

Expert consensus statements and summary of proceedings from the International Safety and Quality of Parenteral Nutrition Summit

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Purpose: The International Safety and Quality of Parenteral Nutrition (PN) Summit consisted of presentations, discussions, and formulation of consensus statements. The purpose here is to briefly summarize the summit and to present the consensus statements.

Summary: There was a high degree of consensus, with all statements approved by all authors/summit experts. These consensus statements should be regarded not as formal guidelines but rather as best-practice guidance intended to complement national and international nutrition society evidence-based guidelines and position statements. This article also summarizes key discussion topics from the summit, encompassing up-to-date knowledge and practical guidance concerning PN safety and quality in various countries and clinical settings, focusing on adult patients. Clear geographical differences exist between practices in Europe and the United States, and different approaches to improve the safety, quality, and cost-effectiveness of PN vary, particularly with regard to the delivery systems used. Discussion between experts allowed for an exchange of practical experience in optimizing PN use processes, opportunities for standardization, use of electronic systems, potential improvements in PN formulations, better management during PN component shortages, and practical guidance to address patients' needs, particularly during long-term/home PN.

Conclusion: The consensus statements are the collective opinion of the panel members and form best-practice guidance. The authors intend that this guidance may help to improve the safety and quality of PN in a variety of settings by bridging the gap between published guideline recommendations and common practical issues.

Keywords: consensus, formulation, parenteral nutrition, safety

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Parenteral nutrition (PN) is an important therapeutic intervention. It consists of supplying intravenous nutrition (eg, amino acids, glucose/dextrose, lipids, electrolytes, vitamins and trace elements) to patients when oral or enteral nutrition is impossible, insufficient, or contraindicated. PN is used in a variety of settings and for various indications in adults and children.^{1,2} Patients may need PN for a number of conditions that prevent oral intake, digestion, or nutrient absorption, such as short bowel syndrome, bowel obstruction, severe

acute pancreatitis, critical illness, major abdominal surgery, and cancer. Some patients may require temporary PN, but others may receive long-term therapy—or even lifelong PN in their own home environment.

PN is one of the most complex medications prescribed routinely in healthcare settings and commonly contains nearly 50 individual active pharmaceutical ingredients.³⁻⁵ The complexity of PN can result in an increased likelihood of errors—from PN prescribing to administration—with

an accompanying potential for patient harm.^{4,7} As such, PN is listed as a high-alert medication and so requires special safeguards to reduce associated risks.^{3,4,8} Safeguarding strategies may include standardization of prescription, ordering, storage, preparation, and administration processes.^{4,8} American and European nutritional societies and experts also advocate the standardization of the entire PN process, as well as interdisciplinary involvement and surveillance for complications.^{2,3,9,10} In recent decades, various approaches have led to increasing standardization, encompassing the compounding process, and/or greater use of market-authorized multichamber bags (MCBs).² MCBs are available in two formats: either as a 2-chamber bag (2CB) containing glucose/dextrose and amino acids, or the more modern 3-chamber bag (3CB) containing glucose/dextrose, amino acids, and lipids.¹¹ Both standardized and customized process have their strengths and weaknesses. Determining the preferred option from a safety and quality point of view can be a complex decision, influenced by factors such as the presence or absence of organizational expertise, the market availability of MCBs, financial considerations, and patient-related factors.²

The International Safety and Quality of Parenteral Nutrition summit was held on November 8 to 10, 2021, at two locations (Charleston, SC, and Bad Homburg, Germany). The summit brought together expert clinicians, pharmacists, and dietitians from Belgium, Poland, Spain, Switzerland, the UK, and the US, to evaluate the current state of knowledge and offer practical guidance on PN safety and quality issues in various countries and clinical settings, with a focus on adults requiring PN. The main goal of the summit was to develop consensus statements to address questions related to the following topics: (1) challenges and strategies to ensure the quality, safety, and cost-effectiveness of PN in different organizational settings; (2) aspects of (further) standardization of the PN process, in particular aspects

KEY POINTS

- The International Safety and Quality of Parenteral Nutrition summit highlights and consensus statements aim to bridge the gap between published guideline recommendations and common practical problems within the field of parenteral nutrition (PN).
- There are major differences between PN practices in Europe and the United States, including delivery systems and formulations.
- Many opportunities to improve PN safety and quality exist, including standardization of PN processes and formulations, the more widespread use of electronic systems, better overall PN management, and greater patient involvement in their own care.

related to standardized compounding or standardization through use of MCBs; (3) the quality and safety of PN formulations, with a particular regard to the composition of PN formulations and management during any PN component shortages. Furthermore, areas for improvement and research gaps were identified.

The summit format was designed to allow interactive discussion and consensus development, with the subsequent consensus statements forming the collective opinion of the panel members, informed and supported by scientific evidence and expert experience. It is important to note that this expert panel (ie, the authors of this article) is neither a formal guideline committee nor an authorized voting body. The panel are all experts from a variety of specialties within the field of PN. In addition to physicians and pharmacists from academic teaching hospitals, the panel included nonacademic members

from smaller organizations from a number of countries. This composition contrasts with formal guideline panels, which tend to focus more on the somewhat optimal situations within academic teaching hospitals, and so the consensus results here may be more relevant to a range of daily real-world clinical scenarios. The consensus statements should be regarded not as formal guidelines but rather as best-practice guidance intended to complement national and international nutrition society evidence-based guidelines and position statements. Thus, the current article summarizes the highlights and consensus statements from the International Safety and Quality of Parenteral Nutrition summit to help inform healthcare professionals by bridging the gap between published guideline recommendations and common practical problems. Other articles within this supplement will provide more detailed reviews of clinical considerations for each topic area covered in the current publication.

