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Premix vs. Custom TPN

Technical Paper

A history of nutritional best practice and an examination of the use of premixed solutions for parenteral nutrition.

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Overview

America's health-system resources are often stretched to the extreme. So the critical question becomes, how can hospital management and staff achieve that fine balance between patient care and cost? In the past decade, hospital and health systems have attempted a myriad of solutions to address this tough question.

Introduction of premixed parenteral nutrition (PN) in different strengths and volumes goes against the industry trend to control inventory (reduce the number of products) in order to decrease the opportunity for errors. Premixed PN can meet the needs of a limited number of adult patients. It's important to note, however, that premixed PN is not appropriate for pediatric, neonate or premature patients¹ nor does it provide for any specialty amino acid formulations or formulations for fluid-restricted patients. Despite this, the industry is being encouraged to revert to a standard of practice that was abandoned in the mid 1980's. An established facility Clinical Nutritional Committee can help determine the best clinical nutritional therapy for a patient and reduce costs through the proper utilization of parenteral and enteral nutrition therapies.

Process control is an integral part of any successful PN program. This starts with having a well-defined policy on PN usage. Developing a clear, concise order form based on the actual PN practice at individual facilities will assist practitioners in the prescribing process. Limiting the PN ingredients available, developing in-depth competency-based training for all personnel, as well as solid Standard Operating Procedures will assist the pharmacy team in addressing the most common critical points of failure. Following these standard practices will provide the nursing staff with consistent, accurate, timely and clearly labeled PN product. By having clearly defined roles and working in concert, the care team will have a tailored PN solution that meets these specific needs and provides the best possible outcome for the patient.

The lack of commercially available software to utilize premixed PN solutions that require additives makes proper labeling, calculations to determine flow rate and setting hang time(s) complex and difficult to achieve. In addition, the facility must manage patients receiving multiple bags per day, multiple hang times, and determine whether incomplete bags are kept hanging into the next 24-hour period or discarded to begin the next order period. Using multiple bags per day doubles or triples the nursing time needed to manage TPNs. Clinicians then must decide how to incorporate these decisions into the patients' daily nutritional calculations. The complexity of these decisions, impact on staff and calculations makes the final determination of nutritional delivery extremely difficult. Policies also must be put in place to prevent the administration of premixed PN bags and lipid piggybacks beyond their labeled expiry.

Introduction

In today's complex healthcare environment, providers are practicing in a healthcare system where navigating through the intricate eco-system is a daunting task that requires the best sources of information in order to make

critical decisions for delivery of care. What makes medical practice most challenging is effectively managing a system that assures consistent quality care amid the maze of changing legislation, regulation, and payor red tape under conditions that are less than optimal in view of the financial constraints and accountability. It's a delicate balancing act to address increasing patient care needs with continual cost increases and diminishing reimbursement.

Since the 1980s, hospitals have seen an explosion in the amount of technology brought from the drawing board to the bedside. Paperless charting, e-prescribing, automated compounders, micro-accurate infusion devices and automated dispensing cabinets have forever changed the face of modern healthcare practice.

Individualized patient-focused care can be lost in the flurry of advances designed to make us better, faster, and more efficient. How is this achieved? All of the improved methodologies and high tech gadgets are provided so we can spend more time with our patients – but is this truly the result? Careful inspection of the system reveals such a state of overwhelming need that any attempt to implement process controls to streamline operations is embraced as an advance in practice.

One example of an attempt to improve productivity is the marketing initiative to encourage the use of premixed Parenteral Nutrition (PN). The argument for premixed PN revolves around misinformation and faulty assumptions. The value proposition suggested by the use of premixed PN is that the cost per dose is lowered by a reduction in labor, materials, and indirect costs such as drug waste, quality assurance and inventory. In reality, premixed PN still requires additives to be injected, even to premixes containing a standard additive profile, and incurs incremental material costs for gravity transfer sets for lipid emulsions or sets to administer lipid piggybacks. Premixed PN is available only in a limited number of volumes, which inhibits clinical considerations for substrate absorption rates and fluid volume delivery. This in turn requires clinicians to make adjustments to the administration rate to deliver the correct amounts of the prescribed ingredients in the time specified. Premixed PN, therefore, forces clinical decisions to be made in order to accommodate manufacturer production decisions rather than appropriateness of the therapy for patient-specific needs.

