

Controversies in Parenteral Nutrition

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DISCLOSURE

In the past 12 months, I have had no relevant financial relationships with the manufacturer(s) of any commercial product(s) and/or provider(s) of commercial services discussed in this CME activity.

Learning Objectives

- To review indications for intravenous fat emulsions in patients with intestinal failure
- To review strategies for parenteral micronutrient supplementation in the setting of manufacturing shortages

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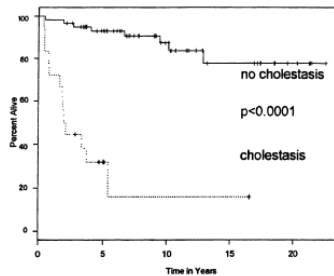
LONG-TERM PARENTERAL NUTRITIONAL SUPPORT AND INTESTINAL ADAPTATION IN CHILDREN WITH SHORT BOWEL SYNDROME: A 25-YEAR EXPERIENCE

RUBÉN E. QUIRÓS-TEJERA, MD, MARVIN E. ANSHT, MD, LAURE RYEN, RN, FAYE HERZOG, RN, MICHELLE MURANANI, MD, NANCY OLIVARES-SERRANO, MD, AND JORGE H. VARGAS, MD

- 78 patients with
 - PN dependence for > 3 months
 - SBS defined as ≤ 75 cm residual small bowel
- 57/78 (73%) alive median age 9 years
 - Median follow-up: 9 years
 - Range of follow-up: 2.1 – 23 years

J Pediatr 2004; 145:157-63

Correlation of survival with cholestasis



J Pediatr 2004; 145:157-63

Natural History of Pediatric Intestinal Failure: Initial Report from the Pediatric Intestinal Failure Consortium

Robert H. Squires, MD¹, Christopher Duggan, MD², Daniel H. Teitelbaum, MD³, Paul W. Wales, MD⁴, Jane Balint, MD⁵, Robert Venick, MD⁶, Susan Rhee, MD⁷, Debra Sudan, MD⁸, David Mercer, MD⁹, J. Andres Martinez, MD¹⁰, Beth A. Carter, MD¹¹, Jason Soden, MD¹², Simon Horslen, MD¹³, Jeffrey A. Rudolph, MD¹, Samuel Kocoshis, MD¹⁴, Riccardo Superina, MD¹⁵, Sharon Lawlor, MBA¹⁶, Tamara Haller, BS¹⁶, Marcia Kurs-Lasky, MS¹⁶, and Steven H. Belle, PhD, MSCHy¹⁶, for the Pediatric Intestinal Failure Consortium*

Among the 168 infants with sufficient data to assess for the presence of cholestasis at baseline, 125 children had cholestasis, and their cumulative percentage of survival was significantly lower than in the 43 without cholestasis (79% vs 95% at 1 year, and 73% vs 88% at 3 years; P = .03).

Birthweight and PNALD

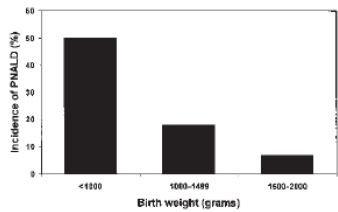


FIGURE 56-1 Relationship between the incidence of parenteral nutrition-associated liver disease (PNALD) and low birth weight. Adapted from Beale EF et al.¹⁷

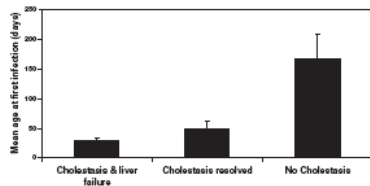


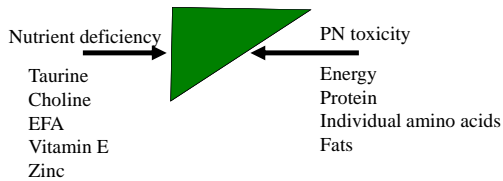
FIGURE 56-2 The effect of age at first infection on the development and severity of parenteral nutrition-associated cholestasis in neonates with intestinal resection. Adapted from Sondheimer JM, Asturias E, Cadnapaphornchai M. Infection and cholestasis in neonates with intestinal resection and long-term parenteral nutrition. *J Pediatr Gastroenterol Nutr* 1998;27:131-7.