Methods

Healthcare professionals with substantial expertise in pharmacology, medicine, pharmacy aseptic services, and clinical nutrition were invited to participate in an international consensus development summit concerning aspects of improving the safety and quality of PN. The main purpose was to offer practical guidance and expert consensus opinion regarding the use of PN in various clinical settings for adult patients. The consensus statements were developed by applying an adapted Delphi technique, which is a group communication method with the goal of convergence of opinion by collecting information on a specific topic within the participants' areas of expertise.¹²

The meeting consisted of various expert presentations summarizing current knowledge, the local implementation of PN quality and safety measures in clinical practice, and sharing of best practices. Presentations were followed by periodic panel discussions focused

on the development of related draft consensus statements, which were circulated among the expert panel for their review and comments. Panel members were asked to indicate electronically, by voting anonymously, whether they agreed with each consensus statement by selecting one of the following options: I agree, I do not agree, or I do not wish to answer.

Results

The consensus statements and corresponding voting results are shown in Table 1¹³⁻¹⁸ and Table 2^{19,20}. Consensus statements were voted on by all 13 expert panel members, and 100% voted “agree” for each statement. Hereafter, the Results section summarizes the highlights of the summit according to the topic areas covered. A more detailed review of each of these topic areas can be found in the accompanying articles in this supplement.

PN in clinical practice: practical aspects. This topic covers the PN use process, pharmaceutical formulation of PN, and also PN shortages and their effects. In addition, the perspective of patients receiving long-term PN has been taken into consideration.

PN use process. PN fits well into the classic model of a drug-use process, as follows: (1) decision whether to use PN; (2) selection of the best PN regimen for each patient; (3) preparation, dispensing, and administration of PN; (4) patient monitoring and assessment; and (5) general involvement of an interdisciplinary team.⁴ As with other medications, errors can happen at each stage of the PN process. Contributing factors in these errors include complexity of the order, limitations in availability of computerized provider order entry, lack of standardization, poor communication (particularly during transitions of care), PN product shortages, and shortages of skilled and competent clinicians. Although there are limited data concerning PN error rates, as a rough estimate there are 3 to 16 errors per 1,000 PN prescriptions.^{21,22} Most PN medication errors happen in the compounding/dispensing and administration steps,⁷

and those most likely to be associated with harm occur during administration.²¹ Anecdotally, many PN medication errors are not even captured or reported for a number of reasons, such as institutions not classifying PN as medication, poor staff education, and a lack of real-time monitoring systems to identify errors or retrospective reviews specific to the PN use process. Today error prevention programs should form an integral part of maintaining a safe, modern PN process (Table 1, statement 10).

An overall perspective of PN challenges and needs within the US healthcare system was discussed, covering aspects of the PN use process. The PN landscape has changed significantly since the 2014 American Society for Parenteral and Enteral Nutrition (ASPEN) formulation guidelines were published,²³ but many challenges remain. Current PN preparations include market-authorized MCBs and compounded bags (either institution-specific standardized preparations or patient-specific customized formulations) (Table 1, statement 3). However, the current availability of commercial MCBs containing glucose/dextrose, amino acids, and lipids in different compositions (ie, lipid components) in the US is much more limited than in Europe. In the US, small- to medium-size hospitals tend to use commercial MCBs much more than larger institutions, mainly as 2CBs that include glucose/dextrose and amino acids (generally, lipids are given separately or added to the 2CB), with overall MCB use increasing year-over-year.²⁴ It is important to consider which patients would benefit most from compounded PN, and who are the best candidates for MCBs, perhaps through the use of standard algorithms.²⁵ Furthermore, it would be beneficial if manufacturers introduced a wider variety of MCBs as 3CBs to the US market, including different types of lipids and macronutrient compositions. Lipids should be an integral part of a PN admixture to better meet the needs of diverse patient populations and improve patients' safety and treatment effectiveness (Table 1, statement 4).

The PN use process within the US hospital system was also discussed with particular regard to experiences within Steward Health Care US hospitals covering 39 states and ranging in size from 38 to 748 beds, as well as in a mid-sized hospital (East Alabama Medical Center) and a large academic hospital (Vanderbilt University Medical Center). PN use processes vary according to hospital size. In smaller centers, PN compounding tends to be more manual in nature, while for larger centers the PN compounding process is likely to be standardized and automated. In general, the smaller the center, the greater the preference for MCBs, but owing to the small range of MCBs available as 3CBs including lipids in the US, smaller centers attempt to work around this issue by using an outsourcing facility to compound PN. Thus, for example, within the Steward Health Care hospitals and East Alabama Medical Center, it is necessary to have outsourced pharmacy compounding and in-house compounding in parallel with commercial MCB use. Maintaining multiple systems for ordering and preparing PN can be burdensome for staff and may increase the risk of errors. All of the institutions discussed consider PN as a medication for error reporting purposes and have implemented comprehensive quality and process improvement programs.

The PN use process within European hospitals was discussed, with a particular focus on practices in large academic hospitals in 3 locations (Lausanne, Switzerland; Ghent, Belgium; and Barcelona, Spain). In general, within Europe, there was an early switch towards a mixture of compounded PN and MCBs including glucose/dextrose, amino acids, and lipids for cost-effectiveness and safety reasons,^{26,27} with compounding often being reserved only for patients with special PN requirements not covered by MCBs (such as pediatric PN for preterm infants or other neonates).^{28,29} Indeed, compounding has a larger role in the homecare setting than for hospital patients in many European countries.

Table 1. Consensus Statements Concerning the International Safety and Quality of Parenteral Nutrition¹³⁻¹⁸**Consensus statement^a**

1. PN is used to provide nutrition therapy for patients when enteral feeding is not possible or sufficient. PN is always life saving or life sustaining. For optimal outcome, the PN formulation should meet the specific nutritional needs of a patient.

2. Healthcare professionals with training and expertise in prescribing, preparing, administering and monitoring PN are ideally organized in an interdisciplinary team consisting of physicians, nurses, dietitians, advanced practice providers (e.g. nurse practitioners, physicians' assistant) and pharmacists to take care of patients requiring PN.

