Focus on patient safety

MEASURING & IMPROVING QUALITY

Medication in paediatric medicine

It's not child's play

9 March 2023

It could happen to you too

Event 1

MORPHINE OVERDOSE IN A 5-YEAR-OLD CHILD RESULTING IN RE-HOSPITALISATION

A 5-year-old child with Angelman syndrome is hospitalised for a painful, serious infection, requiring morphine treatment. To prevent withdrawal syndrome when the child returns home, he is prescribed MORPHINE SULFATE drops. But 24 hours after discharge from hospital, the parents called the emergency services (SMUR mobile medical unit) because the child had fallen into a coma with bradypnoea. The child was then transferred to the paediatric emergency department and admitted to the paediatric intensive care unit.

What happened? *Immediate cause*

MORPHINE SULFATE was administered every 3 hours instead of every 6 hours (doubling of doses for 24 hours).

Why did it happen? *Root causes, barriers absent or deficient*

- The doctor made a dosage error related to the administration frequency: he prescribed administration every 3 hours instead of every 6 hours, leading to doubling of the dose.
- When writing the initial prescription, the prescriber forgot to convert from milligrams into drops (although MORPHINE SULFATE was prescribed in milligrams during hospitalisation, it was meant to be prescribed in drops for administration at home).
- The prescription was written following work interruptions, in a context of maximum workload, and under pressure from the father to have the child discharged quickly because the ambulance had arrived. The prescription was redone twice.
- The pharmacist who dispensed the medication did not raise the alert.

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Event 2

ANTI-EPILEPTIC MEDICATION OVERDOSE IN A 3-YEAR-OLD CHILD RESULTING IN DISTURBANCES AND RE-HOSPITALISATION IN THE INTENSIVE CARE UNIT

A 3 and a half-year-old child is admitted to the emergency department due to an epileptic seizure. This child has known epilepsy, treated with SODIUM VALPROATE and LAMOTRIGINE as dual maintenance therapy. Following clinical assessment, the child is admitted to the short-term stay unit for monitoring and stepping up of anti-epileptic treatment. Two days later, following a favourable clinical course, the child returns home. The parents obtain the treatment prescribed by the hospital doctor from a retail pharmacy in town. But a few days later, they called the SMUR mobile medical unit because their child presented severe neurological disturbances. The child was admitted the paediatric intensive care unit.

What happened? *Immediate cause*

The child received an overdose of anti-epileptic drugs resulting in neurological disturbances and re-hospitalisation.

Why did it happen? *Root causes, barriers absent or deficient*

- When making out the prescription, the doctor made an error in the dosage, which does not correspond to the permitted dose for a child weighing 17 kg.
- At the time of writing out the prescription, the doctor had been working for 6 days consecutively.
- The doctor did not use the computerised prescription module to prepare the hospital discharge prescription.
- The prescription was given to the parents without making sure that they had understood the change in the time of administration: the parents continued to give the child the treatment as two doses, morning and evening, as the treatment had been administered in hospital, instead of as one dose in the evening, as indicated on the discharge prescription.
- The treatment was dispensed by the retail pharmacist, who did not detect the dosage error.

Event 3

CLAVULANIC ACID OVERDOSE IN A NEWBORN INFANT REQUIRING CLINICAL AND LABORATORY MONITORING

On a Sunday, a newborn infant is prescribed paediatric AMOXICILLIN/CLAVULANIC ACID in injectable form (500 mg/ 50 mg). Since this medicinal product is not in stock in the hospital, after informing the paediatrician, it is decided to prepare the dose to be administered using the adult injectable form (1 g/200 mg). On the Monday, in order to make sure professionals had access to the paediatric presentation, the hospital's internal pharmacy was informed about the use of the diluted adult injectable form over the weekend. The pharmacist requested that the treatment be stopped immediately and suggested to the doctor that the infant be placed under clinical and laboratory monitoring to detect any potential toxicity.

What happened? *Immediate cause*

An overdose of CLAVULANIC ACID was administered (the AMOXICILLIN/CLAVULANIC ACID ratio is two times higher in the adult form than in the paediatric form).

Why did it happen? *Root causes, barriers absent or deficient*

- There was no paediatric form of the medicinal product left in stock.
- The paediatric form was replaced by the adult form.
- The adult form of the medicinal product was prescribed at a weekend, and the professionals present were not in the habit of using it.
- No alert was raised in the prescribing support software.
- There was no procedure available to professionals to tell them what to do in such a situation.

Key words: ***paediatric dosage – substitution – dosage adjustment - stock-out – paediatric medication***

So it doesn't happen again

A study published by INSERM* reveals that 86% of children and adolescents received at least one prescription for a medicinal product in the year 2018-2019 (representing a 4% increase compared to 2010-2011). Out of this 86%, 97% were children under 6 years old, the most exposed age group. Good practice guidelines exist to help make the management of paediatric medicines as safe as possible (see the "Find out more – If I want to inform myself" section).