History and Background

The preparation of PN has undergone many changes and trends during the past 40 years in the United States. Originally, manufacturers provided 500 mL bottles of amino acids and 500 mL bottles of dextrose that were combined to produce a 1 Liter bottle or bag. Electrolytes, trace elements, and vitamins were added to prepare a final PN bag(s). This type of preparation rarely took into consideration the excess amount of fluid added, took time to manually prepare, and was administered over 8 to 24 hours. The PN preparations were prone to error and microbial contamination because of how and where the sterile preparations were prepared and the use of multiple source containers in the preparation of each order. Hanging multiple bags was required if the patient needed more than 1 liter per day. The source amino acids and the dextrose concentrations were

limited, thus making the compounding of a truly tailored PN solution for the patient difficult, if not impossible.

As technology advanced and automation came into the IV room, pharmacy personnel gained the ability to pump specified quantities of high-concentration amino acids, dextrose, lipids, sterile water for injection, electrolytes and other micro ingredients. New PN software programs afforded the ability to alter the amount of sterile water for injection incorporated into the PN, so the fluid volume from the electrolytes, trace elements, and vitamins could be compensated for, and the final volume controlled. More advanced PN software programs afforded the user the ability to order specific amounts of anions and cations, then have the software determine the combinations of source ingredients necessary to meet the request. The ability of automated compounders to accurately and consistently pump these solutions, along with the introduction of 2,3 and 4-liter containers, allowed preparation of larger-volume PNs. The larger volumes, encompassing all of the patient's nutritional needs, allowed one PN bag to infuse over a 24 hour period. These larger-volume PN bags reduced the number of PN units prepared daily, allowed a standard hang time for all patients, simplified nurses' medication administration schedules to hang the PN and allowed lipids to be included directly in the PN infusion (also known as 3-in-1 or Total Nutrient Admixture – TNA). The ability of automated compounders to add micro ingredients directly to PN allowed the majority of the compounding process to be automated. This automation improved the accuracy and repeatability of ingredient delivery, reduced the number of manipulations, thereby decreasing the potential for microbial contamination of the final product.

Current State of Parenteral Nutrition

Recommendations from industry leaders (Pharmacy Associations, and Professional groups) and individual clinicians have been made for the establishment of Nutritional Committees at all institutions. These Nutritional Committees should be multi-disciplinary – including physicians, nurses, dietitians and pharmacists, as well as ancillary personnel. The purpose of these committees is to determine the proper course for patients' nutritional needs, provide a standardized ordering method, and at the same time, decrease costs through proper utilization, standardization of bulk component solutions and a once-a-day hang time.^{6,7,8,9,10} This movement toward standardization also drove the types of lab tests and the associated draw times they were to be routinely performed for PN patients.

The ability to individualize PN to a specific patient's need is considered 'state-of-the-art'^{8,9,10} in the United States, as well as other parts of the world. Patients are clinically evaluated to determine their individual nutritional condition, disease state, energy needs and electrolyte status. PN software programs have been developed that allow for individualized patient order preparation. These PN software programs have introduced standardized labels, the ability to set institution-specific warnings for electrolytes, calcium/phosphate curves, and osmolarity cutoff limits for peripheral administration. Complementary automated compounders provide bar-coding to safeguard the patients. Additionally, the

introduction of the routine use of PN software with automated compounders to control the proper sequencing of additive ingredients has significantly decreased patient risk and increased positive patient outcomes.^{15,16}

