

Intravenous multivitamin shortage management for parenteral nutrition: a Swiss perspective from the ESPEN survey

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Objectives The objective of this research was to elucidate the current practice of managing parenteral nutrition during intravenous multivitamin shortages in Switzerland with a focus on the last segment of the supply chain from the hospital to the HPN patient.

Methods We conducted 17 structured interviews based on but also extended from the 2018 ESPEN survey with experts involved in the hospital parenteral nutrition supply (healthcare professionals, a public servant, and industry representatives) and included patients on home parenteral nutrition.

Results Awareness and experience with intravenous multivitamin shortages were high among professionals but not in patients. Overall, eight (47%) of the professionals experienced long-lasting shortages (>90 days). Mentioned reasons for shortages were packaging material and transport issues, problems in the procurement of raw materials, lack of personnel due to the COVID-19 pandemic, changed industrial manufacturing prioritizing, e.g. for mRNA vaccines, the 2021 Suez Canal blockade, low market price, and national authorization withdrawal.

Conclusions The considerations set out in this paper make it clear that a combination of short-term measures is needed. Managing intravenous multivitamin shortages is a common task and European guidelines including prioritization of patients relying on intravenous multivitamins are warranted as the home parenteral nutrition care is complex affecting highly vulnerable patients.

Keywords: deficiency, drug shortage, multivitamin, (home) parenteral nutrition, management guidance

Introduction

Intravenous (IV) multivitamins play a critical role in the parenteral nutrition (PN) regimen for patients who cannot meet their nutritional needs through the oral or enteral route, thus ensuring adequate intake of essential micronutrients [1]. Multivitamin supplementation in the parenteral nutrition setting is essential for comprehensive nutritional care from the very beginning of a PN as partially, e.g. for water-soluble vitamins with no or insufficient body stores; without it, the risk of vitamin deficiencies is significantly increased, with potentially serious or even fatal clinical consequences. Aligned with evidence-based clinical guidelines to optimize patient outcomes, these micronutrients protect against deficiencies and support vital metabolic and cellular functions. However, the supply of these micronutrient supplements has been subject to repeated supply disruptions

over the last years triggered by the economic globalization and dislocation of drug substance manufacturing sites and the related labile resilience of supply chains [2], creating a risk of inadequate care for PN-dependent patients [3, 4]. During the COVID-19 pandemic, these supply problems were exacerbated, leading to significant shortages also of IV vitamins for PN in many countries [5]. Such shortages have far-reaching implications, not only affecting patient care and safety [6], but also placing a significant burden on healthcare professionals (HCPs) and the healthcare system [7, 8].

To mitigate the impact of these shortages and to ensure continued patient safety and quality of care, the current literature and the two most important international nutrition societies, the American Society for Parenteral and Enteral Nutrition (ASPEN) and the European Society for Clinical Nutrition and Metabolism (ESPEN), propose the

following strategic recommendations: Implementation of an evidence-based rationing protocol; use of oral or enteral alternatives when clinically feasible; real-time monitoring and centralized inventory management; engagement with manufacturers and regulatory bodies; multidisciplinary coordination and clinical oversight; education and communication strategies; policy development and emergency preparedness; and research and development of alternative formulations [2, 5, 9-15].

ESPEN has launched an international survey (distributed via newsletter to ESPEN members on August 11, 2021) on the current national practices of managing PN during shortages of IV multivitamins. In Switzerland, the Federal Office for National Economic Supply (FONES) is constitutionally mandated to ensure the supply of essential goods, including essentials health care products when the free market is not more able to provide the necessary supply to patients. Two preventive measures have been introduced and established by the Swiss State Supply Act [16] in a private-public partnership: (compulsory) drug monitoring and reporting for early detection of supply problems, and stockpiling of selected products for a warehousing of 3 months normal use, to be released only upon company (hospital) request and the approval by the federal government [17, 18]. The essentiality of PN and its components has been assessed in a specific FONES report, resulting at that time in a mandatory reporting of supply problems, but not yet the obligation of stockpiling [19].

