Drug Safety Review

Drug shortages may result in errors

There are increasing concerns about the frequency and duration of drug product shortages that have led to adverse patient outcomes. The current U.S. shortage of flu vaccine exemplifies the potential negative consequences of patient care either delayed or not provided. Healthcare professionals have devised methods of dealing with drugs in short supply, but some methods have led to product confusion and/or calculation errors resulting in the inadvertent administration of the wrong drug or wrong dose.

Data collected through USP's MEDMARX and Medication Errors Reporting (MER) programs provide additional information on the negative impact of drug shortages. From January 2003 to August 2004, 832 records were submitted to MEDMARX identifying Drug Shortage as a Cause of Error; 47 error reports involving drug shortages were submitted to the MER program from October 1991 to Oct. 15, 2004. For MEDMARX and MER combined, approximately 2.6% of these reports resulted in some level of patient harm.

The top three most frequently reported Types of Error in MEDMARX were Prescribing Error, Improper Dose/Quantity, and Omission Error (see table). The top three reported error types in the MER program were Improper Dose/Quantity (45%), Unauthorized/Wrong Drug (32%), and Wrong Drug Preparation (8.5%).

There were 301 unique product groups identified in MEDMARX with medication errors involving drug shortages. Methylprednisolone injection was the most frequently reported product.

Selected case reported to USP's MEDMARX and MER programs

Prochlorperazine 5 mg IV was ordered for a patient's nausea, but there was a marketwide shortage of the drug. The hospital's Pharmacy & Therapeutics Committee had approved an automatic substitution of droperidol 0.625 mg when prochlorperazine 5 mg was ordered, but the nurse administering the product, not fully aware of the differences in dosing, inadvertently administered 5 mg of droperidol. The patient became overly sedated, requiring oxygen and increased observation.

Types of errors*

Type of error	n	Percent
Prescribing error	271	34.1
Improper dose/quantity	204	25.7
Omission error	176	22.2
Wrong time	84	10.6
Unauthorized/wrong drug	47	5.9
Wrong drug preparation	43	5.4
Wrong dosage form	21	2.6
Expired product	15	1.9
Extra dose	11	1.4
Wrong patient	9	1.1
Wrong route	5	0.6
Deteriorated product	3	0.4
Wrong administration technique	1	0.1

*Findings from MEDMARX. Type of Error is a multi-select field. Not all records documented a specific Type of Error. Data are based on

Addressing the adverse effects of drug shortages

Drug shortages can lead to adverse patient outcomes. Proactive actions must be undertaken to identify, address, and prevent shortages before patient care is compromised. The following suggestions can help practitioners minimize the negative impact of drug shortages:

1. Determine an appropriate medical-staff committee or governing body that will have the authority to mandate practice changes across medical disciplines, including the approval of using alternative products, prioritizing patients, and product rationing.
2. Develop policies that outline the process for communicating and educating practitioners within the organization when shortages occur that pose a significant threat to patient care. The policies should identify a primary staff position whose purview includes coordinating and managing all the information surrounding the drug shortage.
3. Create ad hoc committees to aid in assessing the potential impact of a shortage. The committees should investigate the anticipated length of the shortage, the degree to which the product is used within the facility, the location of the affected product throughout the facility, how long the current inventory may last, and which patients and services will be most affected.
4. Evaluate various options to address the product shortage, including establishing a prioritization schema for selecting patients who will continue to receive the limited supply, compounding the product or contracting out the compounding, and selecting alternate therapies.
5. Seek out information from the product manufacturer, drug information centers, and in-house clinical staff when evaluating alternative therapies and changes to the facility's clinical pathways and protocols.

by
John P. Santell, M.S., R.Ph.

John P. Santell is Director of Educational Program Initiatives at U.S. Pharmacopeia.

USP operates two complementary reporting programs: the Medication Error Reporting Program, presented in cooperation with the Institute for Safe Medication Practices, and MEDMARX. For more information on how to report errors, visit: **www.usp.org/patient safety**.

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