3. Consistency in the use of terminology for PN formulations must be agreed upon to ensure safety and avoid confusion:

- a) Industrially prepared market-authorized multichamber bags (MCBs) contain fixed proportions of macronutrients (amino acids, dextrose/glucose, lipids) and electrolytes in various quantities and volumes. Individual macronutrients in the final container are separated by a divider that can be activated to combine the formulation (2- or 3-chamber bags). Market-authorized MCBs have a shelf life of months to years and can be kept at room temperature before activation. Market-authorized MCBs have undergone rigorous quality testing (e.g. design of the formula, stability, compatibility) and are produced under industrial GMP standards. Micronutrients are required to be added. Further specific nutrients (e.g. glutamine, omega-3 fatty acids) and electrolytes can be added to the PN formulation where compatibility and stability data are available.*
- b) Where market-authorized MCBs do not meet the specific nutritional needs of patients, customized PN formulations may be designed to these specific needs for macronutrients (amino acids, dextrose/glucose, lipids), micronutrients (vitamins, trace elements), electrolytes, fluids, and volumes.
- c) Compounded PN formulations are prepared either in hospital pharmacies, home infusion pharmacies, or outsourced compounding centers. Compounded PN bags may contain a customized PN formulation or a standardized PN formulation.
- d) Standardized compounded PN formulations are available with predetermined, fixed proportions of the macronutrients (amino acids, dextrose/glucose, lipids) with or without electrolytes designed to meet needs of a subset of patients, and we recommend they should have undergone rigorous quality testing (e.g. design of the formula, stability, compatibility). Micronutrients may be customized to the patient's needs.
- e) Compounded bags and market-authorized MCBs can be simultaneously used as part of a timely and individualized care plan in most hospitals. Hospitals should determine PN prescription policies according to their practice and regulations.

**Stability and compatibility data can be requested from the manufacturers.*

4. Preferences for PN formulations vary across countries. Whereas in the US, PN tends to be compounded by pharmacies or by outsourced compounding centers, the use of market-authorized MCB is widespread in Europe. This may have to do with the broader variety of market-authorized MCB formulations available in Europe compared with the US that allows the nutritional needs of the majority of patients to be covered. It can be anticipated that additional market-authorized MCBs options will become available in the US in the future. Call for action: industrial manufacturers should introduce a broader variety of market-authorized MCBs to the US market to better meet the needs of diverse patient populations, and improve patients' safety and treatment effectiveness.

5.^b PN is likely the most complex medication prescribed for patients. PN – independent of the type of product used – is susceptible to errors owing to its complexity. Errors may potentially result in harm to patients. Healthcare professionals involved in the PN prescription, preparation, transportation, storage and administration, and monitoring processes, must take every effort to mitigate risks associated with PN.

6.^b Owing to its complexity, a high rate of standardization of the PN process is advocated to minimize risk and errors, in accordance with major guidelines.

7. In the PN preparation process, a high rate of standardization can be achieved by either a standardized PN compounding process and/or the use of market-authorized MCB PN formulations. Whether one PN application system is preferred over the other depends on the patient's nutritional needs, local expertise, local resources, local financial considerations, local regulatory requirements, and/or the variety of commercial formulations available.

- a) All PN prescriptions should be reviewed by an expert pharmacist.
- b) Market-authorized MCBs represent an effective PN option. They have undergone rigorous quality testing (e.g. design of the formula, stability, compatibility) and they are produced under industrial standards. In clinical studies, they have shown equivalent nutritional efficacy, and in the majority of the evaluations a reduced risk of PN-associated infections compared with compounded PN, while labor and preparation time was reduced.¹³
- c) A PN prescription should be reviewed and prepared under rigorously standardized processes meeting quality standards (like national pharmacopeia, PIC/S guidelines, or full GMP standards) and supervised by an expert pharmacist.
- d) In certain settings (e.g. home PN), ensure that only qualified and trained individuals handle and manipulate the bags and that an appropriate quality management program is in place.
- e) Any additions including micronutrients to MCBs should be performed using aseptic technique to avoid contamination.
- f) Additives in the customization of market-authorized MCBs (e.g. electrolytes, glutamine, omega-3-fatty acids) can be added if supported by manufacturer stability and compatibility data and should be done under the supervision of an expert pharmacist.

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Table 1. Consensus Statements Concerning the International Safety and Quality of Parenteral Nutrition¹³⁻¹⁸

Consensus statement^a

8. When more than one IV line is required, a dedicated PN IV infusion line is recommended. Medication should ideally be delivered on a separate IV line/lumen line owing to incompatibility risks and risks of infections. Aseptic handling of PN administration is required.

9. Other, best-practice principles for increasing PN safety include comprehensive staff training and competency programs (across all disciplines involved), reinforced inter-disciplinary communication, and vigilant surveillance for complications.

a) The presence of a multidisciplinary team with PN expertise should be implemented.

Transition of care (e.g. from facility to facility, home to hospital, or hospital to home) requires special attention in staff training programs to ensure safety of PN.

10. PN of any type is a medication; errors anywhere in the PN process should be reported and evaluated as a medication error. Under-reporting of medication errors across the PN process remains a concern. If not available, error-reporting systems should be put into place following quality standards. Errors should be reported transparently in a timely manner, and regular nutrition team meetings for reviewing medication safety events (including near-misses) should be institutionalized.

11. Like an enteral formulation, a PN formulation should consist of all macronutrients (amino acids, dextrose/glucose, and lipids), fluids and electrolytes, vitamins, and trace elements, with the aim to meet the patient's nutritional requirements.

a) Society (e.g. ASPEN, ESPEN) or national guidelines provide recommendations for macro-/micronutrients and fluids.

b) Lipids, given as ILEs, are an integral part of a balanced PN formulation; they serve as a condensed source of energy and essential fatty acids. The use of pure soybean-oil ILEs should be strongly discouraged and ideally limited to patients with allergies to new generation lipids or in cases of product shortages as alternatives to newer generation lipids. The use of the new generation of fish-oil containing ILEs should be encouraged owing to clinical outcome benefits.¹⁴⁻¹⁸ Take into account lipid-containing non-nutritional sources (e.g. propofol) when calculating total caloric intakes and deliveries.

c) When designing the PN formulation, consider other fluids a patient receives to avoid dehydration and fluid overload. Consider other carrier solutions than dextrose/glucose-fluid containing infusions.

