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ORIGINAL ARTICLE

Does a parenteral nutrition decision support system for total nutrients improve prescription procedure and neonatal growth?

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ABSTRACT

Background and objectives: Parenteral nutrition (PN) is an integral part of the nutritional support of critically ill neonates in the intensive care units (ICU). The evaluation of a decision support system for total nutrients (DSSFTN) is of great importance for clinical practice. This study's aim was to evaluate the impact caused by implementation of a DSSFTN on PN support and neonatal growth. This pilot work was supported by the hospital PN team (PNT) in order to assess possible benefits stemming from the use of DSSFTN.

Materials and methods: DSSFTN development is based on the incorporation of pharmaceutical and therapeutic protocols. Thirty-eight neonates were recruited. Inclusion criteria included: patients should (a) be hospitalized in ICU, (b) receive PN support at least for 15 days, (c) have birth weight 550–1600 g. One exclusion criterion was applied: patients should have no inborn error of metabolism. 15 doctors prescribed PN for two groups of neonates. PN was calculated by doctors for Group 1 (19 neonates) and respectively was calculated by the DSSFTN (and checked by doctors) for Group 2 (19 neonates). A questionnaire was completed later by doctors to evaluate DSSFTN.

Results: The implementation of DSSFTN led to appropriate composition and administration of PN. Growth was not significantly different between the study groups. Compliance with guidelines was observed. DSSFTN ameliorated intercommunication among doctors.

Conclusions: The implementation of DSSFTN enables health professionals to facilitate the complex task of prescribing. It ensures the consistency of PN prescriptions, as it leads to appropriate dosing in all nutrients. DSSFTN provides real-time PN interventions (clinical conditions and enteral amounts are included additionally) and minimizes exposure to human errors.

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Compliance to guidelines for customized parenteral nutrition; decision support tool; neonates; pharmaceutical and therapeutic protocols; prescribing methods

Introduction

Parenteral nutrition (PN) is a vital therapeutic and life-saving treatment [1] for neonates, infants, and children, when enteral nutrition is limited or not possible due to critical or chronic illnesses. The objective of postnatal intravenous nutrition for premature infants is to achieve approximately intrauterine growth as well as nutrient accretion [2,3]. Appropriate use of this complex therapy maximizes clinical benefit, while minimizing the potential risk for adverse events [4]. PN is invasive, costly, and associated with potentially serious and harmful complications [5].

Avoiding prescription errors in individualized prescription orders is essential. Usually, PN prescriptions in pediatric hospitals are based on general medicinal guidelines, but not on a decision support system for total nutrient administration. The design of a decision support system (DSS) for PN provision should be based on algorithms, combined with protocols which include therapeutic and pharmaceutical strategies. These strategies are described by guidelines for the use of PN which have been developed by several nutrition and health system societies [such as the European Society of Parenteral and Enteral Nutrition (ESPEN), American Society of Parenteral and Enteral Nutrition (ASPEN) and American Society of Health System Pharmacists (ASHP)] [6,7]. Guidelines are intended to be used as a tool in order to aid clinical judgment, but they cannot replace it, as outlined by the Scottish Intercollegiate Guideline Network [8,9]. All the aforementioned information results in a wide

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variety of formulations used for customized parenteral nutrition support.

The PN Consensus Safety Recommendations published by the American Society of Parenteral and Enteral Nutrition in 2014 recommended the use of clinical decision support systems for prescribing PN [10]. A similar idea about the effectiveness of computerized decision support systems was presented by Moja et al. in 2014 [11]. However (to the best of our knowledge), no DSS has prevailed in clinical practice aiming to calculate appropriate dosing in all nutrients for PN of neonates (while taking into consideration the distinct health status per occasion and the gestational age).

Complications may occur because of the PN admixtures and the various processes [4] which are involved (indication, prescription, calculations, entry of patients' data, administration and monitoring). Possible disparities in knowledge, skills and PN practices can contribute to PN-related medication errors. Moreover, deaths have occurred when safe practice guidelines were not followed (concerning eg stability, incompatibility) [12]. The appropriate and safe prescribing and ordering of PN is a critical first step and an essential component of the PN usage process.

Furthermore, the presence of explicit means of communication among physicians, physician extenders/midlevel providers (eg nurse practitioners, physician assistants), registered dietitian's nutritionists, pharmacists and nurses who are involved in the process of administration of PN, is necessary [10]. Therefore, a tool is needed to assist this type of communication.

