

# Drug shortages as an impetus to improve parenteral nutrition practices

KIRANDEEP KAUR, ALICE H. O'CONNOR, SEAN M. ILLIG, AND KATHLEEN B. KOPCZA

**M**edication shortages have been challenging for both patients and health care practitioners for the past four years.<sup>1</sup> Shortages of ingredients necessary for the administration of parenteral nutrition (PN) can directly affect patient outcomes in an acute care setting. PN ingredients involved in the shortages include amino acids, electrolytes, trace elements, i.v. multivitamins, i.v. fat emulsions, and L-cysteine. The supply of PN products has been inadequate since the spring of 2010, with amino acids being the fifth most-involved product in shortages that year.<sup>2,3</sup>

## Background

Baystate Medical Center (BMC) is a 653-bed tertiary care teaching institution that has developed a Drug Shortage Management Team to identify ingredient and process alternatives for addressing all shortages. Prior to the national amino acid shortage in August 2010, BMC had minimal operational and clinical processes in place to ensure ap-

**Purpose.** A medical center's implementation of adult and pediatric parenteral nutrition (PN) algorithms and other strategies for managing PN ingredient shortages are described.

**Summary.** In response to nationwide shortages of amino acids and other PN ingredients in 2010, a large Massachusetts teaching hospital undertook a quality-improvement initiative to ensure appropriate patient selection for PN therapy. A clinical pharmacist was designated as a nutrition support leader with responsibility for the management of PN practices. Clinical pharmacists collaborated with clinical dietitians to establish PN eligibility criteria based on established practice guidelines and developed evidence-based adult and pediatric nutrition support algorithms. In addition, (1) physicians were required to obtain a nutrition service consultation before initial prescribing of PN therapy, (2) the initial ordering of

PN therapy through the computerized prescriber-order-entry (CPOE) system was restricted to clinical dietitians and clinical pharmacists, (3) the use of premixed PN solutions at the discretion of dietitians was increased, and (4) the practice of adding i.v. multivitamins and trace elements to PN solutions was restricted. During the first year after implementation of the PN algorithms, CPOE restrictions, and other process changes, PN orders were reduced by an average of five orders per day relative to the preceding 11-month period, helping to ensure continued patient access to PN therapy.

**Conclusion.** PN ingredient shortages prompted changes in the decision-making process for the prescription of PN. Guidelines for ordering PN were successfully implemented and allowed for the appropriate selection of qualified patients and the management of PN ingredient shortages.

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propriate PN ordering and use by health care providers. All prescribers had the ability to initiate PN for inpatients by placing an order in the computerized prescriber-order-entry

(CPOE) system, which would then generate a consultation request sent to the clinical dietitians. Prescribers could also place an order for a dietitian consultation independent of

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the PN order. Dietitians responded to consultation requests prior to the compounding of PN solutions by the inpatient pharmacy.

### Problem

In responding to problems associated with the 2010 shortage of PN ingredients, BMC took the opportunity to implement a reset of all PN prescribing and compounding processes.

American Society of Parenteral and Enteral Nutrition (A.S.P.E.N.) and Society of Critical Care Medicine (SCCM) guidelines, including A.S.P.E.N. guidelines for nutrition support of the critically ill child, were used to establish adult and pediatric patient eligibility criteria for PN.<sup>4,5</sup> The primary goal for this initiative was to maintain the supply of PN ingredients throughout the shortage period. A secondary goal was to devise a model of collaborative management by pharmacists and dietitians that would help ensure the clinically appropriate utilization of PN in adults and pediatric patients.

