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.

Disclosures

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.

Medical Toxicology Agents Without Alternatives Frequently in Short Supply

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

New Shortages per Year
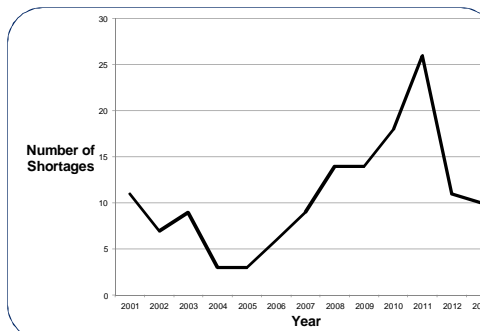
Discussion/Limitations

- 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 asses 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.