STANDARD PRACTICES TO ENSURE SAFE CYTOTOXIC DRUG RECONSTITUTION IN HOSPITAL PHARMACIES: AN INTERNATIONAL REVIEW

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Background

Cytotoxic Reconstitution Services (CRS) have been developed in hospital pharmacies throughout the world. Their aim has been to reduce the number of persons handling antineoplastic agents, thus diminishing the risks for themselves, the nursing staff and the patients. Recent evidence has suggested that pharmacy staff could be exposed to significant amounts of cytotoxic materials despite normal safety measures⁴⁻⁵. The goal of this review was to catalogue the standard practices, guidelines and regulations issued by hospital pharmacy associations, governmental health and safety authorities and medical agencies, concerning the types of safety cabinets recommended in each country and to determine if there was concordance.

Methods

Nine countries were included in the study: Australia, Canada, France, Germany, New Zealand, Sweden, Switzerland, United Kingdom and the USA. The documents obtained from official sources, either by traditional methods or through internet, concerned four types of safety cabinet:

1) Class 2, Vertical laminar flow cabinets (VLFC).
2) Rigid positive pressure isolators (RPPi).
3) Rigid negative pressure isolators (RNPI).
4) Gassed "flexible film" positive pressure isolators (GPPI).

Results

Australia was the first country to have developed Standard Practices for cytotoxic drug reconstitution. VLFC are also allowed. SHPA Standards of Practice for the Safe Handling of Cytotoxic Drugs in Pharmacy Departments. Australian Journal of Hospital Pharmacy. 1999; (2) 29 www.shpa.org.au


The majority of Swedish hospitals use VLFC but some are converting to RNPI. General Recommendations on the Implementation of the Provisions on Cytostatics and Other Drugs with Enduring Toxic Effects. Swedish National Board of Occupational Safety and Health. 9th December 1999; Published in March 2000.

Isolators have not been recommended by QuaPoSi (German Quality Standards). Ergonomic problems have been brought up because of possible ULD (Upper Limb Disease). Quality Standards for the Oncology Pharmacy Service. QuaPoSi 2000 3rd Edition. Oeiras, Portugal.

Only VLFC are directly mentioned in the Swiss guidelines. Isolators of any type can be used if they comply with GMP and the laws governing the security and health of the operators. Directives for Cytotoxic Preparation 2001. Swiss Society of Public Health, Administration and Hospital Pharmacists. www.gesas.ch

Conclusions

It can be seen that each country has its own Standard Practices and for the moment a consensus has not been reached. Moreover, "the negative pressure isolator controversy" is the subject of intense debate between, on the one hand, the Health and Security Authorities and the Medical Agencies on the other. What should be protected first: the product or the operators? Other solutions include GPPI, but this is a very expensive option, and the possibility of "outsourcing" to the pharmaceutical industry. Discussions should be continued on a global basis to establish world-wide standards for oncology pharmacy services, with the objective to protect both the product and the staff.

References

1) Antineoplastic hazards. www.uth.tmc.edu/schools/sph
4) Pharm J. 9th January 1999 ; (262) : 56.
5) Kiffmeyer TK et al. Pharm J. 9th March 2002; (268) : 331 - 337

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