Protein intake

Variable	2.5 g/kg/d	4.0 g/kg/d	P value
Direct bili > 2 mg/dL	27%	33%	NS
Days of PN before cholestasis	47 +/- 6	27 +/- 4	<.01
Peak direct bili	3.2 +/- 0.3	8.4 +/- 1.6	.001

Vileisis, RA et al., J Pediatr 1980; 96:893-897

PN-associated liver disease



Risk Factors for Parenteral Nutrition-associated Liver Disease Following Surgical Therapy for Necrotizing Enterocolitis

¹Debra Duro, ²Paul D. Mitchell, ³Leslie A. Kalish, ⁴Cami Martin, ⁵Maggie McCarthy, ⁶Tom Jaksic, ⁷James Dunn, ⁸Mary L. Brandt, ⁹Kerilyn K. Nobuhara, ¹⁰Karl G. Sylvester, ¹¹R. Lawrence Moss, and ¹²Christopher Duggan

- Cohort study of 464 infants with NEC
- Enrolled across 6 centers
- 2004 – 2007

Duro et al., JPGN 2011

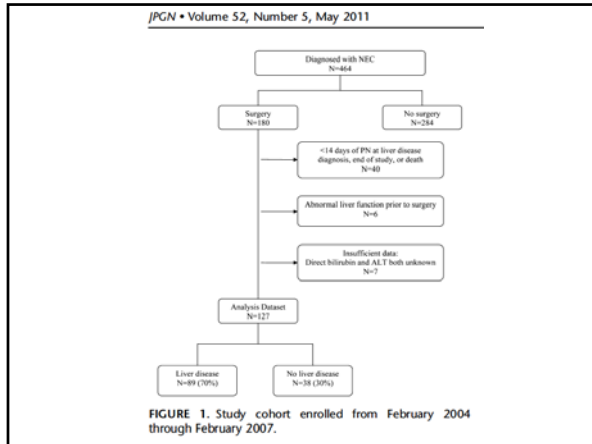


FIGURE 1. Study cohort enrolled from February 2004 through February 2007.

TABLE 2. Risk factors for PNALD, unadjusted (N=127)

	PNALD (n = 69)	No PNALD (n = 58)	P*
Demographic characteristics			
Male sex (%)	62/69 (70)	24/58 (41)	0.47
Gestational age, wk, median (Q1-Q3)	36 (32-36)	36 (32-37)	0.92
Birth weight, g, median (Q1-Q3)	916 (668-1315)	825 (697-1342)	0.95
Birth length, cm, median (Q1-Q3)	51 (51-48)	51 (52-39)	0.84
Maternal information			
Prenatal steroid use (%)	68/67 (85)	29/56 (51)	0.38
History of gestational hypertension (%)	19/62 (31)	7/56 (12)	0.63
History of gestational diabetes (%)	8/61 (13)	2/55 (4)	0.72
Birth information			
Induction at delivery (%)	56/69 (81)	26/58 (45)	0.15
Vaginal delivery (%)	34/69 (49)	19/58 (33)	0.28
Medical history			
PDA confirmed by echocardiography before diagnosis of NEC* (%)	36/65 (55)	17/58 (29)	0.63
Abdominal wall discontinuity (%)	19/69 (27)	18/58 (31)	0.80
Abdominal distention (%)	63/69 (91)	31/58 (53)	0.06
Greenish bloody stools (%)	21/68 (31)	6/58 (10)	0.12
Peritoneal perforation (%)	5/69 (7)	7/58 (12)	0.64
Peritonitis intra-abdominal (%)	40/69 (58)	19/58 (33)	0.05
Pneumonia (%)	16/69 (23)	2/58 (3)	0.06
Feeding intolerance (%)	50/69 (72)	21/58 (36)	0.07
Asphyxia on the day of diagnosis (%)	46/71 (65)	24/54 (44)	0.11
Antibiotic use on the day of diagnosis (%)	63/69 (91)	34/58 (59)	0.73
Vancomycin use on the day of diagnosis (%)	28/69 (41)	13/58 (22)	0.79
Ventilator use on the day of diagnosis (%)	71/69 (102)	24/58 (41)	0.05
Fluoride <100 kcal on the day of diagnosis (%)	16/63 (25)	4/55 (7)	0.28
WBC >12.5 × 10 ⁹ on the day of diagnosis (%)	19/62 (31)	16/55 (29)	0.76
Ever sepsis before surgery for NEC (%)	26/69 (38)	19/58 (33)	0.74
Ever Gram-negative culture before surgery for NEC (%)	17/69 (25)	2/58 (3)	0.14
Feeding history			
Days of PN before surgery for NEC, median (Q1-Q3)	12 (1-22)	8 (0-11)	0.007
Received PN on or before day of diagnosis (%)	76/87 (87)	24/58 (41)	0.01
Received breast milk on or before day of diagnosis (%)	57/77 (74)	12/58 (21)	0.05
Received formula on or before day of diagnosis (%)	40/71 (56)	13/55 (24)	0.01
% of preoperative kcal/kg/day from parenteral carbohydrate	54.2 (49.5-63.0)	55.7 (46.0-61.7)	0.71
% of preoperative kcal/kg/day from parenteral fat	28.1 (13.4-32.7)	27.2 (20.3-36.5)	0.80
% of preoperative kcal/kg/day from parenteral protein	15.4 (13.4-20.2)	15.3 (12.1-19.5)	0.38
Surgical interventions (%)			
Exploratory laparotomy	73/87 (84)	25/58 (43)	0.05
Hemostat valve resection	23/87 (26)	2/58 (3)	0.008
Jejunostomy	17/87 (19)	6/58 (10)	0.004
Large bowel resection	26/89 (29)	9/58 (15)	0.32
Small bowel resection	19/89 (21)	13/58 (22)	0.001
Small bowel resection or jejunostomy	45/89 (50)	17/58 (29)	0.0003