We took the opportunity to first assess the validity of this ESPEN questionnaire for the Swiss supply chain assessment of IV vitamins, and 2nd to investigate the impact of this international IV multivitamin shortages focusing on the so far never evaluated last part of the supply chain, the hospital-to-patient segment, addressing ultimately also the affected HPN patients. Our research aimed to provide data on IV multivitamin shortages for their cause evaluation and the “national” measures in place in hospitals to manage the shortage for the continuity of the care and the avoidance of potential harm to patients with defined, or at best harmonized, approaches and a major responsibility of the hospital pharmacy to guarantee procurement and distribution of IV vitamins to the mostly vulnerable patients on long-term PN as a proposed and agreed strategy to manage shortages in Europe [2].

Methods

Study design

This study employed a qualitative research design utilizing structured interviews to gather insights from various stakeholders involved in PN mainly in the supply segment of hospital to their HPN patients. Therefore, the participants included hospital healthcare professionals such as physicians, hospital pharmacists, and dieticians, as well as employees from industry and representatives from FONES involved in hospital drug procurement, and patients receiving HPN. The structured interviews were conducted as part of an international survey initiated 2021 by the Home Artificial Nutrition and Chronic Intestinal Failure Special Interest Group of the ESPEN and also updating the shortage of micronutrients after corona but published only after termination of our study [5]. For the validation and adaptation purpose, all the ESPEN survey questions were used additional ones were implemented to mirror the specific Swiss situation aimed as national feedback to ESPEN (see interview structure).

Participants and recruitment

A total of 17 structured interviews were conducted as part of a Pharmacy Master's Thesis over a period of six months, from January to July 2022. Participants were selected based on recommendations from the thesis supervisors, without predefined inclusion or exclusion criteria. Potential experienced interviewees were approached through informal channels, including introductions by the supervisors or affiliation within the research team. As the study authors have an established expertise in the Swiss HPN registry and at the university hospital in Bern (Inselspital) carrying most of the Swiss HPN patients [20-22], the interviewees' selection allowed a representative sample for the Swiss situation and including HPN-experienced professionals only. The aim was to achieve a broad representation of individuals involved in the PN supply chain, although no specific target number of participants was set.

Interview structure

Separate questionnaires were developed for each professional group and HPN patients, resulting in six distinct interview templates: one for hospital

pharmacists, one for physicians, one for dietitians, one for industry employees, one for the FONES representative, and one for HPN patients. Each interview template included questions from the ESPEN survey, which were supplemented with additional questions tailored to the national context of the survey. The first interview served as proof of concept and was conducted with the chief hospital pharmacist at the Inselspital, Bern University Hospital. Insights and analysis from this initial interview were used for the adaptation of subsequent questions. Each interview was structured to ensure consistency, and the questionnaires are included in the Supplementary Material (appendix 9 from the Ms Thesis, in German). The interviews covered a range of topics relevant to PN. The interviews were conducted either online or face-to-face, although the specific distribution of online versus offline interviews was not documented nor specifically selected and was due to the availability of the interviewees to keep the restricted study time frame.

Data analysis

Data analysis was performed using Microsoft Excel, focusing on a limited number of key questions that are highlighted in green in the Supplementary Material. The opinions of the interviewees were compared only on the common questions of the questionnaires.

Ethical considerations

For the interviews with HPN patients, the Ethics Commission of the Canton of Bern clarified that the project does not require ethical approval, since it does not fall under the Human Research (reference number Req-2022-00379).

Results

We included 17 respondents in the survey: three physicians, five hospital pharmacists, two dietitians, four industrial employees, one FONES official, and two HPN patients. All physicians, the FONES official, three industrial employees (75%), four hospital pharmacists (80%), and one dietitian had previously experienced shortages of IV multivitamins. In total, eight (47%) experienced a long (>90 days), two (12%) an intermediate (30 days), and two (12%) a short (seven days) supply shortage. Patients did not experience any shortage.

Responses to the open-ended question about

the causes of IV multivitamin shortages were categorized into five categories:

- **Production issues:** Eleven respondents (two dietitians, two physicians, three pharmacists, three industry representatives, one FONES official) noted shortages of raw materials, specific resources needed for production (such as glass vials that were shifted to vaccines during the COVID-19 pandemic and not more available for the IV vitamin vials), or human resources priorities (due to the COVID-19 pandemic or war), and safety issues leading to regulatory production problems.
- **Logistical problems:** Five respondents (one dietitian, two physicians, one pharmacist, one industry representative) mentioned issues related to the transportation and delivery of products. These included supply chains disruptions due to the COVID-19 pandemic and specific events such as the Suez Canal blockage in 2021.
- **Lack of competition / alternatives:** Four respondents (three pharmacists, one industry representative) noted that during the COVID-19 crisis, a company's shift to vaccine production led to increase demand that could not be met by competitors. A similar shortage occurred when a production facility burned down and almost no alternative manufacturer existed for the important antibiotic Active Pharmaceutical Ingredient (API) production [23].
- **Market forces and business decisions:** Two respondents (a physician and a pharmacist) noted that certain products are less profitable, leading companies to de-prioritize their production. In addition, one industry respondent noted the cost and feasibility of maintaining large inventories given the limited shelf life of the products.