In the present study, a DSS for total nutrients (DSSFTN) [which was initiated by a hospital pharmacist (PharmD) specialized on nutrition] was supported by the PNT in a hospital, Athens, Greece. The incorporation of therapeutic and pharmaceutical protocols was accepted by the PNT as well as by the hospital's scientific committee. The DSSFTN was already evaluated for its accuracy (calculations are made automatically in DSSFTN) prior to use by a team of experts in informatics and pharmaceuticals. During its validation period, all necessary calculations were implemented, to test accuracy and reliability.

The ideal scenario was that DSSFTN would ensure that doctors prescribe a customized Total Parenteral Nutrition (TPN), gestational age specific, with more accuracy for all nutrients. This tool would integrate enteral and parenteral amounts as well as clinical conditions. Therefore, the goal was to upgrade individualized prescription orders of PN.

This study's aim was to evaluate the impact caused by the implementation of the DSS (evaluation made by doctors) on PN support as well as neonatal growth.

Materials and methods

Patients and procedures

A randomized study was conducted in 2017 (January to June) in a hospital in Athens, Greece. This study was approved by hospital's Scientific and Ethics Committee. Neonates randomized to the control group (Group 1) received conventional care, in contrast with neonates randomized to the intervention group (Group 2) who received the recommended (by DSSFTN) nutrients' values. A software was used for the randomization. Groups were not randomized by blocks, depending on their gestational age. [The mean value for age per group is presented in Results (Table 1)]. After randomization, the two groups were compared with regards their current medical history.

Table 1. Basic characteristics of groups 1 and 2.

	Group 1 (19 neonates) [mean value ± standard deviation (SD)]	Group 2 (19 neonates) [mean value ± (SD)]	*p* Value
Age (weeks)	28.47 (±1.98)	27.53 (±2.09)	.161
Prematurity	13 very preterm neonates, 6 extremely preterm neonates	9 very preterm neonates, 10 extremely preterm neonates	.189
Sex	6 female, 13 male	10 female, 9 male	.189
Weight1[a] (kg)	1.11 (±0.26)	1.00 (±0.28)	.221
Weight8[b] (kg)	1.06[c] (±0.28)	1.03 (±0.27)	.720
Weight15[d] (kg)	1.18 (±0.31)	1.10 (±0.28)	.433
Albumin 15[e] (g/dL)	3.09 (±0.41)	3.41 (±0.41)	.030
Weight for age Z-score 15[f]	0.35 (±0.25)	0.59 (±0.23)	.495
Change in weight for age Z-score[f]	0.40 (±0.10)	0.47 (±0.10)	.622

[a]Weight 1 = weight on day 1.
[b]Weight8= weight on day 8.
[c]The weight was slightly reduced, but the change was not statistically significant.
[d]Weight15 = weight on day 15.
[e]Albumin 15 = measurement of albumin on day 15. Level of albumin for preterm neonates is equal to 2–3.6 g/dL (in reference [17]) for weight < 2.5 kg and 2.8–4.4 g/dL in hospital's laboratory.
[f]Z-score (or SD-score) = (observed value – median value of the reference population)/standard deviation value of reference population [18].

