the adaptation of an adult system to paediatrics, training, testing, functionality, and the rationale for roll-out.

4.3.6 Staff members’ perception was that the main driver for the paediatric cardiology ward being included in the ePMA system roll-out was to determine how the system functioned in paediatrics. The investigation heard from the clinical staff that other reasons for the implementation were that the ward had fewer beds than other paediatric areas, staff were keen to pilot and the rest of the hospital site was also using the ePMA system. An alternative
hospital site in the same Trust where the majority of children’s services were located, presented challenges with implementation, due to the existence of different systems with limited interoperability.

4.3.7 The Trust’s implementation team told the investigation that the decision to roll out the ePMA system to paediatrics was influenced by the paper-based prescribing errors reported by the specialty. The Trust had discussions with another trust that was using the same ePMA system in paediatrics. The second trust reported that the system offered a number of benefits over paper systems, in particular greater clarity of prescriptions. This trust’s configuration was used by the reference event Trust when it piloted the implementation on the paediatric ward. From a strategic perspective, the Clinical Commissioning Group and national NHS policy was to move to ePMA and electronic systems; however, the deployment of such systems was not a high priority for the Trust at that time.

4.3.8 Following implementation of the ePMA system, some paper prescription charts still needed to be used on the paediatric cardiology ward alongside the ePMA system, resulting in a hybrid situation. Paper prescription charts were available for medicines with variable doses, since these could not be safely managed within the ePMA system. Paper charts were also transferred with patients admitted from the emergency department and PICU, as the ePMA system had not been implemented in these areas.

4.3.9 Training of the paediatric clinical staff on the ePMA system was described as ‘ad hoc’ and took place during the working day. Staff who did the training considered that it did not prepare them to use the system and there was no competency assessment. Telephone support was available 24 hours a day for the first weeks after implementation and there was a paper log on the ward where staff could note issues for troubleshooting. The investigation heard that issue logs from the wards would have been reviewed by the project team, which at this point was led by the ‘eMeds pharmacist’. Usually, issues were discussed with the ward team if clarification was required and triaged for action, depending on whether it related to medication file configuration or required action from the Trust’s IT department or the system supplier. However, the ward team could not recall any improvements being made as a result of the log and the investigation was unable to access a copy to view. The investigation also heard that issues were not always reported on the Trust’s incident reporting system.

4.3.10 The consultants involved in the reference event could not recall receiving any training on the ePMA system, although they acknowledged that it might have occurred alongside other mandatory training. The ST2 recalled receiving training on the ePMA system at the beginning of the year in paediatrics and
was also familiar with the system from previous roles in adult medicine. He found the system fairly straightforward to use adding that he got “on well with computers and technology in general”.

4.4 Confirmation and challenge of the dose

Loss of cues

4.4.1 In pharmacy, the worksheet used for the dispensing process used to be a handwritten transcription of the prescription. The worksheet was yellow for adult patients and pink for paediatric patients. Following the implementation of the ePMA system, all worksheets printed off the system were white. The investigation was advised that this made it difficult to identify a paediatric prescription from the automated worksheet, particularly as it did not state ‘child’ or ‘paediatric’ anywhere on the worksheet. The investigation heard how the colour of the sheet may have previously alerted the dispensing technician to it being a paediatric patient, so acting as a visual cue.

4.4.2 Nursing staff described how in hindsight cues during the medicines administration process led them to believe that it was the correct dose. This was particularly evident in relation to the ongoing administration of the medicine, despite individual concerns. The cues included:

• documentation which described ‘as per discussion with haematology’
• the phone call from pharmacy confirming the dose was high, but appropriate
• the patient’s name on the box containing the dalteparin
• the fact that patients often received doses outside of those in the BNFC
• and following the first dose, the fact it had been given before.

4.4.3 Multiple nursing staff informed the investigation that they recognised the unusually high dose at the time of preparing the dalteparin for administration, and questioned the dose. It appears that the free-text comment on the ePMA, ‘as per discussion with haematology’, may have allayed any concerns, resulting in the medication being administered. The exception was the final dose, at which point the error was detected.

4.4.4 The packaging of the dalteparin, labelled ‘15,000IU/0.6ml’ and with a purple banner (see figure 5), was unfamiliar to staff and the majority of staff did not recognise its significance. The dosing instructions on the box instructed to ‘give the full vial’, so they did. However, while unfamiliar medication packaging acted as a cue for some staff that the wrong medicine dose may have been chosen, it was not a cue for all.
Figure 5 Ward stock of dalteparin (left) and dalteparin 15,000 units
Analysis of the error in administration

Following what might best be described as a ‘mode error’, (a system that permitted the prescribing selection of an adult dose for a child), the conditions were in place to create what is known as a ‘heuristic trap’. This influenced decision making up to the final challenge by Nurse 8.

Heuristics are defined as the decision-making strategies (often thought of as ‘rules of thumb’) that we all use to simplify decision making in everyday life by reducing the number of cues analysed and the complexity of the analysis, thereby reducing the cognitive burden on decision makers and increasing decision efficiency. In this case, reducing the need to cross reference the dose against the BNFC, or escalate challenges in accordance with the code of practice.

Heuristic traps occur when the simple rules we use are influenced by factors not relevant to the actual hazard. In the reference event, the hazard was the dose actually prescribed. The reference ‘as per discussion with haematology’ was not relevant to the hazard, since the specialist trainee 2 doctor (ST2) had not corrected the dose to a level suitable for a 15kg child. Therefore, those questioning the dose, even after reference to the BNFC, would have had to decide whether it was more likely that the dose was correct (as might have been the case in certain circumstances, following multidisciplinary discussions) or that the dose was incorrect and the ST2, pharmacy and haematology had made an error.

The ‘availability’ heuristic is a decision-making rule of thumb whereby people make judgments about the likelihood of an event based on how easily an example, instance, or case comes to mind. Things that are difficult to imagine are deemed to be unlikely. Thus, if it were easier to imagine that the dose was correct rather than incorrect because it had been discussed with haematology and checked by pharmacy, then the dose would be accepted.

More recent and readily available answers and solutions are preferentially favoured because of ease of recall and incorrectly perceived importance.

The free-text comment about the discussion with haematology appears to have prompted a ‘take the best’ approach. Instead of following a series of steps to check the prescription against additional sources of information (that is, searching for all relevant cues) what appears to be the most valid cue is taken as given and any further cues (or checks) are ignored (or discounted). Even checking the dose against the BNFC might, arguably, be a less valid or weaker cue as to the correctness of the dose. This is because, as several interviewees mentioned, in
complex cases, correct doses can be “out of range”. During one of the checks, the second checker remarked that 15,000 units was a “whacking dose”, but this did not influence the decision to administer it. The nurses checked against the BNFC and checked the dose, aware that it was a very high dose for Felicity’s weight, but stated that the BNFC does not always concur with a prescribed dose. The dalteparin box had Felicity’s name and details on it so they gave it.

‘Taking the best’ works well if the cue really is valid and if there is a high degree of redundancy between different cues. It works less well if the cues are not correlated. In the reference event, the statement about haematology was incorrect because the dose was incorrect. In this way cues uncorrelated with the ST2’s comment, which would have revealed the error, were ignored at this time (Bridger, 2021).

Several other nurses challenged the high dose but these challenges were alleviated by the references to discussions with haematology. Thus, once biased, further challenges were also defeated by being ‘anchored’ to the initial source of bias. Anchoring is a cognitive bias where a specific piece of information is relied upon to make a decision. In other words, one factor, often the first one mentioned, is considered above all else in the decision-making processes. Anchoring occurred despite the presence of cues that the dose was unusual. Firstly, the banner on the box was purple, whereas for lower doses used in the children’s ward it would be orange or grey. Secondly, the dalteparin did not need to be diluted before administration as would normally be the case for the correct dose, because it was delivered in a pre-filled syringe. In effect, the process of ‘checking’ was not independent, since all were exposed to the same source of bias, subsequently falling into the heuristic trap.

Taken together, these biases created a kind of ‘follow the leader’ effect where each challenge was subsequently defeated.

In support of this analysis is the statement by Nurse 8, that she was first alerted by the purple-coloured box containing Felicity’s dalteparin. She then checked on the ePMA system and against the BNFC before raising her concerns. Thus, it was the presence of an independent cue (the purple colour of the box containing the dalteparin) that prompted discovery of the overdose. Nurse 8 was accustomed to seeing dalteparin in orange-banned boxes and knew that the usual dose was 100 units/kg, rarely giving more than 5,000 units.

It seems likely that Nurse 8 was able to detect the error because she was alerted by three independent cues that were related to the hazard: the purple colour of the box; the report of blood in Felicity’s nasogastric tube and the bloodstained vomit. She was alerted by these cues before seeing the statement about haematology and therefore avoided the trap.
It would appear that, when deciding whether the dose was correct or not, staff had to consider which of two possibilities was more likely: that the dose was unusual, but correct and checked by the pharmacy and by haematology; or that the dose was incorrect and that ‘the experts’ were wrong. Since the former is, perhaps, more easily imaginable, and therefore more ‘available’ in the minds of staff, it was believed.

Creditable expert opinion and social proof (for example, ‘if people like me believe it then I should too’) are well-known triggers for heuristic traps.

**Second checking of medicines**

4.4.5 The nursing staff who administered the first dose described to the investigation that they were still on the ward at 20:30 hours, and were “shattered” after a 12-hour shift, which should have ended at 20:00 hours. They gave the dalteparin during their shift to support their colleagues on the night shift.

4.4.6 There was evidence of different levels of familiarity with dalteparin among staff on the ward. Some nursing staff described it as being a commonly used medicine in paediatric cardiology and readily knew the dose. Others said it was not used every day. Dalteparin was a stock item on the ward, but not the ‘15,000IU/0.6ml’ concentration. A deep vein thrombosis (DVT) was also described as rare on the ward and this potentially led to rationalisation of the unusual dose, namely that a higher dose was required for therapeutic treatment.

