

Preparation and administration of drugs in children: conformity with official and paediatric literature

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Background

Use of unlicensed drugs and prescription outside drug-labelling is frequent in paediatric patients, due to the fact that few studies are conducted in this population because of ethical or logistical problems and financial and legal concerns.

Many studies have showed the frequent prescription outside drug-labelling in terms of age, indication, dosage and route of administration in paediatric patients, but few studies have focused on preparation and administration steps.

Objectives

- Survey of injectable drug preparation and administration in neonatal and paediatric intensive care inpatients
- Evaluation of the conformity between practice and literature [Fig.1]
 - 1) official drug information (SC: Swiss Compendium 2003)
 - 2) paediatric references (MfC: Medicines for Children 2003; NeoFax: NeoFax 2002)



Fig.1: Literature

Design

One-day per week prospective observation study in two paediatric units: 23 days, from April to November 2003

Creation of a specific Access®-database in order to collect all data [Fig.2]

Analysis of the conformity between practice and references according to the following criteria: license status, availability of official and paediatric product monographs, age, dosage, solvent for reconstitution and/or dilution, concentration after reconstitution and/or dilution, route of administration, duration and drug flow

Setting

Neonatal (15 beds) and paediatric intensive care units (10 beds), university hospital



Fig.2: Database

Results

Over 468 patient-days, 2134 prescriptions were collected. Of 229 drugs, 92 (40%) were unlicensed including 56 (25%) prepared by the hospital pharmacy. 291 (62%) patient-days had at least one unlicensed medication.

Of the 20 most frequently used injectable drugs, 58% had an official information with 44% including paediatric information. [Tab.1]

Top 20 of injectables	
1 Heparin	11 Inositol
2 Morphine	12 Tocopherol (vit. E)
3 Acetaminophen	13 Potassium chloride
4 Epoetin	14 Cefazoline
5 Fat emulsion	15 Vancomycin
6 Furosemide	16 Phytomenadione (vit. K)
7 Gentamicin	17 Milrinone
8 Midazolam	18 Propofol
9 Amoxicillin	19 Dobutamine
10 Omeprazole	20 Adrenaline

Tab. 1: Top 20 of injectables

Of the 868 prescriptions (top 20 of injectables), 275 (32%) were conform for age, 125 (14%) for dosage, 511 (59%) for route of administration, 306 (39%) for duration of administration, and 48 (6%) for drug flow. An adequate solvent and concentration were used in 136 (75%) and 61 (34%) of 181 reconstitutions, respectively. Of 428 dilutions, 139 (33%) were prepared with an adequate solvent and 25 (6%) were administered at a recommended concentration. [Fig.3]

Conformity of prescriptions in terms of age, dosage, duration of administration and dilution increased notably using paediatric references but not for reconstitution.

Less than 15% of prescriptions were conform for drug flow and concentration after dilution mostly because of sparse information in the literature.

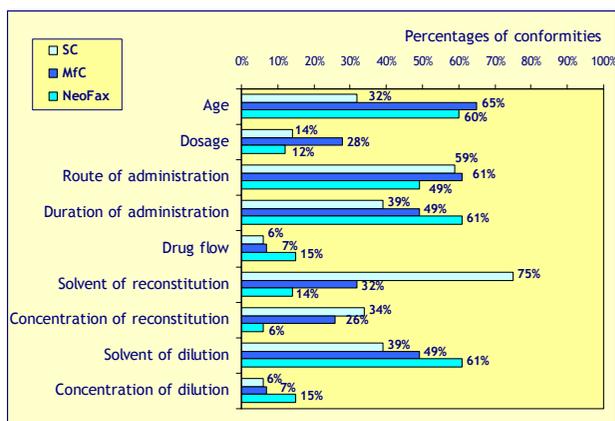


Fig. 3: Results of the top 20 of injectables

Corrective measures already taken

- Sampling precision: case of epoetin β. Preparation of 0.7 mL NaCl 0.9% vials to allow dilution of epoetin β and precise administration of small volumes. [Fig.4]



Fig.6: Omeprazole suspension

- Preparation of ready-to-use syringes of fat emulsion to reduce contamination risk and costs. [Fig. 5]
- Action on the wrong use of a galenic form. Preparation of an oral omeprazole suspension to facilitate administration. [Fig.6]



Fig.4: Dilution for epoetin β



Fig.5: Ready-to-use syringe of fat emulsion

Conclusion

This study confirms the gap between the clinical needs in neonatal and paediatric intensive care units and the official available information.

A minority of drugs were prepared and administered in accordance with official information and with paediatric references which may be associated with an increased risk of adverse events.



References

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