TABLE 3. Independent predictors of PNALD (N = 127)

	Odds ratio (95% CI)	P
Weeks of PN*	2.37 (1.56-3.60)	<0.0001
Small-bowel resection or jejunostomy	4.96 (1.97-12.51)	0.0007

CI = confidence interval; PN = parenteral nutrition; PNALD = parenteral nutrition-associated liver disease.

* Cumulative exposure from birth through 4 weeks after surgery.

Direct bilirubin trends

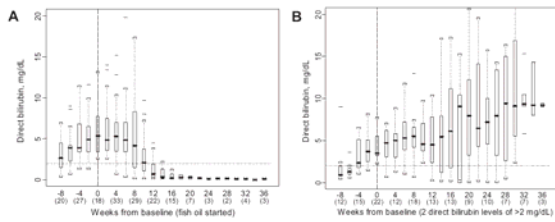


FIGURE 1 Direct bilirubin trajectories over time (weeks from baseline) for the fish-oil (A) and soybean (B) cohorts. Box plots represent the distribution of direct bilirubin levels in each 2-week interval plotted at the end of the interval, except for the bar at week 0, which represents only direct bilirubin measures at baseline. The number of observations contained in each 2-week interval is in parentheses. The solid bar within the box represents the median value; upper boundary of the box, the 75th percentile; lower boundary of the box, 25th percentile. Whiskers extend to the most extreme observation within 1.5 IQR units of the 25th and 75th percentiles.

Pediatrics 2008; 121:e678

TABLE 4 Comparison of Safety Markers for the Period Before Fish Oil, From 30 Days After Starting Fish Oil Until the End of Follow-up (Primary Comparison) and From the Date in Which Fish Oil Was Started Until Day 30 of Treatment

