

## How to deal with micronutrient product shortage - Editorial

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Intravenous micronutrients (MN) shortage has become a recurrent problem for medical nutrition therapy (MNT) and especially for patients depending on parenteral nutrition (PN) [1,2]. Micronutrients, an umbrella term used to describe vitamins and trace elements (TEs), are essential components of nutrition and their absence poses a considerable risk to the patient's nutritional status [3,4] with the development of deficiencies, metabolic dysfunction, and in some cases, death. When PN is total (or exclusive) as in chronic intestinal failure (CIF), it aims to cover the patient's nutritional needs entirely including those of all essential MN [1,2].

Facing recurrent shortages of intravenous MN preparations for PN, the American Society for Parenteral and Enteral Nutrition (ASPEN), published in 2016 shortage considerations to assist clinicians in coping with these periods [5,6]. The authors recommended assessing and reassessing each patient regarding the indication for PN and providing nutrition via the oral or enteral route, when possible: they also recommended switching to orally or enterally administered products when this is possible [7]. A summary of their statements is provided in Table 1: these recommendations remain valid. Facing the repetition of shortage, ASPEN proposed further options online in 2021. The British Society proposed similar recommendations [7], including the advice to monitor MN levels more frequently than previously, especially if there is any clinical suspicion or concern of MN deficiency.

The COVID-19 pandemic worsened the risk of shortage. In several countries, the conversion of production chains towards SARS-CoV2-vaccine, impacted MV provision with the companies Baxter no longer providing Cernevit® in normal amounts until the first quarter of 2022, and Fresenius-Kabi not being able not compensate with the alternative Soluvit®-Vitalipide® combination. Health facilities and wholesale distributors received less than 50% of their normal orders. The situation reverted gradually to quasi-normality from April 2022.

In this editorial, we aim to provide an updated list of general principles to assist professionals in handling the problem of micronutrient shortage in patients receiving PN. These recommendations

### Abbreviations:

CIF	chronic intestinal failure
HPN	home parenteral nutrition
IV	intravenous
MNT	medical nutrition therapy
MN	micronutrient
MTE	multiple trace element
MV	multivitamin
PN	parenteral nutrition
TE	trace element
ASPEN	American Society for Parenteral and Enteral Nutrition
AuSPEN	Australasian Society for Parenteral and Enteral Nutrition
ESPEN	European Society for Clinical Nutrition and Metabolism
HAN-CIF	Home Artificial, Nutrition CIF Special Interest Group
BIFA	British Intestinal Failure Alliance

cover both hospital and home PN, with a special focus on intestinal failure.

### 1. Defining the intravenous micronutrient needs

Awareness of micronutrient needs and deficiencies in PN goes back to the development of PN in the 1960–1970s and the publication of multiple deficiency case reports [8–10]. The limited availability of IV multivitamin (MV) products resulted in deficiencies of several vitamins including the B family, C, A and D, after prolonged PN [11]. Many cases of Zn deficiency were documented, as were Cu-deficient patients who had no Cu added to their PN [12]. The first medical body to react formally to these deficiencies was the Nutrition Advisory group of the American Medical Association: vitamin and trace element requirements received attention in 1979 [13,14]. The FDA validated the proposed intravenous (IV) vitamin formulations, including nine water-soluble and four lipid-soluble vitamins. Also in 1979, the US guidelines for essential trace element preparations for PN were published [14], but included only copper, chromium, manganese, and zinc. Thereafter, numerous case reports described Se deficiency in adults and children on PN without Se for prolonged periods [12], leading to the recommended inclusion of selenium. Further evidence suggested that the available parenteral MTE preparations required revision with recommendations including the reduction of Manganese (Mn) and Copper (Cu) [12,15,16]. It was also stated that there was a need for a separate