Globally, the preparation of PN is in various stages of development. Some countries are in its infancy, preparing one-liter bags and hanging multiple units of these bags per day. This PN process may be automated or manual. Other countries, France in particular, have a limited number of standardized solutions available to provide to the patient. The standard of practice in France has long been to have nurses on the ward add the individual micro-additives to the standardized PN solution.⁴ This type of standardized premixed PN solution decreases pharmacy cost by eliminating the compounding step in the confines of the pharmacy. However, it increases the staffing on the wards which the physician manages and increases the risk to the patient by overloading the nurse and transferring the aseptic risk from pharmacy to the bedside.⁵ Additionally, this practice increases the amount of inventory on the nursing unit and decreases the control of what is being added to the PN. Canada provides both standardized PN and individualized PN, depending on the province, as each province is free to choose its PN method.

Using Premixed PN

Although superficial studies¹² have been conducted with the goal of demonstrating that a high percentage of adult PN falls within a very narrow range of amino acid, dextrose, fluid volume, infusion rate and additive ingredient variations, the reality is that patient-specific formulations are in fact just that – ‘patient specific’ – as determined by the practitioner (i.e., physician, dietitian, pharmacist, nurse, etc.) to meet the clinical nutritional needs of the individual patient. Unlike other premix medications that are administered intravenously such as potassium chloride, magnesium sulfate or premixed anti-infectives, where the dosing ranges and guidelines are broad and well-established; parenteral nutrition is intended to meet the specific needs of a given patient to support nutritional needs, healing and recovery. Generalizations in this regard can substantially affect not only the nutritional status of the patient but the overall effectiveness of any other therapies concurrently used in the care of the patient, and ultimately the patient’s health.

This premixed PN initiative is confusing because up to this point, solution manufacturers, drug distributors and hospital material managers have been encouraging the pharmacy department to reduce the overall inventory items, which include TPN items and therefore carry only limited strengths and package sizes of amino acids, dextrose, lipids, sterile water for injection (SWFI) electrolytes and other micro-ingredients to create individualized PN for all patients. These same manufacturers and drug distributors have been eliminating the availability of multiple strengths of amino acids solutions, amino acids with electrolytes; making some strengths of dextrose unavailable; eliminating partial-fill bags and packaging products in a limited number of volumes. In some cases, Pharmacy departments have been encouraged to carry single strengths of individual electrolytes when two or more strengths are available to reduce the potential for errors during the compounding process.

Recommendations also were made for a standardized hang time, once-a-day dosing, and the addition of lipids directly to the PN to decrease cost and reduce the potential for microbial contamination of the PN. These limitations, therefore, mean clinical decisions are being made for reasons other than clinical rationale. Certainly, cost containment is a universally shared objective in the healthcare industry, however the cost/benefit ratio of premixed PN versus patient specific PN is marginalized by the very minor differences in cost, if any, and the very real possibility that patient outcomes may be adversely impacted in the process.

As mentioned earlier, Institutions have been encouraged to establish nutritional committees^{6,7,8,9,10} to control the use of parenteral and enteral nutrition, determine the best clinical practice, create a standardized PN order form(s) and PN label format(s), and determine the nutritional needs of patients in a multi-disciplinary team approach. These recommendations have merit. Premixed PN offerings to the market, on the other hand, are based on production economics, supported in small measure by limited statistics and carefully constructed clinical studies directed to reach a specific predetermined conclusion.¹²

The Role of Process Control

Central to the argument for premixed PN is the notion that use of a premixed product is an advance in practice to decrease the chance for compounding errors and microbial contamination. Premixed PN may have prevented incidents where sterile water for injection and dextrose were not properly administered.² However, to counter the incorrect addition of components, manufacturers have introduced automated compounders that incorporate barcode technology to prevent incorrect solutions from being introduced into the compounded PN. Premix PN does not prevent errors in the sequence in which ingredients are added³ because sequential addition of ingredients most likely is not controlled and left to individual preference, or compounding personnel may introduce the wrong or incorrectly measured micro ingredients.² In contrast, compounding automation can prevent these common human errors. Additionally, neither custom nor premixed PN products would prevent another common error – administration of a central-line PN into a peripheral line.² Each of these incidents points instead to poor process control.

