



UNLICENSED DRUGS IN PEDIATRIC PATIENTS: A SURVEY OF MANUFACTURED AND IMPORTED DRUGS IN SWISS HOSPITALS

Fonzo-Christe C, Di Paolo ER, Brunner C, Buxtorf R, Halder R, Challet C, Vonbach P
Pediatric working group, Resort "pharmaceutical services", GSASA, Switzerland

Introduction

Due to a lack of suited pediatric formulations, hospital pharmacies have to manufacture or import 25% to 40% of all drugs used for neonatal and pediatric patients (so-called "unlicensed drugs").^{1,2} Use of such drugs may be of concern in terms of drug information (no leaflet or in another language) and continuity of care (availability in public pharmacy, reimbursement).

Methods

Retrospective data analysis : August 2009 to July 2010; 8 representative hospital pharmacies : **university**: HUG Geneva, CHUV Lausanne, Inselspital Bern, Kinderspital Zurich, UHBS Basel; **regional**: ICHV Sion, PIC Morges, EOC Bellinzona

Included drugs: manufactured (8 hospitals) or imported (7 hospitals, UHBS not recorded) drugs primarily for neonatal or pediatric units. Excluded: drugs for enteral nutrition and total parenteral nutrition

Statistical analysis using STATA7. Comparison university/regional hospitals: Fisher's exact test (p<0.05).

Objectives

One-year survey of drugs imported or manufactured for neonatal and pediatric patients in Swiss hospital pharmacies, and evaluation of the most common drug classes and substances.



Results

Most preparations (n=499, 87%) and drugs (n=313, 90%) are manufactured resp. imported by the university hospitals.

Drug classes A-D represent about 50% of the manufactured or imported substances. (Fig.1 and 2)

Production of central nervous drugs and import of new therapeutics (antineoplastic agents) are also common. Many preparations are manufactured or imported by more than 4 hospitals. (Tab.1 and 2)

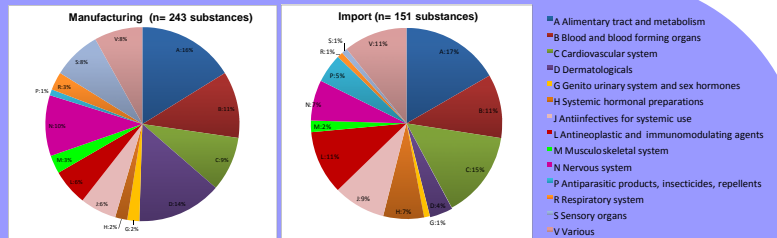


Fig. 1 and 2 ATC-classification of the manufactured and imported substances

Manufacturing

- ❖ Mass productions (59%) are more frequent in university and individualised preparations (53%) in regional hospitals (p<0.001) (Fig.3)
- ❖ Around 25% of the productions are outsourced in university and regional hospitals (Fig.3)
- ❖ Oral preparations represent 50% of the productions, mainly as capsules and oral solutions (Fig. 4)

Nb of hospitals	DCI	ATC drug class	Type of preparation
7	caffeine	class N	oral solution, IV amp. or syringes
7	hydrochlorothiazide	class C	oral solution, capsules
7	spironolactone	class C	oral solution, capsules
6	morphine	class N	oral solution, IV amp.
6	captopril	class C	oral solution, capsules
6	midazolam	class N	oral solution, nasal spray
5	phenobarbital	class N	oral solution, IV amp.
4	omeprazole	class A	oral suspension
4	dexamethasone	class H	oral solution, capsules

Tab. 1 Most commonly manufactured drugs (n=313 drugs)

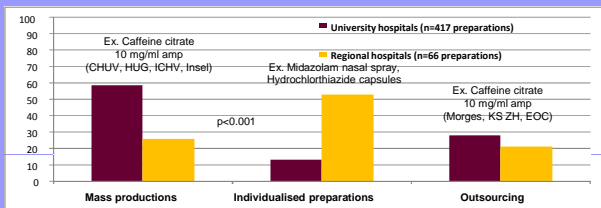


Fig. 3 Type of production (n=483 preparations; 16 unknown)

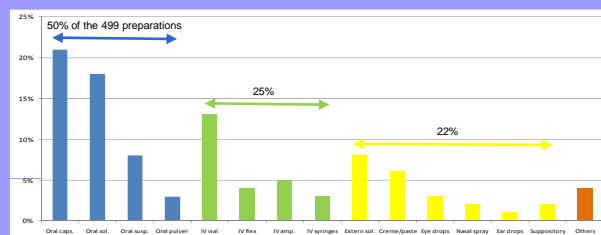


Fig. 4 Pharmaceutical forms (n=499 preparations)

Import

- ❖ Most commonly imported drugs from France (F), Germany (D), England (GB) and the USA (Tab.2)
- ❖ **Causes of import** (Tab.2):
 - Unsuitable drug formulations on the Swiss market
 - IV injectables unavailable on the Swiss market
 - Important substances for pediatric use (ex. intensive care drugs)

Nb of hospitals	DCI	ATC drug class	Product	Box / year	Type
7	digoxin	class C	Digoxin Nativelle (F), Lenoxin (D)	99	Unsuited drug formulations
6	tiagabine	class J	Riladine (F)	48	Unsuited drug formulations
6	arginine	class B	L-Arginine-HCl 21% (D)	208	IV unavailable in CH
5	propranolol	class C	Syrol (GB)	98	Unsuited drug formulations
5	prednisolone	class H	Solopred (F)	392	Unsuited drug formulations
5	separaginase	class L	Asparaginase (D), Erwinase (GB), Oncaspar (D)	403	IV unavailable in CH
4	vitamins ADEK	class A	Aquadex (USA)	266	Unsuited drug formulations
4	gemtacin	class J	Rebiban or Gemtacin (D), Gentalline (F)	1257	Unsuited drug formulations
4	indometacin	class C	Indocil (USA), Prodon (F)	107	IV unavailable in CH
4	vasopressin	class H	Vasopressin (USA), Pitressin (USA)	12	Intensive care
4	nifedipine	class C	Nipress (D)	376	Intensive care

Tab. 2 Most commonly imported drugs (n=313 drugs)

Conclusion

As expected, import and manufacturing of drugs for pediatric patients are frequent in hospital pharmacies and mainly due to unsuited pediatric formulations on the Swiss market.

Most hospitals manufacture or import the same drugs. Therefore, collaboration is needed to elaborate appropriate information leaflets and to centralise manufacturing in the future.

References:

1. Di Paolo ER et al. Swiss Medical Weekly 2006;136:218-22
 2. De Giorgi I et al. Thèse de doctorat, Université de Genève 2009
- <http://archive-ouverte.unige.ch/download/pdf/tp/2mcf3cyp6d6e0e1ef7fmc3/out.pdf>

This poster can be downloaded and printed at following address:
<http://pharmacie.hug-ge.ch/rd/posters.html>