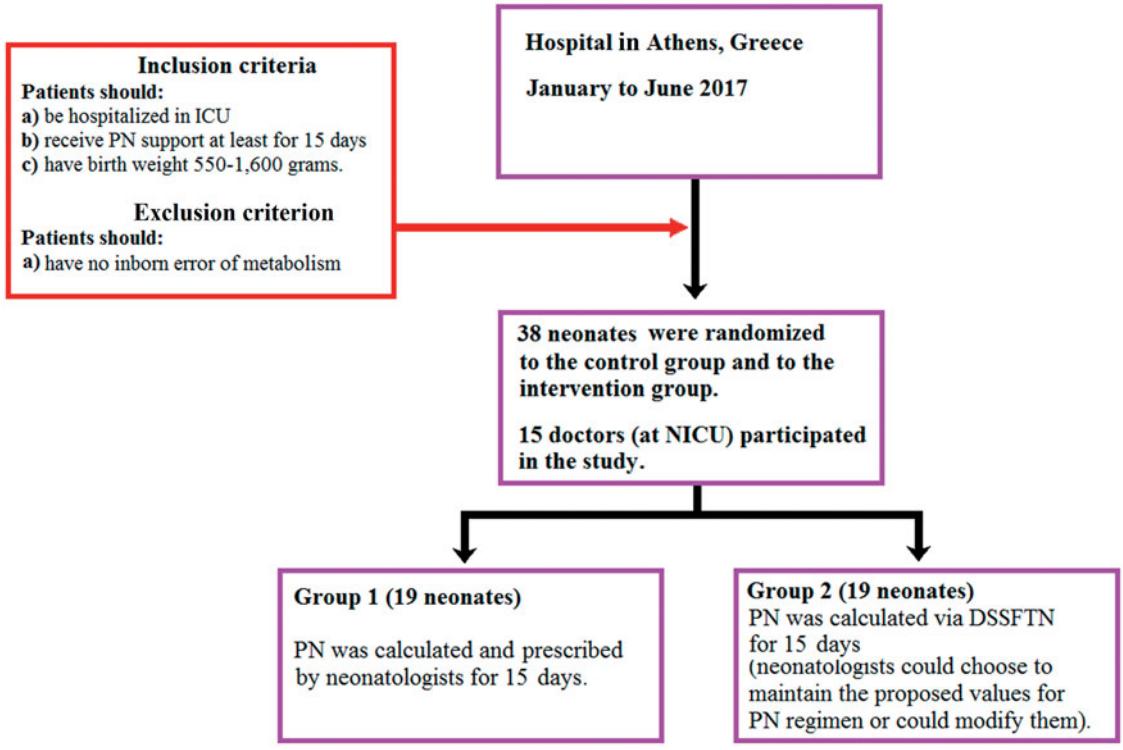

Figure 1. Schematic overview of the design of the study.

In total 38 in-hospital neonates were recruited to this study. There were three inclusion criteria: patients should (a) be hospitalized in ICU, (b) receive PN support at least for 15 days, (c) have birth weight 550–1600 g. The exclusion criterion was that patients should have no inborn error of metabolism. After the recruitment, it was observed that neonates in both groups had the same indications for parenteral nutrition, since they were premature neonates with respiratory distress syndrome. The user of DSSFTN could choose to maintain the proposed values and submit them to the full PN regimen, or could modify them. DSSFTN does not allowvalues out of range of therapeutic and pharmaceutical protocols.

For Group 1 (19 neonates – Figure 1) PN was individually calculated and prescribed by neonatologists, for 15 days in average. For each clinical case, one or more doctors in duty participated in PN prescribing. If enteral nutrition (EN) was applied, the PN would be adjusted accordingly, by subtracting the total volume of EN from the PN regiment. Group 2 (Figure 1) was composed of a respective number of participants (19 neonates), but their PN support was calculated *via* DSSFTN. (Information about the computer literacy of doctors is presented in Supplementary Material.)

The protocols used at the neonatal intensive care unit (NICU) and based on guidelines from ASPEN, ESPEN, A.S.H.P., the American Academy of Pediatrics Nutrition Handbook and Cochrane Library review (which were incorporated into DSSFTN) take into consideration the gestational age (23–27, 28–31 or 32–40 weeks) [8,13–17]. These protocols recommend initiating protein at 2.5 g/kg/day, fat 1 g/kg/day and dextrose 5.8 g/kg/day on the first day of life and increasing it respectively to a maximum of 4, 3 and 17 g/kg/day over 8 days for most neonates. The computerized order entry identifies the required daily total nutrients according to the gestational age and produces a suggested parenteral nutrition regiment for each clinical case (EN and administration of drugs is considered also).

The following sections

i. ***Questionnaire for doctors*** (its description is presented in Supplementary Material and the answers are presented in Supplementary Table 1, respectively)
ii. ***Data collection***
iii. ***Calculation of the caloric requirements and adequate coverage of PN***
iv. ***Regimens prescribed by doctors***
v. ***Technical details of the program*** (including Supplementary Table 2, and supplementary Figures 1–3) are presented in Supplementary Material.

Table 2. The comparison concerning mean nutrients' intake (via PN and EN during the period: day 1 day 15) between group 1 and group 2.

