Monitoring contamination of hazardous drug compounding surfaces at hospital pharmacy departments. A consensus Statement. Practice guidelines of the Spanish Society of Hospital Pharmacists (SEFH)

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Period of study	Literature search period of Medline and Embase databases: January 2009 – July 2019

Objectives

To review the available evidence and establish a set of recommendations for correct surface contamination monitoring in the areas devoted to hazardous drug compounding in hospital pharmacy departments.

Study design

Literature, standards and recommendations review.

Materials and methods

- Committee of Experts of SEFH defined a series of safe practices for the handling and monitoring of hazardous drugs from the following sources: (1) literature search using the Medline and Embase databases January 2009 – July 2019, with search terms agreed by authors; (2) the 527 references identified above supplemented by secondary references to standards and recommendations contained therein; (3) a specific search conducted of the legal and regulatory framework applicable to hospital pharmacy departments.
- Recommendations were finalised by consensus among the members of the expert group in consideration of the recommendations reviewed, the monitoring situation in Spanish hospital departments, and the associated costs.

Key results

Ten recommendations were formulated, structured into eight sections: 1. drugs to be monitored; 2. areas to be monitored; 3. sampling time; 4. risk determination as part of the sampling plan and monitoring frequency; 5. analytical techniques; 6. contamination thresholds; 7. action plan based on the result of the sampling procedure; 8. decontamination. (See Key Figure overleaf).

Caveat

- Recommendations put forward are founded on an expert opinion level of evidence, including clinical experience, descriptive studies or expert committee reports.

Conclusions

- Surface monitoring must be applied to determine the presence of hazardous drugs, and to establish the efficacy of the hospital pharmacy department's hazardous drug management protocol.
- Evaluation must include a consideration of engineering controls, work practices and cleaning and decontamination procedures.

Key figure

	RECOMMENDATIONS	Level of evidence
Drugs to be monitored	Monitor levels of, at least, cyclophosphamide as a surrogate marker for monitoring surface contamination in HDP areas where HDs are handled.	*III: Expert opinion based on clinical experience; descriptive studies; or expert committee reports.*
Areas to be monitored	To be defined depending on each HD handling circuit and the available budget. The following areas of the HPD devoted to HD compounding should be monitored as a minimum: – Central working area of biological safety cabinets. – Floor in front of biological safety cabinets. – Bench-top for final product inspection. – Bench-top for raw materials preparing. – Handle of the door leading to the compounding area.	*III: Expert opinion based on clinical experience; descriptive studies; or expert committee reports.*
Sampling time	Samples should be taken at the end of the working day, before the usual cleaning and/or decontamination protocols are carried out.	*III: Expert opinion based on clinical experience; descriptive studies; or expert committee reports.*
Risk determination as part of the sampling plan. Monitoring frequency	A sampling plan must be established that includes the areas to be sampled and the frequency which they must be monitored, based on each area's contamination risk, the type of HDs handled, and the frequency which they are handled. The initially established sampling frequency must be adjusted on the basis of the results obtained from the baseline samples, increasing the sampling frequency if results show contamination, or decreasing it if 3 consecutive samples are negative. Monitoring frequency should never fall below 6 months.	*III: Expert opinion based on clinical experience; descriptive studies; or expert committee reports.*
Analytical techniques	LFIA can be used for regular monitoring where a fast response is required for decision-making. LC-MS/MS should be used for baseline and/or periodic quantitative measurements. Baseline measurement should be quantitative.	*III: Expert opinions based on clinical experience; descriptive studies; or expert committee reports.*
Contamination thresholds	Establish maximum allowable exposure levels depending on the historical controls performed in the studied environment, with levels above the 90th percentile (or 1 ng/cm2 in the case of cyclophosphamide) considered the threshold above which procedures must be changed.	*III: Expert opinion based on clinical experience; descriptive studies; or expert committee reports.*
Action Plan based on the results of the sampling procedure	Each HPD should have an action plan establishing the steps to be taken according to the results of the surface monitoring analyses.	*III: Expert opinions, based on clinical experience; descriptive studies; or expert committee reports.*
Decontamination	Several products may be combined taking into consideration the characteristics of the different surfaces so as to ensure correct removal of HDs as well as environment sterilisation.	*III: Expert opinions, based on clinical experience; descriptive studies; or expert committee reports.*

HD: hazardous drug; HPD: hospital pharmacy department; LC-MS/MS: tandem mass spectrometry; LFIA: lateral flow immunoassay