

Medical devices

Using them well... to prevent the worst

18 November 2021

It could happen to you too

Event 1

FLUOROURACIL POISONING LEADING TO PATIENT TRANSFER TO HAEMODIALYSIS

A male patient over the age of 60 is hospitalised in the 5-day week hospitalisation department (hospitalisation de semaine - HDS) for FLUOROURACIL chemotherapy. Administration of the treatment by syringe pump led to transfer of the patient to the haemodialysis department with concomitant injection of the antidote.

What happened? *Immediate cause*

The patient received their full FLUOROURACIL course in 3 h instead of 46 h.

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

- The nurse looking after the patient, who was a replacement and not from the HDS department, had not been trained in chemotherapy or in how to programme the new device.
- The nurse asked a nurse from the oncology day hospital used to handling chemotherapy for help programming the syringe pump, but they were not trained in the new equipment:
 - the syringe pumps used in the day hospital for analgesia are set to ml/h, whereas the device used in chemotherapy is set to mg/m²/day or mg/h, mg/kg etc.;
 - the day hospital nurse programmed the device and the HDS nurse connected it.
- The "user" guide to programming the pumps was not provided to the users. Only the HDS nurses, who were off sick, knew how to programme these specific syringe pumps.
- The syringe pump setting was not double-checked by a third-party.

Event 2

RAPID INSULIN OVERDOSE LEADING TO ACUTE HYPOGLYCAEMIA

A 70-year-old male patient is hospitalised in follow-up and convalescence care. After 3 days' hospitalisation, the patient's blood sugar levels are high each time they are tested. Rapid INSULIN (NOVORAPID FLEXPEN), solution for injection in a prefilled pen, was therefore prescribed and administered. In light of life-threatening hypoglycaemia at 1.375 mmol/L, the patient is transferred to the emergency department.

What happened? *Immediate cause*

The nurse administered 60 IU (international units) of rapid INSULIN instead of the 6 IU prescribed.

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

- The doctor prescribed rapid INSULINE for injection in a prefilled pen. However the department only has insulin in 100 IU/ml-10 ml vials.
- A trainee nurse was entrusted with insulin preparation and injection without being supervised by a qualified nurse.
- The IU graduated insulin pen had been replaced by the trainee nurse by a tuberculin syringe graduated in ml (instead of using a 0.5 ml INSULIN syringe graduated in International Units).
- The dose before administration was not double-checked.

OXYCODONE HYDROCHLORIDE OVERDOSE LEADING TO PATIENT DEATH

A male patient just over the age of 50 is admitted to the respiratory medicine department for deterioration in general condition. OXYCODONE HYDROCHLORIDE administered by PCA (Patient Controlled Analgesia) pump is prescribed and the PCA placed. A few hours after PCA placement, the patient sustained respiratory decompensation and died early evening from OXYCODONE HYDROCHLORIDE overdose.

What happened? Immediate cause

The drug was administered over 5 hours instead of 5 days.

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

- The nurse inverted the dose/hour and the dose/24 h on programming.
- The nurse looking after the patient had not been trained in how to use the PCA and asked the nurse from the palliative care mobile team, trained in the use of this model, for help programming the device.
- The “user” guide to programming the pump was not provided to the users.
- The prescription software did not take PCA prescription into account.
- As the programming calculation is not automated, the palliative care nurse made the calculation by inverting the daily dose and the hourly dose when completing the PCA programming spreadsheet.
- No protocol for the surveillance of a patient receiving OXYCODONE HYDROCHLORIDE PCA and for overdose management had been provided to the staff.

Key words: *Hospital admission – Medical device – Drug error – Morphine – Chemotherapy*

So it doesn't happen again

Analysis of serious adverse events in the REX-EIGS (feedback on treatment-related serious adverse events) database showed that for almost 250 drug errors analysed, 25% are related to incorrect use of medical devices, combined for more than 60% of those cases with the use of medicinal products on the *never events* list.