12. Shortages of PN components is an ongoing concern for the safety of PN.

a) At an organizational level, an early alert system should be considered to allow timely communication of shortage issues to staff and ultimately patients (e.g. through the electronic health record system).

b) For tactics to mitigate associated risks with PN component shortages in clinical practice, we refer clinicians to guidance documents from large nutritional societies (ASPEN, ESPEN, BAPEN) and to published expert advice.

c) Once the shortage is resolved, pre-shortage dosing should be resumed in a timely manner to avoid risk of malnutrition, essential fatty-acid deficiency or deficiencies of micronutrients.

d) Issues associated with PN shortages should be reported as a medication event according to national protocols (internally and externally).

13. Foster research to generate patient-centric data such as patient-reported outcomes, quality of life, functional status including physical and cognitive functions, depression, fatigue and/or other outcomes meaningful for patients by using externally validated instruments. These parameters should be regularly reassessed in all PN patients and integrated into the care plan.

14. Standardized trainings programs are needed to:

a) Foster competency in PN prescribing and ensure PN competency exists in each center.

b) Improve educational provisions of health sciences programs (e.g. medical, pharmacy, dietitians, nursing schools), professional societies and/or experts.

c) Ensure that programs translate theoretical knowledge into clinical practice under the supervision of experts.

Abbreviations: ASPEN, American Society for Parenteral and Enteral Nutrition; BAPEN, British Association for Parenteral and Enteral Nutrition; ESPEN, European Society for Clinical Nutrition and Metabolism; GMP, good manufacturing practice; ILE, intravenous lipid emulsion; IV, intravenous; MCBs, multichamber bags; PIC/S, pharmaceutical inspection convention and pharmaceutical inspection co-operation scheme; PN, parenteral nutrition; US, United States.

^aConsensus statements were voted on by all 13 expert panel members, and 100% voted "agree" for each statement.

^bAfter group discussion, statements 5 and 6 were merged to form a single statement before voting, after disagreements concerning these statements in isolation.

International differences in error reporting were also discussed briefly. For example, in Belgium, PN error reporting is part of a well-established standardized safety process, with hospitals having a centralized electronic

system for reporting errors, including those related to PN or other medications, and with feedback including suggested remedial measures to the hospital departments where the PN errors occurred. Corresponding

medication error reporting systems are in place in most US institutions. Nevertheless, a US survey found that 44% of institutions reported either not knowing about PN errors or that they do not track any errors that occur in

Table 2. Additional Consensus Statements Related to Parenteral Nutrition in the Home Infusion Setting/Long-Term Parenteral Nutrition^{19,20}**Consensus statement^a**

HPN 1. Patients requiring long-term HPN may have variabilities in IV fluid, nutritional requirements, environmental factors, and functional limitations. Evaluate carefully if nutritional requirements can be met safely with market-authorized MCBs (possibly customized through additives) or if customized compounded bags are the preferred option.

- a) An organizational specific set of criteria may help to objectively assess the need for customization of the PN formulation.
- b) Experience from the UK showed that market-authorized MCBs can be an option for patients with stable chronic intestinal failure on HPN when appropriate compounding facilities were not available.¹⁹ In the UK case, the risk of bloodstream infections was not increased when patients were changed from compounded to a non-compounded regimen. However, market-authorized MCBs should be available in different formulations and volumes to avoid unnecessary modifications of MCBs and product wastage.
- c) Market-authorized MCBs could be used in the US home infusion setting even within current limited options available. They also could be an option for a number of situations including the following:
 - i. during PN product shortages, supply-chain disruptions and disasters
 - ii. when PN-dependent patients travel for extended periods of time
 - iii. meeting the needs of long-term acute care facilities.

HPN 2. Transition of care (for example from home to hospital or hospital to home) is a particularly critical aspect within the HPN setting.

- a) To ensure accuracy and safety during transition of care, a standardized PN ordering template should be used across institutions (aim for an electronic template).
- b) Detailed communication between the PN prescriber team and the responsible care team is key.
- c) Consider a discharge and ancillary checklist.

HPN 3. Engage the patient/caregiver to become an active participant in their care.

- a) PN consumers should receive clear information about their PN regimen and safety (e.g. catheter hygiene). Ensure that information provided is understandable by laypeople. Multiple tools and channels of communication may be helpful.
- b) Quality of life should be regularly assessed in patients with HPN and integrated into the care plan. When assessing quality of life consider outcomes meaningful for patients and regularly follow-up on the patient's perspective (see [Table 1](#), statement 13).
- c) To foster adherence, the clinical and therapeutic PN regimen needs to be balanced with patients' lifestyle, personal needs, and goals.

Abbreviations: HPN, home parenteral nutrition; MCBs, multichamber bags; PN, parenteral nutrition; UK, United Kingdom; US, United States.

^aConsensus statements were voted on by all 13 expert panel members, and 100% voted "agree" for each statement.

ordering, transcribing, verification/review, compounding, administration, or monitoring of PN.³⁰ This uncertain handling of PN errors in many US institutions may contribute to the underreporting of PN errors. The consensus statements ([Table 1](#)) acknowledge the need to mitigate risks associated with PN (statement 5) and offer further guidance on PN error reporting procedures (statement 10). In addition, the statements advocate standardization by using a standardized PN compounding process and/or the greater use of MCBs when possible, depending on nutritional needs, expertise, resources, financial considerations, regulatory requirements, and availability of commercial formulations (statements 6 and 7).

Pharmaceutical formulation of PN. All-in-one (AIO) admixtures for PN can contain as many as 50 components,

including amino acids, glucose/dextrose, lipids, water- and fat-soluble vitamins, and trace elements, as well as fluid and electrolytes.³⁻⁵ An example of guidelines giving *clinically useful* nutritional requirements are those for chronic intestinal failure in adult patients.³¹ To achieve the best outcomes, PN formulations should meet each patient's specific nutritional needs ([Table 1](#), statement 1). Guidelines on the composition of PN formulations for different indications, patient settings, and age groups are available from the European and American nutrition societies (eg, European Society for Clinical Nutrition and Metabolism [ESPEN] in Europe and ASPEN in the US) ([Table 1](#), statement 11).

