External contamination of antineoplastic drugs vials on the Canadian market

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Background

• Antineoplastic drugs traces can be measured on healthcare centers’ surfaces.
• The exterior of vials is contaminated with drug traces; this contributes to the exposure of workers.
• Workers that are occupationally exposed to antineoplastic drugs and other hazardous drugs are at risk of adverse health effects.

Objectives

• The aim of the study was to determine the contamination of the exterior of antineoplastic drug vials on the Canadian market.

Methods

• Period: between January and March 2018
• One wholesaler and four different oncology pharmacies in Quebec were targeted.
• Nine molecules were measured: cyclophosphamide, docetaxel, fluorouracil, gemcitabine, ifosfamide, irinotecan, methotrexate, paclitaxel and vinorelbine.
• One wipe was used to sample the external surface of five vials from the same manufacturer, dose and batch.
• For each vial, the external surface, the septum and the bottom were sampled with each side of a wipe.
• Analysis were performed by UPLC-MS-MS by the INSPQ.

Results

• 21 samples (100 vials and 5 blisters)
• 9 different manufacturers
• External contamination was found on 15 samples (71.4%)
• Extreme values: <LOD—272 ng/cm² for gemcitabine vials

• Sixteen (76.2%) samples were cross contaminated with other antineoplastic drugs
• A maximum value of 0.20 ng/cm² of 5-fluorouracil was measured on an gemcitabine vial

Discussion / Conclusion

• 50% of the containers were contaminated with at least one antineoplastic drug
• Vials were sampled after their receipt, thus any contamination measured at this step came from the manufacturing process or the wholesaler storage.
• Shipment receipt is one important entry point of environmental contamination with antineoplastic drugs in healthcare settings.
• Manufacturers and wholesalers should ensure that vials are cleaned upon receipt.
• Gloves must be worn by healthcare workers receiving hazardous drugs.
• Vials should also be cleaned upon receipt.

Table 1. Limits of detection and quantification

<table>
<thead>
<tr>
<th>Antineoplastic drug</th>
<th>Limit of detection (ng/cm²)</th>
<th>Limit of quantification (ng/cm²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cyclophosphamide</td>
<td>0.0010</td>
<td>0.0033</td>
</tr>
<tr>
<td>Docetaxel</td>
<td>0.30</td>
<td>0.30</td>
</tr>
<tr>
<td>5-Fluorouracil</td>
<td>0.0400</td>
<td>0.1400</td>
</tr>
<tr>
<td>Gemcitabine</td>
<td>0.001</td>
<td>0.001</td>
</tr>
<tr>
<td>Ifosfamide</td>
<td>0.0040</td>
<td>0.0055</td>
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<tr>
<td>Irinotecan</td>
<td>0.0030</td>
<td>0.006</td>
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<tr>
<td>Methotrexate</td>
<td>0.0020</td>
<td>0.0060</td>
</tr>
<tr>
<td>Paclitaxel</td>
<td>0.04</td>
<td>0.1200</td>
</tr>
<tr>
<td>Vinorelbine</td>
<td>0.01</td>
<td>0.0120</td>
</tr>
</tbody>
</table>


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