Handling hazardous drugs in the health care environment – tools and guidance by INSST

Healthy Workplaces Campaign 2018-19
Manage dangerous substances in the workplace
HWC Summit 2019 Bilbao

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Background

The first group of drugs considered dangerous were **cytostatic drugs** (1979)

Workplace exposure to hazardous drugs has been well documented, and it first became a recognised safety risk in the United States

**Studies:**
- Secondary malignancies were reported in patients (1970s)
- Nurses had higher levels of mutagenic substances in urine
- Chromosomal aberrations in pharmacists and nurses who were handling cytostatic drugs
- Association between exposure to antineoplastic drugs and adverse reproductive effects
- Environmental contamination of areas in health care facilities where cytostatic drugs are prepared and administered (1990s)
Background

Different studies showed the need for:

- Change in the initial preparation form
- Establishment of guidelines for cytostatic drugs preparation
- Centralization in Pharmacy Services
- Other measures (e.g. Ventilation, use of closed-system drug transfer devices)
Objectives

- Raise awareness in the healthcare sector about exposure to dangerous medicines
- Establish a first list of hazardous drugs (HD’s) to provide detailed help for the identification of hazards as a basis for adequate subsequent risk management
- Development of a practical web tool to facilitate the accessibility by the healthcare sector to information on HD’s
- Build alliances with different agencies and with health facilities involved
- Encourage implementation of best practices following the instructions in the published technical documents
Background.

Studies HD’s at the INSST

- **'80s**
  - Mutagenicity
  - Chromosomal Aberrations
  - Cytotoxic drugs

- **'90s**
  - Exposure assessment
  - Cytotoxic drugs.

- **2000**
  - Surfaces contamination
  - Biological monitoring
  - Cytotoxic drugs

- **2016**
  - Guideline
  - INFOMEP tool
  - Hazardous drugs in general

[www.healthy-workplaces.eu](http://www.healthy-workplaces.eu)
What are hazardous drugs?

Medicines with adverse health effects: carcinogenicity, mutagenicity, reproduction and developmental toxicity, genotoxicity

Including cytotoxic drugs for anticancer treatments, and recently other treatments for non-cancerous diseases

Cytotoxic drugs (cytostatic or antineoplastic drugs) describe a group of medicines used in a variety of healthcare settings, prominently in the treatment of cancer and other (non-cancerous) diseases.
Who may be exposed at work?

- Pharmacy workers
- Nurses
- Physicians and physicians’ assistants
- Healthcare auxiliary nurses
- Veterinary workers
- Cleaning workers
- Laundry workers
- Hazardous waste disposal workers
- Transport workers
In this European Parliament Report, there are **11 Policy RECOMMENDATIONS** for the EU and Member States Policy by the exposure of healthcare workers to chemical risks during preparation and administration of cytotoxic and another hazardous drugs.
### Carcinogenic risk of cytotoxic drugs to humans

<table>
<thead>
<tr>
<th>Nº</th>
<th>IARC (International Agency for Research on Cancer)</th>
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</thead>
<tbody>
<tr>
<td>0</td>
<td><strong>4 = Probably not carcinogenic to humans</strong></td>
</tr>
<tr>
<td>15</td>
<td><strong>3 = Is Not classifiable as to its carcinogenicity to humans</strong></td>
</tr>
<tr>
<td>17</td>
<td><strong>2B = Possibly carcinogenic to humans</strong></td>
</tr>
<tr>
<td>13</td>
<td><strong>2A = Probably carcinogenic to humans</strong></td>
</tr>
<tr>
<td>13</td>
<td><strong>1 = Carcinogenic to humans</strong></td>
</tr>
</tbody>
</table>

**IARC** (International Agency for Research on Cancer) studied 140 hazardous drugs. The classification system includes:

- **0 = Probably not carcinogenic to humans**
- **1 = Carcinogenic to humans**
- **3 = Is Not classifiable as to its carcinogenicity to humans**
- **2B = Possibly carcinogenic to humans**
- **2A = Probably carcinogenic to humans**
The NIOSH definition of hazardous drugs is based on a definition developed in 1990 by the ASHP.

Recommendations for assessing the hazards, handling drugs, and using and maintaining equipment.

The latest list of hazardous drugs was published in 2016.