Proper understanding and acceptance of process control will help reduce errors in PN utilization and preparation, especially where these errors point to a lack of training or competence in clinical nutrition, PN preparation³, inattention to detail², improper calculations, lack of a controlled ingredient inventory for PN preparation, inconsistent ordering methods, missing label information, or incorrect PN prescription order transfers. Examination of these possible “points of failure” in a hospital or health-system’s current practices through a failure modes and effects analysis (FMEA) as well as a root cause analysis of any known errors that a hospital or health system has made in the past will also aid in making any PN program better.

The exclusive use of premixed PN seems to go against current recommendations¹³ for process control and indeed the training requirements for USP compliance, as this trend moves pharmacy practice back to multiple premix PN bags per day with varying amounts of manually added components. Premixed PN does remove the task of compounding the base components by pharmacy personnel, while requiring multiple additives to be injected into the final bag. In cases where the patients will require more than one premixed PN unit a day, multiple PN bags per day can increase the risk of infection, potential for medication errors and indeed the cost of labor and materials.¹¹ Replacing Total Nutritional Admixture (TNA) with premix PN and lipid piggyback(s) also is associated with an increase in the risk of infection and increased cost for labor and materials. Current PN administration standards^{17, 14} recommend TNA so that a mixed fuel (dextrose and lipids) is utilized. Care must be taken to prevent administration of premixed PN, amino acids and lipid piggybacks beyond the labeled expiry.

Each institution must have a clear, concise ordering form and ordering methods to prevent transcription errors. The order form and labels must reflect the PN practice of the institution¹⁷, while incorporating ASPEN recommendations for best practice.¹⁸ Judicious effort should be taken when reviewing recommendations for forms and labels. Outside recommendations for any hospital or health system provide only broad direction and areas to examine for improvement of PN compounding.

Efforts have been made to make standardization of PN order forms and premixed PN synonymous concepts.¹² However, standardization of PN order forms and standardization of therapy should be entirely separate ideologies. Ultimately, the quality of care lies in the professional judgment of the clinical nutrition team. Although standardization is efficacious as a management tool, its intrinsic value should not be extended beyond that level. Individualized patient nutritional support needs should be the guidebook for care rather than commercial product marketing and rationales constructed to support the corresponding marketing platform.

Facility-Specific Evaluation of Premix PN

In the United States, what is considered “state-of-the-art” for PN preparation is once again at a crossroad. Standardized premixed PN products are being introduced to replace a few of the individualized adult PN. Recent studies have indicated that these premixed PN solutions still require manual addition of electrolytes, trace elements, and vitamins before administration to the patient.¹⁷ These additives increase the final volume of the preparation. The increased volume, therefore requires calculations to be performed to adjust the administration rate to deliver the correct amount of the nutritional products, electrolytes, trace elements, and vitamins in the time specified.

Premixed PN comes in a limited number of fixed-volume package sizes. Using these fixed-volume packages will result either in some of the solution being wasted, or the necessity of hanging multiple packages in a 24-hour period. If this were not confusing enough, premixed PN does not address the needs of

pediatric, neonate or premature patients¹, nor provide for any specialty amino acid formulations or formulations for fluid-restricted patients. Following the recent regulatory changes with the implementation of USP <797> standards, proponents of premixed PN have argued, inaccurately, that elimination of admixed PN will reduce the compounding risk levels and therefore the cost of capital investment in the preparation of sterile products. In fact, other activities such as batch preparation of antibiotics, standard IV's, cardioplegia solutions and other multiple-ingredient, multiple-manipulation admixtures from the simple (antibiotic reconstitution) to the complex (such as chemotherapy or cardioplegia) still require facilities to be USP <797>-compliant. Using premix PN will not reduce an organization's need to comply with the USP <797> requirements.