Responses to the question "How do you respond to shortages of IV multivitamins and who do you contact?" could be categorized as follows:

- **Consultation and information exchange with hospital internal teams and departments:** Physicians and dietitians report that they first consult with their team leaders or relevant internal departments, such as the hospital pharmacy and the nutritional support team. They would also be informed of any supply shortages by relevant parties, such as the hospital pharmacy.
- **Direct contact with suppliers and manufacturers:** This is often to determine the extent of the shortage, to discuss possible alternatives, or even to negotiate delivery quantities and schedules. Hospital pharmacists need to contact their internal manufacturing units (compounding) or suppliers of the PN multi-chamber bags and of the components to person-

- alize these PN preparations and to deliver the complete (All-in-one) ready-to-use admixtures or regimens to in- and out-patients while dietitians and physicians are only in contact with home care services for HPN.
- **Investigating alternative products or sources:** *If a drug shortage is expected to be prolonged or critical, pharmacists report looking for alternative and substituting products on the domestic or international market, or even the possibility of manufacturing a product themselves. The nutritional support team assesses whether a patient can take a substitute product orally and whether absorption is guaranteed.*
 - **Communication and contingency plans:** *Pharmacists and industry respondents in particular describe developing contingency plans or mechanisms to manage supply shortages, such as maintaining internal stockpiles of essential products, establishing specific stocks for specific customers as experienced during pandemic, issuing shortage bulletins or alerts about supply shortages, or allocating resources based on actual need.*
 - **Involvement of authorities:** *The FONES public servant noted the process of official and mandatory reporting of supply shortages and the role of the authorities in verifying the shortage and its causes, informing stakeholders, and coordinating with other market providers.*

Figure 1 shows the reported extent of agreement of the experienced interviewees with the ASPEN strategies for PN product shortages. There was a 100% consensus among all respondents

about the need for European practical protocols/guidelines. Respondents suggested that the guidelines should cover a wide range of topics, including prioritization of patients, management of shortages alternatives – 2nd line – to standard treatments different dosage forms, monitoring of patients and product availability, the role of authorities, and educating of HCPs.

Discussion

Our results demonstrate the high extent of awareness and experience on this IV vitamin shortage in Switzerland, confirming the complex multifactorial challenges facing global supply chains and the unanimously expressed need to provide better and internationally harmonized guidelines to prevent and resolve such supply problems. HCPs, industry associates, and public servants acknowledged these challenges; however, HPN patients seemed largely unaware of the shortages as their PN delivery was granted due to the prioritization applied to this group. This underscores the considerable efforts being made by HCPs and related responsible teams to mitigate the direct impact on patients in general and the complex care HPN patient in particular. While these efforts are vital, they are placing a strain on healthcare systems [4], demonstrating the need for more robust supply management in case of critical drug shortage situations and the potentially long-lasting shortage character.