### Analysis and resolution

**Algorithm development.** Algorithms were developed to outline the proposed criteria for PN through the collaboration of clinical pharmacists and clinical dietitians. The eligibility criteria to initiate PN in an adult patient included being malnourished, having a dysfunctional gastrointestinal tract, and an anticipated duration of PN of at least seven days. Examples of a dysfunctional gastrointestinal tract included bowel obstructions, prolonged ileus, bowel ischemia, bowel discontinuity after intestinal resection, short-bowel syndrome, and enterocutaneous fistulas. Malnutrition was defined according to body mass index (BMI, calculated as weight [kg]/height [m<sup>2</sup>]) and criteria outlined in the subjective global assessment tool.<sup>6</sup> Specifically, patients were considered to be malnourished if they exhibited two or more of the

following: a BMI of <18.5, weight loss, change in food intake, gastrointestinal symptoms such as nausea or diarrhea lasting more than two weeks, loss of subcutaneous fat, and muscle wasting. The adult nutrition support decision algorithm is shown in Figure 1. Adult patients who were well nourished were not considered to be candidates for PN until day 7 of hospitalization. Adult patients who were malnourished and had a dysfunctional GI tract were considered candidates for PN as soon as they were hemodynamically stable. Pediatric patients were similarly evaluated using the designated algorithm shown in Figure 2. For pediatric patients who met the criteria for initiation of PN, therapy was started as soon as the patient was hemodynamically stable. In any case where the use of enteral nutrition was optional, the clinical dietitian encouraged the use of enteral nutrition in both pediatric and adult patients.

**Restriction of PN order entry.** Physicians desiring to initiate PN were required to obtain a nutrition service consultation. A clinical dietitian assessed the patient's clinical and nutritional status to determine the appropriateness of PN, with initial eligibility determined by the developed algorithm. In an effort to restrict the ordering of PN, initial CPOE ordering was limited to clinical dietitians and clinical pharmacists. The clinical dietitian determined the appropriate PN formulation for the patient and then entered the order in the CPOE system as an agent for the prescriber. Subsequent orders could be renewed by the covering prescriber. If the prescriber wished to pursue the prescription of PN for a patient not considered by a clinical dietitian or a clinical pharmacist to be an appropriate candidate for the initiation of PN, the order was treated as a nonformulary request requiring approval by the chair of the pharmacy and therapeutics (P&T) committee.

**Education and additional process changes.** A clinical pharmacist was identified as the nutrition support leader for oversight and management of PN. Education of all clinical pharmacists involved in PN order verification and compounding was conducted to ensure competency in the care of inpatients receiving PN as well as knowledge of the approved protocols.

Additional PN process changes included the option to administer premixed PN solutions (2-L admixtures of 4.25% amino acid in 5% dextrose or of 5% amino acid in 15% dextrose [final concentrations] plus standard electrolytes) if their use was considered appropriate by the clinical dietitians. Premixed PN solutions are a commercially available alternative source of amino acids, dextrose, and electrolytes that parallels A.S.P.E.N. dosing guidelines for adult patients in need of PN.<sup>7</sup> As the standard electrolyte content of premixed PN solutions may not be appropriate for all patients, these products were typically only used for patients with latex allergies (pharmacy preparation of customized solutions can result in patient exposure to latex).

Shortages of i.v. multivitamins and trace elements led to a decision by the clinical pharmacy and clinical nutrition teams to conserve resources by omitting multivitamins and trace elements from PN regimens for the first five days of PN therapy; after that, the addition of multivitamins and trace elements was restricted to three days of the week (Monday, Wednesday, and Friday). In the neonatal intensive care unit, i.v. multivitamins and trace elements were added to PN admixtures on a Monday-Wednesday-Friday schedule without an initial five-day hold since neonatal patients are at higher risk for vitamin and mineral deficiencies that may produce negative effects on growth and development. If patients were able to take any oral medications or feedings, oral multivitamin and

mineral products were recommended by the clinical dietitian, and the prescriber was advised to order these products through the CPOE system.