4.4.7 The preparation room for medicines was located part way up a corridor on the cardiology ward, away from the central nurses’ station and bed area. Within the room there was a doorbell which was used to summon colleagues to check a medicine when required. The investigation considered this represented a workaround, which was required because of the location of the room. This contributed to an absence of a second checker from the beginning to the end of the medicine process.

4.4.8 The investigation heard how an independent second check took time and this was challenging when there was limited staffing on the ward. If there were only two registered nurses on a shift, they could not both be in the medicines room together because of the need to have sight of the patients. Medicines were therefore often prepared alone with a second check being undertaken before administration. Checking processes, particularly at the point of administration, differed from those specified in Trust policy/procedures.

4.4.9 During the first administration of dalteparin, both nurses were in the medicines room, but preparing medicines for different patients. Nurse 1 asked Nurse 2 about the dalteparin and Nurse 2 directed Nurse 1 to check the medicines guide, as Nurse 2 had never had to administer it fully from a pre-
filled syringe. Nurse 2’s second checking involved checking the prescription and comparing it to medicines guide. They felt the prescription was correct after seeing the note about the haematology plan. Nurse 2 was not familiar with the detail of Felicity’s plan of care.

4.4.10 The investigation heard that the door of the preparation room might be propped open if two nurses needed to be in the room at the same time, and no other staff were on the ward. This was a particular issue out of hours. An investigation into a previous medication incident in cardiology had recommended a reduction in the number of times the door was propped open, to reduce interruptions.

4.4.11 The first dose of dalteparin was given by a nurse who was also the nurse in charge. Nursing staff described short staffing on a number of shifts during the weekend period, resulting in medicines being given late. Nurse 4 was the second checker for the second dose given at 06:35 hours on Saturday 14 March and remembered commenting on the unusually high dose. However, she was then falsely reassured by the note saying it had been discussed with haematology, the pharmacist’s check, Nurse 3’s assurances, the box of dalteparin with Felicity’s name on it and the fact that the medicine was being used to treat a DVT.

4.4.12 There was no specific mention by nurses 1 to 7 of referring back to the medical records to check the documentation of the intended prescription. The intended dose of dalteparin was not documented in the medical records before prescribing, other than in the email which was supposed to be filed in the records. There was an annotation made by the specialist registrar during the Sunday ward round which stated ‘dalteparin 100u/kg BD’. Therefore, unless the nursing staff had seen the email correspondence which included the dosing information, the medical records would not have helped them to detect the error before the Sunday evening dose.

Subject matter advisor’s analysis 4

Analysis of the double-checking process in relation to the role of the second checker

The medication error was identified after seven successive checks were conducted. The checks were not independent for the reasons described in section 4.4 and because the checks were made against the same source of information – the ePMA system.

A flowchart to describe the process of double-checking at the reference event Trust was reviewed by the investigation. The first issue with this concerns the concept of ‘checking’ which appears to be underspecified. This results in
the answers to the following questions being unclear: what requirement is met by a successful check; against what source of information or standard is the check made; and how is it made? There is a difference between ‘checking’ and ‘verification’ (checking that the contents of a syringe agree with what is written on the prescription versus verifying that what has been prescribed is appropriate against a standard). Taken together, completion of checking and verification should validate the process against a therapeutic requirement. These distinctions were not apparent in the evidence collated. Some evidence for the under-specification of checking was heard during interviews with the nursing team:

“During my training I was never taught how to check medications or how to prescribe them, but we are almost checking the that the doctor has written it right.”

The second issue concerns the free-text box used in the reference event and its purpose. The specialist trainee 2 doctor (ST2) suggested that his comments were to reassure nurses over the weekend if there was no registrar or senior house officer on duty. However, this ‘re-assurance’ may undermine the process of independent checking as outlined in the codes of practice and standard operating procedures. If no comment had been made, or if there had been nowhere to record such comments, might those nurses who challenged the dose have sought independent sources of evidence or escalated the matter before proceeding? The statement, ‘as per discussion with haematology’ implies that the dose had already been checked, thus negating the independence of the check by the nurse. To check is to examine something in order to determine its accuracy, quality, or condition, or to detect the presence of something and the statement implied that this had already been done.
5 Analysis and findings – the wider investigation

This section sets out the findings of the investigation’s analysis of weight-based prescribing in children, in the context of the wider healthcare system. This element of the investigation considered national policy and guidance and the regulations that govern this aspect of medical care. The findings are focused on the following areas:

• factors relating to multidisciplinary co-ordination and decision-making in the context of weight-based prescribing

• the effectiveness of checking as a barrier to medication errors

• the implementation of ‘off the shelf’ electronic prescribing systems in specific contexts.

5.1 Exploration of the factors that both support and inhibit multidisciplinary co-ordination and decision-making, including the communication of critical decisions in relation to weight-based medications, in support of a child’s treatment

Interventions which support multidisciplinary communication

Handovers

5.1.1 There is evidence that clinically significant information may be lost during the handover process, and presence of a consultant at handover improves outcomes for children (Royal College of Paediatrics and Child Health, 2015). Relevant to this, one of the standards for acute general paediatric services outlined in ‘Facing the future’ (Royal College of Paediatrics and Child Health, 2015) states: ‘At least two medical handovers every 24 hours are led by a consultant paediatrician.’ The investigation observed and heard that this was not always practical because of the on-call arrangements for consultants, particularly at weekends.

5.1.2 An audit by the Royal College of Paediatrics and Child Health (2013) showed there was support for handovers involving paediatric consultants and senior nursing staff to ensure the multidisciplinary team was kept up to date. It highlighted that ‘many clinical directors and ward managers felt that an inclusive, well documented handover was the glue that held their service together’.
5.1.3 In relation to nursing teams, there are no national handover standards. The investigation contacted the Royal College of Nursing (RCN) about this and was advised about work that was undertaken in 2019 around the use of human factors and the situation, background, assessment, recommendation (SBAR) communication tool in handover (Royal College of Nursing, 2019). This was intended to provide a structured handover framework for nursing teams. The investigation also noted there were local policies in place and observed these in practice during site visits to trusts.

Quality improvement initiatives and huddles

5.1.4 The Royal College of Paediatrics and Child Health (RCPCH) told the investigation that it had previously worked with more than 50 paediatric units over 4 years on the Situation Awareness for Everyone (S.A.F.E.) programme (Royal College of Paediatrics and Child Health, 2018). This was implemented by developing and trialling quality improvement techniques, to improve communication and build a safety-based culture. By using S.A.F.E principles, the RCPCH anticipated that paediatric units could, amongst other outcomes: ‘reduce avoidable error and harm to acutely sick children’ (Royal College of Paediatrics and Child Health, 2018).

5.1.5 S.A.F.E is also a key theme for Making it Safer Together (MiST). This is a paediatric patient safety collaborative of hospitals whose goal is to continually reduce healthcare-associated harm, by sharing experiences, tools, and ideas. The safety ‘huddle’ was included as part of the S.A.F.E. project to improve situational awareness. It has been described as an intervention to improve the quality of care, and has been implemented in various settings within healthcare (Royal College of Paediatrics and Child Health, 2018).

5.1.6 Following on from this, the investigation was advised that a ‘DRUG-gle’ could be a valuable intervention to reduce medication errors (Royal College of Paediatrics and Child Health, 2020). A DRUG-gle is a specific medication-focused safety ‘huddle’, involving the paediatric ward doctors, nurses and pharmacists meeting as part of the ward routine, usually after the ward round. Integral to this is a short, focused discussion when checking individual patient’s medication charts on the ward round. This is described using the acronym ‘APT’:

• ‘Is it Appropriate? – do we need to stop or change it?’
• Is it the correct dose Prescribed? – can it be rationaled?
• Is the Timing OK? – is it ambulatory friendly?’
DRUG-gles were not observed during site visits, but research literature indicates they are undertaken in some organisations across the UK (Shore et al, 2017).

5.1.7 The principles of **S.A.F.E. huddles/DRUG-gles** in paediatrics encourage more multidisciplinary input and have been used at several sites in England. The investigation found that however huddles are not always multidisciplinary; content is varied, as is attendance; and there are no clear aims or objectives. The investigation observed that their primary purpose appeared to be the updating of staff who have not been able to attend the ward round. The investigation observed a huddle during a comparison site visit. The huddle appeared to be informal, with nursing and medical staff gathered behind a nursing station, with frequent interruptions and distractions.

**Subject matter advisor’s analysis 5**

**Performance shaping factors in relation to communication and hierarchies**

Frankel et al (2012) identified some of the non-verbal behaviours that influenced the quality of handovers. They concluded that handover was most effective when all parties had a ‘joint focus of attention on a shared artefact such as a computer screen or a handover sheet’. Non-verbal behaviours ‘to be avoided’ included: one person has the sheet/patient record/computer screen while the other cannot see it; interruptions during handover that divide attention (one person is multitasking while the other is attempting to follow the main task); power imbalance (one person is seated while the other stands). Nurses were engaged in multiple tasks while hearing the handover.

A joint focus of attention can best be achieved if all parties focus on the same artefact, with no distractions either in a private office or at the bedside, handovers are conducted in a defined location and both parties work off the same notes whether written or electronic. A joint focus of attention during handover is likely to promote a ‘shared understanding’ of the patient’s condition and how it is being treated and what must happen next.

5.1.8 In summary, evidence from the reference event investigation, observation undertaken at other trusts and information from the RCPCH and the RCN indicates that while there are handover standards for paediatricians, there are no similar standards for paediatric nursing staff. The SBAR communication tool is advocated by the RCN, but the investigation found no evidence that this has been widely adopted by trusts for the purpose of handovers and huddles. Additionally, there is no standard format for conducting huddles.
HSIB makes the following safety observation

**Safety observation O/2022/145:**
It may be beneficial if a standard format for multidisciplinary care reviews (including handovers and huddles) was adopted by healthcare organisations, with a shared understanding of the management plans for individual patients.

