

Parenteral Nutrition Drug Shortages

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Learning Objectives

- Discuss drug shortages and the causes for their occurrence
- Describe the impact of product shortages on the quality and safety of parenteral nutrition (PN) therapy
- Describe A.S.P.E.N.'s response to PN product shortages
- Describe proposed legislation for FDA regulation of drug shortages

Disclosures

- None

Outline

- The drug shortage crisis
- Reasons for drug shortages
- Impact of shortages on patient safety
 - Examples related to PN
- A.S.P.E.N. collaboration
- CDER Drug Shortage Program
- Legislation

PN Product Shortages

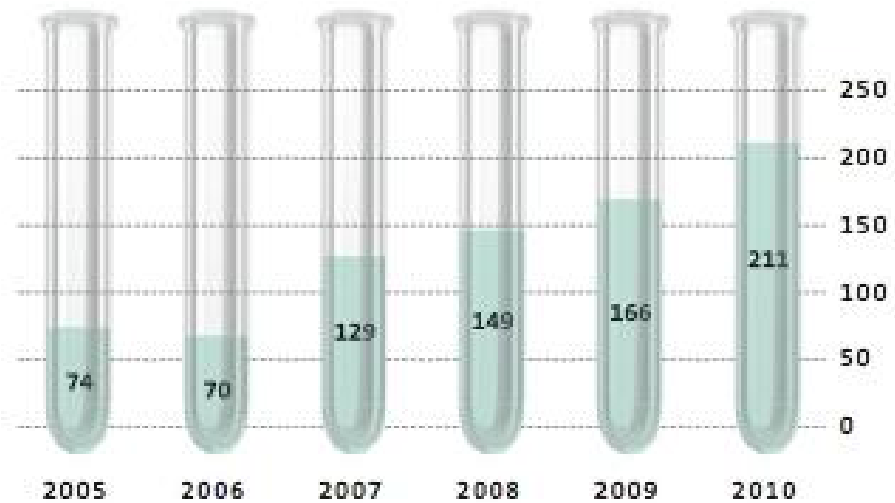
- History
 - Serious deficiencies from vitamin shortages when omitted from PN therapy.
- Recent
 - IVFE: constrained supply
 - Amino acids: access to care
 - Patients may not receive PN when indicated and starve
 - Electrolytes, vitamins, trace elements

MMWR 1989;38:43-46

The Drug Shortage Crisis

- 178 new drug shortage reports to FDA in 2010
- 132 involve sterile injectable drugs
- Increased trend continues in 2011
- Involves all drug classes
- All PN products except dextrose/water have been in short supply at some point since spring of 2010

FIGURE 1:
**Newly Reported
Drug Shortages
(2005-2010)**



Source: Drug Information Service, University of Utah, 2010

Reasons for Shortages

- Raw material quality
- Enforcement of FDA standards and regulations
- Manufacturer financial decisions
- Just in time inventory levels
- Grey market distributors
- Stockpiling by end-users
- Changes in clinical practice

Impact of shortages on patient safety

- Respondent's concerns identified in ISMP survey:
 - Increasing volume of critically important medications
 - Use of less desirable, unfamiliar alternatives
 - Errors and poor patient outcomes due to absence or delay in treatment
 - Preventable adverse events by use of alternatives
 - Lack of advanced warning
 - Precious clinical hours lost to time-consuming activities required to manage shortage

Cohen, Smetzer. Hosp Pharm 2011;46(1):7-11

Errors Due to Shortages

Type of error	Percent of Respondents
Near miss	35
Errors reached patient	25
Errors resulting in patient harm	20

<http://www.ismp.org/Newsletters/acutecare/articles/20100923.asp>

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Deaths of 9 Alabama Patients Tied to Intravenous Supplement

By KEVIN SACK and TIMOTHY WILLIAMS
Published: March 30, 2011

BIRMINGHAM, Ala. — State and federal health officials are investigating the deaths of nine patients at Alabama [hospitals](#) who were all given an intravenous nutritional supplement that investigators have found was contaminated by bacteria.

Ten other patients who received the supplement also were sickened by the bacteria, called *Serratia marcescens*, which is most commonly found in water, including some tap water, and sometimes in

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Alabama Pharmacy's TPN Linked to Nine Deaths

Kate Traynor

BETHESDA, MD 01 April 2011— [FDA](#) and the [Alabama Department of Public Health \(PDF\)](#) on Wednesday announced an outbreak of *Serratia marcescens* bacteremia in six Alabama hospitals that has been linked to the use of total parenteral nutrient (TPN) solutions prepared by a single pharmacy.

