Summary

Weight-based medication errors in children

Independent report by the Healthcare Safety Investigation Branch I2020/026

February 2022
Providing feedback and comment on HSIB reports

At the Healthcare Safety Investigation Branch (HSIB) we welcome feedback on our investigation reports. The best way to share your views and comments is to email us at enquiries@hsib.org.uk or complete our online feedback form at www.hsib.org.uk/tell-us-what-you-think.

We aim to provide a response to all correspondence within five working days.

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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).
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

<table>
<thead>
<tr>
<th>Safety observation O/2022/145:</th>
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<tr>
<td>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.</td>
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<thead>
<tr>
<th>Safety observation O/2022/146:</th>
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<td>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.</td>
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<tr>
<th>Safety observation O/2022/147:</th>
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<tr>
<td>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.</td>
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<th>Safety observation O/2022/148:</th>
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<tr>
<td>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.</td>
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<th>Safety observation O/2022/149:</th>
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<td>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.</td>
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<th>Safety observation O/2022/150:</th>
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<tr>
<td>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.</td>
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In addition, HSIB made the following safety observation in an interim bulletin (March 2021)

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<th>Safety observation O/2021/097:</th>
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<td>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.</td>
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Further information

More information about HSIB – including its team, investigations and history - is available at www.hsib.org.uk

If you would like to request an investigation then please read our guidance before contacting us.

@hsib_org is our Twitter handle. We use this feed to raise awareness of our work and to direct followers to our publications, news and events.

Contact us

If you would like a response to a query or concern please contact us via email using enquiries@hsib.org.uk

We monitor this inbox during normal office hours - Monday to Friday from 09:00 hours to 17:00 hours. We aim to respond to enquiries within five working days.

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