**Table 1**  
Summary of the principal recommendations made by the ASPEN clinical practice committee.

ASPEN Vitamins [6]	ASPEN Trace elements [5]
Assess and routinely reassess each patient as to the indication for parenteral nutrition (PN) and provide nutrition via the oral or enteral route when possible. Reserve intravenous multi-vitamins and trace elements for those patients receiving solely PN or those with a therapeutic medical need for intravenous multivitamins. Purchase only as much supply as needed	
Use a 13-vitamin product	If IV MTE products are no longer available, administer individual parenteral trace element entities
Use a 12-vitamin product (without vitamin K) if 13-vitamin product is unavailable	
In patient on warfarin:	
Use a 12-vitamin product (without vitamin K)	When all options to obtain IV Adult multi-trace element products have been exhausted, ration IV Adult MTE products in PN, such as reducing the daily dose by 50% or giving 1 MTE product infusion 3 times a week
Use a 13-vitamin product (with vitamin K) if the 12-vitamin product is unavailable: monitor and adjust anticoagulation	
When all options to obtain IV multivitamins have been exhausted, ration IV multivitamins in PN, such as reducing the daily dose by 50% or giving 1 multivitamin infusion dose 3 times a week	Withhold IV Adult MTE products from adult patients receiving partial enteral/parenteral nutrition or who can tolerate oral/enteral supplements.
If IV multi-vitamins are no longer available, administer individual IV vitamin entities: Thiamine 6 mg, ascorbic acid 200 mg, pyridoxine 6 mg, folic acid 0.6 mg daily, and B <sub>12</sub> 100–1000 mcg, vitamin K 150 mcg may be given weekly <sup>a</sup>	Consider withholding IV adult MTE products for the first month of therapy to newly initiated adolescent and adult PN patients who are not critically ill or have pre-existing deficits
The use of pediatric IV multivitamins for adults is not recommended	The use of Pediatric and Neonatal IV multi-trace element products for adults is strongly discouraged

<sup>a</sup> Because individual IV vitamin entities are highly concentrated and very small volumes are required to provide a recommended dose, the ASPEN authors consider administering larger doses less frequently than daily.

injectable vitamin D preparation [16]. Today iron deficiency remains frequent in HPN affecting over 30–60% patients as shown by a cohort of 185 patients [17] as iron remains absent from the MTE products in numerous countries.

In addition to the above uncertainty regarding the MN needs, it became apparent in the early 21st century that the day-to-day administration of vitamins and TEs in routine clinical practice was highly variable, and often considered optional in some countries, particularly regarding TEs [3]: the name “total” PN was misleading giving the illusion that every nutrient was included in the macro-substrate bags. This led the European Society for Clinical Nutrition and Metabolism (ESPEN) to state in 2009 the necessity to prescribe one IV MV and a multiple trace element (MTE) dose for each day of PN [18], a statement that was reinforced in 2019 [19]. A similar statement was published by ASPEN in 2012 [16], and by the Australasian Society for Parenteral and Enteral Nutrition (AuSPEN) [20,21]. In the 2022 ESPEN micronutrient guidelines [4], practical recommendations have been included, recognizing that the needs differ in patients with long-term PN or HPN, from those with high requirements (GI losses, continuous renal replacement therapy, hypermetabolism, malnutrition or depletion before commencing PN, and in pregnancy).

## 2. Classification of intestinal failure

Intestinal failure has been classified by clinical criteria (intravenous supplementation volume and energy needs), pathophysiological criteria (short bowel, dysmotility, fistulas, obstruction, mucosal disease), and functional criteria (type I acute, short-term condition, type II - prolonged acute condition, and type III - chronic) [22]. The management of these differs, as does the dependence on intravenous nutrient supply [23].

## 3. Consequences of shortage

The MNs discussed above are by definition “essential”: so, do the shortages have consequences? Certainly, but this has been poorly documented, being only described in a few papers as “low plasma levels”, i.e. levels below their laboratories reference ranges without documenting level of inflammation [4,24]. Nevertheless a large observation study in 96 HPN patients showed a high proportion of low TE levels during shortage periods [25].

## 4. Monitoring to detect deficiencies

Regardless of the approach utilized, close monitoring of MN will be essential to prevent complications. Depending on the duration of the shortage, we encourage a more frequent assessment of blood levels, especially when an upcoming shortage is announced. Despite the pitfalls associated with interpretation on context of inflammation that diverts the MNs from the circulating compartment, a repeated determination (together with CRP) will enable detecting an undesired decrease in the levels. Adding functional markers of MN status to reach a clinically relevant diagnosis will reduce the uncertainty [24]. For each home PN patient, a protocol for tests required both on commencing and during MNT may be helpful [24]. Obviously, in case of a shortage, it is even more important to determine the status of the MNs at risk and increase the frequency of this monitoring. The time between reviews will largely depend on the patient's anatomy, medical co-morbidities, care setting, duration of nutrition support as well as the expected speed with which the impairment of a parameter is likely to occur, but also test availability and reimbursement (see Table 2).

