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A Chapter of the American Society for Parenteral and Enteral Nutrition

Newsletter

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President's Welcome

GASPEN has had a very busy summer! In August, we hosted our second summer meeting at Emory Saint Joseph's Hospital with presentations on ethics, acid-base, pediatric and neonatal nutrition, volume-based feedings, nutrition support teams, enteral nutrition nightmares, nutrition support in critically ill adult patients, and micronutrient deficiencies! In November, we co-hosted a CE program with the Southeast Chapter of Critical Care Medicine (SCCM). Dr. Jayshil Patel gave a wonderful presentation on the topic of early exclusive and supplemental parenteral nutrition in the critical care setting. The live meeting was hosted at Northside Hospital in Atlanta but was broadcasted at 7 different locations! All meetings were well-attended and well-received. I would like to thank our wonderful active GASPEN board members for all of their hard work preparing for these meetings. You can read recaps of the meetings in our newsletter.

While GASPEN has been very busy planning continuing education activities, there are also many ASPEN activities available. ASPEN continues to offer a robust selection of webinars. Don't forget to sign up for ASPEN's Nutrition Science and Practice Conference 2019 in Phoenix, Arizona! If you are a pharmacy resident or dietetic intern interested in nutrition support, stay tuned! We would like to send one resident or intern to ASPEN 2019. We will post the criteria for consideration for the scholarship on our Facebook page in the upcoming months.

We welcome any suggestions and comments from GASPEN members for CE programs, newsletter articles and any other ways that we can benefit our members. Do you have an interesting case that you would like to present? Would you like to share a research project or quality improvement initiative? Consider sharing with other members by publishing in our newsletter. We also would like to welcome any GASPEN members who would like to become involved on our board.

I look forward to another wonderful year with GASPEN!

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GASPEN President

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Member Spotlight!

Ashley DePriest, left, with Marlene Neville at the 2018 GASPEN Summer Meeting.

Ashley DePriest attended the University of Tennessee, where she received a Bachelor's Degree in Nutrition, then Georgia State University's Coordinated Program in Nutrition, where she completed the dietetic internship and earned a Master's Degree in Nutrition. Ashley has been involved with the Southeast Chapter Society of Critical Care Medicine (SCCM) for 6 years, currently serving as the Chapter President-Elect. She also serves on SCCM's national Social Media Task Force and is a Stress Ulcer Prophylaxis Guidelines Panel member. For the last two years, Ashley has served as a GASPEN Board member and is the Social Media Chair.

In the past, Ashley has worked as a clinical dietitian at Grady Health System and as a nutrition support team member at Northside Hospital Atlanta. As of December 2018 she is the Clinical Nutrition Manager for WellStar Kennestone Hospital.

Meetings in Review

Adina Hirsch, PharmD, BCNSP

On August 10, 2018, GASPEN sponsored our second annual 6-hour continuing education (CE) multidisciplinary meeting at Emory Saint Joseph's Hospital in Atlanta, Georgia. The speakers were specialists in nutrition support and included pharmacists and dietitians and an ethicist from a variety of healthcare systems in the Atlanta area including Emory University Hospital, WellStar Kennestone and Atlanta Medical Center, and Northside Hospital. We were also fortunate to have visiting speakers from outside of Georgia including Carolyn Kusenda, RD, CNSC from The King's Daughters in Norfolk Virginia and Gordon Sacks, PharmD, BCNSP, FASPEN from Auburn, Alabama. There were 84 interprofessional attendees at the meeting, including pharmacists, dietitians, students, and nurses. Although most of the attendees were from Georgia, we had representation from all over the Southeast including North Carolina, South Carolina, Tennessee, Florida, and Alabama.

Following breakfast, networking, and booth exhibition, the morning one-hour CEs covered the following topics: Ethical dilemmas in artificial nutrition and hydration, Acid-Base Disturbances, Pediatric and Neonatal Parenteral Nutrition and Volume Based Feeding.

During the lunch break, attendees had additional time to network with colleagues and exhibitors. The afternoon clinical pearls session provided four 30-minute discussions on the ASPEN/SCCM 2016 Nutrition Support Guidelines, Micronutrients in Nutrition Support, Enteral Nutrition Nightmares, and the Value of the Nutrition Support Team. After the final session, we held a raffle for nutrition support resources from ASPEN and a Southeast Society for Critical Care Medicine annual membership.

The GASPEN summer meeting was well-received by attendees, with > 95% agreeing or strongly agreeing that the program met its objectives as well as their own personal and professional objectives for attending. We are grateful for the financial support of our exhibitors who allowed us to once again provide a high quality educational programming for clinicians involved in the provision of nutrition support. We look forward to another successful summer meeting in August 2019. Stay tuned for details!