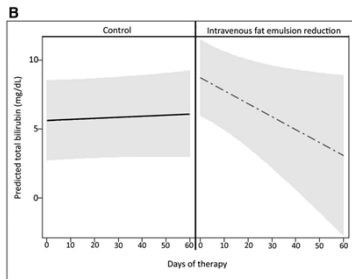
Variable	Before Fish Oil (N = 17)*	After Fish Oil	
		30 d to End (N = 17)*	0-30 d (N = 18)
Essential fatty acid deficiency			
Triene/tetraene ratio >0.2, n (%)	—	1 (5.9)	1 (5.6)
Maximum triene/tetraene, median (minimum, maximum)	—	0.05 (0.016, 0.28)	0.04 (0.02, 0.33)
Hypertriglyceridemia (triglycerides > 400 mg/dL), n (%)	1 (5.9)	0 (0.0)	0 (0.0)
Maximum triglycerides, median (minimum, maximum)	196 (89, 441)	162 (51, 336)	182 (107, 383)
Bleeding and coagulopathies			
INR >2, n (%)	1 (5.9)	0 (0.0)	0 (0.0)
Mean INR, median (minimum, maximum)	1.1 (0.99, 1.71)	1.1 (0.96, 1.33)	1.1 (0.92, 1.39)
Mean level of platelets, median (minimum, maximum)	175 (78, 390)	292 (103, 462)	220 (88, 380)
Minimum level of platelets, median (minimum, maximum)	104 (30, 298)	179 (26, 331)	145 (41, 268)
Infections			
No. of new infections per week, median (minimum, maximum)	0.24 (0, 1.29)	0.25 (0.06, 1.56)	0.25 (0, 1.0)
No. of central line infections per week, median (minimum, maximum)	0.13 (0, 0.57)	0.18 (0, 1.0)	0 (0, 0.67)
No. of Gram-positive infections per week, median (minimum, maximum)	0 (0, 0.29)	0 (0, 0.35)	0 (0, 0.25)
No. of Gram-negative infections per week, median (minimum, maximum)	0 (0, 0.26)	0.01 (0, 1.0)	0 (0, 0.33)
Growth			
Weight-for-age z score, mean ± SD	-4.2 ± 1.6	-4.5 ± 2.0	-4.4 ± 1.7

Unanswered questions

- Are these “Omegaven” or “absence of Intralipid” effects?
- What is the natural history of infants treated with omegaven?
- Does improvement of cholestasis herald prevention of cirrhosis?
- Can PNALD be prevented with omega-3 fats?
- Mechanisms?

Intravenous Fat Emulsions Reduction for Patients with Parenteral Nutrition-Associated Liver Disease

Mary Petrea Cober, PharmD, BCNSP, Ghassan Killu, PharmD, Allison Brattain, PharmD, Kathleen B. Welch, MS, MPH, Shaun M. Kunisaki, MD, and Daniel H. Teitelbaum, MD



J Pediatrics 2011

Controversies

- Is it safe to provide so many calories using parenteral dextrose?
 - Dalton et al., NASPGHAN 2013
- Is it effective to limit fat to 1 g/kg/d re: cholestasis prevention?
 - Nehra et al., JPEN 2013
 - Levit et al., PAS 2013

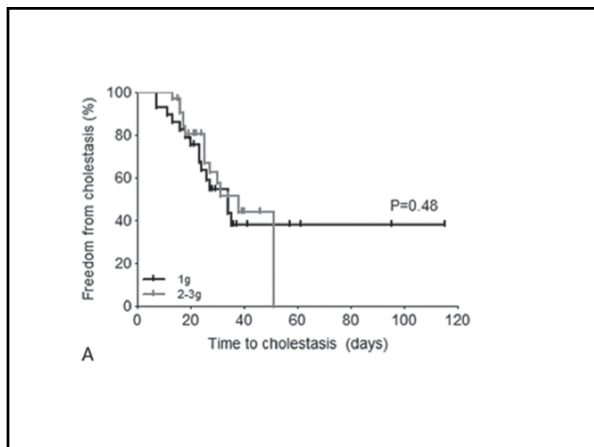
Provision of a Soy-Based Intravenous Lipid Emulsion at 1 g/kg/d Does Not Prevent Cholestasis in Neonates

Deepika Nehra, MD¹; Erica M. Fallon, MD¹; Sarah J. Carlson, MD, MSc¹; Alexis K. Potemkin, RN²; Nathaniel D. Hevelone, MPH¹; Paul D. Mitchell, MSc¹; Kathleen M. Gura, PharmD¹; and Mark Puder, MD, PhD¹

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- 61 infants with surgical GI disease who received PN for at least 3 weeks at BCH
- 29 received 1 g/kg/d of IL
- 32 received 2-3 g/kg/d



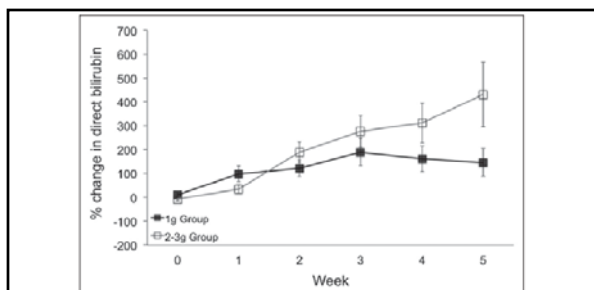


Figure 3. Percent change in direct bilirubin from baseline (week 0) to week 5 for the 1-g and 2- to 3-g groups. The percent change in direct bilirubin compared with baseline increased over time in both groups ($P < .001$), with the 2- to 3-g group marginally higher than the 1-g group at week 5 only ($P = .05$). Data represent mean \pm SEM (adjusted for baseline direct bilirubin using the generalized estimating equation model).