Measurements after day 15 of PN	Group 1 ($n = 19$) mean ± standard deviation (SD)	Group 2 ($n = 19$) mean ± SD	p-Value
Glucose (g/kg) administered by PN	11.14 (±3.13)	12.01 (±3.17)	.001
Glucose (g/kg) administered by EN	0.56 (±1.44)	0.44 (±1.43)	.001
Total[a] glucose (g/kg)	11.91 (±3.13)[b]	12.36 (±3.16)[b]	.268
Amino acids (g/kg) administered by PN	2.62 (±0.65)	3.22 (±0.81)	<.0001
Amino acids (g/kg) administered by EN	0.15 (±0.40)	0.12 (±0.40)	.005
Total[a] amino acids (g/kg)	2.79 (±0.63)[b]	3.31 (±0.75)[b]	<.0001
Fatty substances (g/kg) administered by PN	2.10 (±0.77)	2.51 (±0.82)	<.0001
Fatty substances (g/kg) administered by EN	0.29 (±0.73)	0.22 (±0.74)	.001
Total[a] fatty substances (g/kg)	2.46 (±0.86)[b]	2.71 (±0.93)[b]	<.0001
g protein/100 kcal	4.05 (±1.10)	4.29 (±0.98)	.005
Total energy derived from PN(kcal/kg/day)	67.11 (±17.15)	76.27 (±18.16)	<.0001
Total PN volume (mL/kg)	136.57 (±28.50)	138.03 (±26.15)	.527
Total kcal derived from milk (kcal/kg/day)	5.48 (±13.94)	4.27 (±13.97)	.001
Milk volume (mL/kg)	10.00 (±10.00)	6.12 (±6.12)	<.0001
Osmolarity (mosmol/L)	715.35 (±223.66)	1029.55 (±230.63)	.019
Glucose infusion rate (mg/kg/min)	8.53 (±1.23)	9.87 (±2.08)	.778
Na (meq/kg)	2.65 (±1.73)	2.70 (±1.51)	.691
K (meq/kg)	1.56 (±0.77)	1.72 (±0.78)	.019
Mg (meq/kg)	0.72 (±0.20)	0.79 (±0.36)	.003
Ca (meq/kg)	1.99 (±0.57)	1.80 (±0.82)	.002
PO_4 (mmol/kg)	1.11 (±0.50)	1.08 (±0.53)	.508
Trace minerals (mL)	0.47 (±0.45)	0.57 (±0.52)	.025

[a]Administered by PN and EN.
[b]More information (about calculating the new standard deviation, after adding two values which have standard deviation) is provided in the Supplementary material.

Statistical analysis

All statistical analyses were performed using the SPSS software for Windows (version 19.0; SPSS, Inc, an IBM Company, Chicago, IL). Continuous variables were expressed as mean value ± standard deviation. Comparisons between the two subgroups were performed by using an independent samples *t*-test and a Mann–Whitney test for continuous variables that were normally and non-normally distributed, respectively (Kolmogorov–Smirnov test). Fisher's exact test was used for dichotomous variables. A one-sample *t*-test was performed to test the mean intake of amino acids and lipid (g/kg/d) versus the reference values or guidelines in both groups. A paired sample *t*-test was used to compare the weight for age *Z*-score between the beginning and the end of the study for each group. The between groups statistical comparisons were made using (i) a Bonferroni adjustment related to prescription procedures [$\alpha = 0.05/14$; $p < .003$ (where 14 represents the following: osmolarity, glucose infusion rate, PN amino acids, lipids, glucose, protein/100 kcal, TPN volume, total energy derived from PN, sodium, potassium, calcium, phosphorus, magnesium and trace minerals)] and (ii) a Bonferroni adjustment related to neonatal growth [$\alpha = 0.05/6$; $p < .008$ (where 6 represents the following: weight on day 1, weight on day 8, weight on day 15, albumin on day 15, weight for age *Z*-score 15 (on day 15) and change in weight for age *Z*-score)] [18]. For the other analyses, the statistical significance threshold was set at $p < .05$.

Results

Basic characteristics of both groups are shown in Table 1. The total age range was 25–31 weeks. According to World Health Organization categorization [19], Group 1 consists of 13 very preterm neonates and 6 extremely preterm neonates in contrast with Group 2 which consists of 9 very preterm neonates and 10 extremely preterm neonates.

