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BACKGROUND & OBJECTIVES

In hospital setting, healthcare professionals may be exposed to hazardous drugs. Risks and protective measures needed when handling parenteral cytotoxic drugs are well described, whereas information related to drugs like monoclonal antibodies or antivirals are lacking. Only the National Institute for Occupational Safety & Health¹ (NIOSH) published an exhaustive list of hazardous drugs. To edit recommendations of effective but applicable protective measures in our hospital, we developed a standardized method to evaluate occupational risks and to recommend protective measures.

DESIGN

Development of an algorithm for toxicity evaluation using Material Safety Data Sheet (Risk and Safety phrases²), International Agency for Cancer Research (IARC³) classification and official manufacturers' data⁴. (Fig. 1)

1. Evaluation of chronic toxicity (mutagenicity, carcinogenicity), acute toxicity (sensitisation or irritation in contact with skin, eyes or by inhalation) and toxicity to reproduction;
2. Balance of toxicity according to the risk of exposure (e.g. pharmaceutical forms);
3. Assessment of protective measures during preparation and administration (e.g. centralization of drugs' preparation in the pharmacy, wearing of mask, gloves and/or glasses).

For details <http://pharmacie.hug-ge.ch/rd/publications.html>

RESULTS

Toxicity

- Occupational risks of 59 substances (86 pharmaceutical forms) were analysed.
- 27% were mutagen and carcinogen (fig.2).
- 53% were potentially toxic to reproduction.
- 54% were irritating to the skin or respiratory tract.
- Monoclonal antibodies were found not to be at risks of mutagenicity or carcinogenicity and only gloves and sometimes masks will be recommended for their manipulation. (Table 1)
- No "class-effect" has been pointed out (e.g. only a few antivirals were found to be hazardous).

Centralization in the pharmacy

- According to our algorithm, 17% of i.v. liquids and 38% of i.v. powders preparation should be centralized in the pharmacy (in practice, two new i.v. powders prepared in the pharmacy [cidofovir, ganciclovir]). 25% of tablets should be crushed in the pharmacy (e.g. valganciclovir). (Table 2)
- Information on protective measures to be worn by nurses for handling drugs will be distributed as a pocket card and included in the electronic prescription tool.

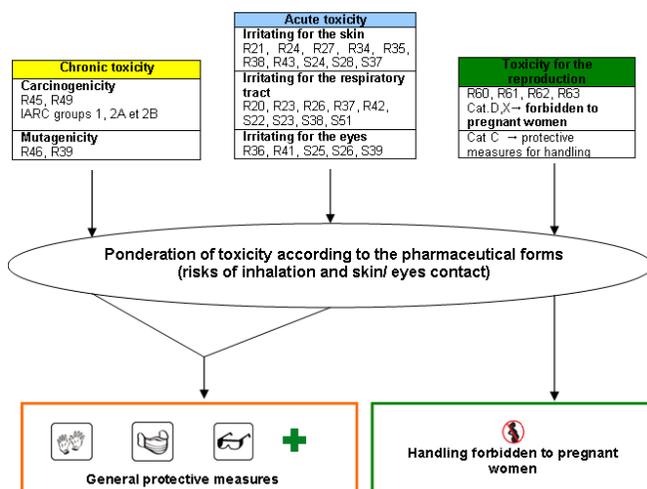


Fig. 1: Algorithm for toxicity evaluation

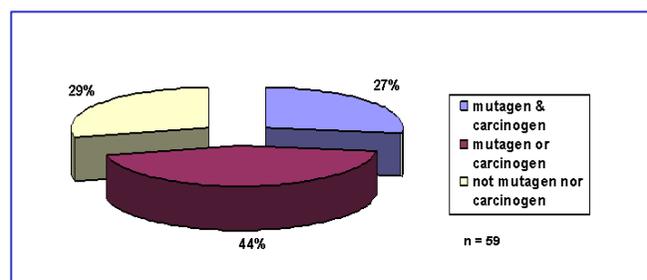


Fig. 2: Number of products with mutagenic or carcinogenic risks

Table 1: Protective measures recommended for preparation and administration of monoclonal antibodies

INN	Brand name	Pharmaceutical forms				Pregnant women
abciximab	Reopro®	iv solution	✓			
adalimumab	Humira®	sc solution	✓			
alemtuzumab	MabCampath®	iv solution	✓			
basiliximab	Simulect®	iv powder	✓			
bevacizumab	Avastin®	iv solution	✓			
cetuximab	Erbix®	iv solution	✓			
daclizumab	Zenapax®	iv solution	✓			
efalizumab	Raptiva®	iv powder	✓	✓		
gemtuzumab/ozogamycine	Mylotarg®	iv powder	✓	✓		⚠
infliximab	Remicade®	iv powder	✓			
muromonab-CD3	Orthoclone OKT3®	iv solution	✓			
palivizumab	Synagis®	iv powder	✓	✓		
rituximab	Mabthera®	iv solution	✓			
trastuzumab	Herceptin®	iv powder	✓			

wear gloves wear mask wear glasses
⚠ handling forbidden to pregnant women

Table 2: Tablets to be crushed and new i.v. powders to be prepared in the pharmacy

INN	Brand name	Pharmaceutical forms	(preparation) (administration)	Pregnant women
azathioprine	Imurek®, Azarek®	coated tablets when crushed	+	⚠
chlorambucil	Leukeran®	coated tablets when crushed	+	⚠
cidofovir	Vistide®	iv powder	+	⚠
cyclophosphamide	Endoxan®	coated tablets when crushed	+	⚠
ganciclovir	Cymevene®	iv powder	+	⚠
melphalan	Alkeran®	coated tablets when crushed	+	⚠
mercaptopurine	Puri-Nethol®	coated tablets when crushed	+	⚠
valganciclovir	Valcyte®	coated tablets when crushed	+	⚠

⚠ handling forbidden to pregnant women

+ products prepared at the Pharmacy and administered with gloves, mask, protecting garment and glasses

CONCLUSION

Our method has allowed evaluating in a standardised way whether a drug should be treated as hazardous or not. Results have been discussed institutionally in order to implement applicable security policies and procedures for healthcare professionals.

References: 1) <http://www.exposurecontrol.nl/publications/NIOSH2004.pdf> 2) http://www.ccohs.ca/oshanswers/chemicals/risk_phrases.html 3) <http://monographs.iarc.fr/ENG/Monographs/index.php> 4) www.kompendium.ch

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Conflict of interests: nothing to disclose