The role of lipids as a component of PN admixtures was discussed throughout the meeting. It was acknowledged that lipid emulsions should be an integral part of PN. However, there was some

concern over the continued widespread use of pure soybean oil lipid emulsions, particularly in the US. This is despite mounting evidence demonstrating improved clinical outcomes with more modern multicomponent lipid emulsions containing fish oil that reduce patient exposure to soybean oil¹⁴⁻¹⁸ ([Table 1](#), statement 11b). In Europe and other countries outside the US, there is widespread use of modern multicomponent lipid emulsions including fish oil and corresponding 3CBs, and several commercial lipid emulsions containing fish oil are available. When given according to the prescribing information and published recommendations, modern composite lipid emulsions, with or without fish oil, typically cover essential fatty acid requirements.³²

The choice of PN delivery systems, such as MCBs and hospital/pharmacy-compounded bags, was another

aspect that received particular attention during the meeting. AIO admixtures (ie, standardized compounded bags), and MCBs in particular, are now standard in many locations as they are associated with a reduced risk of infection, shorter length of hospital stay, ease of prescription, and savings in healthcare staff time and overall costs compared with multicomponent systems that were used previously.^{13,33,34}

As already indicated, preferences for PN formulations and delivery systems vary across countries. For example, in the US compounded PN bags prepared by pharmacies or outsourced sterile compounding facilities are very common, while commercial MCBs (2CBs) are mainly used in smaller centers with fewer PN prescriptions. In Europe and other countries outside the US, the use of 3CBs is established and they are often the primary PN delivery system in large academic hospitals, mainly for safety, workload/capacity issues, and cost reasons. As a consequence of the widespread use of MCBs in Europe, there is certainly a broader range of 3CB products available than in the US, for example. These geographical differences have been demonstrated by a cross-sectional survey comparing commercial MCB use with compounding in the US and different European countries for home PN (HPN) patients.³⁵ In Europe, up to 82% of patients received commercial MCBs (with or without added fluid and electrolytes), while in the US 90% of patients were given compounded PN preparations.

AIO PN admixtures can include a large number of components, mostly representing reactive species, and thus they must be thoroughly evaluated for stability and compatibility to ensure the safety and quality of PN.³⁶ Both stability and compatibility for any such AIO PN admixtures should be guaranteed up to the declared expiry date/time of administration under defined conditions. The physicochemical stability of a compounded PN formulation depends on numerous factors, including whether all macronutrients are admixed,

micronutrients are added, or light-proofed bags are used.³⁷

ASPEN guidelines have been published for PN prescribing, order review, and preparation of PN formulations,²³ and a standardized ASPEN model for PN administration competency has been approved.⁹ Major issues regarding the quality and safety of PN formulations and the PN process were identified during the summit. These include (1) continued poor availability of innovative technologies for the ordering and preparation of PN, (2) a very limited range of MCB/3CB formulations, particularly in the US, (3) a lack of education concerning the relative safety of lipids as part of PN, (4) the continued use of pure soybean oil formulations rather than moving towards newer lipid emulsions containing fish oil that can reduce infections and improve clinical outcomes,^{14-18,20} (5) continued PN product shortages, including vitamins, minerals, and trace elements, and (6) the need for strategies to assist with PN product shortages.

PN product shortages. A drastic shortage of single amino acid solutions occurred within the US healthcare system following the 2017 hurricane in Puerto Rico, which closed down major international PN manufacturing facilities. Thus, several hospitals had to switch to using MCBs/3CBs instead of compounded PN. Furthermore, in the US there have been long-running and constant shortages of adult multivitamins and multi-trace elements for PN, with discontinued product lines worsening this situation. Clearly, additional options are needed. In the US, information on drug shortages can be obtained from the American Society of Health-System Pharmacists (ASHP) drug shortages website,³⁸ the ASPEN PN shortage website,³⁹ and the US Food and Drug Administration (FDA) website on current and resolved drug shortages.⁴⁰ In the FDA database in June 2022, eight shortages were identified for items classified as “total parenteral nutrition,” namely injectable lipid emulsions, parenteral multivitamins, multi-trace elements, and intravenous electrolytes. In

Europe, the European Medicines Agency (EMA) publishes information on medication shortages, including a list of national registers for individual countries containing medicine shortage information.⁴¹ As of June 2022, none of the shortages reported in the EMA database pertained to PN components. The broad range of PN products available in Europe may be of help in finding strategies to overcome any shortages.

ASPEN has developed recommendations to help clinicians manage PN product shortages,^{42,43} and these useful documents are also used by European experts. The ASPEN website³⁹ provides regular updates on PN product shortages, and an ASPEN task force has prepared practical strategies to deal with shortages. One practical example for dealing with single amino acid solution shortages in one institution was shifting from compounded PN to MCBs whenever possible, which resulted in a 75% reduction in use of these amino acid solutions.⁴⁴ Likewise, a recent editorial has addressed how to deal with micronutrient product shortages from a European perspective,⁴⁵ and in the UK a British Intestinal Failure Alliance position statement has also addressed this issue.⁴⁶ Principles to address PN shortages are summarized in consensus statement 12 (Table 1).

PN in the hospital setting and short-term PN.

Within the acute care setting, the PN process has developed and improved over time, largely driven by academic centers and hospitals with ample expertise in this area. Although the need to make PN safer and more efficient is universal, different paths have been taken in Europe and the US to achieve these results. In the US, more attention has been given to compounding safety and efficiency, with commercial MCBs (usually 2CBs) used mainly in smaller/nonacademic centers with fewer PN prescriptions. However, in Europe, compounded PN is used predominantly in patients whose nutritional needs are not covered by commercially available formulations (eg, for PN in preterm infants or neonates with specialized

nutritional needs), and in clinical practice MCBs/3CBs are used widely.^{2,28,29,47,48} This led to a wider range of MCBs (typically containing all 3 macronutrients and a variety of lipid sources) becoming available at an earlier date in Europe than in the US. Thus, in Europe, where the nutritional needs of the majority of adult patients are covered by MCBs/3CBs, this has further facilitated the use of PN in centers with only a few PN prescriptions per day,²⁸ a trend that is also increasingly being noticed in the US.^{2,24}

During the summit, the PN use process and efforts to overcome current challenges were discussed, as mentioned previously, with regard to hospitals covering 39 US states and ranging in size from 38 to 748 licensed beds, mostly in acute care. Measures taken to improve the safety and quality of PN were in line with expert recommendations^{2,5,9} and included PN process standardization, implementation of electronic order sets and systems, fostering interdisciplinary communication, vigilant surveillance for complications, and staff education. One aim of this PN quality program is to reduce outsourced and manually prepared PN and move towards the use of commercially prepared MCBs for most adult patients. In most hospitals this strategy was acceptable and worked well, but in other locations compromises between clinical efficiency and current practice were necessary for hospitals to retain their autonomy.

