Think Safety First
An analysis of aseptic compounding practice

Introduction

Pharmacy staff prepare hazardous drugs in negative pressure isolators using needles and syringes. Operators have reported droplets leaking from vials during the compounding process. This is also reported in the literature.1–6. During batch production, vials may be punctured multiple times resulting in bung coring. This slows down the compounding process, and poses a risk to the quality of the final product.

The Safety, Health and Welfare at Work (Chemical Agents) Regulations 2001 governs the protection of employees from hazardous substances. It recommends to assess the following hierarchy of control measures to be applied if risks are identified: 1. Elimination of the hazard by changing the process or product. 2. Substitute another, non-hazardous or less dangerous chemical. 3. Where 1 and 2 are not possible, control measures should be implemented to remove or reduce the risks to employees’ health. The employer must ensure adequate equipment and materials, to reduce the release of dangerous substances1.

Aim and Objectives

Aim: To review compounding practice to reduce the risk of droplets leaking from vials, and bung coring.

Objectives:
- Part I – Review aids/devices available to aid the compounding process
- Part II – Assess the cost of implementing the use of compounding aids/devices
- Part III – To validate microbiologically the use of the compounding device
- Part IV – To implement the use of a new compounding aid/device. To risk assess changes to practice and identify staff training needs.

Results

Part I: Our literature review identified 10 vial access devices, 8 bag access devices and 5 syringe adaptors. In Europe many hospital pharmacies are using compounding devices. International guidelines recommend the use of devices/techniques that reduce or eliminate the risk of needle stick injury, aerosols or vapour release.1,2,3,4,5,6,7
2. Hospital Pharmacy Survey Results: see Technician poster HPI conference 2012.
3. In-house review of devices. (See Table 1)

Method

Part I:
1. A literature review was undertaken to collect all information on the use of compounding devices and to investigate the use of compounding devices internationally.
2. A survey of Irish Hospital Pharmacy Aseptic Units was undertaken to assess practice in Ireland (See HPAT Technician Poster 2012).
3. All compounding devices available in Ireland were reviewed and rated using an in-house rating system. Samples of devices were obtained and tested in the unit. Devices were rated out of a total of 10 points based on:
   - Literature support for safety for personnel handling the device
   - Literature support for microbiological safety of the device
   - Ease of use for the operator
   - Risk of drops/leaks seen by compounding staff

Part II:
Microbiological integrity studies show that the PhaSeal is a closed device. This means that part used vials can be recycled.2 Vandenbroeck et al have shown that using the residual components that would be used to compound all products was recorded. The cost of these PhaSeal components was calculated. 3. The cost difference between the cost of PhaSeal® components and the cost of marketed medications was calculated.

Part III:
Broth tests were undertaken using the PhaSeal® system. The vial recycling procedure was validated using broth and contact plate tests.

Part IV: Implementation of the PhaSeal® System.
- To gather information on compatibility between PhaSeal® and compounded medications
- To complete the in-house change control form
- To identify and address the training requirements for pharmacy staff.
- To identify and address the training requirements and equipment required for nursing staff administering cytotoxic medications
- To train staff on the vial recycling procedure
- To update Standard Operating Procedures on operator validation, aseptic technique, tray set up, tray check, compounding, final product check and training.

Table 1: Result of in-house review of compounding devices available in Ireland.

<table>
<thead>
<tr>
<th>Company/Supplier</th>
<th>Device</th>
<th>Rating (Max 10 points)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baxter</td>
<td>Chemo-Aide bag adapter</td>
<td>Not rated – samples not provided</td>
</tr>
<tr>
<td>Fannin</td>
<td>Chemo-Aide mini vented spike syringe</td>
<td>6</td>
</tr>
<tr>
<td>Medisource</td>
<td>Genie Clave MD Access spike syringe</td>
<td>9</td>
</tr>
<tr>
<td>Helapet</td>
<td>Spiris Syringe adapter</td>
<td>6</td>
</tr>
<tr>
<td>PhaSeal System</td>
<td>Roswespike</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Pharmavent</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Spike vent</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Needle vent</td>
<td>5</td>
</tr>
<tr>
<td>B Braun</td>
<td>Chemo Dispensing Pin</td>
<td>8</td>
</tr>
<tr>
<td>Tova</td>
<td>Tepadator syringe adaptor system</td>
<td>7</td>
</tr>
<tr>
<td>Shield</td>
<td>Chemo dispensing pins</td>
<td>7</td>
</tr>
</tbody>
</table>

Table 2: Cost analysis of using the PhaSeal® system.

<table>
<thead>
<tr>
<th>Data Analysed</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>The cost of medication discarded (i.e. part vials)</td>
<td>€9,196.30</td>
</tr>
<tr>
<td>The cost of PhaSeal® components</td>
<td>€5,365.30</td>
</tr>
<tr>
<td>The savings using the PhaSeal® system</td>
<td>€3,831.00</td>
</tr>
<tr>
<td>Potential annual saving</td>
<td>€49,803.00</td>
</tr>
</tbody>
</table>

Conclusion

Compounding using the PhaSeal® system is significantly safer for operators. There is no risk of needle stick injury, reduced risk of aerosols, vapours and spillages. The use of the system allows for significant drug savings due to the ability to recycle drug vials.

References
8. QUAPOS (Quality Standard for the Oncology Pharmacy Service) Published by German Society of Oncology Pharmacy (DSOP) 2009 http://www.esop.li/downloads/library/quaapos4_english.pdf