The evaluation of premixed PN for use at an individual facility requires a serious examination of its PN practice. The operational requirements¹⁷ of individual facilities should mandate:

1. Review of the practice of hanging one bag per day.
2. If using TNA, determination if the premixed PN allows for the addition of lipids or if lipids will need to be hung separately.
3. Setting order cut-off times.
4. Required/desired delivery times to the floor/unit and standard hang times.
5. Evaluating the scheduling effects of hanging multiple bags with varying hang times.
 - a. Pharmacy Impact:
 - i. Will PN need to be prepared on all shifts?
 - ii. Are competent and trained staff available on all shifts to prepare PNs?
 - iii. How will this change in compounding impact the pharmacy's ability to comply with USP <797>, especially as it relates to beyond-use-dating (BUD)?
 - b. Nursing Impact:
 - i. Are there additional nursing staff available for administration of multiple PN bags in a 24-hour period; and are they trained in the associated recalculation of rates and daily nutritional calculations?
 - ii. Are all shifts trained and competent for safe PN administration?
 - iii. How do you manage the increased risk of incompatibility, such as concentrated electrolytes meeting at the Y-site?
 - iv. Are pumps available for electrolyte, lipid piggybacks?
 - v. How difficult will it be for materials management to track pumps and tubing and bag usage?
 - c. Lab Schedule Impact:
 - i. Are PN labs drawn at the same time each day?
 - ii. Will results be received and reviewed on a timely basis? If changes are necessary in the TPN, how and when will this take place if a full bag is already hanging?
 - iii. How will the administration of multiple bags alter the testing needs or disrupt the operations of the lab staff?
 - iv. Will the lab be able to process specimens all day long for PN patients?

6. Verification of whether the available premixed PN solutions meet the clinical needs of the institution.
7. Evaluation of software needs:
 - a. Is the software capable of determining the required rate to deliver the needed amino acid and dextrose?
 - b. Can the software compensate for delivering the ordered electrolytes, trace elements, and vitamins in the specified period?
 - c. Does the software label the modified premixed PN products correctly to comply with ASPEN recommendations?
8. Comprehensive evaluation of whether using premixed PN saves time and money for pharmacy, nursing, laboratory, materials management, Bio-Med and central sterile processing.
9. Quantification of the additional cost of carrying inventory of multiple premixed PN solutions and volumes; as well as the cost (in time, labor, inventory, etc.) of adding items to the premix PN.
10. Evaluation of the skills required to support ad hoc calculation of flow rates, hang times, and other adjustments to address the patients' nutritional calculations.
11. Analysis of the potential risks in moving away from automation to manual mixing for medication errors and patient safety.

Conclusions

Recently, premixed PN base solutions, augmented by manual additions, have been promoted as 'best practice'¹² for parenteral nutrition. This is a standard of practice that was abandoned in the mid 1980's as IV pharmacies moved to prepare PN with the specialized technology and bar coding provided by automated compounding devices (ACDs). Premixed PN solutions are a less-satisfactory option than these patient-specific PN solutions for a number of reasons, including:

1. Premixed PN is not a complete system.

- Premixed PN can meet only the needs of a limited number of adult patients.
- Premixed PN is not appropriate for pediatric, neonate or premature patients, nor does it provide specialty amino acid formulations for fluid-restricted patients.
- Using premixed PN does not eliminate the need to compound base solutions and ingredients.
- Premixed PN does not eliminate the need to further manipulate the patients' bag. Additional electrolytes, trace minerals and/or drugs may need to be added.
- Using premixed PN attempts to address errors in the base compounding process but does not address the need for multiple critical additives and patient-specific additives.

2. Procedures associated with premixed PN violate good process control and the intent of USP<797>.

- Promoting the use of premixed PN where it is not a good clinical fit is counter to most process control recommendations. The inconsistency in

using multiple premix PN bags, with varying amounts of manually added components, is counter to the best practices approach encouraged by USP <797>.

- ACDs can add micro ingredients directly to PN. Automation improves the accuracy and repeatability of ingredient delivery, reduces the number of manipulations, and decreases the potential for microbial contamination of the final product. This process control is what is intended by USP <797>.

