The Operational Impact of Parenteral Nutrition Drug Shortages

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Background

Pharmacists and patients have encountered parenteral nutrition drug shortages since the mid-1980s.[1] The prevalence of drug shortages has risen due to multiple reasons including supply, demand, and regulatory challenges.[2] Supply issues include manufacturing challenges, business predicaments, logistical disruptions, and the unavailability of raw materials required to produce the drug.[2] United States Pharmacopeia (USP) reports that drugs are more susceptible to shortages when they have low prices, possess high manufacturing complexity, limited sources for active ingredients or when there are quality-related concerns with the drug.[3] Although most shortages are considered temporary, the average length of a drug shortage is 3 years, significantly impacting parenteral nutrition (PN) compounding.[3]

Although there has been fluctuation in the number of parenteral drug shortages over the years, there have been a total of 15 parenteral nutrition drugs on shortage over the last 24 months.[4] At the time of this observational study, there were 24 different types of fluids and electrolytes in shortage, 8 of which are directly associated with parenteral nutrition.[5,2] The prevalence of parenteral nutrition drug shortages has led to the need for providers to change nutrition formulas for patients, the increased potential for medication errors, and the development of multiple management recommendations by the American Society of Health System Pharmacists (ASHP).[6,7]

ASHP states that the best practices for the management of these shortages include conservation of drug, inventory control, and updating pharmacy operational strategies.[7] In order to conserve parenteral nutrition drugs, ASHP recommends that providers evaluate the following prior to each dispense; the clinical need of each parenteral drug in a formula, using smaller volumes when possible, and switching to oral administration when possible.[7] Conservation of drug and inventory control are strategies that help ensure there will be adequate parenteral drug supply on hand for the entire patient population through the duration of the shortage.[7]

Purpose

This study aimed to evaluate the overall operational impact of parenteral drug shortages on the patient and the dispensing pharmacy. Ongoing shortages require formula changes to ensure patients receive adequate parenteral nutrition, while ensuring parenteral drug conservation in the process. The study's main endpoint was the number of changes to PN formula and implementation of those changes.

Methods

This retrospective, multi-center chart review analyzed data from patients aged 18 and older receiving PN over a 24-month period starting January 1, 2022. The study assessed formula changes prompted by national PN drug shortages. Exclusions included patients who required a formula adjustment for clinical reasons outside of drug shortage mitigation.

Baseline demographics and changes in therapy were also reviewed. Patients were stratified according to the drug change required due to the shortages. Information regarding specific formula changes was gathered by utilizing clinical documentation and reporting. This information was compared to dispense records to determine the average number of changes required for new formulas.

Results

During the 24-month study period, 223 patients were identified as requiring a formula adjustment due to a parenteral nutrition drug shortage. Patients were separated into five specific shortage groups: multivitamin, calcium, lipid, sodium chloride, and potassium chloride *(Figure 1)*. While most patients only had one change to their parenteral nutrition formula, 24 patients (10.76%) had multiple changes implemented in their parenteral nutrition formula.

A total of 55 patients required changes to the use of multivitamins within their parenteral nutrition formula due to national drug shortages. Fifty had the recommended changes implemented, whereas five (9%) did not. A total of 74 patients had necessary adjustments to the use of calcium due to national shortages. Seventy-two of these patients had the recommended changes implemented, whereas two of them did not.

A total of 30 patients required a change to the lipid used in their formula due to national shortages. Twenty-five of these patients had the recommended changes implemented, whereas five of them did not. Forty-eight total patients called for a necessary adjustment to the use of sodium chloride in their formula due to national shortages. Forty-five patients had the recommended changes implemented and three of them did not. Sixteen patients required an adjustment to the amount of potassium chloride used due to national shortages. Eleven patients had the recommended changes implemented, whereas five of them did not.

Figure 1: Overall Total of Recommended Changes

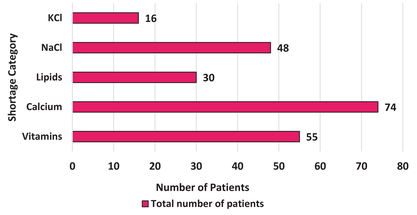


Figure 2: Total Number of Patients with Implemented Changes

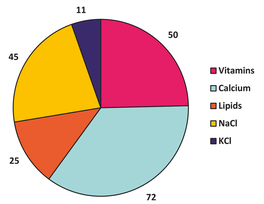
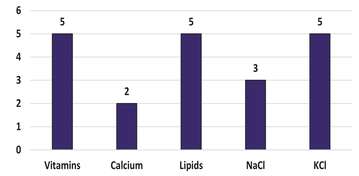


Figure 3: Total Number of Patients without Implemented Changes



Discussion

This study identified some of the additional operational burden placed on clinicians to adjust formulas due to mitigation strategies. When comparing the types of changes, calcium had the highest number of changes (32%) *(Figure 2)*. This is most likely due to the fact there is less likelihood that calcium needed to be adjusted due to a clinical reason outside of the shortage.

The second most frequent adjustment was sodium chloride, which was most likely due to the sheer volume this is used in parenteral nutrition. Of the 223 patients identified, 20 (8.7%) were unable to follow the mitigation strategy *(Figure 3)*. One of the major limitations of this study was the small sample size. This was mainly due to excluding the patients that would have had a change to their parenteral nutrition formulas anyway due to clinical needs. Being able to stratify the clinical adjustments with the shortage mitigation efforts could have provided more insight into the impact of these shortages.

Conclusions

This study demonstrated the amount of changes that occur due to a shortage. Future studies could also assess the time required for the approval of changes outside of those caused by national drug shortages. Lastly, being able to stratify the changes due solely to mitigation and compare to those that also include clinical need could provide further information crucial to supply chain.

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Disclosures

Authors of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation: Kayla Rafferty; Christopher Roy; Jessica Monczka; Maria Giannakos: Nothing to disclose.

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