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ISOPP Standards of Practice

Safe Handling of Cytotoxics

Important statements/quotes – a summary

Section 1 – Introduction (p. 4)

Conclusions

Working with or near hazardous drugs in health care settings may cause skin rashes, has been associated with infertility, miscarriage and birth defects, and raises concerns about the possible development of leukaemia or other cancers. To provide workers with the greatest protection, employers should:

- (a) Implement necessary administrative and engineering controls and
- (b) Assure that workers use sound procedures for handling hazardous drugs.

Section 5 – Hierarchic order in protection measures (p. 15–16)

It is imperative that the sequence of protection levels starts with level 1 and ends at level 4 = TOP → BOTTOM. In other words, one is not free to choose the measures in protection to exposure of cytotoxic drugs. The levels of protection measures are in descending order of importance:

Level 1: Elimination, substitution, replacement

Change the product to another product which is non-toxic or less toxic.

Level 2: Isolation of the hazard/source containment

Contain the toxic product in its container or at source.

Level 3: Engineering controls/ventilation

Apply local and general ventilation or extraction in order to dilute the toxic product.

Level 3 B: Administrative controls/ organization measures

Organise the work in such a way that the duration of exposure is reduced.

Level 4: Personal protective equipment

Individual protection by using personal tools.

Section 7 – Special devices (p. 27–30)

These special devices may be considered in 3 categories:

- (a) Devices to protect the handler of the vial/ampoule
- (b) Devices to protect the operator during preparation
- (c) Devices to protect the administrator during administration of the cytotoxic drug to the patient

(a) Devices to protect the handler of the vial/ampoule

It is the responsibility of pharmaceutical manufacturers to guarantee that the external surfaces of drug vials are free of contamination.

(b) Devices to protect the operator during preparation

It is very important that the term “closed system” is clearly defined. A clear distinction must be made between a closed system in the context of microbiological contamination and a closed system in the context of chemical contamination and occupational exposure.

The word “closed” in terms of **microbiological contamination**

Examples of definitions:

One withdraw out of an ampoule or one puncture through a rubber stopper of a vial and in a class A environment. (United Kingdom).

The word “closed” in terms of **chemical contamination**

Examples of definitions:

A drug transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapour concentrations outside the system. (USA)

- Filters with a diameter of 0.22 mm and HEPA filters **DO NOT** retain the vapour of cytotoxic products.
- Filters with active carbon can absorb vapours on a temporary basis only and therefore should be accompanied with studies indicating the maximum loading, working conditions and the minimum and maximum retention time of the filter capacity.
- The NIOSH definition is therefore the most comprehensive and complete.

Closed System Drug Transfer Device

A drug transfer device which mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapour concentrations outside the system.

Manufacturers of special preparation devices must clearly indicate:

- (a) If the device covers all steps in the preparation process or if it covers only some of the steps in the process. If the latter applies, then the manufacturer should indicate clearly where the closed properties of the device are NOT retained.
- (b) If the device retains its closed characteristics when more than one vial is used for a particular preparation.
- (c) If studies have shown the device to fulfil the aim of eliminating or reducing the environmental contamination in daily practice and to what degree.

To avoid confusion, it is strongly recommended that if a device claims to prevent chemical contamination the term used should be **Containment Device (This is a Leakproof, airtight device)**.

(c) Devices to protect the administrator during drug administration of the cytotoxic drug to the patient

The NIOSH definition of a closed system drug transfer device may also be applied to the administration of hazardous drugs:

A contained administration system is a drug administration device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapour concentrations outside the system.

In addition the manufacturer of special administration devices must clearly indicate:

- (a) For which routes of administration the containment is guaranteed.
- (b) If the device covers all steps in the administration process or if it covers only some of the steps. If the latter applies, then the manufacturer should indicate clearly where the closed properties of the device are **NOT** retained.
- (c) If the device retains its closed characteristics when more than one administration of hazardous drug is to be performed using the same device.
- (d) If studies have shown the device to fulfil the aim of eliminating or reducing the environmental contamination in daily practice and to what degree.

It is strongly recommended that if a device claims to prevent chemical contamination during drug administration then the term used should be **Containment Device (This is a Leakproof, airtight device)**.

Own note: All references (except NIOSH) in section 7 are PhaSeal references.

Section 8 – Ventilation tools (p. 31–42)

A BSC where air is exhausted into the workroom must be avoided. Class II A cabinets are not recommended as they are not suitable for the manipulation of volatile toxic chemicals (A1) or for only minute quantities of volatile chemicals (A2) unless special containment devices (leakproof, airtight devices) are used during the preparation (see Section 7).

Section 12 – Administration of cytotoxic drugs (p. 53–54)

- If bags or syringes prepared in the pharmacy are contaminated on the outer surfaces, nurses will come into contact with the pure concentrated cytotoxic drug.
- The disconnection procedure is a risk for nursing staff and a containment (leakproof, airtight) device for administration should preferably be used.
- Tubing should never be removed from an IV bag containing a cytotoxic drug.
- The same hierarchic order in prevention must be applied for the work of the nurses.
- If possible, contained systems (leakproof, airtight) for parenteral administration should also be used.