**Ward rounds**

5.1.9 In the case of the reference event, the nursing and pharmacy teams did not appear to be completely integrated into the cardiology multidisciplinary team. This was particularly evident in relation to irregular attendance and active participation in ward rounds. In addition, the nursing and pharmacy teams were not integral to the discussions about the initiation of anticoagulant therapy.

5.1.10 The investigation heard that the irregular ward round attendance by the nursing and pharmacy teams was resource and capacity related, in addition to the timing of the round, which took place when other tasks needed to be undertaken. The pharmacy team reflected on whether their attendance on ward rounds was routine practice:

“It is in an ideal world, and I have done in the past where possible. It’s not always possible to follow the ward round around because they don’t always happen at the same time of day.”

The Trust where the reference event took place reflected that for ward rounds, ‘work as done’ (that is, the way staff did them in practice) (Shorrock, 2016), did not meet the national guidance ‘Standard Ward Round NHS Improvement’. This was because 'standards and expectations were inconsistent'.

5.1.11 The investigation observed practice at a comparison site trust and noted that the pharmacist was an integral part of the ward round, amending any changes to the children’s medicines directly on the ePMA system during the ward round. In addition, the investigation observed the nursing staff caring for the individual patients providing a direct handover to the consultant leading the ward round. The nurse in charge was not part of the round, but joined a post-round huddle to ensure they were updated in respect of key changes.

5.1.12 The Royal College of Physicians (2021) states that all professional staff should input into ward round discussions, adding that the nurse caring for the patient was essential to these discussions. The role of the ward co-ordinator is also described as a key role, particularly in respect of inputting into pre- and post-ward round huddles, and receiving updates during the round.
5.1.13 In relation to pharmacists, the ‘Modern ward rounds’ guidance published by the Royal College of Physicians (2021) states that: ‘Pharmacy input is also essential for most patients and, where resources allow, there are demonstrable benefits to the ward pharmacist being part of the ward round.’ The guidance specifically refers to medication reviews being incorporated into ward rounds. ‘Professional standards for hospital pharmacy services’ (Royal Pharmaceutical Society, 2017) similarly advocates that:

‘Pharmacy team members are integrated into multidisciplinary teams across the organisation and provide patient facing clinical services to ensure safe and appropriate medicines use for all patients …’

5.1.14 Sutherland et al (2019) found that while there are currently no paediatric interventional studies evaluating the impact of ward-based pharmacists in the UK, their study demonstrated their contribution to the detection and resolution of medicine-related issues. Their study on prescribing errors in paediatric intensive care units found that pharmacists were an important control for medication error, but were only present on an ad hoc basis (Sutherland et al, 2019).

5.1.15 In the reference event, the lack of a 7-day clinical pharmacy service meant that the specialist pharmacists were not present on the cardiology ward from Friday (when the dalteparin was dispensed) until the following Monday. A higher level of pharmacy service would have afforded a daily review of Felicity’s medication chart and pharmacist presence on the ward, both of which would have provided an opportunity to verify the dose of dalteparin.

5.1.16 The requirement for improved 7-day services has been recognised for many years, as outlined in the publication ‘Transformation of seven day clinical pharmacy services in acute hospitals’ (NHS England, 2016a). This includes potential solutions to improve workforce capability 7 days a week, and the means by which national/local organisations and individuals can support delivery. This is an existing focus for improved 7-day services.

5.1.17 Additionally, HSIB has previously made a safety recommendation to the Royal Pharmaceutical Society (RPS) relating to hospital clinical pharmacy provision. This was in connection with the national investigation ‘The role of clinical pharmacy services in helping to identify and reduce high-risk prescribing errors in hospital’ (Healthcare Safety Investigation Branch, 2020a). The aim of the safety recommendation was to reduce variability in hospital clinical pharmacy provision and is therefore relevant to this investigation. The investigation was advised that the RPS was planning to start refreshing its professional standards for hospital pharmacy services at the end of 2021. However, implementation has been delayed pending the provision of funding for the development of the guidance.
5.1.18 Evidence gained through analysis of the reference event, comparison site visits, discussions with the RCPCH and the RCN and a review of the research literature indicates that there is no standardised approach to conducting ward rounds in paediatrics.

5.1.19 Recent work has been undertaken to update the ‘Modern ward rounds’ guidance (Royal College of Physicians, 2021). A multidisciplinary approach to modern ward rounds was adopted within this guidance, with a focus on the inclusion of patients, carers and families in decision-making processes and communication. Ward rounds were described as being a:

‘... focal point for a hospital’s multi-disciplinary teams to undertake assessments and care planning with their patients. Co-ordination of assessments, plans and communication is essential for effective and efficient care.’

5.1.20 The guidance also specifies that information on the patient’s condition gathered at the shift handover should be discussed in a board round or huddle prior to the ward round, attended by all members of the multidisciplinary team (Royal College of Physicians, 2021).

5.1.21 The publication reflects that ‘most ward rounds in UK hospitals require considerable improvement and research and quality improvement is necessary to inform effective practice’. It incorporates best practice principles for multidisciplinary teams such as ‘Agree principles, standards, functions and structure for local ward teamworking’ and ‘Clarify each team member’s role’ (Royal College of Physicians, 2021).

5.1.22 The ‘Modern ward rounds’ guidance (Royal College of Physicians, 2021) is currently for clinicians treating adult patients and not children. There is no specific guidance for ward round management in paediatric settings.

5.1.23 The RCPCH told the investigation that if the guidance was to be used in paediatrics, it would require greater emphasis on the views of the parents and the voice of the child, both during ward round discussions and decision making. The RCPCH advised that there would also need to be consideration of the role of the paediatric pharmacist in supporting the ward round process in different hospital environments. This role includes prescribing during the ward round, stopping medications/reducing a dose, reviewing the length of treatment and monitoring of pros and cons of the medicine.
HSIB makes the following safety recommendation

**Safety recommendation R/2022/175:**
HSIB recommends that the Royal College of Paediatrics and Child Health identifies the best practice principles for effective paediatric ward rounds in relation to medicines, and disseminates them to its members.

5.2  **Understand the factors which contribute to a reduction in the effectiveness of checking as a barrier to medication errors, including those that result in workarounds**

5.2.1 Children are estimated to be three times more likely than adults to experience medication-related harm (Sutherland et al, 2019), which is thought to be related to the increased complexity in the approach to medication for children. Administration errors are reported to occur in 20% to 25% of dose administrations (Koyama et al, 2020). In a systematic review that included paediatric and adult medicines administration, Koyama et al (2020) identified that interventions to reduce errors during this stage in the process are particularly important, since it is the final step before a patient receives a medicine.

5.2.2 Information technology is increasingly being used by hospitals to facilitate the medication administration process and associated with this is the implementation of significant workflow changes (Koyama et al, 2020). This provides an opportunity to examine work practices and to reconsider long-held practices. While the implementation of ePMA systems has reduced the risk of transcription errors, the technology may have unintended consequences. One of these consequences is that it takes longer to complete the medicines administration process, due to both nurses needing to log on to the system independently to verify the second-checking process (Koyama et al, 2020).

5.2.3 Qualitative studies also indicate that nurses are significantly less likely to second check medications when using an ePMA system. There is evidence of substantial disruption to nurses’ work in both seeking out and responding to requests for second checking, which can contribute to task errors and potentially increased safety risks (Westbrook et al, 2020).

5.2.4 The investigation was advised by a comparison site trust that many ePMA systems are configured to mandate a second check for certain medications or certain types of patients. Therefore, this step cannot be omitted since it requires the second nurse to add their ‘PIN’ (unique registration code) before they can document the administration of the medication.
Analysis of the medicines administration process

During a site visit to a children’s hospital, the investigation was provided with a demonstration of the medicines checking process on a ward, using the online system. This was ‘work as prescribed’ (by policies/procedures) though as opposed to ‘work as done’ (operational work by clinical staff) (Shorrock, 2016), as evidenced by observations of clinical practice.

The process itself appeared to be ‘mechanistic’, with no mention of the experiences and knowledge that staff bring to bear during the daily conduct of their duties. However, people often use mental ‘short cuts’ to simplify decision making under uncertainty and the use of these short cuts can lead to errors in the behaviour of individuals and teams. These shortcuts, known as ‘heuristics’, are discussed in subject matter adviser’s analysis 3, on page 55.

The medicine administration process consisted of nine steps, with seven items to check against two reference sources. Step 6 onwards required two nurses and varied depending on the level of risk. The process started with the prescription written by a doctor:

1. Receipt of the prescription written by doctor initiates the task.

2. The prescription is checked against the British National Formulary for Children or other reference (on screen). Essentially, this is not a check, but a verification of the prescription to ensure that it is appropriate for the child, taking into consideration: the dosage; the child’s weight; the frequency of administration; why it is needed; and the contra-indications.

3. The nurse then refers to the ‘labs’ screen and checks the medicine levels (current levels) to ensure that the prescribed dose is not toxic. This is a safety check against Trust guidelines (which are on a separate screen). There is another safety check against allergies; and to verify that the record of the child’s body mass is up to date (no more than 7 days since last measurement).

4. On completing steps 1 to 3, the prescription is considered to have been validated.

5. The nurse then prepares the medicine in accordance with the medicines preparation and administration guide.

6. A second nurse is called to carry out the second check. If the medicine is ‘high risk’, nurse 2 then repeats steps 1 to 4; if ‘low risk’, nurse 2 checks the product against the prescription and the intravenous administration guide to ascertain if the prescription is correct and the medicine is in date. Nurse 2 also checks
blood levels to ensure that the prescription will not cause medicine levels to exceed toxic limits. Nurse 2 signs it off before nurse 1 goes to the patient to administer the medicine.