Ashley DePriest, MS, RD, LD, CNSC

On November 13, 2018 the Southeast Chapter of Critical Care Medicine welcomed Dr. Jayshil Patel, assistant professor at the Medical College of Wisconsin, to discuss updates to the use of parental nutrition in critically ill adults. Dr. Patel reviewed guideline recommendations for the initiation of enteral and parenteral nutrition as well as recent evidence from randomized controlled trials. The CALORIES and NUTRIREA-2 trials evaluated the role of early enteral and early exclusive parenteral nutrition and did not detect a mortality difference between the two routes of delivery. Infections acquired in the intensive care unit (ICU) did not differ between the enteral and parenteral groups in either study, suggesting that parenteral nutrition may be a safe alternative when enteral nutrition cannot be provided. Dr. Patel then reviewed recent literature assessing the role of supplemental parenteral nutrition. The EAT-ICU study found that supplemental parenteral nutrition improved energy and protein balance but did not have an impact on 6 month performance score, length of ICU hospital stay or 28-day or 6-month mortality. The TOP-UP trial investigated provision of supplemental parenteral nutrition in underweight and obese ICU patients. Supplemental parenteral nutrition improved calorie and protein provision, but did not have a significant impact on hospital mortality or quality of life. Further studies are needed to investigate the role of parenteral nutrition in patients at high nutritional risk.

Alternative Fish Oil-Containing Lipid Injectable Emulsions in Critical Illness

Maria Sheridan, PharmD, BCNSP

Lipids are an integral component of parenteral nutrition (PN). They provide the body with a source of fuel and fatty acids (FAs), which are necessary for the formation of cell membranes and biochemical mediators. Introduced in 1961, the first successful lipid injectable emulsion (ILE) was made from soybean oil (SO) and provided a breakthrough in PN.[1] This first-generation ILE was made available in the US in 1975, and initially used to prevent essential fatty acid deficiency (EFAD). Clinical practice has since evolved to include lipids as an energy source, due to the dangers of excessive dextrose provision, such as hyperglycemia and hepatic steatosis.[2,3] However, complications such as exaggerated inflammatory response in the critically ill, reticuloendothelial system suppression, and liver dysfunction were identified and attributed to the high ω-6 FA content in SO.[3-5] Omega-6 FAs are precursors to pro-inflammatory eicosanoids and may promote their overproduction and increase oxidative stress in sepsis and trauma. Subsequent generations of ILEs utilize alternative oil sources to reduce ω-6 FA content and provide FAs that exert more favorable effects on immune function and inflammatory status.[3]

Alternative ILEs have been utilized in Europe for over 30 years, but remained unavailable in the US until recently. Oil sources in these products include medium chain triglyceride (MCT) oil, olive oil (OO), and/or fish oil (FO). MCT oil provides a source of FAs that are readily oxidizable for energy and lack pro-inflammatory properties. OO provides a more immune neutral source of ω-9 FAs and a small amount of essential fatty acids (EFAs). FO provides ω-3 FAs with less pro-inflammatory and inflammatory-resolving properties.[4] FO is either added as a supplement to ILEs or included in commercially manufactured products, constituting the fourth-generation of ILEs. All generations of ILEs must contain or are indicated to be utilized in conjunction with SO, as it is an excellent source of EFAs, linoleic acid and α-linolenic acid. A fourth-generation ILE composed of SO/MCT/OO/FO was FDA-approved for use in adults in 2016 and is commercially available in the US.[6]

During critical illness, pathophysiological modifications occur due to acute stress. This catabolic state causes impaired immune function and altered inflammatory response. Alternative ILEs may differentially modulate immune and inflammatory reactions depending on their FA composition.[7] The ω-3 FAs in FO, eicosapentaenoic acid (EPA) and docosahexanoic acid (DHA), are precursors to less pro-inflammatory eicosanoids, as well as specialized pro-resolving mediators (SPMs).[8,9] Therefore, use of alternative ILEs with supplementary FO are of interest in the critically ill population.

Literature on FO-containing ILEs in critical illness is limited to trials which have small sample sizes and utilize varying doses of FO in conjunction with different oil sources, making it challenging to compare formulations.[4,7] Results of individual studies show decreased cytokine levels in sepsis, decreased CRP and shifts to less pro-inflammatory leukotriene levels in ICU patients when including FO.[10-12] Meta-analyses comparing FO-containing ILEs to non-FO-containing ILEs in ICU and post-surgical patients give precision to outcomes evaluated in smaller studies. Significant decreases in infections are seen in separate meta-analyses performed by Pradelli, Wei, Chen, Li, Manzanares, and Bae.[13-18] Significant decreases in ICU length of stay (LOS) were reported by Pradelli, Wei, and Chen, and in a subgroup analysis of high quality studies evaluated by Manzanares.[13-15,17] Palmer reported significantly reduced hospital LOS but no difference in ICU LOS or frequency of new infections.[19]

