Critical Drug Shortages: Management Strategies for the Nutrition Support Professional
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General Do’s & Don’t’s of Managing Parenteral Nutrition (PN) Related Product Shortages

Do’s

- Assess each patient for appropriate indication for PN
- Consider providing nutrition via the oral/enteral route whenever possible
- Purchase only as much supply as needed
- Use neonatal/pediatric specific products ONLY for their indicated population
- Prioritize product and conserve supply for vulnerable populations
  - Neonates
  - Pediatric patients
  - PN dependent/ home PN patients
  - Short bowel syndrome
  - Malabsorption syndromes
- Increase awareness and ongoing patient monitoring for deficiencies and complications
- Minimize use of electrolyte/trace mineral additives to intravenous fluids
- Compound PN in a single location in order to avoid waste
- Report severe product shortage information to the FDA Drug Product Shortage Program
- Report patient related problems to the ISMP Medication Errors Reporting Program
- Observe and maintain compliance with product labeling, USP General Chapter 797, Pharmaceutical Compounding Sterile Preparation, and state Boards of Pharmacy

Don’ts

- Do not stockpile
- Do not use neonatal/pediatric specific products for adult patients
- Do not use adult specific products for neonatal/pediatric patients
- Do not use parenteral electrolyte/mineral products for enteral supplementation
- Do not use pediatric/neonatal multi-trace elements for adult patients.
**Product Shortages Affecting Parenteral Nutrition: Alternatives, Consequences, and Special Considerations**

*Material adapted from ASPEN website ([www.nutritioncare.org](http://www.nutritioncare.org))*