7 Nurse 1 then checks the patient’s wrist band to ensure it is the right patient.

8 If it is the right patient, the medicine is administered (both nurses go if the medicine is high risk)

9 Nurse 1 then scans the patient’s wrist band to record the medicine ‘as administered’.

Based on the information reviewed, ‘checking’ as described in the references above, is really a stepwise process that consists of ‘checks’ (against indications to do a task; including the timing of the operation, usually by a second person); ‘verification’ (a precaution wherein the prescription is referred to standards); and ‘testing’ (which involves challenging and problem identification). Overall, this process ‘validates’ administration of the medicine to the patient.

The distinction between ‘verification’ (what is prescribed is appropriate and meets the therapeutic requirement) and ‘checking’ (that what is subsequently administered to the patient is ‘as prescribed’), needs to be made explicit. At a children’s hospital where the investigation undertook observational work, a ‘traffic light’ system automatically checked the dose against standards with respect to patient parameters. Such systems are not influenced by heuristic traps.

Second-checking process

5.2.5 Within the research literature, definitions of second checking vary considerably, with terminology often used interchangeably. Several studies have demonstrated that organisational second-checking policies often differ in terms of how the process should be conducted, which contributes to variation in how nurses apply the policies (Koyama et al, 2020). This was also demonstrated by the investigation’s analysis using the Functional Resonance Analysis Method (FRAM) to explore variability in the application of organisational policies (see figure 6).

5.2.6 Some organisations require second checking for all medicines while others only require it for high-risk medicines. Koyama et al (2020) also reported that the majority of non-numerical qualitative studies they reviewed and cognitive theory (focused on thought), provided limited detail on the steps in the medication administration process which required second checking.
5.2.7 Second checking of medications has been implemented in hospitals based on an assumption that it will result in fewer errors (Koyama et al, 2020). However, to date there is limited evidence of the effectiveness of second-checking procedures to reduce errors in prescribing for children, despite the extensive use of the policy in paediatric hospitals worldwide (Westbrook et al, 2020). Koyama et al (2020) attribute the limited evidence to the paucity of high-quality randomised controlled trials.

5.2.8 ‘Primed double-checking’ (see section 1.4) may lead to confirmation bias (the tendency to focus on or interpret information that confirms one’s existing beliefs) (Westbrook et al, 2020). As the Institute for Safe Medication Practices (2019) states:

‘Two people working independently are less likely to make the same mistake; if they work together or suggest what the checker should find, both could follow the same path to error.’

There is limited information on how independent and primed double-checking is differentiated (Koyama et al, 2020). However, independent double-checking is preferred since if the checker is primed, an error may not be detected due to confirmation bias (Koyama et al, 2020).

5.2.9 In relation to ‘independent double-checking’ (see section 1.4), published studies have produced conflicting findings. Findings by Konwinski (2020) indicated that ‘there was no compelling evidence to adhere to the IDC [independently double-checked] process at all’. The Institute for Safe Medication Practices (2019) believes that the selective and proper use of manual independent double-checks can play an important role in medication safety, particularly among vulnerable patients (including children) and for high-risk medications. Koyama et al, (2020) concluded that independent double-checks should minimise errors that arise from one individual, providing that an independent calculation is carried out by a clinician with no prior information, to avoid influencing their decision making.

5.2.10 Several studies (see appendix 3) have demonstrated the ability of independent double-checks to detect up to 95% of errors (Institute for Safe Medication Practices, 2019). Despite positive attitudes about their use, independent double-checks have ‘long been disputed, discounted, and misused in healthcare’ (Institute for Safe Medication Practices, 2019). As outlined by Dickinson et al (2010):

‘The adoption of IDC [independent double-checks] in health care settings must have in place: policy and guidelines that clearly define the process of checking, educational support, an environment that supports peer critique and review, well-designed medication areas and accessible resources to support drug administration.’
5.2.11 Westbrook et al (2020) suggested that the current application of double-checking policy may no longer be fit for purpose in modern clinical settings. Pfeiffer et al (2020) supported this, stating that consideration should be given to reconceptualising the double-check process to include a wider range of options, such as ‘single-person double-checking’.

5.2.12 A hospital in the US used a human factors approach to minimise medication administration errors by piloting and introducing ‘single-checks’ (Konwinski et al, 2021). This resulted in a reduction in the medication error rate from 1.21% to 0.78%. In addition, less time was spent searching for another to nurse to perform the check and to document medication administration.

**Figure 6 Functional Resonance Analysis Method**

The investigation reviewed several trusts’ work procedures that set out the processes for checking medications for children. These represented the expected processes for staff to follow. The Functional Resonance Analysis Method (FRAM) was used to describe how the activities involved in the outlined processes should function (Hollnagel, 2012). This then allowed exploration of the variability in the activities in practice which alone or combined could result in unintended consequences.

FRAM models were developed based on two trust work procedures and discussions with trust representatives. Simplified versions of the FRAM models are shown below. These models represent the trust’s expected processes for checking medicines for children that require a second check. Through observations and interviews, the investigation compared these models to the way checking was undertaken in practice.

**Trust 1 (the reference event Trust)**

The FRAM model from Trust 1 (**Figure A3**) describes a process involving a primary and secondary checker. The primary checker first validates the chart and prescription, and then prepares the medicine. Validation of the chart includes checking patient identification, recent weight, allergies, and contraindications (reason not to give a medication because it may be harmful). Validation of the prescription includes checking the medicine name, dose, frequency, and route against the British National Formulary for Children (BNFC). A secondary checker is then requested to independently validate the prescription and check the prepared medicine.

The work procedure describes that the primary checker must only prepare the medicine up to the point of adding any diluent (diluting agent) (if required); mixing with diluent must be observed by both checkers. Any calculations must also be
undertaken independently by both checkers. Administration involves both checkers going to the bedside to check the patient and infusion pump (for giving the medicine, if applicable). The secondary checker is then released and the primary checker completes the administration.

In practice, the investigation heard of the variability in primary checkers accessing secondary checkers. This was often because of limited staff availability and other demands on staff, which resulted in minimal time to undertake the checks. Variability in the scrutiny of the checks was also heard; calculations were not always undertaken and checking of dose against the medicines management guidance (such as the BNFC) was often not done if the dose had been given previously.

**Trust 2 (observation site)**

The FRAM model from Trust 2 (Figure A4) describes a process involving an administering practitioner and an independent check practitioner. Following validation of the medication chart an independent checker joins the process to observe and confirm silently as the rest of the process continues. If the process is interrupted or incorrect, the work procedure states that the practitioners must start again. The administrator and independent check practitioner work through the process of medicine selection, independent calculations, preparation, the programming of an infusion pump and administration. The principles in the Trust 2 policy more closely aligned with observations outside of healthcare (see learning case study 1).

The investigation observed in practice the process for intravenous administration of medicines that required an independent check. It was observed that administering practitioners undertook the validation and preparation steps before requesting an independent check. The independent check practitioners then came to the medicines preparation area and viewed the computer prescription, medicine container and prepared volume. The administering practitioners then went on their own to the patient and administered the medicine via an infusion pump.

This observed variation from the work procedure was heard to arise from factors such as the availability of trained staff to undertake the checks and the perception that the medicine to be administered was a simple preparation. The patient had received the medicine multiple times before (and no calculation was observed), therefore there was an assumption that the dose on the ePMA system was correct.

**Comparison**

The two work procedures described in the FRAM models are different in their use of the second checker. In both cases, it could be argued that the second check is not independent as several steps in the process involve the second practitioner reviewing the activities or selections of the first.
The findings demonstrate that while the process may be clearly described in work procedures, undertaking it in practice is challenging because of contextual factors. There is also no evidence across trusts of a standard approach that involves truly independent checks.

**Cognitive processes involved in checking medicines**

5.2.13 Koyama et al (2020) have explored the factors which may further influence the reliability and effectiveness of double-checking. These include the following, many of which were evident from the analysis of the reference event:

- the automatic nature of the task which may decrease staff members’ attention
- failure to look for and process additional information once initial information looks correct (‘satisficing’)
- excessive trust in the person whose work is being checked
- deference to authority when a junior nurse may not challenge an error made by a more senior colleague
- distractions and interruptions
- diffusion of responsibility (where person is less likely to take responsibility when other colleagues are present) and an overreliance on double-checking, in which staff believe someone else will catch any mistakes, leading to a false sense of safety (Koyama et al, 2020).

5.2.14 The ‘Efficiency-Thoroughness Trade Off’ concept (Hewitt et al, 2016) and ‘Social Loafing’ (observed when checking another person’s work) (Koyama et al, 2020) are said to contribute to the diffusion of responsibility and lack of concentration on the task. Koyama et al (2020) found that in the case of medicines administration tasks, where independent double-checks were required, these factors contributed to errors not being detected during the checking process.

5.2.15 There are different cognitive processes involved in checking medicines. Double-checking against a prescription requires a person’s attention for the activity, but not their critical thinking (White et al, 2010). However, critical thinking is required (using a nurse’s own knowledge) to evaluate whether a dose calculation is correct and for identifying an error in the prescription (Dickinson et al, 2010). Pfeiffer et al (2020) consider that calculations involve generating (as opposed to comparing) information, with the calculated value
being new, ‘generated’ information. It was suggested that creating space and points in time in the medication process for plausibility reviews (using own knowledge) represents a way of using reflective thinking for detecting errors (Pfeiffer et al, 2020).

5.2.16 The investigation observed that what was often missing in the independent double-check process was a ‘sterile cockpit’ environment – that is, an environment void of unnecessary distractions. According to Federwisch et al (2014), this should improve patient safety if applied at key points in clinical procedures.