Experience with PN was also shared from a US medium-sized hospital, the East Alabama Medical Center. This is a community teaching hospital and acute regional referral center with 340 beds and an electronic health record system (Cerner Millennium), as well as an automated compounding device (ACD), with on average about 10 adult and 5 neonatal PN prescriptions per day. At times, this institution has used 3 different PN systems running in parallel: MCBs (2CBs) for amino acids and dextrose/glucose, with intravenous lipid emulsion given separately; an in-house, hospital-compounded

AIO PN bag; and outsourced custom-compounded AIO PN (for neonates). This poses problems with PN inventory management, concerns over storage and product expiration dates, staff confusion, and requirements for extra training to enable successful transition between systems. The hospital also took part in a multicenter, prospective, observational study to evaluate PN preparation time and resource use with either MCBs containing the 3 macronutrients (amino acids, dextrose/glucose, and lipids) or hospital compounded bags (HCBs).³⁴ MCBs (3CBs) reduced staff time by 62% and direct costs by 37%. As these data indicate, use of 3CBs may offer savings of staff time and costs, but a wider variety of commercial 3CB products need to be available to meet the needs of patients at this institution.³⁴

Three European academic centers (in Lausanne, Switzerland; Ghent, Belgium; and Barcelona, Spain) shared experiences to improve PN safety and quality. In Switzerland, MCB/3CB use is preferred for reasons of better safety and reduced cost,²⁶ as is the case elsewhere in Europe,⁵ with compounding usually only performed in large university hospitals and for a few patients in need of a tailor-made PN formulation. Current data was shared regarding PN usage in the intensive care unit (ICU) of the academic teaching hospital in Lausanne, in which patients requiring PN typically receive supplemental PN (SPN). To decide when SPN is indicated, the Swiss SPN trial criteria are followed⁴⁹ (for more insights, see the article on short-term PN in this supplement). This strategy can reduce the incidence of infectious complications and reduce costs in critically ill adults within this Swiss population when enteral nutrition is insufficient to meet energy requirements.²⁷ In the Lausanne center, nutritional needs are covered with MCBs/3CBs for about two-thirds of ICU patients requiring PN, with additions of vitamins and trace elements from day 1 of PN and, in the sickest of patients (including those receiving continuous renal replacement therapy),

glutamine if they are given PN for more than 5 days. Other ICU patients require individualized tailor-made compounded PN prepared by the hospital pharmacy.

In University Hospital Ghent, the PN process has evolved over the last 20 years, prompted by efficiency requirements, new patient safety recommendations, and approval and availability of MCBs. It is a tertiary teaching hospital with 1,062 beds that uses 36,000 PN bags per year for adult, pediatric, and neonatal ICU patients (hospital and homecare), with about 15,000 of these being either compounded bags or customized MCBs (for adult patients). The latter are commercial MCBs that require additives other than just trace elements and vitamins (eg, extra electrolytes, glutamine) that are assembled within the hospital pharmacy; otherwise, MCBs are handled directly in the wards by trained nurses. (For more insights on this topic, see the article on short-term PN in this supplement.) Measures to improve patient safety include calcium additions to MCBs being performed by the hospital pharmacy to prevent calcium phosphate precipitation, use of an electronic ordering system with the provision of predefined medication order sets for PN, and the standard use of MCBs whenever possible. These are all well-established means of reducing transcription, calculation, or compounding errors, as well as stability and incompatibility issues, and of lowering the risk of infections.^{2,13,23,50}

The University Hospital Vall'Hebron, Barcelona, Spain, uses 15,000 PN bags per year, of which 8,000 are MCBs and 7,000 are compounded. MCBs are given whenever possible, while compounded PN is generally for patients whose nutritional needs are not met by commercially available MCBs or for those with volume restrictions. All additions to MCBs are performed in the pharmacy under aseptic conditions: Trace elements and vitamins are added to all bags (unless recommended otherwise), close to 20% are amended with electrolytes, and about

8% are supplemented with additional glutamine (not FDA approved for use in the US). The University Hospital Vall'Hebron has participated in several studies investigating the safety and cost-effectiveness of MCBs versus HCBs.^{5,13,51,52} For example, a retrospective survey followed the transition towards a policy to use MCBs for adult patients when possible.⁵² Use of commercial MCBs increased from 47.5% to 85.7% ($P < 0.05$), with no significant difference in quality criteria, but costs were decreased by 19.5%, with an estimated annual cost saving of €86,700 for the hospital.⁵² A prospective, observational study across 10 Spanish hospital pharmacy services showed cost and time savings per 3CB were \$5.71 and 38 minutes compared with equivalent HCBs, with a lower error rate for 3CBs.⁵

PN use at home/long-term PN: international examples.

In the US, the Vanderbilt Center for Human Nutrition Experience serves about 150 patients receiving HPN. In this setting, all HPN bags are compounded, including some 2CBs (compounded, with a separate lipid bag), but no commercially available 3CBs are used. Standardization of the HPN process has encompassed both ordering and compounding. Ordering has been standardized by the use of a proprietary HPN order template built into electronic medical record systems (for computerized physician order entry), facilitating transitions of care to HPN (or other settings). Compounding consists primarily of individual customized PN bags, prepared in 7-day batches, designed to meet all intravenous nutritional and fluid needs. This does not include multivitamins, which must be added by the patient/caregiver just before administration owing to lack of long-term stability. It is difficult to perform more additions (eg, electrolytes, micronutrients) to bags within the HPN environment. There is a limited role for customized commercial MCBs (ie, during product shortages or patient travel). The center has identified PN transitions of care as major potential sources of errors (Table 2, consensus

statement HPN-2). To improve patient safety, the center incorporates twice-weekly multidisciplinary rounds or huddles to prepare patients for discharge home on PN and enable good communication, as well as a quarterly quality improvement program that targets hospital discharge events that can potentially result in patient harm. Patients are also encouraged to be active participants in the error identification and reporting process.