[4170.4] Intravenous Fat Emulsion (IFE) for the Prevention of Parenteral Nutrition Associated Liver Disease (PNALD) in Preterm Neonates

Orly L. Levit, Kara L. Calkins, Lorraine I. Kellef-Quon, Leena C. Gibson, Daniel T. Robinson, David A. Elashoff, Tristan R. Grogan, Matthew J. Bizzarro, Richard A. Ehrenkranz. Pediatrics, Yale University School of Medicine, New Haven, CT; Pediatrics, David Geffen School of Medicine-UCLA, Los Angeles, CA; Statistics, David Geffen School of Medicine-UCLA, Los Angeles, CA; Pediatrics, Feinberg School of Medicine, Northwestern University, Chicago, IL.

Variable	Arm Mean(SD,%)	3gm/kg/d(N=66)	p-value
BW(gm)	884 (278)	930 (288)	0.34
GA(weeks)	26.4 (1.7)	26.4 (1.7)	0.79
Male gender	40(64)	40(61)	0.73
SGA	17(27%)	11 (17%)	0.16
NEC	11(18%)	9 (14%)	0.52
Weight at 28 days	1120 (356)	1210 (362)	0.17
Weight velocity at discharge	20.0(4.3)	20.1(4.4)	0.86
Duration of TPN	25.5(20.4)	24.7(19.7)	0.83
TB at full feeds	2.7(2.4)	3 (2.7)	0.55
DB at full feeds	0.9(1.4)	0.7(1)	0.56
PNALD	41 (71%)	37 (62%)	0.30
Length of stay	96.5 (53.0)	86.7(34.0)	0.22

“Our” Current Approach

- Limit IL dose to 1 g/kg/day among all patients likely to be on PN for > 3 weeks
 - NAC
 - Including NICU
 - Make up calories with dextrose
- If a patient meets criteria for Omegaven protocol, switch them to 1 g/kg/day of this experimental therapy

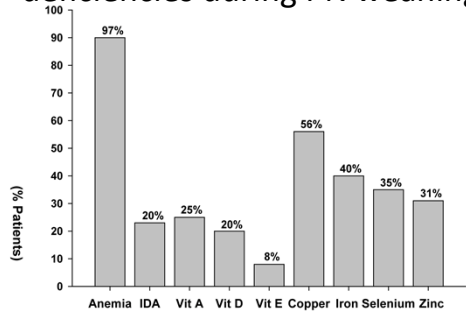
Learning Objectives

- To review indications for intravenous fat emulsions in patients with intestinal failure
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“Total” parenteral nutrition

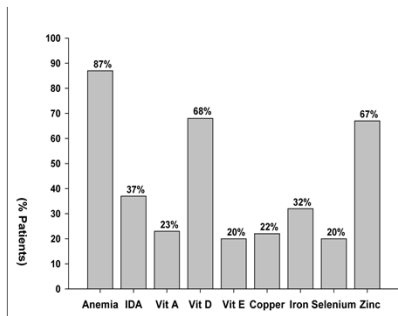


Prevalence of micronutrient deficiencies during PN weaning



Yang et al., J Pediatr 2011

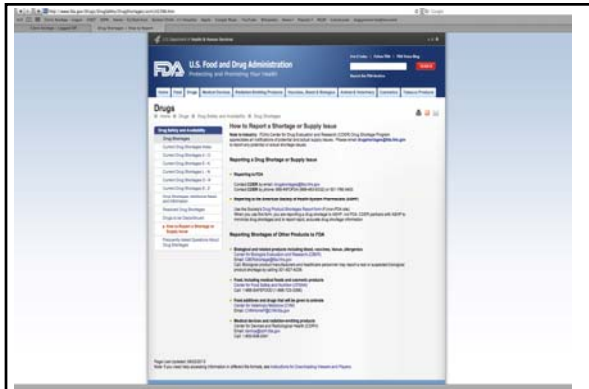
Prevalence of micronutrient deficiencies during full EN