5.2.17 To broaden the understanding of double-check processes, the investigation explored how other, high-reliability industries carried out their checking processes. It was noted that checks that rely on humans pose a safety risk in all industries. This is exemplified in various reports by the Air Accidents Investigation Branch (2020; 2018). The investigation also had the opportunity to observe checking processes in helicopter engineering and simulated flight processes during a visit to a Royal Naval Air Station. The sterile cockpit concept was observed, where pilots and staff were required to refrain from non-essential activities during critical phases to reduce distractions to a minimum. The investigation’s learning from the visit is provided in learning case study 1.

Learning case study 1

Learning from the Royal Navy at Royal Naval Air Station Yeovilton

825 Naval Air Squadron (NAS) of the Royal Navy’s Fleet Air Arm flies the ‘AugustaWestland Wildcat’ helicopter. 825 NAS is responsible for aircrew and engineer training on the Wildcat.

The investigation observed three levels of engineering checks to ensure the continuing airworthiness of an aircraft following tasks such as repairs, replacements, or servicing. The levels escalate the scrutiny of the check in line with the safety-criticality of the aircraft system that has been tasked to be worked on. Each task has a defined level of check associated with it:

• Level 1 – a ‘self-supervisory check’ for tasks involving non-safety-critical systems; an engineer can undertake their own check.

• Level 2 – a ‘supervisory check’ for more safety-critical elements; a trained and competent supervisor checks the task has been completed to the standard required.

• Level 3 – an ‘independent’ check for safety- or flight-critical systems; a trained and competent independent checker who has not been involved in any of the tasks up to the point of the check, observes the steps of a task and independently checks it against a standard.
The independent check is undertaken for defined, specific task steps and is checked against a standard (engineers handbook or policy). If at any point an issue is spotted, the engineer will be told to stop by the checker, disassemble the equipment and restart.

The Royal Navy has a clearly defined framework for competency assessment of engineers to undertake tasks. Each engineer has a level of competency that is regularly reviewed depending on their experience; this could range from monthly to yearly. An independent checker is required to attend a 3-week course, complete written/verbal/practical assessments, and abide by strict rules for what they can and cannot independently check.

The observations and discussions with 825 NAS allowed comparison with healthcare. It was acknowledged that contexts are different, but that elements of the checking process provide useful insights for healthcare.

While the engineers agreed with the investigation that human checks are limited in their effectiveness as a barrier to errors occurring, they described strict checking processes reduced the occurrence of incidents at 825 NAS. The independent checking process differed from healthcare in that it: had clearly defined and specific tasks that required an independent check; was as independent as possible with the checker being uninvolved previously and observing the full task; and was checked directly against a standard (the engineers handbook). In healthcare that standard may be the British National Formulary for Children or a medicine guide.

**Figure 7** Trainee Air Engineers of 825 Naval Air Squadron prepare a Wildcat helicopter on the deck of a Royal Navy Destroyer

Image courtesy of Royal Navy.
5.2.18 In summary, evidence from the reference event investigation, observations of work during comparison site visits, learning from the Royal Navy, learning from Air Accidents Investigation Branch and a review of the research literature (Westbrook et al, 2021; Koyama et al, 2020; Castiglione and Ekmekjian, 2017; Hewitt et al, 2016; Schwappach et al, 2016) undermine confidence in the effectiveness of second checking in healthcare.

5.2.19 There is limited evidence comparing the effectiveness of independent versus synchronous (checking side by side) manual second checks on reducing the risk of medication administration error (Castiglione and Ekmekjian, 2017). The whole process of ‘checking’ appears not to be specified in sufficient detail. According to Koyama et al (2020), there remains a need for higher-quality studies to determine if, and in what context, second checking produces sufficient benefits in patient safety to warrant the considerable resources required.

**HSIB makes the following safety recommendation**

**Safety recommendation R/2022/176:**
HSIB recommends that the National Institute for Health Research assesses the priority, feasibility and impact of future research on processes for second checking medication, and considers the most appropriate way of building up the evidence base on this topic.

5.2.20 The investigation recognises that the safety recommendations made in this report focus on checking processes that are reliant on humans. The investigation also found evidence, supported by research literature, of the important role of the working environment in supporting effective checking processes. For example, the investigation saw how the set-up and environments within which medicines were being checked resulted in distractions and interruptions.

**HSIB makes the following safety observation**

**Safety observation O/2022/146:**
It may be beneficial for trusts to consider creating the optimum environment and conditions to support medication checking processes, by reducing distractions and interruptions to a minimum.
5.3 Implementation of ‘off-the-shelf’ electronic prescribing systems in specific contexts, particularly paediatric weight-based prescribing

Uptake of electronic systems and the impact on medication errors

5.3.1 Data indicates the use of health IT systems is becoming increasingly widespread and the functionality more sophisticated (NHS Digital, 2018). NHSX, the organisation tasked with driving forward digital transformation in healthcare, advised the investigation that around 50% of trusts are using ePMA systems, with a further 25% to 30% funded for go-live dates over the next 12 to 18 months. It was anticipated that the increased uptake of ePMA systems by trusts would correspond with a 30% reduction in medication errors (NHS England and NHS Improvement, 2019).

5.3.2 In paediatrics, ePMA systems were viewed as being key improvement measures to reduce medication errors (Mohsin-Shaikh, 2019; Campbell et al, 2006). In support of this finding, the investigation regularly heard from frontline staff that their perception was that the ePMA systems would prevent medication errors.

5.3.3 However, contrary to expectations, the findings of a recent systematic review and meta-analysis conducted by Gates et al (2021) concluded that ePMA systems had variable impact on medication errors and harm. Furthermore, NHS Digital (2021) stated that while ‘it must be recognised that failure, design flaws or incorrect use of such systems have the potential to cause harm to those patients that the system is intended to benefit’. This is supported by Sutherland et al (2019) who state that poor design and the implementation of ePMA systems can lead to a worsening of safety, and higher numbers of deaths.

5.3.4 According to Fox et al (2019), there are three types of ‘technology-related errors’ created by ePMA systems; these are discussed further in subsequent sections:

- not preventing the majority of harmful prescription errors
- the varying levels of decision-making support and warnings provided to prescribers
- differences in the systems being used, and between the same system on different sites.
5.3.5 Sutherland et al (2019) reflected that with the drive to improve safety in the NHS by introducing more technology, there was a need to understand these systems and how people and technology work together to ensure patient safety. This has been recognised by NHSX in its Digital Clinical Safety Strategy (NHSX, 2021), which includes ‘Ensuring that rapidly evolving digital systems do not cause or contribute to adverse events’ as one of its system-wide priorities.

Weight-based prescribing in paediatrics

5.3.6 Many medication doses in paediatrics need to be based on either the child’s body weight or body surface area to achieve the most appropriate dose (Paul et al, 2011). The investigation was advised that the weight of children can vary greatly, by 200-fold differences in some cases (for example, a 500g baby versus a 100kg teenager). Therefore, an individualised approach to treatment is required, sometimes without suitable preparations of medicines.

5.3.7 Weight-based calculation has been shown to generate risks in prescribing (80% of errors) and administration (16% of errors) (Tse and Tuthill, 2020). This study highlighted that half of all prescribing errors resulted from incorrect dose selection, and technical prescribing errors occurred almost twice as often as clinical errors. This is attributed to a lack of standardised methods for the preparation and administration of medicines for children, resulting in adult formulations often being adapted for administration (Furniss et al, 2018).

5.3.8 Sutherland et al (2019) found that while dosing errors were the second most prevalent type of error in prescribing for children, the proportion of errors involving a 10-fold dose or more was uncertain. While acknowledging that there are many factors that can cause dosing errors, the problems relating to decimal points in clinical practice when calculating and measuring doses have been highlighted. Interventions over the years have not provided a solution and there has not been a systematic approach to reduce these problems in the UK (Rashed and Tomlin, 2020).

Use of ePMA systems in paediatrics

5.3.9 The investigation was told by a software manufacturer that some ePMA systems were not yet being used in paediatrics because the manufacturer wanted to ensure optimum safety in terms of the functionality before such systems were implemented. The investigation was advised by one manufacturer that it wanted to include functionality that allowed a standardised approach, preventing mis-selection of adult dosing. This would include controls for certain patient groups, including weight, different levels of alerts and permissions.
5.3.10 The investigation observed ePMA systems designed for adult patients being modified for paediatric patients. This included paediatric-only facilities, where the age and weight ranges of patients sometimes resulted in adult equivalent doses of medicines being prescribed.

5.3.11 In the reference event, trust-level configuration resulted in access to adult doses (of dalteparin) in a paediatric environment. As outlined in this investigation’s interim bulletin, published in March 2021 (Healthcare Safety Investigation Branch, 2021), the investigation identified the following safety observation from the investigation of the reference event.

In addition, HSIB made the following safety observation in an interim bulletin (March 2021)

Safety observation O/2021/097:
It would be beneficial for trusts that have adult and paediatric prescribing supported through the same ePMA system to ensure they have adequately risk assessed the way in which the system supports the calculation of doses to ensure that adult doses do not require manipulation for paediatric patients.

5.3.12 Evidence over a number of years indicates that local configuration of ePMA systems has resulted in different outcomes in simulation testing, including adverse consequences (Metzger et al, 2010). Local configuration introduces variability and may introduce deviations in terms of a system’s functionality. A key observation made by the investigation was that all the ePMA systems observed were systems that were initially configured for prescribing for adults which were then adapted for paediatrics.

5.3.13 The investigation explored with trusts and software manufacturers the risks caused by having adult and paediatric prescribing in the same ePMA system. It was established that the risks needed to be adequately identified and mitigated with clear documentation in safety cases. Safety cases form part of a proactive safety management approach (Sujan and Habli, 2021) and are discussed in further detail in this section, from 5.3.34.

