Drug Shortages: Implications for Medical Toxicology

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Introduction

• Prescription drug shortages have become increasingly prevalent over the past decade.
• There are limited data as to how drug shortages can impact medical toxicology.
• Research Question: To describe drug shortages affecting the management of poisoned patients.

Methods

• Drug shortage data from January 2001 to December 2013 were obtained from the University of Utah Drug Information Service (UUDIS).
• Two medical toxicologists reviewed pharmaceutical products affected by shortages and identified agents that are used to treat poisoned patients.
• Shortage data were analyzed focusing on the type of drug involved, formulation, reason for shortage, shortage duration, marketing status (brand vs. generic), and if the drug was a single source product (produced by one manufacturer).
• The availability of a substitute therapy and whether the alternative was also affected by a shortage at any time during the study period was also noted.

Results

• Of 1,751 products in shortage during the study period, 141 (8.1%) were used in medical toxicology.
• The number of new shortages reported annually increased steadily from the mid-2000s, reaching a high of 26 in 2011, with a decline in recent years. Thirty-seven drugs had multiple shortages.
• Of 141 shortages, 21 (14.9%) were unresolved as of December 2013. The median duration of resolved shortages was 166 days (IQR 85-469).
• Generic drugs were involved in 85.1% of shortages and 41.1% were single-source products. Parenteral drugs were more commonly affected by shortages (126, 89.4%).
• Single-source products had a significantly longer median shortage duration (10 vs. 5 months, p=0.0011). There was no difference in median shortage months when comparing brand to generic medications (p=0.34).
• The most common type of medication involved were sedative-hypnotics (benzodiazepines/barbiturates).
• Anti-hypoglycemic agents had the longest median shortage duration (17.5 months, IQR 7.5 – 28).
• An alternative agent was available for 121 (85.9%) drugs; however, 88 (72.7%) of these alternatives were affected by a shortage at some point during the study period.
• When present, the most common reason reported was manufacturing delays (20.6%), followed by supply/demand issues (17.0%). No reason was reported for 48.2% of drugs.

Discussion/Limitations

• Drug shortages can result in delayed or suboptimal therapy as well as medication errors.
• Shortages may occur for a variety of reasons, including consolidation of facilities, quality issues, and a lack of financial incentives for manufacturers.
• A multi-faceted approach involving stakeholders from government, industry, and healthcare organizations will be required to solve the shortage problem.
• Medical toxicologists must be aware of current shortages and implement mitigation strategies to optimize patient care.
• We were unable to assess the direct impact reported shortages had on patient care.

Conclusions

• Drug shortages affected a substantial number of agents used in the management of poisoned patients.
• Future studies should focus on how shortages directly impact patient care and resource utilization.

Medical Toxicology Agents Without Alternatives Frequently in Short Supply

<table>
<thead>
<tr>
<th>Agent</th>
<th>Number of Times in Shortage</th>
<th>Shortage days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antivenin Latrodectus mactans</td>
<td>3</td>
<td>362, ongoing since 12/2010</td>
</tr>
<tr>
<td>Digoxin rescue agents</td>
<td>2</td>
<td>262</td>
</tr>
<tr>
<td>Lipid emulsion</td>
<td>1</td>
<td>2107, ongoing since 11/2008</td>
</tr>
<tr>
<td>Methylene blue</td>
<td>3</td>
<td>898, ongoing since 3/2013</td>
</tr>
<tr>
<td>Naloxone</td>
<td>6</td>
<td>1601</td>
</tr>
<tr>
<td>Pralidoxime</td>
<td>2</td>
<td>987</td>
</tr>
<tr>
<td>Protamine</td>
<td>4</td>
<td>1228</td>
</tr>
</tbody>
</table>