**Table 2**  
Main additional ESPEN recommendations.

General considerations	Specific situations
All compensatory measures should be considered as “degraded alternatives” and therefore require increased monitoring of nutritional status of micronutrients	Return to current recommendations as soon as shortage ends
Reserve IV MV or MTE in some priority indications and temporarily use the oral/enteral route for MV or MTE administration	Do not use paediatric IV MNs for adults, as this will deplete the stock of these products and paediatric patients have an even greater needs to enable growth and development.
Provide MNs via the sublingual, oral or enteral route when possible and deemed to be safe (excluding patients with malabsorption syndromes)	
During shortage, reserve IV and TE micronutrient products for those patients receiving PN or those with a therapeutic medical need for	<b>High risk patients:</b> <ul style="list-style-type: none"> <li>• Neonates</li> <li>• Paediatric patients receiving PN and unable to tolerate oral/enteral MNs.</li> </ul>

**Table 2** (continued)

General considerations	Specific situations
IV vitamins/trace elements such as high-risk patients	<ul style="list-style-type: none"> <li>Inherited metabolic disorders.</li> <li>Patients with intestinal failure unable to absorb any oral or enteral MN preparations.</li> <li>Patients on long-term home PN (<math>\geq 3</math> months).</li> <li>Patients on home PN unable to absorb any oral or enteral MN preparation</li> <li>Patients who are intolerant with confirmed side effects or allergic to oral or enteral MN preparations.</li> <li>Intestinal failure with high GI losses (high output ostomies, fistulae, etc.)</li> <li>Patients at extremely high risk of refeeding syndrome upon initiation of PN</li> <li>Patients on PN requiring critical care</li> </ul>

## 5. Alternatives in case of shortage

### 5.1. Oral multivitamin option

The parenteral MV shortages that were initially described in the US resulted in proposing oral alternatives, but the length of time a patient on HPN could be maintained on oral MNs is not clear. Data are limited, but three studies indicate that the oral route is likely to result in deficiencies.

During a prolonged MV shortage, daily MV doses were reduced to 3 times weekly in 8 patients on HPN [26]. Blood testing for vitamins was increased. Ascorbic acid was the most affected with blood level reduction in 7/8 patients: low levels of retinoids, niacin, pyridoxine, and riboflavin were less frequent.

**Table 3**  
Specific recommendations.

Setting	Multivitamin Shortage	Multi-trace element shortage
Hospital Setting	<ul style="list-style-type: none"> <li>Consider the use of single MN formulation depending on the type of patient and availability in each country.</li> </ul>	<ul style="list-style-type: none"> <li>Consider the use of single trace element formulation depending on the type of patient and availability in each country.</li> </ul>
<b>Type 1 acute IF</b> requiring exclusive PN for a few days (7–10 days)	<ul style="list-style-type: none"> <li>If IV MV are not available, administer individual IV vitamin entities according to clinical requirements.</li> <li>Thiamine, ascorbic acid, pyridoxine, and folic acid should be given daily according to clinical requirements.</li> </ul>	<ul style="list-style-type: none"> <li>If IV MTE are not available, in the absence of specific needs the risk of clinical significant deficiencies is low and does not require administration of individual parenteral trace elements</li> </ul>
<b>Type 2 prolonged acute IF</b> , requiring PN for weeks/months	<ul style="list-style-type: none"> <li>Exclusive (total) parenteral nutrition with no oral/enteral intake: one MV product in each PN bag</li> <li>Supplemental PN with oral/enteral intake: one MV in each bag</li> </ul>	<ul style="list-style-type: none"> <li>Exclusive (total) parenteral nutrition with no oral/enteral intake: one MTE product in each PN bag</li> <li>Supplemental PN with oral/enteral intake: one MTE in each bag</li> </ul>
<b>Type 3 Chronic IF</b> , requiring PN for months to years	<ul style="list-style-type: none"> <li>Exclusive (total) parenteral nutrition with no oral/enteral intake: one MV produce in each PN bag                             <ul style="list-style-type: none"> <li>Alternatively, administer individual parenteral vitamin entities with suggested daily IV doses of thiamine 6 mg, folate 0.6 mg, ascorbic acid 200 mg, and pyridoxine 6 mg unless deficiency not suspected or otherwise clinically indicated.</li> <li>IV vitamin K dosing is 0.5–1 mg/day or 5–10 mg per week.</li> <li>Administer cyanocobalamin (B12) 100–1000 mcg intramuscular or deep subcutaneous at least once monthly, 500 mcg intranasal once weekly or 1000 mcg sublingual once daily.</li> </ul> </li> <li>Supplemental PN with oral/enteral intake: one MV in each bag and oral MV on all non-PN days</li> </ul>	<ul style="list-style-type: none"> <li>Exclusive (total) parenteral nutrition with no oral/enteral intake: one MTE product in each PN bag</li> <li>Supplemental PN with oral/enteral intake: one MTE in each bag and oral TE provided on the day off of IV supplementation along with monitoring of nutrition status (zinc, selenium, copper).</li> <li>When all options to obtain IV MTE products have been exhausted, ration IV MTE products in PN by reducing daily dose by 50% or giving one MTE product infusion 3 times per week.</li> </ul>