NIOSH: National Institute for Occupational Safety and Health, USA
ASHP: American Society of Hospital Pharmacists
Hazardous drugs included in NIOSH list

Drugs considered hazardous include one or more of the following effects in humans or animals:

- Carcinogenicity
- Teratogenicity or other developmental toxicity.
- Reproductive toxicity
- Organ chronic toxicity at low doses
- Genotoxicity
- Structure and toxicity profiles of new drugs that mimic existing drugs determined as hazardous.
Hazardous drugs in NIOSH list

**Group 1:** Antineoplastic drugs

**Group 2:** Non-antineoplastic drugs that meet one or more of the NIOSH criteria for a Hazardous drugs

**Group 3:** Drugs with reproductive risk, including those relevant to men and women trying to conceive and women who are pregnant or breast feeding
Knowing the dangers of hazardous drugs is essential for risk management of these medications within healthcare professionals and other workers.
¿HOW TO IDENTIFY HAZARD?

Hazardous drugs information

CLP regulation does not apply
Lack of safety data sheets for medicinal products.
No labels with hazard pictograms, and hazard statements.

Medicinal products Directive.
Information in the medicinal products datasheet and the package leaflet.

Lack of hazardous drugs information for workers that are handling them

Only sometimes information on preventive measures in the datasheet is available
GUIDELINE. Hazardous Drugs. Prevention measures for preparation and administration. INSST (2016)
173 medicines for humans from the NIOSH list marketed in Spain in juny 2016.

The name of medicinal product marketed and galenical form were included for each medicine.

Recommendations: NIOSH, USP 800, ISOPP, Guide of best practices for the preparation of medicines of the Ministry of Health, SEFH Monograph, AMMTAS Guide, were evaluated.

Working groups of the Spanish Society of Hospital Pharmacists (SEFH) participating: Oncology Pharmacy Group, Pharmacotechnics Group and Health Products Group of different hospitals in Spain.

USP : United States Pharmacopeia  
ISOPP: International Society of Oncology Pharmacy Practitioners  
AMMTAS: Association of Occupational Health in the Healthcare from Madrid
Active substances classified by NIOSH as dangerous (2016)… and the medicines that contain them.

It includes general preventive recommendations. This tool is not a workplace risk assessment.

It’s an initial hazard identification
Información para trabajadores sanitarios sobre medicamentos peligrosos

<table>
<thead>
<tr>
<th>Medicamento</th>
<th>Principio activo</th>
<th>Motivo</th>
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</thead>
<tbody>
<tr>
<td>Presentación</td>
<td>Grupo Terapéutico</td>
<td></td>
</tr>
</tbody>
</table>

Resultados de la búsqueda

Criterios de la búsqueda:
Todavía no se ha realizado ninguna búsqueda

Descargar: CSV EXCEL

<table>
<thead>
<tr>
<th>Especialidad</th>
<th>Principio Activo</th>
<th>Presentación</th>
<th>Categoría de riesgo</th>
<th>Acciones</th>
</tr>
</thead>
</table>

Todavía no se ha realizado ninguna búsqueda
The list of all pharmaceutical specialties marketed in Spain, included in the “medicinal products database”, is included. The database has provided knowledge to professionals who are not experts about pharmacology.

- Includes preventive recommendations based on the galenical form for each medicine.
- Includes other data of interest, such as drug classification, from the IARC document.
- Web tool allows periodic update.
- In collaboration with SEFH.
RISK ASSESSMENT PROCESS

Hazard identification

Risk assessment

Control measures

EFFECTIVENESS
HIERARCHY OF CONTROL

Source: Report: Preventing Occupational exposure to cytotoxic and other hazardous drugs
The technical document has helped to put on the table the hazardous properties of some drugs that were not taken into account previously.

The web tool has helped to inform and raise awareness.

Dissemination actions have been carried out and best practice guidelines have been developed in some regions of Spain.

The workers representative and unions are collaborating in the dissemination of the guide and the database.

Health facilities are reassessing the risk to adapt control measures.
Thank You!

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Specific Technical Documents. INSST

NTP 163: Occupational Exposure to cytotoxic drugs (1984)


Reports from the INSST


Exposure to cytostatics in health facilities. Determination of cyclophosphamid on work surfaces and on the outside of vials. Xavier Guardino Solá, Mª Gracia Rosell Farrás, Susana Torrado (2005)