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HEALTHCARE SAFETY INVESTIGATION BRANCH

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Interim bulletin

Weight-based medication errors in children

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This interim bulletin contains facts which have been determined up to the time of issue. It is published to inform the NHS and the public of the general circumstances of events and incidents and should be regarded as tentative and subject to alteration and correction if additional evidence becomes available.

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The Healthcare Safety Investigation Branch (HSIB) was notified by a hospital of a safety risk relating to an inadvertent overdose of a medicine. This notification followed the reporting of a serious incident in March 2020, via the Strategic Executive Information System (StEIS) [1].

The incident related to a weight-based medication error involving a child who received ten times the intended dose of dalteparin on five occasions over a period of three days. This occurred following prescribing by a junior doctor, using the Trust's electronic prescribing and medicines administration (ePMA) system. Similar errors had previously been reported at the Trust, both prior to and following the implementation of the ePMA system.

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 (for example, body surface area). 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 focussed on paediatrics, but may be applicable to wider patient cohorts where medicine dose calculations are required.

The investigation may lead to the development of safety recommendations to improve current and future medicines management in children, where weight-based calculations are required.

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National context

The prescribing and administration of medicines are the most common healthcare interventions.

It is estimated that 237 million medication errors occur at some point in the medication process in England annually; 66 million are potentially clinically significant (Elliott et al, 2020). Within the paediatric population, 13% of prescriptions written for children contain errors (Ghaleb et al, 2010).

Errors can occur at many points of the medicines administration process. These include prescribing, dispensing, administration and monitoring (Peth, 2003). Within the paediatric population, specific factors complicate prescribing and administration of medicines and these factors can contribute to errors. They include those factors shown in the figure below (Conn et al, 2019).

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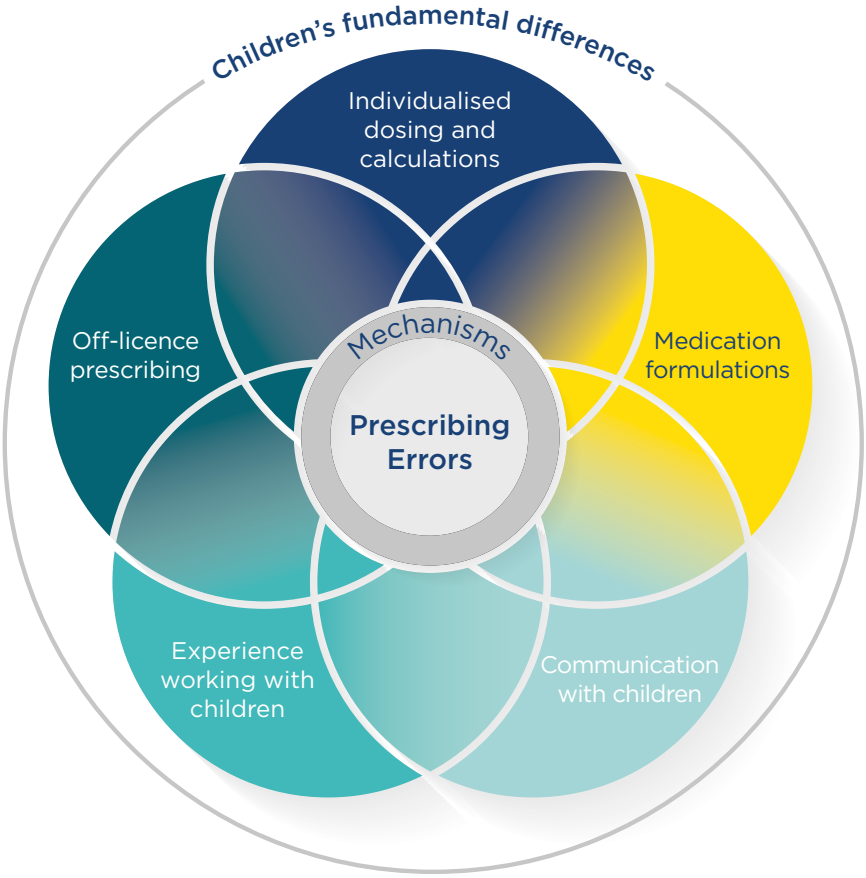
Fig 1 Paediatric factors leading to prescribing errors in paediatrics

(adapted from Conn et al, 2019).



Conn et al (2019) identified the need to further understand the causes of medication errors in the paediatric population. Their review highlighted that growth and changing size necessitate individualised prescribing, typically based on weight, age or body-surface area. This requires prescribers to perform calculations for each child based on, for example, milligrams per kilogram or units per kilogram (as occurred in the reference event). Calculations are often manually undertaken in paediatrics as some electronic prescribing systems do not have automated calculation, and some systems with automated calculation are not used (Shah, 2019).

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These potential limitations of electronic prescribing system(s) have been reported as major causes of error in the academic literature. Other error types have been outlined in published HSIB reports: **ePMA and safe discharge - Healthcare Safety Investigation Branch** (hsib.org.uk) and **Inadvertent administration of an oral liquid medicine into a vein - Healthcare Safety Investigation Branch** (hsib.org.uk).

Exploring the literature, improvement work in medicines safety has included examples such as:

- standard formularies for paediatric patients and varying concentrations of medicines (Benjamin et al, 2018)
- pharmacist support for paediatrics (Benjamin et al, 2018)
- weight-based dosing calculators in electronic systems (Ginzburg et al, 2009)
- implementation of ePMA systems.

The World Health Organisation (WHO) has previously highlighted the challenge of medication errors. In 2017, its third Global Patient Safety Challenge was launched, 'Medication Without Harm' (WHO, 2017). This aimed to reduce the global burden of severe and avoidable medication-related harm by 50% over five years.