The state health department is aware of 19 cases of *Serratia marcescens* bacteremia, 9 of them fatal, in patients who received TPN solutions from Meds IV Pharmacy of Birmingham. All compounded i.v. products produced by the company were recalled March 24.

The health department reported that one case occurred in January and another in February. All other cases occurred in March.

According to the health department, the six hospitals with reported cases of *Serratia marcescens* bacteremia are contacting patients who received TPN solutions linked to

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ISMP Medication Safety Alert!® Acute Care

TPN-RELATED DEATHS CALL FOR FDA GUIDANCE AND PHARMACY BOARD OVERSIGHT OF USP CHAPTER <797>

From the April 7, 2011 issue

Last week, the Alabama Department of Public Health (ADPH) reported an ongoing investigation of an outbreak of *Serratia marcescens* bacteremia associated with contaminated total parenteral nutrition (TPN) bags in six Alabama hospitals.(1-4) The outbreak was identified after two of the six hospitals reported an unusual number of cases of *Serratia marcescens* bacteremia to the ADPH and the Centers for Disease Control and Prevention (CDC). An investigation was immediately started.

A total of 19 patients from six hospitals were adversely affected after receiving the contaminated TPN. The CDC determined that all six hospitals had received TPN produced by a single compounding pharmacy, Meds IV. Nine of the 19

Resources

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A.S.P.E.N. Collaboration

American Society of Parenteral and Enteral Nutrition

Food and Drug
Administration

American Society of Health-System
Pharmacists (ASHP)
www.ashp.org/shortage

A.S.P.E.N. Staff
And Volunteers

Institute for Safe
Medication Practices (ISMP)

Manufacturers

A.S.P.E.N. members and
non-members



A.S.P.E.N. Guidance

- A.S.P.E.N. has published recommendations for managing shortages of PN products
- A.S.P.E.N. collaborates with other organizations and government agencies to identify and resolve PN product shortages

A.S.P.E.N. Guidance

- Continuing communications with FDA
 - Telephone conferences
 - Letter requesting the FDA to
 - Investigate the national patient supply and demand for concentrated IV electrolyte and mineral injections in the U.S.
 - Determine if there are measures that can be taken in order to increase the supply and distribution of these critical products.
 - Consider importation of internationally produced IV electrolyte and mineral injections for temporary approval in the U.S.

Information for Managing PN Product Shortages

- Recommendations for shortages
 - Multivitamins – adult and pediatric
 - IV fat emulsions
 - Amino acids
 - Electrolytes/minerals
 - Trace elements
- A.S.P.E.N. web site www.nutritioncare.org
 - Search specific product shortage information
 - Professional Resources>Guidelines and Standards>A.S.P.E.N. Documents Library

CDER Drug Shortage Program

- Center for Drug Evaluation and Research (CDER)
- Address potential or actual shortages of drugs that have significant impact on public health
 - Medically necessary products
 - Greatest impact on public health

<http://www.fda.gov/Drugs/DrugSafety/default.htm>

Drugshortages@fda.hhs.gov

What is being done?

- Drug Shortage Summit in Nov, 2010
 - Participants provided 21 recommendations
 - Met with legislators for inclusion in proposed bills
- FDA and ASHP maintain websites of shortages

Senate bill addresses shortages

- S. 296
 - To amend the Federal Food, Drug, and Cosmetic Act to provide the Food and Drug Administration with improved capacity to prevent drug shortages
- Preserving Access to Life-Saving Medication Act

S. 296 Preserving Access to Life-Saving Medications Act

- The legislation directs the FDA to
 - address drug shortages by requiring manufacturers to notify FDA about manufacturing problems or when a drug product will be discontinued
 - requires the agency to maintain an online list of drugs in shortage situations,
 - revises FDA's definition of medically necessary.

H.R.2245 Preserving Access to Life-Saving Medications Act of 2011

- Companion bill to S. 296
- To amend the Federal Food, Drug, and Cosmetic Act to provide the Food and Drug Administration with improved capacity to prevent drug shortages.
- A manufacturer of a drug that is subject to section 503(b)(1) and marketed in interstate commerce shall notify the Secretary of a discontinuance or interruption in the manufacture of such drug.

What you can do

- Write your legislators about PN product shortages and to support S. 296 and H.R.2245
- Utilize providers with expertise in nutrition support



Questions?