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The sufficiency of oral MV administration was assessed in 10 adults with short bowel syndrome, dependent on PN for a range of 4–101 months [27]. PN cycles during regular hospital admissions (mean 4 days) were alternated with oral nutrition and vitamin supplements at home: 20% of patients had low adherence to oral vitamins. Folic acid and vitamin B<sub>12</sub> levels were little affected but vitamins A, C, and E levels became low [27].

Intermittent cycles of PN during hospitalization and oral feeding at home were tested in 8 patients with short bowel syndrome: PN with IV multi-MN was administered for 5–8 days with an interval of 10–40 days of oral feeding and multi-MNs between cycles [28]. Upon readmission to hospital, vitamin C, D, E and K were low, showing inadequacy of the oral intake.

In cases of oral MV delivery, the risk of reduced intestinal absorption must be considered: increasing the standard dose of the MN may be needed, with appropriate onward close monitoring. Another risk is the insufficient supply of oral MV products if the latter are being increasingly used to address parenteral shortages. Further the generalisation of oral MV administration incurs the risk of not returning to parenteral when these become available. Furthermore, as noted above and as evidenced following bariatric surgery [29] adherence to oral complements can be low. In some countries, lack of reimbursement for oral therapies may reduce adherence. It is vital to explain the importance of these oral treatments to patients.

### 5.2. Rationing IV multi-micronutrients

To increase the number of patients benefiting from limited supplies, rationing the IV MN is an option. The aim is to prioritize patients at high risk for developing deficiencies such as those with the shortest remaining small bowel and/or absent/insufficient oral intake. Thus, patients with severe malabsorption and/or minimal oral intake, and/or total PN dependence should be considered a priority in comparison those receiving supplemental PN or non-daily PN (see Table 3).

**Table 3** (continued)

Setting	Multivitamin Shortage	Multi-trace element shortage
	<ul style="list-style-type: none"> <li>When all options to maintain stock levels of adult IV MV products have been exhausted, ration adult MN infusions (e.g. give 2–3 times per week instead of daily and supplement with oral/enteral and/or intramuscular preparations.</li> <li>Increase frequency of monitoring of vitamin status is recommended depending on clinical status.</li> <li>Given the stock of certain vitamins and in the absence of deficiencies prior to shortage, for patients on stable HPN, assessment of vitamins should be performed every month instead of 3–6 months (e.g. vitamin A, E, D, Folate, B12, B1, as well as prothrombin level).</li> </ul>	<ul style="list-style-type: none"> <li>Alternatively, consider administration of individual parenteral TE entities (e.g. zinc 5 mg per day and selenium 100g per day).</li> <li>Increased frequency of monitoring of TE status is recommended depending on clinical status.</li> <li>Assessment of TE (zinc, copper, and selenium) should be performed on a monthly basis instead of 3–6 months.</li> </ul>

## 6. Conclusion

Shortages of varying components of PN have been exacerbated by supply chain issues in the setting of COVID-19 pandemic. At the level of each country, in addition to a patient-specific approach, it is important to integrate factors such as reimbursement, logistical aspects for vitamin/TE delivery, as well as practical methods of disseminating information to all hospitals, and relevant physicians, pharmacists, dietitians, nurses, home care agencies, and patients (patient associations). Significant changes may be necessary to prevent inventory waste, such as centralizing the compounding of PN (either in a centralized pharmacy or as outsourced preparation), preventing or reducing the unnecessary use of IV multi-MN in other indications such as patients receiving enteral nutrition or those capable of oral intake. In addition, there may be a need for increased monitoring for inadequacies or deficiencies followed by targeted replacement of individual micronutrients. Additionally, national PEN societies should be proactive in keeping patients and providers informed regarding shortages and adjusting alternative and safe approaches based on current national and/or local inventory levels. The PEN societies should call for careful blood monitoring during these periods. Importantly the shortage recommendations should not be used at other times outside of this crisis.