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<th>Oral options?</th>
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| Intravenous fat emulsion (IVFE) | No | No | • Essential fatty acid deficiency (EFAD)  
• Malnutrition/poor growth  
• Hypertriglyceridemia and/or glucose intolerance due to excessive administration of glucose | • Adult hospitalized patients on PN <2 weeks, should not receive intralipid unless essential  
• Adult patients on >2 weeks PN should receive 100g fat per week in order to prevent EFAD  
• Patients with glucose intolerance, severely malnourished patients, pregnant women, and pediatric/neonatal patients should receive intralipid on a daily basis |
| Amino acids | No | No | • Use of a less concentrated stock solution may cause fluid overload  
• Electrolyte abnormalities, compatibility differences between amino acid stock solutions  
• Inability to provide PN if completely unavailable  
• Increased cost of using off-contract products  
• Increased risk of contamination and instability with compounded products | • Restrict high concentration products (>10%) for fluid restricted patients  
• Use commercially available premixed PN formulations if clinically appropriate  
• Increase restriction criteria for use of PN  
• Avoid manipulation of amino acids from original container to avoid risk of contamination/instability  
• Verify PN compounding processes if amino acid product is changed, as amino acid solutions are not directly substitutable (i.e. variances in pH, phosphorus content, calcium-phosphorus solubility, etc.) |
| General considerations for electrolytes | • Multiple changes in electrolytes due to shifting shortages may lead to errors  
• Decrease amount given to adults to conserve for neonatal and pediatric patients  
• Decrease use of IV supplementation outside of PN: ICU replacement algorithms/protocols, use of IV products for oral liquid formulations  
• Increase monitoring when making changes or restricting amounts in PN – long-term/home patients especially  
• Increased cost of off-contract or compounded products  
• Ability to use compounded electrolyte products in PN (may increase risk of contamination)  
• Utilize oral/enteral electrolyte and premixed products when possible for replacement therapy  
• Use premixed PN products if possible | • Consider using alternative IV phosphate salt and balance sodium and potassium as necessary  
• Maintain awareness of potassium and sodium content when changing phosphate salts  
• Utilize oral/enteral products when clinically able  
• Conserve supply for neonatal/pediatric patients and those with medical need for phosphorus (reduce to least possible amount) |
| Potassium phosphate & sodium phosphate | Yes – many oral phosphate products | Potassium phosphate or sodium phosphate | • Hypophosphatemia if both potassium and sodium phosphate unavailable  
• S/S hypophosphatemia: respiratory compromise, hypoxia, decreased cardiac contractility, weakness, neurologic dysfunction, seizures, death | • Consider using alternative IV phosphate salt and balance sodium and potassium as necessary  
• Maintain awareness of potassium and sodium content when changing phosphate salts  
• Utilize oral/enteral products when clinically able  
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| Potassium acetate & sodium acetate | Potassium chloride, sodium bicarbonate | Other salt forms         | • Acidosis if unable to provide enough acetate as either sodium or potassium acetate   | • Consider using alternative potassium salts as clinically able  
  • Use oral/enteral potassium for replacement where possible  
  • Use premixed IV products as much as possible and avoid potassium acetate additive to IV fluids. |
| Sodium chloride            | Yes- However, oral options do not serve the same clinical purpose | Less concentrated stock solutions | • Alkalosis if using excessive acetate salts  
  • Fluid overload if using less concentrated products  
  • Development of hyponatremia  
  • S/S hyponatremia: headache, lethargy, N/V, muscle cramps and/or weakness, seizures, coma, death | • Inability to provide adequate nutrition in neonatal and pediatric patients if less concentrated stock solution is used due to volume limitations  
  • Consider using alternative IV salt (i.e. sodium acetate) where appropriate  
  • Consider mixing other IV medications in 0.9% NS instead of D5W and/or changing other IV fluids to 0.9%NS if appropriate |
| Magnesium sulfate          | Yes, but causes diarrhea | Magnesium chloride       | • Hypomagnesemia  
  • S/S hypomagnesemia: ECG changes and arrhythmias, seizures, coma and death  
  • Risk of compatibility problems if other salts used | • Lack of compatibility data with magnesium chloride  
  • Utilize premixed IV magnesium products  
  • Minimize use of IV magnesium additives to intravenous maintenance fluids |
| Calcium gluconate          | Yes, other salt forms more common | Calcium chloride         | • Hypocalcemia  
  • S/S calcium deficiency: tetany, neuromuscular, CNS and cardiovascular symptoms  
  • Growth delays and metabolic bone disease in pediatric and long-term PN patients  
  • Risk of compatibility problems if other salts used | • Lack of compatibility data with calcium chloride in PN formulation (PN solubility curves are based on calcium gluconate)  
  • If removed from PN and calcium chloride administered outside of PN, need for central IV access  
  • Necessity to increase monitoring of serum calcium, albumin, and ionized calcium concentrations  
  • Consider multi-electrolyte products and standardized PN products that contain calcium where clinically appropriate |
| General considerations for TE and MVI products | | | • Should not use pediatric products in shortage of adult products or adult products in shortage of pediatric products  
  • Increased monitoring for deficiencies when restricting or eliminating products from PN  
  • Increased cost of off-contract or compounded products  