Current US guidelines have not been updated to reflect approval of alternative ILEs, including the most recent from SCCM/ASPEN on nutrition support in the critically ill from 2016. These guidelines state "when these alternative [ILEs] (SMOF [SO, MCT, OO, and FO emulsion], MCT, OO, and FO) become available in US, based on expert opinion, we suggest that their use be considered in the critically ill patient who is an appropriate candidate for PN".[20] In countries where alternative ILEs have been used for many years, the guidelines are more specific. The European Society for Parenteral and Enteral Nutrition (ESPEN) guidelines state "addition of EPA and DHA to lipid emulsions has demonstrable effects on cell membranes and inflammatory processes. FO-enriched lipid emulsions probably decrease length of stay in critically ill patients".[21] The ESPEN Expert Group's recommendations on lipids in the ICU state "Compared to SO and SO/MCT, FO-enriched PN may provide clinical benefits for a wide range of ICU patients" and "If PN is required post-operatively in the ICU, 2nd or 3rd generation lipid emulsions may be administered, and in the case of surgical complications, FO-containing PN is

Lipid Injectable Emulsions in Critical Illness, continued

recommended".[22,23] Canadian guidelines recommend "when PN with intravenous lipids is indicated, IV lipids that reduce the load of ω-6 FAs/SO emulsions should be considered. However, there are insufficient data to make a recommendation on the type of lipids to be used [to do so] in critically ill patients receiving PN".[24] When using different lipid emulsions, it is necessary to note product differences to ensure appropriate dosing and administration. Of the two available ILEs in the US, caloric content is equivalent based on the total grams of lipid provided. However, EFA content varies significantly, as SO/MCT/OO/FO ILE contains less than pure SO. In order to ensure adequate EFA provisions based on adult recommendations, 13-25% of total calories should be provided from SO/MCT/OO/FO ILE on a daily basis compared with 8-10% of total daily calories or a minimum of 100 g of SO per week.[25,26] All ILEs should be administered with a non-DEHP, non-PVC IV administration set due to leaching of plasticizers from the line caused by the fat emulsion. In addition, all ILEs should be administered with a 1.2 micron in-line filter.[6,27-29] The recently approved FO-containing ILE provides another lipid option with a less pro-inflammatory FA profile for the critically ill adult in need of PN. In the meantime, there is still a need for more research on alternative ILEs and it is essential for us to publish our experiences to fill literature gaps and provide the best possible care for our patients. Future research may also bring us new insights on the role of specific nutrients, including ω-3 FAs, as pharmaconutrition. Areas of interest include ω-3 FA modulation of the inflammatory response in critically ill populations such as cardiac surgery, and the effects of SPMs on clinical outcomes such as physical function.[30,31] The optimal dose of ω-3 FAs still needs to be determined, as it varies in clinical trials, but shows encouraging improvements in clinical outcomes in the range of 0.1-0.2 g/kg/day.[32] Currently available ILEs are both safe and effective sources of calories and EFAs for adult PN patients. Alternative FO-containing ILEs may be beneficial in critical illness, as meta-analyses have consistently shown decreases in infection and LOS. The inclusion of ω-3 FAs in PN may improve the balance of nutritional provisions and lead to advancements in patient care.

Disclosure: Maria Sheridan is a Medical Science Liaison in Clinical Nutrition at Fresenius Kabi .

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Considerations for Injectable Lipid Emulsion Administration: In-line Filters and DEHP-Free Tubing

Adina Hirsch, PharmD, BCNSP

Introduction:

In January 2016, an Institute for Safe Medication Practices (ISMP) Medication Safety Alert was published highlighting the current recommendation in all US injectable lipid emulsions (ILE) prescribing information (PI) to use a 1.2 micron filter when infusing injectable lipid emulsions in both total nutrient admixtures (TNA) and when infused separately.[1] The ISMP Safety Alert stated that the use of 1.2 micron filters could minimize fat emboli, precipitate matter, air and microorganisms from parenteral nutrition (PN) and ILE from reaching the patient.1 The Safety Alert highlighted a prescribing information change for ILE in the United States that occurred in 2014. Prior to 2014, package inserts for ILE stated that "filters of less than 1.2 microns must not be used." Despite the ISMP alert, many clinicians are still either unaware or non-compliant with the practice of filtering lipids. In July 2017, ASPEN published the results of a lipid usage survey that found that 10 - 20% of respondents were not compliant with the practice of filtering lipids. The authors stated that this gap in practice was due to either lack of knowledge or a perception that filtering is unnecessary.[2] Another requirement for administration sets for ILE is that they be free of DEHP (di-(2-ethylhexy-l phthalate) free. This article will discuss the rationale for filtration of parenteral nutrition (PN), review American Society for Parenteral and Enteral Nutrition (ASPEN) guidelines and recommendations regarding filtering of PN and ILE, and summarize current package insert statements concerning filtering of ILE. In addition, the rationale for using DEHP-free tubing with ILE will be reviewed.