Here are some barrier principles to put in place to avoid them:

- involve users in the purchase of a new pump model or brand as far as possible;
- have an identical pump or syringe pump on each floor or in each building to mitigate the risks where a device has to be loaned between departments and staff are reassigned;
- provide simplified instructions or procedures of use of pumps or syringe pumps (or even a surveillance check-list for patients on a syringe pump or receiving PCA);
- ensure training/assessment of healthcare professional users:
 - regular skills assessment and refresher training to take account of upgrades to the MDs,
 - assessment of new staff (including temporary staff and replacements), and provision of training in the use of the medical devices they will be brought to handle;
- harmonise protocols for the prescription of medicinal products for syringe pump administration;
- standardise preparation methods;
- ensure dose calculations and pump settings are double-checked by a third-party.

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 information sheet focusses on the occurrence of adverse events incriminating the inappropriate use of a medical device. This sheet relates events with which healthcare professionals have been confronted and which are always associated with a series of dysfunctions.

Find out more:

- Circular DGOS of 14 February 2012 concerning the management of the quality of medication management in healthcare organisations
solidarites-sante.gouv.fr/fichiers/bo/2012/12-03/ste_20120003_0100_0037.pdf
[archiveansm.integra.fr/Dossiers/Securite-du-medicament-a-l-hopital/Les-evenements-qui-ne-devraient-jamais-arriver-Never-Events/\(offset\)/0](http://archiveansm.integra.fr/Dossiers/Securite-du-medicament-a-l-hopital/Les-evenements-qui-ne-devraient-jamais-arriver-Never-Events/(offset)/0)

- **If I want to assess myself**

Concerning device programming errors (infusion pumps, syringe pumps)

- Administration devices: summary of existing barrier measures
www.omeditbretagne.fr/wp-content/uploads/2019/11/Dispositifs-dadministrations-synthese-des-mesures-barrieres-existantes-V4.pdf
- E-Learning
www.omedit-centre.fr/debit/co/module_3_Debit_Perfusion.html
www.omedit-centre.fr/PCA/co/module_PCA.html
https://www.omeditbretagne.fr/omeditelearning/PSE2/SCO_0001/

On INSULIN

- E-Learning
www.omedit-centre.fr/insuline_web_gen_web/co/Insuline_Never_Event_web.html
www.omedit-centre.fr/stylo/co/administration_insuline_web.html
www.omeditbretagne.fr/omeditelearning/insuline/SCO_0001/index.html

- **If my organisation wishes to self-assess**

Self-assessment form: securing the syringe pump and infusion pump circuit

www.omeditbretagne.fr/dispositif-dadministration

- **If I want to train**

HAS. Tools for securing and self-assessment of drug administration. May 2013

www.has-sante.fr/jcms/c_946211

Concerning device programming errors (infusion pumps, syringe pumps)

www.omedit-grand-est.ars.sante.fr/system/files/2019-07/BABA%20de%20la%20PCA.pdf

www.omedit-normandie.fr/media-files/28243/guide-pca-revu-v-2020-vf.pdf

www.omedit-centre.fr/portail/gallery_files/site/136/2953/5062/6459.pdf

www.omedit-grand-est.ars.sante.fr/system/files/2018-12/Guide%20bon%20usage%20pompes%20PCA%20Om%C3%A9dit%20Normandie%20juin-2014.pdf

On INSULIN

www.omedit-centre.fr/portail/gallery_files/site/136/2953/5062/9548.pdf

www.omedit-centre.fr/portail/gallery_files/site/136/2953/5062/10876.pdf

www.omeditbretagne.fr/outils-de-formation/e-learning/

- Video: proper use of insulin pens in healthcare organisations (OMEDIT Brittany)
vimeo.com/118323372
www.omedit-normandie.fr/boite-a-outils/never-events/never-events,2798,3177.html

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