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* Institut national de la santé et de la recherche médicale [French National institute of health and medical research]: presse.inserm.fr/en-france-les-prescriptions-medicamenteuses-chez-les-enfants-se-maintiennent-a-des-niveaux-eleves/43431.

When prescribing medication:

- **USE** the paediatric form where one exists;
- **ADJUST** the dose and the pharmaceutical form prescribed on the basis of the age and weight of the child or adolescent (the weight and age must be specified on the prescription);
- **BE PARTICULARLY VIGILANT** in the case of a medication with a specific prescribing protocol in terms of dosage (e.g. antibiotics);
- **BE CAREFUL** with dosages, **AVOID** confusions between mg and mL;
- **ENSURE PARENTS ARE AWARE** of the need to follow medical prescriptions: dosage and duration of prescription, and **INFORM** them of any change in dosage, presentation, dosing times, etc. for the return home.

When dispensing medication:

- **EXPLAIN** the prescription to patients (dosage, times and doses, etc.) and **MAKE SURE** they have properly understood it by having them repeat it back in their own words;
- **WARN** parents about the use of dosing devices (pipettes, dosing cups, etc.) for medications and remind them that each device is specific to a given medication.

When administering medication[1]:

- **PROVIDE** professionals with aids such as conversion tables, correspondence tables,
- dose calculation tables, adapted to the sector in question;
- **STANDARDISE** preparation methods as far as possible;
- **SYSTEMATICALLY DOUBLE-CHECK** medications considered to be risky, injectable medicines and, in general, any preparations requiring reconstitution;
- **INFORM** in the event of any stock-outs and **COMMUNICATE** the procedures to be followed for the prescription, preparation or administration of the new medicinal product;
- **REMIND** parents that the pipette for an oral medication is specific to that product and that it is inappropriate and dangerous to use it for any other medicine.

The “Focus on patient safety” collection

The “Focus on patient safety” collection aims to draw the attention of and raise awareness among healthcare professionals as to risk management. Each focus covers a specific and recurrent risk based on care-related adverse events, identified and selected from national care-related serious adverse event reporting databases or doctors’ accreditation. This focus on patient safety concerns serious adverse events having occurred in paediatric medicine. It relates events with which healthcare professionals have been confronted and which are always associated with a series of dysfunctions. For this specific focus on patient safety, the events are not described in their entirety and the analyses reported have focused on the consequences to patients of using medicinal product presentations not appropriate for paediatric medicine.

Find out more:

Focus on patient safety
www.has-sante.fr/jcms/p_3240311

HAS – Guideline on “Outils de sécurisation et d’autoévaluation de l’administration des médicaments” [Safety and self-assessment tools for the administration of medicinal products] (2016)
www.has-sante.fr/jcms/c_946211

- **If I want to inform myself**

  ANSM guidelines
  ansm.sante.fr/dossiers-thematiques/medicaments-en-pediatrie-enfants-et-adolescents/recommandations-generales-aux-parents-et-aux-prescripteurs

  Les règles d’or de l’administration des médicament [The golden rules for administering medication] (Le Quotidien du pharmacien, published on 30-06-2020)
  www.lequotidiendupharmacien.fr/formation/specialites-medicales/pediatrie/les-regles-dor-dadministration-du-medicament-lenfant

- **If I want to train**

  Guide d’aide à la prescription, la dispensation et l’administration en pédiatrie [Guidelines for prescribing, dispensing and administering paediatric medications] (OMéDIT Normandie)
  www.omedit-normandie.fr/boite-a-outils/pediatrie/pediatrie,4349,5738.html

  La boîte à outils des populations à risque [The toolbox for at-risk populations] (OMéDIT Pays de la Loire)
  www.omedit-paysdelaloire.fr/boite-a-outils/populations-a-risque

  Analyse de scénarios cliniques [Analysis of clinical scenarios] (OMéDIT Bretagne)
  www.omeditbretagne.fr/qualite-securite-vigilance/boite-a-outils-qualite-securite-vigilance/analyse-de-scenarii-cliniques/

  www.youtube.com/watch?v=vO8LGXMTS9s&list=PLZ6thpXxeKjYHeTb4BX6tyjiws4g2l2id&index=7

  Pédiatrie : situations & médicaments à risque [Paediatrics: risky situations & medicinal products] (OMéDIT Bretagne)
  www.omeditbretagne.fr/activites-et-thematiques/pediatrie/

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1. “Dose calculation” patient safety focus: www.has-sante.fr/upload/docs/application/pdf/2022-01/spa_205_flash_calcul_doses_cd_2021_12_16_v1.pdf.

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