History and Background:

The first American Society of Parenteral and Enteral Nutrition (ASPEN) PN Safety Guidelines were published in 1998 and included an entire section (section VI) devoted to the filtration of PN solutions.[3] The initial guidelines recommended using a 0.2 or 1.2 micron filter for 2-in-1 PN solutions and a 1.2 - 5 micron filter for TNA. The guidelines further recommended changing filters every 24 hours, and cautioned to never remove a clogged filter from the administration set, but rather, to replace the clogged filter with a new in-line filter and cautioned that a clogged filter is generally indicative of a problem with the PN solution.[3] In 2004, ASPEN published an updated version of the PN Safety Guidelines which narrowed the recommendations for filtration of PN solutions to a 1.2 micron filter for TNA (instead of a 1.2 - 5 micron filter). They also noted that while a 1.2 micron filter was acceptable for use in both 2-in-1 and TNA preparations these filters would filter particulate matter and micro-precipitates only and not microorganisms.[4] Of note, neither the 1998 nor the 2004 ASPEN PN Safety Guidelines specifically address filtration of ILE when infused separately, although the 1998 guidelines did state that TNA or lipids given separately could be safely administered using a 1.2 micron filter. In 2014, ASPEN published two PN Safety papers: ASPEN Clinical Guidelines for Parenteral Nutrition Ordering, Order Review, Compounding, Labeling and Dispensing, and ASPEN PN Safety Consensus Recommendations.[5,6] The latter paper addressed the issue of filtration of PN in Question 3: Administration (A3). Guideline recommendations for filtration were slightly modified from the 2004 guidelines, and included a recommendation to consult pharmacy if a filter clogs to determine if compatibility issues are the cause of the problem, and a recommendation to change in-line filters every 12 hours for ILE administered separately. The recommendation to change in-line filters every 24 hours for TNA was maintained.[6] For a summary of ASPEN PN safety guidelines and recommendations regarding PN filtration, refer to table 1.

Why filter Parenteral Nutrition?

The rationale for guideline recommendations to filter parenteral nutrition is that filters can prevent the administration of particulate matter, air and microorganisms.[3,7] In 1994, in response to reports of two deaths and at least two cases of respiratory distress in patients receiving TNA due to precipitates (thought to be calcium phosphate), the Food and Drug Administration (FDA) issued a Safety Alert about the risks of precipitation in PN.[7] The FDA Safety Alert contained seven recommendations to prevent

Table 1: Summary of ASPEN PN Safety Guidelines regarding in-line filters for IV lipid emulsions

Year	Publication	Recommendations
1998	PN Safety Guidelines JPEN 1998; 22(2): 49 – 66	Section VI: In-line filtration A 0.2 micron filter should be used for 2-in-1 formulations. A 1.2 – 5 micron filter should be used for TNAs. Alternatively, a 1.2 micron filter may be used for all PN formulations TNA OR lipids can be safely administered with a 1.2 micron in-line filter. 3. A filter that is clogged during administration of PN is indicative of a problem and may be replaced but should never be removed.
2004	PN Safety Guidelines (revision) JPEN 2004; 28(6): S39-S70.	Section VII: Parenteral Nutrition Administration 1. For PN administration, a 0.22 micron filter is recommended for a 2-in-1 formulation 2. A 1.2 micron filter should be used for TNAs 3. When considering particulate matter and micro-precipitate contamination only, a 1.2 micron filter can be used for all PN formulations.
2014	PN Safety Consensus Recommendations JPEN 2014; 38(3) 296-33.	Question 3: Administration (A3) 5. PN infusions shall be infused through a filter appropriate for the type of formulation (0.22 micron for 2-in-1, 1.2 micron for TNA) 6. An occluded filter should never be removed in response to occlusion alarms. When an occluded filter triggers a pump alarm, stop the PN infusion and consult pharmacy to determine if compatibility issues are a cause of the problem. 8. Administration tubing and filters shall be changed with each new PN container (every 24 hours for TNAs and 2-in-1; 12 hours for ILE infused separately). Topics for further research: Clarification of the appropriate use of filters with ILE administration

precipitation in parenteral nutrition admixtures and to minimize adverse events regarding precipitation, including the use of filters when infusing either central or peripheral parenteral nutrition admixtures. The Safety Alert recommended a 1.2 micron air-eliminating filter for lipid containing admixtures and a 0.22 micron air-eliminating filter for non-lipid containing admixtures. [7]