In response, the Medicines Safety Improvement Programme (NHSI, 2019) was established. The programme addresses the most common causes of severe harm related to medicines, most of which have been recognised for many years, but continue

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to challenge our health and care systems. The programme influences safety culture, safety systems and high-risk medicines in common use, bringing the science of continuous safety improvement to bear on this complex problem. The programme is supporting the development and implementation of enabling activity, including ePMA, structured medication review, and the discharge medicines service. It has a current focus on anticoagulation, opioid use in chronic non-cancer pain, problematic pharmacy and the safer administration of medicines in care homes.

Decision to investigate

HSIB conducted a preliminary investigation following which the Chief Investigator authorised a full investigation as the risk met the following criteria:

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

- Elliott et al (2020) identified that adverse drug reactions cause or contribute to 1,708 deaths per year. Other harms can result from worsening of underlying conditions or side effects.

- Within the National Reporting and Learning System (NRLS), medication incidents account for the fourth most common incident type with around 220,000 reported per year based on October 2018 to September 2019 data (NRLS, 2020), of which 150 and 63 were reported as severe or catastrophic harm, respectively.

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- Between 1 April 2017 and 10 June 2020, there were 1,943 medication incidents reported within StEIS; 158 of these appear to be related to paediatrics based on the age recorded at time of reporting (where available). There were 23 specific serious incidents where weight-based prescribing and administration were an issue; five of these appeared to relate to paediatrics.

- Financially, Elliott et al (2020) also identified that definitely avoidable adverse drug events are estimated to cost the NHS £98,462,582 per year and consume 181,626 bed-days.

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

- Within the NRLS (2020) medication errors occur across all healthcare settings and are in the top five incident types for acute and general hospitals.

- Medication errors occur in all populations, but are believed to occur more in the paediatric population due to the specific nuances of this group (Shah and Chui, 2019).

- Medication errors remain persistently high in the NHS. Specific factors complicate prescribing in children and increase the risk of errors.

- Research has often clarified the extent of the problem in children, but the causes of errors are still poorly understood and adult research is of limited value to paediatrics (Conn et al, 2019).

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

- Academic research states that although 'voluminous body of work is done in the field of patient safety and medication errors, little research has examined prescribing errors in paediatric population' (Shah and Chui, 2019).

- Conn et al (2019) identified the need to understand the causes of medication errors more in the paediatric population. Their review suggested that growth and changing size necessitated individualised dosing, requiring prescribers to perform calculations. This was identified as a major cause of error in the academic literature.

- ePMA systems are being used increasingly in the paediatric population and are often seen as a key improvement to reduce mediation errors (Campbell et al, 2006). However, these systems may create new technology-related errors. Examples include (Fox et al, 2019):

  - not preventing the majority of harmful error prescriptions

  - levels of decision making support and warnings provided to prescribers varying

  - differences both in the systems being used and between the same system on different sites.

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The reference event

The child was four years old at the time of the incident. She was transferred from Hospital 1 and admitted to a cardiology ward at Hospital 2 in mid-February 2020. She was diagnosed with a recognised and common complication of a complex heart procedure which had been undertaken three months previously.

During her stay at Hospital 2, the child underwent a further complex heart procedure and was under the care of the paediatric cardio-respiratory team. In March 2020 a large Deep Vein Thrombosis (DVT) was diagnosed (a blood clot which had developed in her right leg).

It was identified that there was a need to balance the risk between providing blood thinning medicine for the child's heart condition and to manage the DVT, without compromising the possibility of a bleed on the brain. A multidisciplinary team agreed that the child should be prescribed dalteparin 100units/kg twice daily. This recommendation was in accordance with the British National Formulary for Children (BNFC). The drug was prescribed by an approved prescriber using the Trust's electronic prescribing and medicines administration system. The child's weight at the time of the prescription was 15.2kg so the dose for administration should have been 15.2x100 = 1520units twice daily rounded down to **1500units twice daily**. The child was inadvertently prescribed 15,000units of dalteparin twice daily. The approval, dispensing, checking and administration steps did not identify the incorrect prescription meaning the child received **15,000units** (10 times the dose intended) of dalteparin on five occasions over three days. Identified safety issues.

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Weight-based prescribing in children can be challenging since each calculation and subsequent dose is unique to each child. In the reference event, the prescribing of the dalteparin was particularly difficult because:

1 There were factors that both supported and inhibited multidisciplinary co-ordination and decision-making, including the communication of critical decisions in relation to weight-based medicines in support of a child's management.

2 The process of double-checking was not a strong barrier in preventing the incorrect dosage from being administered.

3 The configuration of the ePMA system in paediatrics resulted in the dalteparin field auto populating as an adult dose therefore requiring manual intervention to enter the correct quantity.

Safety observation

HSIB's investigation to date has shown that many ePMA systems used by hospitals are configured locally. These local configurations may mean that some ePMA systems designed for adult patients are then modified for paediatric patients. The investigation has also seen that even in paediatric only facilities, the age and weight ranges of patients may mean adult equivalent doses of medicines are sometimes needed.

Although HSIB has yet to fully assess the extent of modifications to ePMA systems for paediatric patients, the investigation has identified the following safety observation from the investigation of the reference event.

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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.

Next steps

HSIB is engaging with national organisations, industry, and other healthcare organisations across the UK. Where appropriate, the investigation will use subject matter advisors to advise the investigation team on elements of the investigation.

The investigation will continue to explore the identified safety issues and welcomes further information that may be relevant from any source.

HSIB will report any significant developments as the investigation progresses.

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[1] The StEIS is a national database that facilitates the reporting of serious patient safety incidents and the monitoring of investigations between NHS providers and commissioners.