The comparison concerning nutrients intake (*via* PN and EN) between Group 1 and Group 2 is presented in Table 2 as well as Supplementary Tables 3 and 4 (after day 15, after day 8 and after day 1, respectively). PN clinical protocols are designed to steadily increase macro and micro nutrients during days 1–8. After eighth day, the protocol remains the same until the patient has discontinued PN. Furthermore, while on concurrent enteral and parenteral feeds, PN decreases (total nutritional protocol minus the enteral feed intake).

Neonates were fed either with breast milk or with a substitute. A lot of information about milk intake and doctors' decision, if feeding will take place via mouth or tube, is presented in the Supplementary Material (rationale is described) [17].

A lot of statistically significant differences were found after the Bonferroni adjustment was applied. These differences are presented below (they are separated in two different periods).

i. Statistically significant differences at the end of the study (day 1–day 15)
   - The quantity of amino acids (g/kg) administered by PN was greater for Group 2.
   - Total amino acids (g/kg) [administered by PN and EN] was greater for Group 2.
   - Fatty substances (g/kg) [administered by PN] was greater for Group 2.
   - Total fatty substances (g/kg) [administered by PN and EN] was greater for Group 2.
   - Total energy derived from PN (kcal/kg/day) was greater for Group 2.
   - Milk volume was greater for Group 1.
   - The quantity of Ca was greater for Group 1.

ii. Statistically significant differences on day 8 (day 1–day 8)
   - The quantity of amino acids (g/kg) [administered by PN] was greater for Group 2.
   - Total amino acids (g/kg) [administered by PN and EN] was greater for Group 2.
   - Total fatty substances (g/kg) [administered by PN and EN] was greater for Group 2.
   - Fatty substances (g/kg) [administered by PN] was greater for Group 2.
   - Osmolarity was greater for Group 2.
   - Total energy derived from PN (kcal/kg/day) was greater for Group 2.
   - Trace minerals (mL) was greater for Group 2.

Two figures (Supplementary Figure 4 and Supplementary Figure 5) show the mean values for glucose, fat and amino acids as function of parenteral nutrition day, both, for electronic and handwritten protocols. Handwritten protocols showed a sharp increase regarding fat and glucose intake and in general they provided less fat and glucose. The electronics protocols provided a greater amount of amino acids, which did not remain statistically significant after the corrections for multiple comparisons.

Discussion

Main results

Concerning neonatal growth, the following extra information emerged. Within groups comparisons show statistical significant increase in weight for age *Z*-scores between the beginning and the end of study in both groups (Supplementary Tables 5 and 6). Weight-for-age *Z*-score was an outcome variable related to neonatal growth. *p* Values of weight for age *Z*-score 15 (on day 15) between two groups was 0.495 (Table 1). The two groups were not different with regards the number of days that neonates did or did not receive milk [any type (Supplementary Table 7)]. Information about enteral nutrition applied (Group 1 and 2) is presented in supplementary Tables 8 and 9.

In this study, the DSSFTN was implemented and evaluated with the support of PNT in order to assess prescription procedures and compliance with guidelines. The idea for the use of DSSFTN was to prevent improper PN prescriptions and minimize human errors. The usage and usefulness of the DSSFTN for the doctors involved in PN support were investigated.

The aforementioned results show that both, regimens prescribed by doctors as well as regimens proposed by the DSSFTN comply with official guidelines. However, there are differences (mentioned above) between these two prescribing methods. Since the two groups had similar general characteristics (Table 1), the similarities in anthropometric measurements between the two groups might be expected.

Since 1970 health providers involved in PN have made an effort to create DSSs to prevent PN prescription errors in NICU [20]. As a result, tools which provide calculation assistance and validation for ordered dosages have been created [21,22]. The described DSSFTN is an integrated tool, which is based on therapeutic protocols and takes also into consideration enteral feeding.

Doctors' answers to the questionnaire led to the conclusion that DSSFTN is a tool which assists prescription procedures for individualized PN. [13 doctors out of 15 declared that DSSFTN assists prescribing]. Physicians' time spent on the prescription of TPN formula was 1.1. min with DSSFTN and 7.1 min for handwritten prescriptions. The DSSTPN also facilitates production because it is connected to a mixing device machine. Other significant findings are presented to the following list.