Safety functionality in ePMA systems

Use of the free-text field in ePMA systems

5.3.14 During the investigation, the usability and safety functionality of ePMA systems in paediatrics resulted in an exploration of user-testing and the implementation in different settings. One example was the use of the free-text field. The investigation was advised that the free-text box was not consistently populated in terms of content; ePMA systems ranged from having no free-text options at all to multiple free-text options. They
usually had a specific focus on aspects such as additional instructions and administration information, and some of the free-text information was thought to be valuable when used within local guidance. NHSX advised the investigation that it was not feasible to recommend that ePMA systems were amended to remove free-text boxes, and that removing them may in fact have a detrimental impact.

Subject matter advisor’s analysis 7

Performance shaping factors in relation to the ePMA system

There are three mechanisms by which people detect their own errors (Sellen, 1994). ‘Action-based detection’ occurs when the person detects incorrect actions as they are being performed. This requires that the person attends to feedback from the task and understands what the feedback means. ‘Process-based detection’ occurs when events in the real world ‘short-circuit’ the action sequence (for example, the system detects that 15,000 units is out of range for a child of 15kg). ‘Outcome-based detection’ occurs when the former two processes fail and the error is made apparent by its consequences. In this case, a prompt to end the dialogue, such as: ‘Are you sure you want to prescribe a dose of 15,000 units based on this weight? Y/N’ may have prompted the specialist trainee 2 doctor to confirm the dose to end the dialogue.

During an observational visit to another trust, the investigation observed some of the features of an ePMA system developed by another manufacturer. This system would “hard stop” a prescription such as that in the reference event, by cross-referencing it against standards. Hard stops on this system had to be manually overridden. This system had a traffic light warning indicator which indicated whether a prescription was ‘in range’. This is an example of ‘process-based detection’ that alerts the pharmacist to a problem or issue using colour. The pharmacist at this trust informed the investigation that their system would “red light” it and hard stop it, which may have alerted the prescriber in time to correct the error. In the reference event, it appears that the comment ‘as per discussion with haematology’ negated subsequent checks.

5.3.15 It is evident that free-text fields in ePMA systems enable staff to supplement standard data capture with important information. There are however no standards in place guiding the use of these fields, resulting in varying interpretation and inconsistent use at an organisational level. This may have unintentional consequences, as occurred in the reference event. The free-text information ‘as per discussion with haematology’ was misleading when read in context of the dose prescribed.
HSIB makes the following safety observation

Safety observation O/2022/147:
It may be beneficial for trusts to evaluate the use of the free-text fields in electronic prescribing and medicines administration systems and to define their purpose, to ensure they are used in the way intended and used consistently to prevent unintentional consequences.

Clinical decision support

5.3.16 It has been suggested that the clinical decision support (for example, dose range checking (DRC) built into most e-prescribing systems is mainly derived from adult dosing, which may contribute to the reported dosing errors in children (Wald et al, 2018). The investigation heard from NHSX that DRC (to help clinicians monitor the appropriateness of medication dosing) may have prevented the adult dose being selected and prescribed at the reference event Trust. However, DRC is often not individualised for each patient and there are different levels of maturity in the various software applications used by trusts.

5.3.17 During a comparison site visit to another trust, the investigation was told about the challenges of identifying and developing DRC software for paediatrics, because of the wide range of doses used for differing medical conditions. At this trust, the ePMA system used a decision support system from an external provider. However, only 30% of medications could have DRC applied and they were not the most frequently prescribed medications, for example, paracetamol. As a workaround, the ePMA team at the trust built local DRC rules for the 10 most commonly prescribed medications.

5.3.18 The investigation also considered the configuration of clinical decision support software in the context of alerting. Evidence from the visit to the reference event Trust and other comparison sites indicated that potentially fatal medication dosages could be entered (as test cases) into ePMA systems without this triggering an alert. This was due to the way in which the software had been configured by organisations and the level of alerts built into the system. Conversely, ‘alert fatigue’ could be an issue for system users, as described by trust during a comparison site visit. The trust told the investigation that they had opted to ‘switch off’ the lowest level of medication interaction alerts on their ePMA system because of this.

5.3.19 A safety recommendation was made to the Department of Health and Social Care as part of HSIB’s investigation ‘Electronic prescribing and medicines administration systems and safe discharge’ (Healthcare Safety Investigation Branch, 2019). The safety recommendation was to:
‘... 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.’

A study was commissioned which focused on the importance of human factors and the human-computer interaction in the system design of ePMA systems, with a plan to commission primary research on this topic in the future.

**Dose rounding**

5.3.20 The investigation heard that a current limitation of ePMA systems is that they cannot convert complex specific doses that have been prescribed to doses that support ease of administration. This has also been referenced in the research literature. Wald et al (2018) found that most ePMA systems do not easily generate doses required for administration in children and ‘rounding tolerances’ (rounding the dose up or down) depend on a child’s age and medical condition.

**Weight-based dose-bands**

5.3.21 Standard dosing bands (NHS England, 2016b) based on body weights were introduced as a way to ensure safe prescribing for children. Implementing dose-banding limits, and guidelines to support the process of administering medicines in hospitals, were found to be important in minimising medication errors and promoting medication safety (Al-Turkait and Khan, 2015).

5.3.22 The establishment of weight-based dose bands, in conjunction with dose-rounding tolerances, could be of fundamental importance in developing paediatric medicine catalogues, to aid safe and effective e-prescribing for children (Rashed and Tomlin, 2020).

**Use of the calculator function**

5.3.23 As mentioned in section 4.2.8, the ePMA system used by the reference event Trust had a calculator function, which was recommended by the manufacturer but not routinely used by the Trust. The decision was instead taken (after consultation with other sites using the same system in paediatrics) to build ‘dose sentences’ for medicines, to assist dosing.

5.3.24 During a site visit to another trust, the investigation observed there was an inbuilt calculator for commonly used medicines or for those that were the subject of errors. For those medicines, a recommended dose would
be provided to select from, alongside the possibility of self-populating or editing the dose. The trust had optimised safety by ensuring that generally (depending on the medication), a low dose would be auto-populated for the prescriber to increase, rather than the other way round.

5.3.25 During comparison site visits to a number of trusts, the investigation observed demonstrations of ePMA system functionality in test settings. It was apparent that the configuration of their trusts’ ePMA systems may have prevented the reference event. Mitigating factors were automatic functions being built into the system to prevent the prescription of excessive doses and mandating particular ways of prescribing in paediatrics, for example using a protocol-based system.

**Governance of ePMA systems**

5.3.26 Information standards from various national bodies are used to strengthen and support national healthcare initiatives. These standards ‘provide the mechanism for introducing requirements to which the NHS, those with whom it commissions services, and its IT system suppliers, must conform’ (NHS Digital, 2018).

5.3.27 The two standards relating to the clinical safety of health information technology are DCB0129 and DCB0160, as outlined in ‘Clinical risk management standards’ on page 50. These standards are intended to provide clarity for users and developers with regards to the registration of standalone software as a medical device and how to comply with the standards (NHS Digital, 2018).

5.3.28 The investigation found that software (‘a set of instructions that processes input data and creates output data’ (Medicines and Healthcare products Regulatory Agency, 2021c)) could qualify as a medical device if it meets the definition, set out in the Medical Device Regulations 2002 (as amended) (Medicines and Healthcare products Regulatory Agency, 2021a).

5.3.29 The Medicines and Healthcare products Regulatory Agency (MHRA) launched a public consultation in September 2021 on the regulation of medical devices (Medicines and Healthcare products Regulatory Agency, 2021a). A broad range of regulatory issues were considered, including the updating of regulations that apply to software as a medical device.

5.3.30 Guidance on regulating medical devices in the UK was published in 2020 and updated in January 2022 (Medicines and Healthcare products Regulatory Agency, 2022a). The guidance states that since January 2021, there have been a number of changes to how medical devices are placed on the market in Great Britain. This was introduced through secondary legislation. It contains a
key requirement relevant to this investigation: ‘all medical devices, including in vitro diagnostic medical devices (IVDs), custom-made devices and systems or procedure packs, need to be registered with the MHRA before they are placed on the Great Britain market’. The investigation has identified that once introduced, the legislation applied to devices already on the UK market.

5.3.31 The MHRA has advised the investigation that given the description of the functionality of the ePMA system used by the reference event Trust, the product would most likely qualify as a Class I medical device (Medicines and Healthcare products Regulatory Agency, 2021b). This is in accordance with the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (Medical Devices Regulations 2002).

**HSIB makes the following safety observation**

**Safety observation O/2022/148:**
It would be beneficial if manufacturers of electronic prescribing and medicines administration systems conducted assessments of their products against the relevant regulation, to identify whether their systems meet the definition of a medical device and, if so, ensure associated regulatory requirements are met.

5.3.32 There are requirements arising from this legislation at manufacturer and healthcare organisation levels. The manufacturer has a responsibility to ensure that the device is compliant with the Medical Devices Regulations 2002, as outlined by the Medicines and Healthcare products Regulatory Agency, (2020):

- ‘Manufacturer shall ensure that the system is designed to safety principles, taking account of the generally acknowledged state of the art.’

- The manufacturer shall provide adequate information so that the device can be used safely and properly, taking account of the training and knowledge of the potential users. This shall indicate any warnings and/or precautions to take, for example, specific instructions for paediatrics.

- The manufacturer shall review experience gained from devices in the post-production phase and apply any necessary corrective actions, for example, reviewing why users do not use specific safety features.’

5.3.33 The MHRA has produced a software flowchart for the developers and manufacturers (and users) of software as a medical device to guide them in respect of what is likely to meet the definition of a medical device (Medicines and Healthcare products Regulatory Agency, 2021b).
5.3.34 The investigation found that guidance is required to provide specific information to manufacturers of ePMA systems to ensure they are compliant with the requirements under the Medical Devices Regulations 2002.

