Complete Summary

GUIDELINE TITLE

Sterile compounding of parenteral nutrition formulations. In: Safe practices for parenteral nutrition.

BIBLIOGRAPHIC SOURCE(S)

Mirtallo J, Canada T, Johnson D, Kumpf V, Petersen C, Sacks G, Seres D, Guenter P, Task Force for the Revision of Safe Practices for Parenteral Nutrition. Sterile compounding of parenteral nutrition formulations. In: Safe practices for parenteral nutrition. JPEN J Parenter Enteral Nutr 2004 Nov-Dec;28(6):S57-61. [11 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Conditions and disease states requiring parenteral nutrition

GUIDELINE CATEGORY

Management
Technology Assessment

CLINICAL SPECIALTY

Family Practice
Geriatrics
Internal Medicine
Nursing
Nutrition
Pediatrics
Pharmacology

INTENDED USERS

Advanced Practice Nurses
Dietitians
Hospitals
Nurses
Pharmacists
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To provide guidelines with supporting evidence to foster quality parenteral nutrition (PN) therapy
- To reduce errors and improve safety in patients receiving parental nutrition

TARGET POPULATION

Adult and pediatric patients receiving parental nutrition

INTERVENTIONS AND PRACTICES CONSIDERED

1. Screening the parenteral nutrition (PN) order
    - Review for each prescription
    - Assessment of components for appropriateness of dose, compatibility and stability
    - Clarification and questioning of nutrient doses outside the normal range
2. PN compounding
    - Optimization and validation of additive sequence
3. Quality assurance of the compounding process
    - Gravimetric analysis
    - Chemical analyses
    - Refractometric analysis
    - In-process or end-product testing
    - End-product testing of PN formulations prepared with automated compounding devices
    - Ensuring aseptic sterile preparations

MAJOR OUTCOMES CONSIDERED

Frequency, severity, and type of complications that could result from errors in compounding of parenteral nutrition therapy

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The Task Force reviewed existing published literature in electronic databases and secondary source literature on order writing practices for parenteral nutrition.

Because clinical guidelines cannot be based solely on prospective randomized trials, the American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) Task Force for Revision of Safe Practices for Parenteral Nutrition conducted the 2003 Survey of Parenteral Nutrition (PN) Practices, focusing on policies and procedures relating to ordering, compounding, and administering PN and quality oversight of this process (see "Availability of Companion Documents" field). The final document published as "Safe Practices for Parenteral Nutrition" was based primarily on the recommendations of experts in the field and was evidence-based for as much as the literature provided evidence to support these recommendations. The results from this survey were used as a basis for the revised "Safe Practices for Parenteral Nutrition" to enhance the quality and efficacy of nutrition support.

Development of the Survey Instrument

One of the survey objectives was to identify common practices related to ordering and compounding, administration of PN, and quality oversight of this process. A questionnaire based upon the existing A.S.P.E.N. "Safe Practices for Parenteral Nutrition" was developed to obtain an overview of the variance and consistency with current practices from a variety of healthcare settings. It was designed to include both hospital- and non-hospital-based PN practices. The survey instrument was not tested or validated before its distribution, but it was reviewed by a multidisciplinary panel of nutrition support practitioners and revised before becoming available for participant responses. The survey was administered electronically through the A.S.P.E.N. website and announced to the membership via society journals and A.S.P.E.N. list servers. Announcements inviting participation were also sent to selected professional groups, including the American College of Clinical Pharmacy, the American Society of Health-System Pharmacists, the National Home Infusion Association, and others. Participation in the survey was completely voluntary. The survey instrument consisted of 45 questions with multiple-choice and free-text responses. It was organized into 5 sections: demographics of the respondent, writing PN orders, computer order entry of PN orders, problems with PN orders, and adverse events related to PN. Questions in the demographic section focused on information such as professional background (i.e., MD, RN, RD, RPh, other) and primary practice setting (i.e., hospital, homecare, etc). The order writing section was designed to identify the discipline responsible for writing PN orders, whether or not standard PN order forms were used, and the manner in which PN components were ordered (i.e., dextrose in percent final concentration vs g/day, electrolytes in mEq/L vs per day,

etc). The computer order entry section was designed to quantitate the use of computerized order entry systems and automated compounding devices. The final 2 sections, problems and adverse events related to PN, were developed to capture the type and frequency of harm associated with the compounding and administration of PN formulations.