The experienced respondents are convinced

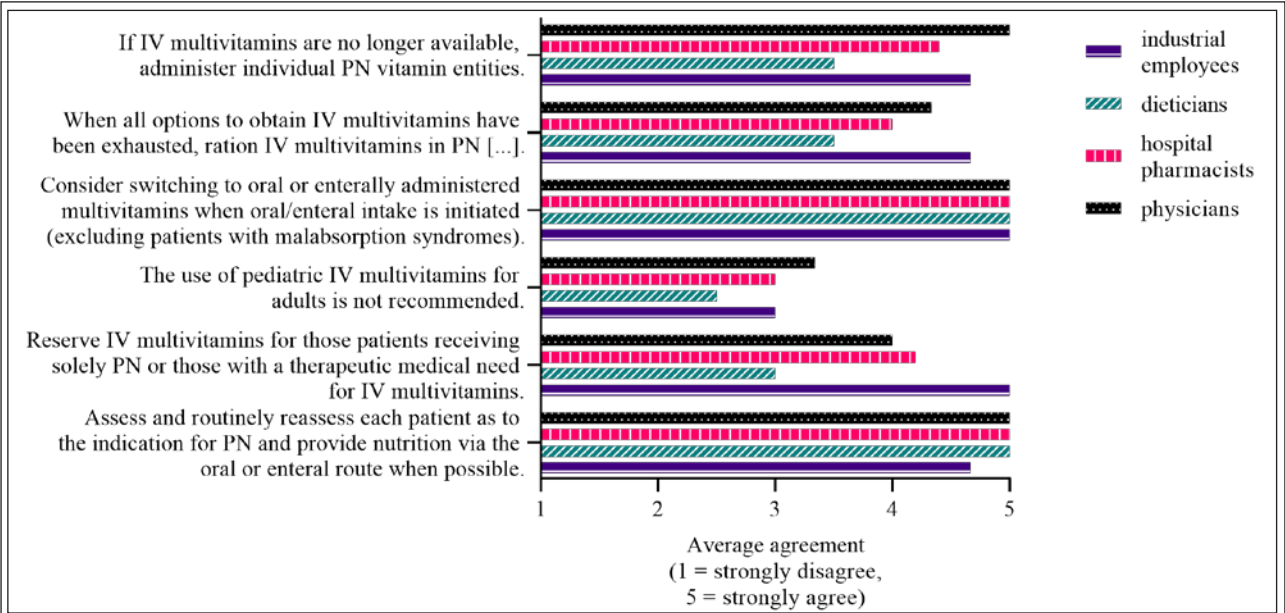


Figure 1 Extent of agreement with the strategies on parenteral nutrition product shortages by the American Society for Parenteral and Enteral Nutrition (ASPEN)

that to prioritize the indication for use of IV multivitamins, health care facilities should adopt standardized, evidence-based rationing and related harmonized international guidelines. The global character of such shortages needs new strategies on a supra-national level to guarantee continuity of care within the National Health Care Systems [2] and to alleviate the burden on and responsibility of the HCP in charge. Priority should be given, as positioned in some societies, to high-risk populations, such as neonates, critically ill patients, and those on long-term PN [13, 24]. When needed, clinicians should consider switching from intravenous to oral or enteral multivitamin formulations in patients with partially or fully functioning gastrointestinal tract and respect the necessary dosing to compensate reduced enteral bioavailability. This approach helps conserve limited IV supplies for patients without alternative routes and fully dependent on PN [13]. Pharmacists, dietitians and clinicians should work together to assess the specific nutrient needs of the patient and to tailor PN formulations and nutritional regimen accordingly [11, 12]. This team-based approach ensures that any substitutions or omissions are clinically justified and are appropriately monitored for efficacy and safety [13]. Centralized inventory management system should be in place to track inventory levels, forecast demand, and minimize waste by also centralizing compounding and ready-to-use preparation in a delivery center like a hospital pharmacy or home care unit. This system can help prevent stockpiling or expiration of unused products and facilitate timely redistribution of supplies between institutions [5, 8, 11, 24].

The reasons for the national and global IV multivitamin shortages identified in our study ranged from production issues and logistical difficulties to the lack of competition and market influences. These aspects appeared to be intertwined with broader global events, such as COVID-19 pandemic and the 2021 Suez Canal blockage, reflecting the criticality of IV multivitamin supply chains with a very limited number of raw material manufacturing sites and therefore, prone to large-scale disruptions, an aspect of the high vulnerability of PN components supply chain and the related complex care [5, 8, 25]. Institutions should establish formal policies outlining actions to take ahead and during shortages, including triggering thresholds for conservation measures and ethical frameworks for allocating resources. These strategies should be part of broader emergency preparedness plans for such essential