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Francisca Joly\*<sup>1</sup>

Department of Gastroenterology and Nutritional Support, Center for Intestinal Failure, Reference Centre of Rare Disease MarDI, AP-HP Beaujon Hospital, University of Paris Inserm UMR 1149, Paris, France

Manpreet Mundi<sup>1</sup>

Division of Endocrinology, Diabetes, Metabolism, and Nutrition, Mayo Clinic, Rochester, MN, USA

E-mail address: [mundi.manpreet@mayo.edu](mailto:mundi.manpreet@mayo.edu).

Rocco Barazzoni<sup>1</sup>  
Department of Medical, Surgical, and Health Sciences, University of  
Trieste, Trieste, Italy  
E-mail address: [barazzon@units.it](mailto:barazzon@units.it).

Mette M. Berger<sup>2</sup>  
Dpt of Adult Intensive Care, Lausanne University Hospital (CHUV),  
Lausanne, Switzerland  
E-mail address: [Mette.Berger@unil.ch](mailto:Mette.Berger@unil.ch).

Frederico Bozzetti<sup>1</sup>  
Faculty of Medicine, University of Milan, Milan, Italy  
E-mail address: [federicobozzetti@gmail.com](mailto:federicobozzetti@gmail.com).

Cristina Cuerda<sup>1</sup>  
Departamento de Medicina, Universidad Complutense de Madrid,  
Nutrition Unit, Hospital General Universitario Gregorio Marañón,  
Madrid, Spain  
E-mail address: [cuerda.cristina@gmail.com](mailto:cuerda.cristina@gmail.com).

Palle B. Jeppesen  
Department of Intestinal Failure and Liver Diseases, Rigshospitalet,  
Inge Lehmanns Vej 5 Opgang 3, 12. Og 16. Sal 2100 København Ø,  
Denmark  
E-mail address: [Palle.Bekker.Jeppesen@regionh.dk](mailto:Palle.Bekker.Jeppesen@regionh.dk).

Simon Lal  
Gastroenterology, Salford Royal & University of Manchester, UK  
E-mail address: [Simon.Lal@srft.nhs.uk](mailto:Simon.Lal@srft.nhs.uk).

Georg Lamprecht<sup>1</sup>  
Department of Medicine II, Division of Gastroenterology and  
Endocrinology, Rostock University, Medical Center, Rostock, Germany  
E-mail address: [georg.lamprecht@med.uni-rostock.de](mailto:georg.lamprecht@med.uni-rostock.de).

Kinga Szczepanek<sup>1</sup>  
General and Oncology Surgery Unit, Stanley Dudrick's Memorial  
Hospital, Skawina, Poland  
E-mail address: [kingaszczm@interia.pl](mailto:kingaszczm@interia.pl).

André Van Gossum<sup>1</sup>  
Department of Gastroenterology and Clinical Nutrition, Hopital  
Erasme/Institut Bordet Brussels, Belgium  
E-mail address: [Andre.VanGossum@erasme.ulb.ac.be](mailto:Andre.VanGossum@erasme.ulb.ac.be).

Stéphane Schneider<sup>1</sup>  
Gastroentérologie et Nutrition Clinique, CHU de Nice, Université Côte  
D'Azur, Nice, France  
E-mail address: [stephane.schneider@univ-cotedazur.fr](mailto:stephane.schneider@univ-cotedazur.fr).

Alan Shenkin<sup>2</sup>  
Institute of Aging and Chronic Disease, University of Liverpool,  
Liverpool, UK  
E-mail address: [shenkin@liverpool.ac.uk](mailto:shenkin@liverpool.ac.uk).

Geert Wanten<sup>1</sup>  
Department of Gastroenterology and Hepatology, Radboud University  
Medical Center, 6500 HB Nijmegen, the Netherlands  
E-mail address: [Geert.Wanten@radboudumc.nl](mailto:Geert.Wanten@radboudumc.nl).

Loris Pironi<sup>1</sup>  
Alma Mater Studiorum -University of Bologna, Department of Medical  
and Surgical Sciences, Italy

IRCCS Azienda Ospedaliero-Universitaria di Bologna, Centre for  
Chronic Intestinal Failure - Clinical Nutrition and Metabolism Unit,  
Italy  
E-mail address: [Loris.pironi@unibo.it](mailto:Loris.pironi@unibo.it).

\* Corresponding author.  
E-mail addresses: [francisca.joly@aphp.fr](mailto:francisca.joly@aphp.fr), [francisca.joly@gmail.com](mailto:francisca.joly@gmail.com)  
(F. Joly).

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<sup>1</sup> Members of the ESPEN Home Artificial, Nutrition Chronic Intestinal Failure (CIF) Special Interest Group.

<sup>2</sup> Members of the ESPEN Micronutrient special interest group.