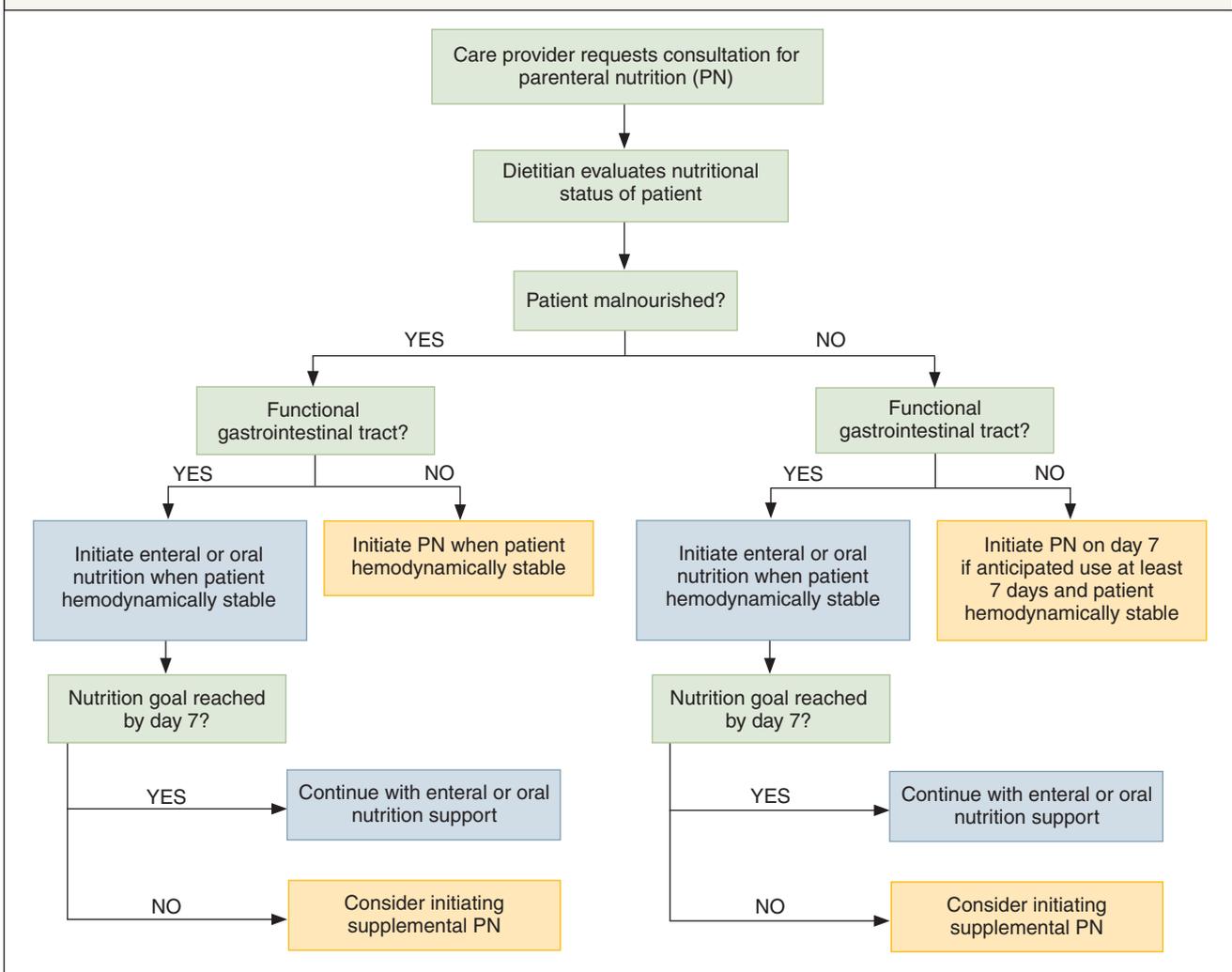
**Program implementation.** The algorithms and restrictions described above were approved by the P&T committee and implemented on October 1, 2010. A retrospective review of historical data on PN volumes covering an 11-month period was conducted to assess the effect of the PN process changes. The volume of PN orders was determined before and after the implementation of the PN prescribing algorithms, and the percent change in the volume of orders was calculated.