A 0.22 micron filter can filter bacteria, air and particulate matter, whereas a 1.2 micron filter can remove particulate matter and air but can only remove larger microorganisms such as *Candida albicans,* but not bacteria. Lipid emulsions contain particles ranging from about 0.1 micron to 1 micron, and can, therefore pass through a 1.2 micron filter. Per United States Pharmacopeia (USP) chapter <729>, the mean droplet size of lipid globules should be no greater than 0.5 microns and the proportion of lipid globules greater than 5 microns should be no greater than 0.05%.[7] It is the larger lipid globules (> 5 microns) that pose the greatest risk since particles of this size can lodge in pulmonary capillaries and cause complications including embolic events. [7,9] In 1996, Driscoll et al published a study evaluating the effects of in-line filtration on TNA and found that 1.2 micron filter significantly reduced the number and concentration of large lipid globules. The authors concluded that in-line filtration of TNA should become the standard of practice.[9] The reason that use of filters of less than 1.2 microns should not be used with IV lipid emulsions or TNA is that a smaller filter size can disrupt the stability of the IV lipid emulsion by shearing lipid particles in the TNA.[7,8,9]

As stated above, the smaller pore size of the 0.22 micron filter has the ability to filter smaller microorganisms such as bacteria, whereas a 1.2 micron filter only filters larger microorganisms such as fungi, and therefore, there is a theoretical benefit in using a 0.22 micron filter for PN to reduce the incidence of PN-related infections due to a contaminated PN solution. In a review paper of 2-in-1 PN versus TNA by Slattery et al, there was no increased risk of infection associated with TNA versus 2-in-1 PN .[10] The 2014 ASPEN Clinical Guidelines also conclude that there is no difference in infection risk when comparing 2-in-1 PN to TNA.[5]

Why filter Injectable Lipid Emulsions specifically?

A review of the literature did not identify any specific adverse events based on case reports or case series to explain the recent labeling change requiring filtration of ILE when given separately. Nevertheless, ASPEN has endorsed this labeling change. ASPEN states that in order to comply with this new recommendation, two filters are necessary when administering PN as a 2-in-1 solution (dextrose and amino acids) with ILE administered separately: A 0.22 micron in-line

Table 2: Summary of PI recommendations for ILE approved in the United States

	Prior to 2014	After 2014
Intralipid®[16, 17]	**Bulk containers:** "Filters of less than 1.2 micron pore size should not be used with admixtures containing Intralipid 30%".	**Bulk containers**: "Use a 1.2 micron filter with admixtures containing Intralipid. Filters of less than 1.2 micron pore size must not be used."
	Non-bulk containers: "Filters of less than 1.2 micron pore size must not be used with Intralipid."[8]	**Non-bulk containers**: "Use a 1.2 micron filter with Intralipid. Filters of less than 1.2 micron pore size must not be used."
Nutrilipid®[18]	NA	"Use a 1.2 micron in-line filter."
Clinolipid®[19]	NA	"Fragments of the administration port membrane could be dislodged into the bag after spiking. Use a 1.2 micron inline filter during administration of CLINOLIPID injection (alone or as part of an admixture) to remove particulate matter or micro-precipitate contamination during administration of CLINOLIPID injection (alone or as part of an admixture). Particulate matter > 5 microns has the capability of obstructing blood flow through capillaries, which could lead to embolism and vascular occlusion. Do not use filters of less than 1.2 micron pore size with lipid emulsions."
Smoflipid®[20]	NA	"Use a 1.2 micron in-line filter."

filter should be used for the dextrose/amino acid solution and a 1.2 micron filter for ILE. ASPEN recommends that ILE be infused via a y-site connector placed closer to the patient than the 0.22 micron filter or via a separate venous access device.[11] The new recommendation for filtering ILE has also been included in the Intravenous Nurses Society's 2016 Infusion Therapy Standards of Practice.[12]

Practices regarding filtering ILE outside of the United States vary. Canadian prescribing information for ILE does not include the requirement for the use of an in-line filter.[13] European Society for Pediatric Gastroenterology Hepatology and Nutrition (ESPGHAN) guidelines for parenteral nutrition in the pediatric population recommend the use of in-line filters for ILE when administered separately or via TNA.[14] However, package inserts (known as summaries of product characteristics (SmPC)) for lipid emulsions outside of the United States do not contain the specific requirement for use of an in-line filter with ILE. ESPEN (European Society for Parenteral and Enteral Nutrition) guidelines for adult parenteral nutrition do not recommend using in-line filters in order to reduce the risk of PN-associated infections and have no other specific recommendations regarding the use of in-line filters for parenteral nutrition. [15]

Summary of package insert recommendations for use of in-line filters:

Currently, as stated in all ILE package inserts in the United States, a 1.2 micron filter should be used when infusing IV lipid emulsions separately or as part of a total nutrient admixture (TNA). In addition, prescribing information states that "filters of less than 1.2 microns must not be used" with ILE.[16 -20] Prescribing information for ILE approved in the United States is summarized in table 2.