**HSIB makes the following safety recommendation**

**Safety recommendation R/2022/177:**

HSIB recommends that the Medicines and Healthcare products Regulatory Agency works with the manufacturers of electronic prescribing and medicines administration systems to provide guidance on their obligations under the Medical Devices Regulations 2002 (as amended).

5.3.35 Healthcare organisations are responsible for ensuring that devices are deployed and used in line with manufacturers’ instructions (Medicines and Healthcare products Regulatory Agency, 2021c):

- ‘A device management policy should help to ensure that risks associated with the use of medical devices are minimised or eliminated.

- Users need to carefully consider the content of all warnings of risks and the device should only be used and maintained in line with the manufacturer’s instructions.

- Training is a key element in device safety. Ensure adequate training programmes are in place for users. Ensure such training programmes are repeated regularly, where necessary.’

**HSIB makes the following safety observation**

**Safety observation O/2022/149:**

It would be beneficial if those organisations procuring electronic prescribing and medicines administration systems ascertain whether the product they are procuring meets the definition of a medical device and, if so, whether the manufacturer meets the expected regulatory requirements and the product is either UKCA marked or CE marked to demonstrate conformity.

5.3.36 In line with MHRA guidance, there is also a requirement to report suspected adverse reactions to medicines in children and young people under 18 years through the Yellow Card Scheme (Medicines and Healthcare products Regulatory Agency, 2022b). Yellow Cards can be used for reporting suspected adverse drug reactions to medicines. This includes suspected adverse drug reactions associated with overdose and medication. Adverse incidents involving medical devices can also be reported to the MHRA through the Yellow Card Scheme.
Clinical safety cases and the role of clinical safety officers

5.3.37 Clinical safety officers (CSO) are people in organisations who are ‘... responsible for ensuring the safety of a Health IT System ... through the application of clinical risk management’ (NHS Digital, 2018). CSOs are expected to be knowledgeable about risk management and its application to clinical domains, ensuring that expected processes are followed (NHS Digital, 2018).

5.3.38 The DCB0160 implementation guidance (NHS Digital, 2018) outlines the training requirements of a CSO. These include being qualified in risk management or having an understanding of risk and safety in relation to health IT systems. The investigation was told that training is provided by NHS Digital in partnership with other bodies if staff have not acquired skills not through academic study. Training includes the consideration of the responsibilities of CSOs and expected safety standards for their organisations.

5.3.39 The investigation was told of the importance of CSOs having appropriate knowledge, skills and support to safely manage the implementation and continuing configuration of ePMA systems in trusts. However, while the aforementioned training from NHS Digital is available, the investigation heard that uptake is limited. The NHS Digital training is not mandated and training is available from third-party suppliers.

5.3.40 In 2021, NHS Digital trained 800 people, double the number trained in 2019. The investigation heard that requests for training are increasing and are anticipated to rise further following publication of the Digital Clinical Safety Strategy (NHSX, 2021). NHSX and NHS Digital are looking to deploy a ‘train the trainer’ system over the next 12 to 18 months with the responsibility for training sitting within integrated care systems (partnerships between health and care organisations that co-ordinate and plan services for a specific geographical area). NHS Digital informed the investigation that this decision was made based on the NHS not accepting responsibility and ownership for digital safety and the requirements of the DCB standards.

5.3.41 The investigation was also advised of the importance of providing training for staff who are responsible for the day-to-day management of ePMA systems. However, it was heard that few of these staff had accessed the first level of clinical safety risk management training.

HSIB makes the following safety observation

Safety observation O/2022/150:
It may be beneficial for healthcare organisations to ensure that any clinical staff responsible for the day-to-day management and configuration of electronic prescribing and medicines administration systems access clinical safety risk management training.
5.3.42 A core responsibility of CSOs is to approve clinical safety case reports (NHS Digital, 2018). These are defined as:

‘A report that presents the arguments and supporting evidence that provides a compelling, comprehensible and valid case that a system is safe for a given application in a given environment at a defined point in a Health IT System’s lifecycle.’

They are seen as integral to the governance of ePMA systems in healthcare.

5.3.43 Essentially, safety cases provide a transparent, evidence-based argument for why a system is safe for use in a particular environment/situation (Sujan and Habli, 2021). One of the commitments of the Digital Clinical Safety Strategy (NHSX, 2021) is to:

‘Ensure the transparent nature of documentation used to build a safety case for existing clinical safety standards. This will be led by NHSD [NHS Digital] and industry partners on an ongoing basis.’

5.3.44 The investigation was given the opportunity to review the safety case for a previous release of the ePMA system used in the reference event. This described efforts to ‘identify, assess and, where appropriate, mitigate hazards associated with this product’ (anonymous source). It also stated that if used as specified, the ‘release did not include any clinical hazards or functionality which could give risk to unacceptable clinical risk to patients’.

5.3.45 The safety case acknowledged the role of local configuration and stated an expectation for the customer to conduct comprehensive user acceptance testing and mitigation of any local hazards through configuration. For example, testing of the system needs to ensure lists of prescribable medications are presented to each local user, depending on their role (such as paediatrics).

5.3.46 The investigation heard that a manufacturer’s safety case is specific to the version of the ePMA software released, based on the scope of the release. Items in that release that may pose safety risks at local implementation are described. The investigation was advised by a manufacturer that it is an expectation that clients will review their safety cases. Further, the decision whether to test according to the advice the manufacturer provides, is at clients’ discretion.
5.3.47 During site visits, the investigation asked those involved in the implementation of ePMA systems whether they had safety cases in line with DCB160. One trust only had its original safety case for adult prescribing from the software manufacturer for the system, and not a local safety case for modifications or roll-out to paediatrics. Several trusts referred to the existence of a risk register or risk logs, by way of a response to the investigation and they questioned how widely the safety case requirements had been disseminated.

5.3.48 At a national level, when looking at a new system, a safety case/hazard log is part of the procurement/implementation process and is accessed from the manufacturer. NHS Digital advised the investigation that the impact of the statutory requirements behind the standards for health IT were that a system should not be permitted to roll out more widely until the safety case/hazard log had been reviewed.

5.3.49 The investigation found evidence of safety cases not being available or not being used in line with the expectations of DCB0160. There was also found to be limited awareness of the need for or role of safety cases. It was apparent that national work was needed to support organisations to understand the requirements and their responsibilities.

5.3.50 Safety cases are commonly used in other safety-critical industries, such as the nuclear industry (Sujan and Habli, 2021). Therefore, the investigation approached the Office of Nuclear Regulation (ONR) to understand how the nuclear industry uses safety cases (see learning case study 2). The learning from ONR aids understanding in respect of how to structure a safety case, the evidence needed, the role of testing, and the need for a comprehensive assessment of safety, where equipment has been further adapted. In healthcare, a comparison could be made with a situation where an adult ePMA system is adapted for paediatric use and the need to test, assess, and evidence the safety of the adaptations before activation.

Learning case study 2

Safety cases – Office of Nuclear Regulation

The nuclear industry is regulated by the Office of Nuclear Regulation (ONR). The ONR has established principles for inspectors to assess safety cases of nuclear facilities (Office of Nuclear Regulation, 2019). To the ONR, the term ‘safety case’ encompasses all documentation developed by a designer, licensee, or responsible person to demonstrate nuclear safety. The documents describe risk in terms of the hazards, potential outcomes, and measures that need to be implemented to prevent or minimise harm.
A safety case is structured around claims, arguments and evidence. The claim that a particular piece of equipment is as safe as possible is argued through the provision of evidence. The argument must show how the equipment complies with international standards and manufacturer expectations, and testing has been undertaken to build confidence in the safety measures. Testing includes user testing and wider analysis in static and dynamic situations.

The ONR expects a safety case to include:

- the hazards assessed by a thorough and systematic process
- potential points of failure
- demonstration of conformity with relevant safety principles
- argument for why risks are as low as reasonably possible with evidence
- requirements necessary to maintain the safety case such as surveillance, maintenance, and inspection.

The ONR told the investigation that where a piece of equipment has been used or adapted outside of the original scope defined by the manufacturer, particular attention is needed. In these situations, the safety case must comprehensively demonstrate why the equipment is still safe, with supporting evidence. This should include user testing in multiple situations to, so far as is practicable, ensure that the system can behave in accordance with user-defined requirements in all modes of operation.

5.3.51 The issue of safety cases has been highlighted by HSIB in its report on the ‘Procurement, usability and adoption of ‘smart’ infusion pumps’ (Healthcare Safety Investigation Branch, 2020b). Following on from this, the investigation has identified the need to further establish the role and importance of safety cases in healthcare. The aim of this is to improve the availability and quality of safety cases, and support CSOs (and other staff involved in the local configuration of ePMA systems) to undertake their roles with appropriate training and support.
HSIB makes the following safety recommendation

Safety recommendation R/2022/178:
HSIB recommends that NHS Digital and NHSX promote the organisational requirements for digital clinical safety, including organisations’ responsibilities in terms of safety cases and clinical safety officers, to encompass system functionality and processes.

5.3.52 In support of this safety recommendation, the Care Quality Commission (CQC) has agreed to review whether a provider’s assurance of their compliance with the standard specific to ePMA systems in healthcare (including the authoring of a DCB 0160), can form part of the CQC’s developing regulatory model in the future.