The Intestinal Failure Center at Stanley Dudrick's Memorial Hospital in Skawina, Poland, is one of the largest HPN centers in Poland and is organized as a "one-stop shop," offering all services around HPN, so transition of care is not generally considered an issue. In Poland, clinical nutrition is regarded as a multidisciplinary, multiprofessional process starting with clinical diagnosis and screening for malnutrition risk and underlying diseases, then progressing to prescription and subsequent delivery of enteral nutrition and/or PN, to help improve patients' outcomes. The multidisciplinary HPN team consists of physicians (eg, an intensivist, a surgeon, and a gastroenterologist), nurses with specialist expertise (eg, stoma care, wound care, and/or HPN specialists), a dietitian, a pharmacist, a psychologist, and other specialists as needed. Patient education is considered as essential for successful HPN, and this can be a complex and lengthy process. Thus, at Stanley Dudrick's Memorial Hospital, patients' HPN training schedule lasts 2 to 3 hours per day for 1 to 2 weeks. Patients need to be capable, willing, and trained for managing PN outside the hospital setting.^{31,35,53-55} They should also be aware of HPN treatment goals, such as maintaining fluid, electrolyte, and nutrient balance and reducing the risk of metabolic complications and catheter-related bloodstream infections.^{35,56,57} HPN patient education is also addressed in statement HPN 3 (Table 2).

In patients with chronic intestinal failure receiving HPN, protein and energy requirements should be based on each patient's individual condition and

needs and evaluated regularly by using clinical, anthropometric, and biochemical parameters.³¹ Moreover, lipid emulsions are a crucial component of HPN, and in addition to providing essential fatty acids and nonprotein energy, they can have anti-inflammatory and immunomodulatory properties owing to addition of fish oil as a lipid source.³¹ Patients with chronic intestinal failure without ongoing metabolic complications can be treated safely by limiting the provision of soybean oil lipid emulsions to no more than 1 g of lipids per kilogram of body weight per day.³¹ The choice of lipid emulsion is a key issue for HPN in particular. A common strategy in Poland and elsewhere in Europe is to use mixed lipid emulsions containing soybean oil, medium-chain triglycerides, olive oil, and/or fish oil, which can provide additional benefits in terms of liver function during long-term HPN. Furthermore, a survey of HPN modalities in 3,239 patients with chronic intestinal failure in 22 countries revealed that PN modalities (ie, commercial premixed PN or customized/compounded PN) and admixture supplementation (ie, with extra fluids and electrolytes) differed greatly between countries and according to whether patients had benign or malignant intestinal failure.³⁵ As these variations can affect HPN safety and effectiveness, it could be beneficial to formulate criteria to optimize PN components for patients on HPN.

A UK perspective on HPN was shared, detailing that most HPN for chronic (type 3) intestinal failure is provided generally as compounded PN. There are national templates for formulation requests and prescriptions for HPN. A sudden and unexpected decrease in compounding capacity within the UK in 2019 resulted in an increased use of MCBs (ie, 3CBs), as well as the provision of contingency noncompounded HPN prescriptions for all patients in case of future shortages. The choice of HPN modality is a multidisciplinary decision and depends on whether nutritional needs can be met safely by an MCB, with or without additions. There are still

pressures on capacity for compounded HPN within the UK. Thus, patients with the highest clinical need for tailor-made compounded admixtures are identified using a scoring system and are given the highest priority to receive compounded HPN. While there were some challenges for patients previously receiving compounded HPN to get used to MCBs, generally MCBs meet the requirements of many HPN patients, are simpler to use, do not need refrigeration before activation, and require less frequent deliveries. In the UK, shortages of PN compounding capacity have had a long-lasting effect, such as the setting up of an HPN clinical advice and management group. Hospitals with patients assessed as requiring compounded HPN are referred to this multiprofessional expert group, and a clinical decision is now made for each patient as to whether compounding is necessary. This is done according to the feasibility of using 3CBs (with or without intravenous fluids/electrolytes and separate micronutrient infusions).

PN use at home/long-term PN: patient perspectives. Patient perspectives concerning HPN were also shared, including experiences from a pharmacist with extensive experience in HPN who is also an HPN consumer. It was acknowledged that HPN care quality in the US is highly variable because of different HPN providers, differing patient personal situations and environments, and regulatory requirements. Patients undergoing HPN would also benefit from 24-hour support from PN healthcare staff (Table 1, statement 13). Moreover, greater flexibility is vital, as even with the current limited availability of 3CBs/MCBs in the US, these alternatives clearly should be available to people receiving compounded HPN in case of traveling or emergencies (Table 2, consensus statement HPN-1). Occasional use of MCBs during a normal daily routine may also be beneficial, allowing patients to practice using them.

HPN compliance and patients' quality of life was also considered as a relevant topic. One problem is the

lack of dissemination of nutritional society guidelines to local clinicians and patients, which contributes to a decrease in awareness. One method to address this problem is to reconsider how to inform HPN patients and how to prepare them for a much more active role in their own healthcare (Table 2, consensus statement HPN-3).⁵⁸ For example, a lay version of guidelines should be available, and a plan to disseminate the guidelines should be written at the start of the development process.⁵⁸ Barriers to the implementation of guidelines (ie, compliance) by physicians and other healthcare professionals include resistance to change practices/behaviors, lack of awareness or experience, resource constraints, lack of time, and numerous, complex, overly long, or outdated guidelines.^{59,60} The role of patient adherence is also particularly vital in the HPN environment. This can be addressed by better education to inform patients why they should follow the prescribed regimen and also to involve the patient in decisions concerning the best way to fit the HPN regimen to their schedule, enabling them to continue with their normal daily activities. As such, the monitoring of health-related quality of life is imperative for HPN, though the importance of patient-centric data is frequently overlooked (Table 1, consensus statement 13).