DEHP-free tubing:

It is important to note that administration sets for ILE are recommended to be DEHP (di-(2-ethylhexyl)phthalate) free per manufacturer prescribing information.[16-20] DEHP is a plasticizer commonly used in polyvinylchloride (PVC) tubing in order to improve flexibility, strength and resistance to kinking. Lipid emulsions can leach DEHP from PVC tubing and is associated with adverse events including an increased risk of parenteral nutrition associated liver disease, especially in children.[21,22] Faessler et al conducted a study to determine the amount of leaching of different plasticizers in ILE administration sets with different

Considerations for Injectable Lipid Emulsion Administration, continued

lipid emulsions: Soybean oil ILE (SO), olive oil and soybean oil ILE (OO/SO) and a 4-oil lipid emulsion containing soybean oil, medium chain triglycerides, olive oil and fish oil (SMOF). The study found that there was no difference in the amount of leaching of plasticizers with the three different lipid emulsions and that DEHP was leached significantly more from tubing than other plasticizers studied.[21]

Summary:

The use of a 1.2 micron in-line filter that is DEHP-free for ILE when administered separately or as part of an admixture (TNA) is required for all injectable lipid emulsions in the United States. ASPEN recommends that healthcare organizations that do not filter PN admixtures or ILE reevaluate these decisions and consider the small price of filters in comparison to increased morbidity and mortality that may result from not filtering ILE or PN.[2] Clinicians are encouraged to contact their IV tubing/filter manufacturers regarding which products are suitable for their institution. Clinicians should also be aware that an occluded filter may be a sign of compatibility problems with the PN solution and that filters should be replaced, but never removed, in order to ensure patient safety.

Disclosure: Adina Hirsch is a Medical Science Liaison in Clinical Nutrition at Fresenius Kabi.

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A large health-system's experience implementing an interface between computerized prescriber order entry system and an automated compounding device (ACD)

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Background:

Piedmont Healthcare (PHC), an eleven-hospital health-system, has historically been on the forefront in using medical technology to enhance patient safety. Early use of medication dispensing robotic system, bedside scanning and barcoding, computerized physicians' order entry (CPOE) and use of smart pumps with standardized drug libraries have all been implemented to enhance patient safety at PHC.

Parenteral Nutrition (PN) safety was identified as an important next step in improving patient safety. The Institute of Safe Medication Practices (ISMP) considers PN a high-alert medication since PN formulation is a complex, high-risk process wherein small errors can cause clinically significant effects. [1, 2] A patient's daily PN admixture may contain

A large health-system's experience an interface, continued

at least 40 active ingredients, each with dosing implications and interaction potential. As such, safeguards are required to minimize error risk from PN to enhance patient safety[3]. Having an interfaced electronic system for efficient transfer of PN orders from a computerized prescriber order entry (CPOE) system directly to the automated compounding device decreases the rate of PN errors.[4, 5] The American Society for Parenteral and Enteral Nutrition, (ASPEN) recommends that "PN should be prescribed using a CPOE system that is fully integrated with an automated compounding device (ACD).

At Piedmont Healthcare, prior to this recent change, a pharmacist or clinical dietitian entered PN orders into the EPIC® electronic health system. Once the order gets verified by a pharmacist, a paper requisition prints out. Another pharmacist then manually transcribed the orders into outsourcing company's PN ordering system. Piedmont Healthcare outsources its PN to Central Admixture Pharmacy Services (CAPS). With this process, transcription of the TPN ended up being one of the most common sources of PN errors. As efforts were being made to minimize transcription, pharmacy administration started having discussions with the information technology (IT) team, specifically the EPIC® team as well as CAPS about steps needed to be taken to eliminate the transcription and develop an interface directly from EPIC® to the CAPS system.

The Project:

Prior to implementing this, and in an effort to standardize PN order sets within the EPIC system for all the hospitals, there was extensive collaboration between clinical pharmacists and clinical dietitians who manage PN in each facility. After review of the current order sets and published best practice for PN, the decision was also made to go to ion-based electrolyte orders versus salt-based for micronutrients, and grams versus percentages for macronutrients. Another suggested change was to convert how PN is ordered to the ASPEN recommended method of listing ingredients in amounts per day for adults (or amount per kilograms per day for pediatric and neonatal patients). Thus macronutrients will be ordered in grams per day and for micronutrients, mEq, mMol or mg per day.[6] A refresher course was provided for clinicians who managed PN across the system.