HSIB makes the following safety recommendation

Safety recommendation R/2022/179:
HSIB recommends that the Care Quality Commission (CQC) reviews whether a provider’s assurance of its compliance with the Clinical Risk Management standard specific to electronic prescribing and medicines administration systems in healthcare, can form part of the CQC’s developing regulatory model.
6 Summary of findings, safety recommendations and safety observations

6.1 Findings

The investigation found that:

**Multidisciplinary co-ordination and decision-making**

- Email discussions may be being used for discussion of critical decisions in relation to patient care, with limited dissemination to the wider team.
- There is limited standardisation of handovers, ward rounds (visits to each patient in a ward to review and discuss their care) and huddles (short, focused staff briefings), in terms of which members of the multidisciplinary team are involved, and how they are conducted for maximum effectiveness.
- There is limited national guidance on the management of ward rounds in paediatrics (as is available for adult care).
- There is variability in hospital clinical pharmacy provision. This reduces the availability of ward-based pharmacists and may result in a dispensary-based service only at weekends.
- Nursing staff perceived themselves to be the final barrier to prevent an incorrect dose prior to the administration of medication, resulting in them feeling accountable for the error.

**Factors undermining the effectiveness of checking as a barrier**

- Multiple cues influenced whether staff considered medication doses to be correct.
- Processes for the checking of medicines varied without evidence of what constituted the most effective process.
- The distinction between verification and checking was not explicit, that is, checking that the prepared medication correlated with the prescription versus verification that the prescription was appropriate against a standard.
- The environments within which staff prepared and checked medicines influenced their performance.
- Environmental layouts and limited resource resulted in workarounds.
Implementation of ‘off-the-shelf’ electronic prescribing systems in specific contexts

• There are no standards for what safety-critical functionality should be available in ePMA systems configured for use in paediatrics (for example, the use of weight-based dose bands, where individually calculated doses are rounded to a set of predefined doses).

• The use of free-text comment boxes in ePMA systems is not specified or standardised.

• The usability and functionality of ePMA systems need to be assessed through user-testing across a range of different settings.

• Local configuration of ePMA systems potentially introduces variability and risks if not undertaken with clear understanding of the potential hazards and their mitigations.

• Software could qualify as a medical device if it meets the definition, set out in the Medical Device Regulations 2002 (as amended).

• Local governance of ePMA systems is limited with evidence of gaps in training and an absence of safety cases (reports that provide a transparent, evidence-based argument for why a system is safe for use in a particular setting).

6.2 Safety recommendations

HSIB’s safety recommendations are directed to a specific organisation for action. They are based on information derived from the investigation or other sources, such as safety studies, and are made with the intention of preventing future, similar events.

The HSIB investigation focused on errors in the prescription of weight-based medication for children, in the context of electronic prescribing and medicines administration (ePMA) systems. The responsibility for ensuring the safety of medicines prescribing and administration is with individual trusts, with input from NHSX, NHS Digital and the Medicines and Healthcare products Regulatory Agency (MHRA). Therefore, safety recommendations made in this respect are directed towards those organisations. Different parts of the healthcare system have also been identified to address the other risks highlighted in this investigation relating to paediatric ward rounds and second-checking processes. Safety recommendations have been directed to them accordingly.
HSIB makes the following safety recommendations

Safety recommendation R/2022/175:
HSIB recommends that the Royal College of Paediatrics and Child Health identifies the best practice principles for effective paediatric ward rounds in relation to medicines, and disseminates them to its members.

Safety recommendation R/2022/176:
HSIB recommends that the National Institute for Health Research assesses the priority, feasibility and impact of future research on processes for second checking medication, and considers the most appropriate way of building up the evidence base on this topic.

Safety recommendation R/2022/177:
HSIB recommends that the Medicines and Healthcare products Regulatory Agency works with the manufacturers of electronic prescribing and medicines administration systems to provide guidance on their obligations under the Medical Devices Regulations 2002 (as amended).

Safety recommendation R/2022/178:
HSIB recommends that NHS Digital and NHSX promote the organisational requirements for digital clinical safety, including organisations’ responsibilities in terms of safety cases and clinical safety officers, to encompass system functionality and processes.

Safety recommendation R/2022/179:
HSIB recommends that the Care Quality Commission (CQC) reviews whether a provider’s assurance of its compliance with the Clinical Risk Management standard specific to electronic prescribing and medicines administration systems in healthcare, can form part of the CQC’s developing regulatory model.

HSIB makes the following safety observations

Safety observation O/2022/145:
It may be beneficial if a standard format for multidisciplinary care reviews (including handovers and huddles) was adopted by healthcare organisations, with a shared understanding of the management plans for individual patients.

Safety observation O/2022/146:
It may be beneficial for trusts to consider creating the optimum environment and conditions to support medication checking processes, by reducing distractions and interruptions to a minimum.
Safety observation O/2022/147:
It may be beneficial for trusts to evaluate the use of the free-text fields in electronic prescribing and medicines administration systems and to define their purpose, to ensure they are used in the way intended and used consistently to prevent unintentional consequences.

Safety observation O/2022/148:
It would be beneficial if manufacturers of electronic prescribing and medicines administration systems conducted assessments of their products against the relevant regulation, to identify whether their systems meet the definition of a medical device and, if so, ensure associated regulatory requirements are met.

Safety observation O/2022/149:
It would be beneficial if those organisations procuring electronic prescribing and medicines administration systems ascertain whether the product they are procuring meets the definition of a medical device and, if so, whether the manufacturer meets the expected regulatory requirements and the product is either UKCA marked or CE marked to demonstrate conformity.

Safety observation O/2022/150:
It may be beneficial for healthcare organisations to ensure that any clinical staff responsible for the day-to-day management and configuration of electronic prescribing and medicines administration systems access clinical safety risk management training.

In addition, HSIB made the following safety observation in an interim bulletin (March 2021)

Safety observation O/2021/097:
It would be beneficial for trusts that have adult and paediatric prescribing supported through the same ePMA system to ensure they have adequately risk assessed the way in which the system supports the calculation of doses to ensure that adult doses do not require manipulation for paediatric patients.
7 References


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Appendices

Appendix 1 Systems Engineering Initiative for Patient Safety (SEIPS)

SEIPS is a systems engineering approach with human factors principles embedded within it (figure A1). SEIPS describes how components of the work system produce work processes which result in different outcomes. Work system factors are described below (Holden et al, 2013; Carayon et al, 2006):

- person(s): the people working in the particular system and the patient
- tasks: undertaken by the persons which may vary in complexity or variety
- tools and technology: used to undertake the tasks which may vary in usability and functionality
- internal environment: the physical space around the persons, for example layout, noise, and temperature
- organisation: conditions external to the persons to support the organisation of, for example, resources and activity
- external environment: factors outside of the healthcare institution that might include policy, societal or economic factors.

Processes can be physical, cognitive, or behavioural and lead to outcomes for the patients, professionals, or healthcare institutions. The interactions between the various components of the work system lead to different outcomes, both positive and negative. The framework includes feedback loops which represent the adjustments systems make over time.
Figure A1 Systems Engineering Initiative for Patient Safety (SEIPS) (Holden et al, 2013; Carayon et al, 2006)

- Work system
- Process
- Outcome

Organisation  Environment

People  Task  Equipment

Patient outcomes:
- Quality of care
- Patient safety

Process:
- Care process
- Other processes

External environment
Appendix 2 Functional Resonance Analysis Method (FRAM)

FRAM aims to reflect risks within complex systems. It does this through describing variability in the functions within the system and looks to model what is needed for everyday performance to go right.

The FRAM involves exploring ‘work as done’ with frontline staff to identify the ‘functions’ that are being performed. A function is defined as ‘the activities – or set of activities – that are required to produce a certain outcome’ (Hollnagel, 2012). In doing this, FRAM develops a model of the core functions to illustrate how each links, how variability might occur, and how this may affect outcomes. To achieve this, links are created between functions by identifying six specific aspects of each function: input, output, preconditions, resources, controls, and time factors.

Identified system functions were entered into the FRAM Model Visualiser software (FMV).

**Figure A2 Functional Resonance Analysis Method**
Figure A3 Functional Resonance Analysis Method for Type I

1. Medicine prescription
   - First validation of prescription
   - Calculation of medicine dose
   - Preparation of medicine
   - Requesting a second check
   - Medicine management training
   - Administration of medicine

2. Medication management
   - Medication schedule
   - Dosage calculation
   - Monitoring

3. Patient care
   - Patient evaluation
   - Health status management
   - Prescription verification

4. Medication compliance
   - Medication adherence
   - Medication history
   - Medication status update
### Appendix 3 Examples of studies on the impact of double-check systems (Institute for Safe Medication Practices, 2019)

<table>
<thead>
<tr>
<th>Description</th>
<th>Error rate (ER) or Error detection rate (EDR)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Campbell and Facchinetti, 1998</strong></td>
<td>EDR: 95%</td>
<td>An independent double-check detected 95% of errors, leading to a reduction in the error rate from 5% to 0.25%</td>
</tr>
<tr>
<td><strong>Grasha et al, 2001</strong></td>
<td>ER per 5,700 prescriptions: 4.2%</td>
<td>Double-checks identified 4.2% of errors not detected prior to dispensing; of these, 2.1% were potentially clinically significant</td>
</tr>
<tr>
<td><strong>Grasha et al, 2001</strong></td>
<td>EDR: 95%</td>
<td>The ability to detect and correct 95% of errors with an independent double-check was not affected by workload or time on shift</td>
</tr>
<tr>
<td><strong>Jensen et al, 2004</strong></td>
<td>EDR: 58%</td>
<td>Second person double-check was the single most effective measure in the study</td>
</tr>
<tr>
<td><strong>White et al, 2010</strong></td>
<td>EDR with checklist: No prompt: 15% With prompt: 80%</td>
<td>Use of checklist with prompts when conducting a second nurse double-check led to higher (433% increase) detection of wrong patient errors</td>
</tr>
<tr>
<td><strong>Douglass et al, 2018</strong></td>
<td>EDR: Dosing: Single check: 9% and Double-check: 33% Wrong vial: Single check: 54% and Double-check: 100%</td>
<td>Use of a double-check was significantly more effective than a single check at detecting wrong-vial errors; also, more effective but less pronounced for detecting weight-based dosing errors</td>
</tr>
</tbody>
</table>
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