- DSSFTN was friendly to user (14 doctors)
- Computerized formulation guidance used, ensured proper composition of PN (14 doctors)
- All the doctors were satisfied by the incorporation of protocols (therapeutic and pharmaceutical) to the software (15 doctors)

- DSSFTN ameliorates/reminds the knowledge related to pharmaceutical limitations while the doctors prescribe PN order (13 doctors)
- All the doctors declared that with the use of the DSSFTN, they can avoid dosage calculation mistakes (15 doctors)

Questionnaire results were the outcome variables concerning the hypothesis of improving prescription procedure via DSSFTN.

The implementation results show that the DSSFTN provides in total, a customized, more thorough, safe and objective prescription methodology. It also provides compliance to guidelines (protocols accepted by the scientific committee). In addition, DSSFTN may educate *in situ* young doctors about TPN (since they can study the theory behind each step of PN). It can provide education to less experienced physicians that can lead to reduced prescribing errors, clinical appropriateness, improved efficiency/productivity, safety, and ultimately reduced cost [23]. It ensures the consistency of PN prescriptions in general and facilitates the effective collaboration of doctors. It eliminates the complex task of prescribing and formulating customized PN solutions and thus improves PN work flow for the benefit of both, the patient and the doctor.

It is also important to understand the impact of human error on PN. If a doctor, for example, prescribes less quantity of nutrients (because of human error during calculations), deficiencies will appear. More specifically, nutritional deficiencies, especially protein deficiency, affect somatic growth adversely [24]. Generally, malnutrition is a major contributor to increased morbidity and mortality, decreased functionality and quality of life, increased frequency and length of hospital stay and in addition it is related to higher healthcare costs [25].

The possibility to have access and study on the screen (when it is necessary) the theory involved in each step of decision making at the time of prescribing, minimizes human errors. Furthermore, it is important for the doctor to find recorded PN data of previous days and as a result he has the opportunity to adjust the prescription order easily. Access to all recent data provides the health team a better overall picture of the patient status. However, the combination of the electronic protocols and experts' surveillance is preferable, in order to prevent prescribing and ordering errors, in macronutrients, micronutrients and/or medications which may exceed recommended/safe clinical limits or limits of compatibility [22,23,26].

A standardized process promotes uniformity among clinicians and health care facilities and in the meanwhile amplifies the homogeneity of customized PN regiments (regarding similar clinical cases) [7]. On that base, the Agency for Health Care Research and Quality reported a meaningful reduction in errors at a children's hospital which adopted a standardized ordering and administration process of PN [27]. The study of Maat et al. demonstrated that computerized PN resulted in a significant 16% reduction for simple and 60% reduction for complex calculations [22].

One additional advantage is that DSSFTN gives the opportunity to users to organize research tasks by providing all the appropriate information. This nutrition support system tool records data, which can be used for further statistical evaluations. In contrast, regimens prescribed by doctors fail to achieve similar organized data recording.

Standardizing the content and procedure, and introducing a DSSFTN tool for PN with the incorporation of clinical conditions and therapeutic and pharmaceutical protocols will improve clinician's prescribing of a complete, customized, balanced formulation, thereby avoiding nutrient omission and subsequent deficiency symptoms or nutrient excess and toxicity symptoms [7,28,29].

Limitations

The study has particular limitations. DSSFTN was locally developed. An alternative would be to produce a similar cloud-based DSSFTN and test its application to more hospitals. The number of doctors, who completed the questionnaire, was limited (15 doctors). More doctors should use the DSSFTN and their opinion could lead to improvements of the program. DSSFTN should be tested also for children since our hospital has a pediatric section with different protocols.

Conclusions

Taking into consideration the fact that clinical assessment made by a doctor is irreplaceable, we evaluated a DSSFTN tool for individualized PN. This study demonstrated that the DSSFTN interventions could influence doctors' prescription procedure. The incorporation of therapeutic and pharmaceutical protocols in a DSSFTN tool for PN facilitates the prescribing and dispensing of customized TPN. To the best of our knowledge, the DSSFTN assessed in our study is the only tool which includes this combination. This

DSSFTN provides also real-time PN interventions (clinical conditions and enteral amounts are included additionally) and minimizes exposure to human errors. Doctors have better control of their PN prescription order, because DSSFTN provides the theory behind each step of decision. This advantage leads also to compliance with guidelines.

A future research suggestion is to design similar studies in Greece with a greater number of clinical cases and doctors in order to confirm conclusions. Then, results from different hospitals should be compared.

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Disclosure statement

No potential conflict of interest was reported by the authors.

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