Patient adherence to a PN regimen is essential for PN quality and safety, and so patient-centered outcomes are also considered to be at least as important as hard clinical endpoints when assessing PN therapy success. Patients and their families should be involved as active participants in care, particularly within the setting of long-term PN, and the effect of PN on each patient's quality of life should be assessed routinely. This patient-centered care approach requires patient education tools that allow patients and their families to understand treatment goals, options, benefits, and risks. To help with this objective, guideline recommendations should be produced in formats that are understandable by patients, perhaps in

the form of practical short documents, such as "one pagers," providing clear and explicit information. Furthermore, physician and patient priorities for PN may differ, and a patient-centered approach can help to foster compromise between these viewpoints. This can result in mutually beneficial outcomes such as patients experiencing greater autonomy in their daily life and an improved ability to cope with the stresses and burdens associated with PN and their medical condition.⁵⁶

Safety and quality of PN: future perspectives. During the summit the attendees discussed challenges and unresolved issues associated with PN and formulated ideas for improvements, particularly regarding PN prescribing and administration. A central issue for PN prescribers is to ensure that every patient needing PN is given a formulation to meet their nutritional requirements, regardless of where it is prescribed and administered. It is important to "close nutritional gaps" by identifying patients with malnutrition or at risk for malnutrition, and to give them timely nutritional support—preferably using a standardized approach. The Global Leadership Initiative on Malnutrition (GLIM), alongside other national and international nutritional societies, recommends (1) screening to identify patients with malnutrition or at risk for malnutrition by using a validated screening tool, and (2) an assessment for the diagnosis and severity grading of malnutrition.⁶¹ Expertise to achieve these goals is not available in all centers, but consultancy and training services provided by larger institutions or national nutritional societies can fill this knowledge gap. Thus, for example, smaller institutions with less PN expertise and/or low PN prescription volumes could partner with larger centers with ample PN capability, and national nutritional societies could also offer consultancy services.

Discrepancies between intended clinical processes for PN ordering, prescribing, compounding/preparation, and administration and the actual PN process were identified as critical issues

for many centers. It is important that recommended routines and safety precautions are followed, as PN is highly complex and carries the risk of serious complications, including intestinal failure-associated liver disease, thrombosis, metabolic complications, and (mainly as a result of poor handling processes) central line-associated bloodstream infections.^{56,62,63} Poor practice within PN centers can result from a lack of knowledge and proper training, insufficient education and awareness about the importance of nutrition support (eg, leading to PN being considered a “cost item” rather than a general and integral service), and PN not being recognized as a medication by many organizations, particularly in the US, leading to underreporting of errors.¹ Therefore, PN staff training and error reporting programs are advocated (Table 1, consensus statements 9, 10, and 14).

Patient adherence to PN processes is a particular challenge in long-term HPN for several reasons.⁵⁶ Transition of PN prescriptions from one institution to another location is a risk factor. There are also patient-associated risk factors (eg, some patients may not be capable and/or willing to follow instructions owing to issues such as poor cognition or fatigue); and there may be problems related to the acquisition, distribution, and storage of compounded PN admixtures during emergency situations.⁵⁶ One solution is to have a small emergency stockpile of 3CBs/MCBs for these circumstances. It is important that PN is prescribed, prepared, and given by healthcare staff whose competencies are regularly reassessed. Ideally, interdisciplinary nutrition support teams are involved in patient care throughout the PN process,⁶⁴⁻⁶⁶ to better align patients and healthcare staff, facilitate a safe transfer from the hospital to the home setting, and fulfill patients' priorities, such as maintaining their quality of life and independence. Participation in interdisciplinary rounds to discuss patient cases can help to develop and improve knowledge,⁹ as can *jours fixes* (regular scheduled meetings), which

can be more memorable and thus, presumably, better attended than ad hoc gatherings.

Following evidence-based guidelines for PN prescribing, order review, and preparation,²³ and a standard model for PN administration competency, should ensure that patients receive PN according to state-of-the-art principles. However, routine compliance in line with nutritional guidelines is often poor. Moreover, there is often a lack of clinical expertise on best-practice PN care in line with current guidelines.^{67,68} This underscores the need for effective remote education strategies. Remote education strategies can help to bring medical expertise to underserved regions.⁶⁹ For example, the Extension for Community Healthcare Outcomes (ECHO) model uses videoconferencing technology to move specialized medical knowledge from academic centers to primary care providers in the community.⁶⁷

Many institutions are still using handwritten PN orders and must transcribe them multiple times (into the electronic health record and then into the ACD), and in other hospitals electronic health records do not interface with ACDs, so transcription of orders into the compounding must occur. Thus, it is important to foster more widespread and better-integrated advanced technologies in compounding. These could include barcode-assisted medication preparation systems, further reducing transcription errors, and fulfilling safety precautions such as hard-stop upper limits for electrolytes.⁷⁰ Although electronic health records usually function well within one institution, when several institutions are involved interface problems can occur. This can be a common issue for long-term PN patients transitioning from hospital to home or alternative care settings, and vice versa. A manual transcription of the PN orders is usually required and can involve different level of coordination by healthcare staff. However, practical recommendations are available for these scenarios.^{1,71}

Conclusion

This article provides a set of expert consensus statements resulting from the International Safety and Quality of PN Summit and also provides a summary of the main topics that were presented and discussed at the meeting. The authors hope that the consensus statements will be useful in daily clinical practice, forming best-practice guidance and complementing national and international nutrition society evidence-based guidelines and position statements. In particular, presentations and discussions involving a variety of international PN experts (clinicians, pharmacists, and dietitians) helped to formulate these statements, with the intention of helping to bring about international improvements in the quality and safety of PN that might be applicable to institutions of all sizes and/or in the home environment. At the summit, and in this article, the authors have searched for and implemented an approach that is pragmatic and affordable—realistic rather than idealistic. Rather than viewing such an approach as a compromise, the authors feel that their pragmatism may be of more universal utility than some formal nutrition society guidelines, which have sometimes advocated goals that are not viable for many smaller centers or poorer countries.

Data availability

No new data were generated or analyzed in support of this article.

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