**Order volume and cost analysis.**

Reduction of PN volume was the primary endpoint measured. The implementation of the PN process guidelines resulted in an average reduction of 5 PN orders per day (an approximately 33% reduction relative to the previous 11 months) across both adult and pediatric patient populations. More specifically, from November 2009 through September 2010, there was an average of 15 PN orders per day for both adult and pediatric patients. Following the changes in the standard of PN practice at BMC, there was an average of 10 PN orders per day for adult and pediatric patients from October

2010 through October 2011. Approximately 24 premixed PN solutions were used during the period April–October 2011. As mentioned above, a physician’s request to initiate PN despite the patient being designated as ineligible for PN after assessment by the clinical dietitian was handled as a nonformulary request. During the time of the retrospective review, there were no such nonformulary requests for PN. The implemented PN restrictions and algorithms enabled the BMC pharmacy department to successfully manage the PN ingredient shortages and sustain adequate nutritional support for inpatients.

Figure 1. Baystate Medical Center adult nutrition support algorithm.



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The PN process changes were also beneficial in terms of cost savings for the institution. Given that the average ingredient cost of one adult or pediatric PN solution (per 2010 purchasing data) was estimated to be \$68, the change in PN practice standards at BMC, resulting in an average reduction of five orders per day, led to approximate cost savings of \$10,200 per month.

**Discussion**

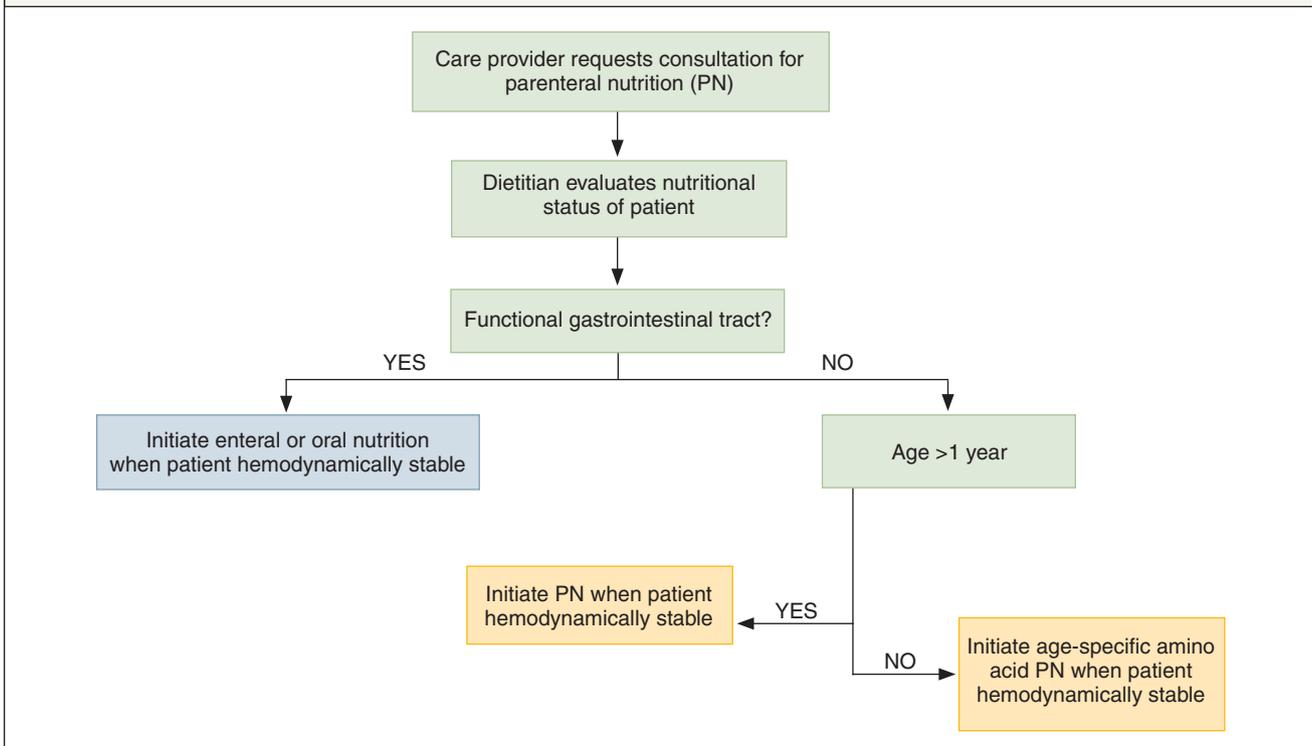
Shortages of PN components pose a challenge for health care providers due to the need to omit, substitute, or ration limited ingredients. Also, inconsistencies in supplies could compromise patient health care outcomes. At the time of the study, amino acid solutions, injectable multivitamins, and trace element products were in short supply. At the time of writing, amino acid, multivitamin, and trace element products continued to appear on the list of current drug shortages maintained by the