3. Using premixed bags is not likely to lower the costs associated with USP <797>.

- Proponents of premixed PN have inaccurately argued that elimination of customized PN will reduce the total IV pharmacy risk level from medium to low; or completely eliminate the need to comply with USP <797>, therefore lowering capital costs. The reality is other common activities such as batch preparation of antibiotics, standard IV's, cardioplegia solutions and other multiple-ingredient, multiple-manipulation admixtures will require low- to medium-risk-level facilities and adherence to the <797> requirements.

4. Premixed TPN is actually counter to current industry standardization good practices.

- Efforts have been made to make standardization of PN order forms and premixed PN synonymous concepts. Standardization of PN order forms and standardization of therapy are entirely separate ideologies.
- Introducing premixed PN in different strengths and volumes goes against the industry trend to eliminate products in order to decrease the opportunity for errors.
- Solution manufacturers, drug distributors and hospital material managers have encouraged pharmacies to carry only one size of amino acids, specialty amino acids, dextrose, lipids, sterile water and minimal numbers of electrolyte solutions to create individualized PN. Premixed PN is a complete reversal of this long-standing trend.

5. Patient specific PN compounded with Automated Compounding Devices (ACDs) uses sophisticated software and barcodes to prevent human errors.

- ACDs represent advanced technology and bar code automation for the IV room.
- ACDs and their related software provide individualized patient order preparation in ways that include standardized labels, institution-specific warnings for electrolytes, calcium/phosphate curves and osmolarity cutoff limits for peripheral administration.
- Premixed PN lacks commercially available software for proper labeling, ingredient mixing order, and calculations to determine flow rate and setting hang times. Premixed PN solutions lack software or bar coding to verify if the correct ingredients were added in the correct volumes and sequences.

6. The premixed PN process reintroduces procedural problems that had been solved by once-a-day PNs.

- The larger-volume bags compounded by ACDs allow PN to infuse over a 24-hour period. These larger-volume PN bags reduce the number of PN units prepared daily, allow a standard hang time, simplify nurses' medication administration schedules to hang the PN and allow lipids to be included directly in the PN infusion.
- The result is that institutional lipid infusion policies must be readdressed.
- Facilities must evaluate the scheduling effects of hanging multiple bags with varying hang times in the pharmacy, nursing and laboratory departments.
- Premixed PN have variable final volumes through additives and overfill that again throw off PN bag infusion times and rates.
- Clinicians will have difficulty determining *daily* nutritional intake values.

7. Clinical benefits gained by using once daily PN and ACDs are being pushed aside by poorly documented economic considerations.

- Premixed PN is available only in a limited number of volumes. Premixed PN forces clinical decisions to accommodate manufacturer production decisions, rather than the appropriateness of the therapy.
- Superficial studies have been conducted with the goal of demonstrating that a high percentage of adult PN falls within a very narrow range of amino acid, dextrose, fluid volume, infusion rate and additive ingredient variations. The reality is that patient-specific formulations are in fact specific to the individual patient, as determined by the practitioner for that exact clinical situation.

8. Premixed PN can increase costs over once-a-day PN.

- Premixed PN still requires additives, even to premixes containing a standard additive profile.
- Premixed PN requires incremental material costs for gravity transfer sets for lipid emulsions or sets to administer lipid piggybacks.
- Premixed PN comes in a limited number of fixed-volume package sizes. Using these fixed-volume packages will result either in some of the solution being wasted, the necessity of hanging multiple packages in a 24-hour period, and hanging the PN beyond stated expiry.
- Replacing Total Nutritional Admixture (TNA) with lipid piggyback(s) so that premixed PN can be used is also associated with an increase in the risk of infection and increased cost for labor and materials.
- Cost containment is an obvious objective but the cost/benefit ratio of premixed PN versus patient-specific PN is marginalized by the very minor differences in cost and the very real possibility that patient outcomes may be adversely impacted in the process.

Given the issues outlined in the foregoing paper, and the points summarized above, a thorough examination of the PN practice at your facility must be undertaken before considering the use of premixed PN.

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