Next, the Piedmont IT group worked with the CAPS IT group to develop an interface between the two systems. Once this was done, key players were identified to begin pre-planning discussions. The key players involved were pharmacy, dietary, local EPIC® IT, local CAPS pharmacist and a CAPS IT representative. It goes without saying that having IT expertise was essential to the success of this undertaking.

After many months of critical planning, the build phase began. To start the build phase, Pharmacy had to evaluate all current PN processes. This included reconfiguring the PN EPIC® templates to match the CAPS template to ensure they crossed the interface appropriately. The templates were also built to include products on formulary, coordinating with the local CAPS facility to make sure the concentrations matched the stock products they use to compound the PN. Alerts in EPIC® had to be built to match alerts in the CAPS system as closely as possible. Clinical decision support was made within electronic PN orders to alert and prevent prescribers from ordering doses of macronutrients and micronutrients that exceed recommended/safe clinical limits or that exceed limits of compatibility (e.g., hard limits when maximum concentrations have been exceeded). All clinically relevant alerts needed to match in both systems to maximize efficiency and safety in ordering PN.

The next phase included testing of the interface by both the CAPS IT team and the EPIC® IT team. Once the interface was validated, testing was done using current patients' PN orders to make ensure that local CAPS facility was receiving the orders appropriately and the labels being generated were appropriate and accurate. Key fields included on the label were: patient name, date of birth, medical record number, room number, order number, latex allergy (if applicable), patient's weight and the PN components.

Procedures for ordering and managing PN were updated for each facility depending on whether a pharmacist or a clinical dietitian manages PNs. Appropriate education for pharmacists, dietitians and nursing staff was done throughout the health-system. The revised process for ordering PN included the following: PN is ordered by a pharmacist, the order gets verified by the pharmacist in the EPIC® system. The orders transmit through the interface into the CAPS system. The CAPS pharmacist validates the orders and the PN is mixed. When the PN is ordered by a dietitian, the order is verified by a pharmacist in the EPIC® system, then crosses into the CAPS system and the above

A large health-system's experience an interface, continued

outlined process is followed. This eliminated the transcription that was previously done from a paper requisition of the EPIC® orders.

As the implementation day approached, weekly meetings with all key players were held. Numerous additional meetings were held in the final few days prior to implementation. Of note, although there were 9 hospitals within Piedmont Healthcare at the time, the decision was made to roll this project out one hospital at a time to make sure any unforeseen issues were worked out one facility at a time.

In May 2018, Piedmont Atlanta Hospital, the largest hospital in the system was the first to go live. This was due to availability of resources as well as the volume of PN at the facility. The other hospitals went live in 2-3 week intervals. Seven of the 9 hospitals went live between May and August 1, 2018, and the other two went live with their EPIC® go-live on October 1, 2018. Although there was much preparation prior to this monstrous project, there were still hiccups on go-live dates. For each go-live, conference calls were scheduled on the day of go-live, then daily for at least two or three days following go-live to discuss any issues. The lead project pharmacist, a pharmacist and dietitian (if dietitians manage PN) from the facility, IT representatives from Piedmont and CAPS and a pharmacist from the local CAPS facility were all involved in the calls.

To date, all Piedmont Healthcare hospitals that have EPIC® are live with the EPIC®-CAPS interface. Months after all the go-live, the implementation group had another conference call to discuss optimization of the system to continue to improve patient safety and the PN ordering processes.

Issues encountered during go-live:

- On the first day of go-live, the orders did not cross the interface into the CAPS system. After hours of investigation, it was identified that the Piedmont IT firewall was blocking the orders from "crossing" the interface.
- The next issue identified almost immediately was that when orders were modified in the EPIC® system, duplicate orders transmitted into the ACD (the new order and the modified order). The CAPS pharmacist had no way of identifying which order was the most current. This led to duplicate bags being made for patients. As a result, a decision was made to have the orders populate in a work queue in the CAPS system and a pharmacist from Piedmont Healthcare had to validate and "release" the order before the final step of the transmission.
- Another issue identified was that when a custom additive was added to the PN order in EPIC®, it didn't cross the interface. Hence, the pharmacy team worked with the IT department to add templates of additives that were used only periodically, such as zinc sulfate, sandostatin, and copper.

Lessons learned:

- The importance of planning cannot be overstated. Have all key players involved from the beginning.
- For multi-hospital systems, it's advisable to roll out one hospital at a time to make sure as many issues are corrected before rolling out other hospitals.
- It is important to continue meetings as each hospital goes live to maximize communication and safety, especially if the various hospitals have different processes pertaining to the ordering of PN.
- All key players should have a designated back-up person if possible. For example, a couple of the roll-outs were delayed because a key IT individual was on vacation.
- Prior to go live, make sure written procedures are in place for all workflow changes.
- Troubleshoot with daily conference calls during and after implementation.
- Develop a back-up manual method to order PN if technology fails.