American Society of Health-System Pharmacists.<sup>8</sup> These shortages have extended to additional products used to compound PN solutions, such as electrolytes and lipid emulsion. After the initiation of PN restrictions and algorithms, designed through collaboration between the BMC clinical pharmacy and clinical nutrition teams, the selection of appropriate inpatient candidates for PN support was improved.

Adult and pediatric PN algorithms were developed in accordance with A.S.P.E.N. and SCCM guidelines.<sup>4,5</sup> These algorithms directed the use of either enteral or PN for inpatients. The A.S.P.E.N.–SCCM guidelines recommend that in a previously healthy adult patient with no evidence of malnutrition, PN should be initiated when enteral nutrition is not possible, after the first seven days of hospitalization, and when PN therapy is anticipated to be at least seven days in duration.<sup>4</sup> Also, withholding PN until

at least day 8 of hospitalization in patients for whom enteral nutrition is insufficient has been shown to be associated with faster recovery and fewer complications in critically ill adults.<sup>9</sup> A decreased risk of intensive care-related infections, shorter durations of mechanical ventilation, and lower health care costs have also been correlated with later initiation of PN in critically ill adult patients.<sup>9</sup> Therefore, the algorithms allowed for the initiation of PN therapy only after the first seven days of hospitalization and when enteral nutrition support was not possible for previously well-nourished adult patients. A crucial deciding parameter in the algorithm was the anticipated duration of PN for an adult inpatient. Initiation of PN was deemed appropriate if the anticipated duration of use was to be at least seven days. The expected duration of therapy was discussed by the clinical dietitian and the ordering prescriber at the time of the initial nutrition consultation. In ac-

Figure 2. Baystate Medical Center pediatric nutrition support algorithm.



cordance with the A.S.P.E.N.–SCCM guidelines, the algorithm allowed for initiation of PN during the first seven days of hospitalization in an adult patient if there was evidence of malnutrition on admission and the use of enteral nutrition was not feasible.<sup>4</sup> Pediatric patients were started on PN therapy when hemodynamically stable if they met the criteria for initiation of PN.

Changing the PN practice standards at BMC through algorithms developed by a team of clinical pharmacists and clinical dietitians was an effective plan for managing the PN ingredient shortage and ensuring that appropriately selected patients had access to PN. Improved collaboration among dietitians, pharmacists, and prescribers in determining the most appropriate means of nutritional support was also noted.

The effect of the implemented algorithms on the number of dietitian consultations was not assessed in this

retrospective review. Also, the direct effect of the established guidelines on the overall health of the patient, either positive or negative, was not assessed in this retrospective study. Nonetheless, requiring a dietitian consultation and pharmacist order review ensured that the initiation of PN in patients was based on established algorithms.

### Conclusion

PN ingredient shortages prompted changes in the decision-making process for the prescription of PN. Guidelines for ordering PN were successfully implemented and allowed for the appropriate selection of qualified patients and the management of PN ingredient shortages.

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