Yang et al., J Pediatr 2011

Parenteral component shortages

- Phosphate
- Multivitamins
- Trace elements
- Ethanol



<http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm142398.htm>

Centers for Disease Control and Prevention
MMWR Morbidity and Mortality Weekly Report
Weekly / Vol. 62 / No. 7 February 22, 2013

Notes from the Field

Zinc Deficiency Dermatitis in Cholestatic Extremely Premature Infants After a Nationwide Shortage of Injectable Zinc — Washington, DC, December 2012

- 3 premature infants in NICU with cholestasis and PN dependency developed skin lesions
- Blood, urine, CSF and wound cultures were negative

FIGURE. Zinc deficiency dermatitis manifesting as bullous and erosive lesions on the hands and feet of a newborn infant — Washington, DC, December 2012



Photo: S.A. Norton, Children's National Medical Center

CASE REPORT

Drug Shortage—Associated Increase in Catheter-Related Blood Stream Infection in Children

AUTHORS: Matthew W. Raftis, MD,* R. Alexander Blackwood, MD, PhD,* Meghan A. Arnold, MD,* M. Luisa Partigilo, PharmD, BSNP,† James Dimond,* and Daniel H. Teterbeum, MD†

abstract

BACKGROUND: Ethanol lock therapy (ELT) has been shown to reduce Teterbeum, MD†

TABLE 1 Mean Rate of CRBSI per 1000 Catheter Days ± SD

	Pre-ELT (historical)	Daily ELT (historical)	Daily ELT	Less than daily ELT*	P value
Daily ELT ^{historical} VS Daily ELT ^{current}	8.0 ± 5.4	1.3 ± 3.0	0.68 ± 1.27	6.16 ± 2.5	.55
Daily ELT ^{historical} VS less than daily ELT		1.3 ± 3.0	0.68 ± 1.27	6.16 ± 2.5	<.001*
Daily ELT ^{current} VS less than daily ELT			0.68 ± 1.27	6.16 ± 2.5	<.001*
Pre-ELT ^{historical} VS less than daily ELT	8.0 ± 5.4			6.16 ± 2.5	.27

* Less than daily is defined as either twice weekly or weekly administration.
 † Statistically significant.

Parenteral Component Shortages

- Raw material shortages
- Discontinuations
- Fewer manufacturing firms
- Limited capacity of remaining companies to increase supplies

« **People & Politics** »

“Children Are Dying”

Comments (2) | Published May 22, 2013



In October 2011, President Obama signed an executive order telling the FDA to work harder to address drug shortages. Health advocates say the crisis he forecast at that time is now here. Photograph by Kristoffer Tripstam-Pool/Getty Images.

<http://www.washingtonian.com/articles/people/children-are-dying/index6.php>

« **People & Politics** »

Celebrity Trend Uses Nutrients Hospitals Desperately Need

Experts say, “We’ve got babies’ lives hanging in the balance while we’re worried about getting through a hangover.”
By *Alexandra Robbins*

Comments (2) | Published July 26, 2013

It’s been called the new “it” bag. The “vitamin drip”—a trendy, expensive treatment of vitamins and nutrients delivered intravenously—is billed as a way to energize and reenergize those who are tired, stressed out, dehydrated, or too hungover to get a good night’s sleep.

X Factor judge Simon Cowell swears by it. Madonna, Cissy Crawford, and the Miami Heat’s Rashard Lewis have been rumored to be fans.

Meanwhile, unbeknownst to them, patients across the country—especially premature babies—have been malnourished because of a lack of some of the same nutrients used in the vitamin drip.

In late May, *Washingtonian* reported that nationwide shortages are threatening the lives of patients who need IV nutrition to survive. Hospitals have resorted to hoarding, rationing, and bartering. At least 15 people—almost certainly more—have died. The shortages particularly endanger infants in neonatal intensive-care units (NICUs), whose





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Miami IV Nutrition Menu

Services > IV Therapy > IV Therapy > IV Nutrition Menu



Adonis Maiquez, MD
 Director of Wellness & Regenerative Medicine
 Wellness & Anti-Aging Physician

There is a connection between feeling well, being well and living a full, vibrant life. Dr. Adonis Maiquez believes this should be the norm, not the exception to the rule of aging. If you feel

SBAR: 4/24/2013 Medication Backorders

S Sodium Phosphate and Potassium Phosphate are on national backorder at this time.