drugs [11, 15, 24]. These reasons are similar to those reported in the literature (regulatory issues, natural disasters, voluntary recalls, raw materials shortage, increased demand, loss of manufacturing site, quality issues, business decision to discontinue, and too few manufacturers producing generic sterile injectables) [4] and are common causes for drug shortages [26]. Our survey also explored how HCPs are adapting to and managing these shortages, highlighting the importance of strong and established communication channels, contingency planning, and exploration of alternative products. Healthcare institutions and professional organizations should maintain active communication with pharmaceutical manufacturers and regulatory agencies. Advocacy for increased production, accelerated import of approved international alternatives, and regulatory flexibility in times of shortage are mandatory [11, 12]. Similar strategies have been described in the literature, mostly focusing on the United States of America [4, 8], but more recently addressing also a supranational approach in Europe [2, 25]. However, while necessary, these solutions represent a reactive approach, that may be insufficient in the face of recurrent or long-term supply shortages. Our study demonstrated the importance of national coordination to streamline activities and make them efficient. Therefore, as a preventive measure, the medicinal products division of FONES has requested the compulsory reporting of supply problems for IV vitamins [19]. This investigation focused on the last segment of the supply chain with the users and finally the vulnerable patient with the complex HPN care, an aspect merely addressed. It showed that this aim was fully accomplished for the multivitamin shortage in Switzerland as none of the HPN patients suffered from lacking IV micronutrient therapy. Therefore and as an aim of the study, the result showed successful management of the IV vitamin shortage for the most vulnerable patients.

The unanimous consensus of the experienced interviewees on the necessity of European protocols/guidelines indicates a desire for a more proactive, structured response to IV multivitamin shortages. Such guidelines could be adapted from existing ASPEN guidelines to fit the European context, and could provide a framework for prioritizing patients, managing shortages, identifying appropriate alternative treatments, and defining the necessary shortage team in place importantly on the hospital level and the roles of different stakeholders during supply disruptions. Since this investigation, members of the ESPEN Special In-

terest Groups Home Artificial Nutrition and Chronic Intestinal Failure have provided European guidance in the form of an editorial [5]. To ensure compliance with guidelines/protocols and prevent inappropriate use of IV multivitamins, clear communication with healthcare professionals is stressed. Educational initiatives should include training in the identification of deficiency symptoms and understanding of the rationing strategies [13]. Long-term solutions should include investing and research to develop and authorize stable, alternative formulations of multivitamins that are less reliant on complex manufacturing processes or cold chain logistics. This will improve the resilience of the supply chain. As the micronutrient intake through food is not sufficient to cover the need, supplementation is necessary to avoid harm [15]. This is even more important in patients dependent on medical nutrition and in the extreme case of long-term PN. The availability of IV multivitamins and the urgency to fight such shortages and showing evidence for effective management are priorities.

The aim of the study to validate the ESPEN 2021 questionnaire revealed that the initial format and content covered many aspects of the intended international survey but had to be extended for interviews with the different professionals working together to provide the complex specific care in HPN. By evaluating the identical questions like the agreement with the 2024 ASPEN strategies to manage PN products shortages (Figure 1), the importance of addressing the different specialists but also a high extent of the agreement could be demonstrated. Such aspects were partially included in the editorial on micronutrient product shortages by the ESPEN special interest group [5] published after the termination of this investigation.

There are some limitations to this research. Given the small sample size and variability in the number of participants from each group (ranging from 1 to 5), the authors do not consider the survey results to be representative and reflect an informed expert opinion, based on structured interviews among colleagues involved in PN supply and care. The low number of interviewees per group, along with the fact that many participants worked within the same team, limits the generalizability of the findings. No specific measures were implemented to minimize interviewer bias during the interviews. Nevertheless, there were important findings for the Swiss situation in HPN patients allowing further steps and international cooperation to

improve the management of critical PN components supply and initiate ongoing research along the supply chain to make it more resilient.

CONCLUSIONS

The awareness and experience with IV multivitamin shortages are high among HCPs, public servants, and industrial employees. Due to the efforts to ensure preferential care for patients with PN, they do not seem to experience insufficient or inappropriate IV multivitamin delivery at home in Switzerland. The reflections set out in this paper make it clear that a combination of short-term measures - such as rationing and substitution with enteral or oral alternatives - and long-term strategies - such as the development of more stable formulations and improved communication with regulatory authorities - are needed to address the issue holistically. HCPs would appreciate European protocols/guidelines with algorithms for prioritizing patients during IV multivitamin shortages, which could be incorporated in national and local protocols/guidelines. Proactive drug logistics, led by a national office, are needed to allow an organized supply management, thereby minimizing the workload during shortages.

Of note, is the importance of early notice of potential supply problems as requested by an authority body and the centralized stock management and inventory with the interprofessional management to best match individual patient needs with available resources. The current situation underscores the need for essential medicines supply strategies to be not only reactive, but also preventive and systematic. Only targeted coordination at institutional, national and international levels can sustainably strengthen the resilience of medical care in the face of supply shortages.

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