In conclusion, PN safety has been significantly improved at Piedmont Healthcare. An entirely paperless environment with seamless transmission of PN orders from EPIC® to CAPS compounding pharmacy has been achieved. This process required technological expertise and a lot of patience and perseverance. The improved process allows for overall improved PN safety and efficiency as well as patient safety.

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Parenteral Nutrition Component Shortages Update

Yolanda Whitty, PharmD, BCPS

Per ASPEN's Clinical Practice Committee Shortage Subcommittee:

- Do not ration PN nutrients if the supply is sufficient to provide the full daily dose.
- Follow the recommendations for PN management on the ASPEN Product Shortage Management website.
- Return to appropriate dosing as soon as the shortage has been resolved.
- Avoid suboptimal dosing due to potential cost incentive and lack of perceived adverse effects to patients.

Current shortages of parenteral nutrition (PN) components are summarized in the table below.

Intravenous (IV) Parenteral Nutrition Component Shortages

PN Component	Reason for Shortage	Availability of Alternatives
Calcium gluconate, 100 mg/mL 10-, 50-, and 100- mL vials	2/4/19: American Regent is no longer marketing product.	Fresenius Kabi has supply.
Magnesium sulfate, 500 mg/mL 10-, 20-, and 50-mL vials; 40 mg/mL 50-, 100-, and 1,000-mL	2/4/19: American Regent is no longer marketing product. Two other manufacturers discontinued product. Fresenius Kabi and WG Critical Care have shortages due to increased demand. Pfizer has shortage due to manufacturing delays.	Exela Pharma Sciences has the 10-mL vials. Fresenius Kabi has the 2-, 10-, and 20-mL vials and the 50-mL vials are expected in February.
Multi-vitamin infusion (adult & pediatric)	12/26/18: Pfizer has shortage due to manufacturing delays.	Baxter has all presentations fully available at this time.
Potassium phosphate (Glycophos®) 3 mMol/mL 15- and 50-mL vials	2/4/19: American Regent is no longer marketing product. Fresenius Kabi has shortage due to increased demand. Pfizer has shortage due to manufacturing delays and a recall due to sterility concerns.	Glycophos® 1 mMol/mL 20-mL vials are available. Potassium phosphate 3 mMol/mL 5-mL vials are available. Fresenius Kabi may have resupply in February for the 50-mL vials and March for the 15-mL vials.
Potassium acetate 2 mEq/mL 50-mL vials	1/18/19: Pfizer has shortage due to manufacturing delays.	Potassium acetate 2 mEq/mL 20-mL vials are available from Exela Pharma Sciences and Pfizer.
Potassium chloride 2 mEq/mL 5- and 20-mL vials	1/17/19: Pfizer and ICU Medical have shortages due to increased demand and discontinuations.	Pfizer has the 5-mL vials and the 10-, 20-, and 30-mL vials are readily available.
Sodium chloride 23.4%, 30-, 100-, and 200-mL vials	2/4/19: Fresenius Kabi and Pfizer have shortages due to increased demand.	Resupply is expected in mid-February and late-March for the 30- and 100-mL vials and 200-mL vials, respectively.
Sodium phosphate, 3 mMol 5-, 15-, and 25-mL vials	2/4/19: Fresenius Kabi has shortage due to increased demand. Pfizer has shortage due to manufacturing delays.	Glycophos® 1 mMol/mL 20-mL vials are available. Resupply is expected by mid- to late February.
Sterile water, 20-, 50-, and 100-mL vials	2/4/19: Pfizer and Fresenius Kabi have shortages due to increased demand.	American Regent has 5-, 10-, and 20-mL vials. Hikma has 10-mL vials. Fresenius Kabi has 5-, 10-, and 20-mL vials. Pfizer has 10-mL vials.

Note: Where applicable, use oral/enteral formulations for administration via oral/enteral routes and restrict IV agents to PN use only, if possible . Reserve pediatric multivitamin supply for children < 2.5 kg or < 36 wk gestational age. Avoid use of pediatric products in adult PN.

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Upcoming Events

- Free Webinar from ASPEN: The Role of Protein and Parenteral Nutrition in the Critically Ill Adult: What is New Since Release of the 2016 ASPEN/SCCM Guidelines, February 27th
  More information available at www.nutritioncare.org

- ASPEN 2019 Nutrition Science & Practice Conference, March 23rd to March 26th | Phoenix, AZ
  More information available at www.nutritioncare.org

- 2019 GASPEN Summer Meeting, TBD

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