B These products are used in parenteral nutrition, hypophosphatemia, and in diabetic ketoacidosis IV fluids. These electrolytes have been on backorder with small allocations for a period of time and supply is now almost depleted.

A

1. Sodium Phosphate 3 mmol/mL injection – 3 vials remaining
2. Potassium Phosphate 3 mmol/mL injection – 5 vials remaining

R

Effective immediately – 4/24/2013

- **Sodium Phosphate** injection – Supply is depleted except for a very small number of vials (3). These vials will be sequestered for ICU emergent use and/or in the DKA patient population. Pharmacy is expecting a shipment by the end of this week.
- **Potassium Phosphate** injection– Supply is almost depleted except for a very small number of vials (5). This product will be sequestered for ICU emergent use and/or in the DKA patient population.
- DKA floorstock fluids as they currently exist will no longer be manufactured by Pharmacy due to this backorder.
- Phosphate will NOT be included in parenteral nutrition mixtures at this time.

Recommendations for Trace Element Shortages

For patients receiving 7 nights of parenteral nutrition (PN) and/or <50% enteral feeds

Biochemical monitoring: complete blood count (CBC) with differential, copper, ceruloplasmin c-reactive protein (CRP), vitamin A*

*Vitamin A to be checked if not monitored in the past 6 months. Rationale: evaluate for risk of hypervitaminosis A

Patients 2 years and older:
 Start Flintstones® Complete multivitamin for supplementation

Patients under 2 years of age:
 Provider discussion

For patients receiving less than 7 nights of PN and >50% enteral feeds:

Biochemical monitoring: CBC with differential, copper, ceruloplasmin, CRP at time patient is impacted.

If impacted by zinc or selenium shortage, monitor these levels

No additional supplementation needed. Encourage copper (zinc if applicable) rich foods (see appendix)

Repeat CBC with differential, copper, ceruloplasmin (zinc and selenium as applies) in 2 months' time

Courtesy Home PN Program Boston Children's Hospital

Peditrace™

Concentrate for solution for infusion

Trace element additive solution for pediatric patients on total parenteral nutrition.

COMPOSITION

1 ml contains:

Zinc chloride	521 µg
Copper chloride 2H ₂ O	53.7 µg
Manganese chloride 4H ₂ O	3.60 µg
Sodium selenite anhydrous	4.38 µg
Sodium fluoride	126 µg
Potassium iodide	1.31 µg
Hydrochloric acid to pH 2	
Water for injections to 1 ml	

PROPERTIES

Sterile solution containing trace elements for addition to amino acid solution or glucose solution (see compatibility) in the parenteral nutrition of premature and fullterm infants and children.

0

IV Multivitamin Reference Tool:

Vitamin	Pediatric Hospira (5ml)	Pediatric Infuvite Baxter (5ml)	Adult Hospira (10ml)	MVI-12 Hospira (10ml)	Adult Infuvite Baxter (10ml)
A	0.7mg (retinol)	2300 units (palmitate)	1 mg (retinol)	1mg (retinol)	3300 units (retinol)
D	10mcg (ergo)	400 units (chole)	5mcg (ergo)	5mcg (ergo)	200 units (chole)
E	7mg	7 units	10 mg	10mg	10 units
K (phytonadione)	200mcg	200mcg	150mcg	None	150mcg
C (ascorbic acid)	80mg	80mg	200mg	200mg	200mg
B-1 Thiamine	1.2 mg	1.2mg	6mg	6mg	6mg
B-2 Riboflavin	1.4mg	1.4mg	3.6mg	3.6mg	3.6mg
Niacinamide	17mg	17mg	40 mg	40mg	40mg
Dexpanthenol	5mg	5mg	15mg	15mg	15mg
Biotin	20mcg	20mcg	60 mcg	60mcg	60mcg
B-12	1 mcg	1 mcg	5 mcg	5mcg	5mcg
B-6 Pyridoxine	1mg	1mg	6mg	6mg	6mg
Folic Acid	140mcg	140mcg	600mcg	600mcg	600mcg

Table courtesy Home PN Program Boston Children's Hospital

Conclusions

- Current approach to prevent/treat PNALD is not 100% clear at this time.
- Shortages of components of PN have significant implications for our patients.
- Biochemical monitoring is critical to document nutrient deficiency states.
- Advocacy efforts must continue.