  • Ability to use compounded products in PN (may increase risk of contamination)  
  • Avoid the use of IV products for oral liquid formulations and administration  
  • If eliminating or decreasing dose of vitamins or TE, monitor serum levels on monthly basis for long term PN patients |
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| MTE-5/ MTE-4 | See individual TEs | Other MTE products, individual TEs | • See individual TEs | • Conserve by reducing dose by 50% or consider dosing on non-daily basis (i.e. 3 days per week)  
• If also receiving EN, consider omitting TE for 1st month of PN in adult patients if not previously on PN, non-critically ill, with no documented deficiencies  
• Consider administering individual TE if products available |
| Adult MVI | Yes | Some components available individually | • Vitamin deficiencies | • Avoid use for non-PN indications – i.e. restrict “banana bags”  
• Conserve MVI by reducing dose by 50% or administering on non-daily basis  
• Education necessary for home PN patients when reducing frequency  
• Avoid use of pediatric MVI |
| Pediatric/ Neonatal Trace Elements | Yes; some individual trace elements | Yes; trace element combination products | • Deficiencies (see individual trace elements) | • Avoid use of adult trace elements |
| Pediatric MVI | Yes | Some components available individually | • Vitamin deficiencies  
• Monitor for vitamin deficiencies and aluminum toxicity | • Maintain awareness of components of available MVI products; products differ in components and additional supplementation may be necessary  
• Use enteral route where appropriate  
• Consider administration of 50% dose in select patients  
• Reserve pediatric MVI for patients <2.5 kg or patients less than 36 weeks gestational age  
• May consider use of adult MVI product in patients >2.5 kg |
| Selenium | Yes | Yes; multiple trace element combination products | • Cofactor for glutathione peroxidase, important in protecting cells from oxidative damage  
• Deficiency takes years to develop in otherwise healthy individuals  
• S/S of selenium deficiency include: cardiomyopathy, myalgias, impaired cellular immunity, hemolysis | • Use oral/enteral supplementation where possible |
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<td>Zinc</td>
<td>Yes (some may be difficult to administer in pediatric patients)</td>
<td>Yes; zinc chloride, zinc sulfate</td>
<td>- Cofactor for several enzymes, helps maintain normal growth, skin hydration, and senses&lt;br&gt;• s/s of zinc deficiency include: dermatitis, alopecia, decrease appetite/anorexia, altered taste, immune system compromise and poor wound healing</td>
<td>Use oral and enteral supplementation if possible</td>
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<td>Chromium</td>
<td>No</td>
<td>Yes; multiple trace element combination products</td>
<td>- Necessary for glucose tolerance, carbohydrate, lipid and protein metabolism, and peripheral nerve function&lt;br&gt;• S/S of chromium deficiency include: peripheral neuropathy, encephalopathy, glucose intolerance, hyperlipidemia, fatigue</td>
<td>Generally no need to supplement during shortage unless s/s of clinical deficiency present</td>
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<td>Copper</td>
<td>Yes (some may be difficult to administer in pediatric patients)</td>
<td>Yes; multiple trace element combination products</td>
<td>- Cofactor for serum ceruloplasmin and helps maintain normal rates of red and white blood cell formation, bone formation, skeletal mineralization and integrity of connective tissue&lt;br&gt;• s/s of copper deficiency include: anemia, neutropenia, bone demineralization, hair and skin depigmentation, impaired elastin formation, hypotonia, and central nervous system dysfunction</td>
<td>Use oral/enteral supplementation if possible</td>
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<td>Manganese</td>
<td>No</td>
<td>Yes; multiple trace element combination products</td>
<td>- Activator for several enzymes necessary for growth and maintenance of connective tissue, cartilage and bone&lt;br&gt;• Manganese deficiency (very rare); impaired growth/weight loss, poor bone formation/skeletal defects, abnormal glucose tolerance, change in hair growth/color, dermatitis, altered lipid metabolism, N/V</td>
<td>Manganese is generally a contaminant&lt;br&gt;• No need to supplement during shortage, unless s/s of deficiency are present</td>
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<td>Carnitine/ levocarnitine</td>
<td>Yes</td>
<td>No</td>
<td>• Carnitine is an endogenous substance used for energy metabolism</td>
<td>• Monitor weight gain, triglycerides, free and total serum carnitine levels and acylcarnitine levels</td>
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<td>• Carnitine deficiency may develop</td>
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<td>Cysteine</td>
<td>No</td>
<td>No</td>
<td>• Nutrient imbalances, especially in neonates</td>
<td>• Dose conservation</td>
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<td>• Change in calcium-phosphorus solubility</td>
<td>— Conserve for patients &lt;1 kg or neonates &gt;1 kg who are at high risk for cysteine deficiency (i.e. post-surgical, sepsis)</td>
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<td>— 20 mg/kg L-cysteine is adequate</td>
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<td>• If providing 3 g/kg/day of protein, no need to supplement PN with L-cysteine as this will provide adequate methionine</td>
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<td>• Avoid using L-cysteine to re-establish catheter patency</td>
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<td>• Add cysteine to PN as a single product rather than to amino acid solution; add prior to calcium</td>
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<td>• Re-evaluate calcium-phosphorus solubility data if L-cysteine removed from PN where previously added</td>
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References