Data Collection

The survey was announced on the A.S.P.E.N. website, in the society journals (e.g., *Journal of Parenteral and Enteral Nutrition*, *Nutrition in Clinical Practice*), and list servers (e.g., ASPENet) between June 1 and 30, 2003. Messages were subsequently posted to inform potential respondents of the deadline for final submission of survey responses. Participants were assured that their responses would be confidential and that only aggregate responses would be reported.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Data Analysis

Descriptive statistics were used to characterize the frequencies of surveyed practices. Questions with free text responses were analyzed for content to determine if the responses were significant to the study. Data were analyzed with the SPSS 11.5 (SPSS, Inc, Chicago, IL) statistical package. Frequency data were assessed with chi-squared. The *a priori* level of significance was set at ≤ 0.05.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Realizing that the original Safe Practice guidelines were not consistently implemented, the Task Force used this information to identify practices pertinent to the revision of the Safe Practice guidelines. The survey results presented in this document are those findings pertinent to the development of the guideline. This snapshot of current practices and expert opinion or consensus provided by both external and internal reviews was compiled into the current Safe Practices.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

This document was internally reviewed by the American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) Standards Committee as well as the Dietetic, Nursing, Medical, and Pharmacy Practice Sections and approved by the A.S.P.E.N. Board of Directors after external review by individuals and other associations of health care professionals. A.S.P.E.N. recognizes that the practice guidelines will have broad ramifications in changing clinical practice in many health care settings for pharmacists, physicians, nurses, dietitians, and technical support personnel. It is hoped that these guidelines will be accepted and used to prevent future patient harm, and will serve as a catalyst for future research.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Screening the Parenteral Nutrition (PN) Order

1. The calorie, protein, fluid, electrolyte, vitamin, trace element and medication content is reviewed for each and every PN prescription to assure that a complete and balanced nutrient formulation is provided. *Balanced* is defined as the presence of the proper proportion of calories, protein, fluid, electrolytes, vitamins and trace elements, to assure adequate use by and assimilation into the body.
2. Each of the PN components should be assessed for appropriateness of dose and for the potential of a compatibility or stability problem.
3. Any dose of a nutrient outside a normal range that is not explained by a specific patient condition or history shall be questioned and clarified before the PN is compounded.

PN Compounding

1. The additive sequence in compounding shall be optimized and validated as a safe and efficacious method.
2. If the manual method currently in use at an institution has not been recently reviewed, or if the contract with a particular manufacturer of macronutrients is about to change, then a review of the compounding method is strongly recommended. This review shall include an evaluation of the most current literature as well as consultation with the manufacturer when necessary.
3. Manufacturers of automated methods of PN compounding shall provide an additive sequence that ensures the safety of the compounding device. This compounding sequence should be reviewed with the manufacturer of the parenteral nutrient products used by the institution. As most institutions in the U.S. are represented by buying groups with many participants, such buying groups should not only ensure the safety and support of the automated compounding device, but should avoid splitting PN contracts (mixing brands of amino acids, dextrose and Intravenous Fat Emulsion (IVFE) unless such combinations have adequate physicochemical data that ensures the stability, compatibility and safety of the final formulations commensurate with the data for single source PN products.
4. Each PN formulation compounded should be visually inspected for signs of gross particulate contamination, particulate formation and/or phase separation of Total Nutrient Admixtures (TNA).

Quality Assurance of the Compounding Process

1. Gravimetric analyses that indirectly assess the accuracy of the individual additives delivered or the final contents of the PN can be readily applied in the pharmacy practice setting. Particular attention should be focused on the most dangerous additives that tolerate the least margin of error, such as the potassium salts.
2. Chemical analyses that directly measure the final content of the individual additives can be incorporated into the PN compounding operations of the pharmacy. The accuracy of the PN dextrose content is an example of an additive that may be associated with significant morbidity and mortality.
3. Refractometric analysis is an alternative, as well as an indirect measure of the final additive concentration. For example, dextrose concentration is frequently assessed by this technique. However, this method is limited to PN formulations that do not contain IVFE.
4. In-process or end-product testing of PN formulations is recommended daily so as to assure a safe, final formulation is dispensed to the patient.
5. End-product testing of PN formulations prepared with automated compounding devices is recommended to verify compounding accuracy.
6. The aseptic sterile preparation of intravenous admixtures intended for patient administration should adhere to the USP (797) Pharmaceutical Compounding-Sterile Preparations Chapter and the American Society for Health-System Pharmacists (ASHP) Guideline on Quality Assurance for Pharmacy- Prepared Sterile Products.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are supported by a review of the literature as well as results from the 2003 American Society for Parenteral and Enteral Nutrition Survey.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate sterile compounding of parenteral nutrition formulations will help to reduce errors and improve patient safety.

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) Practice Guidelines for Safe Practices for Parenteral Nutrition are based upon general conclusions of health professionals who, in developing such guidelines, have balanced potential benefits to be derived from a particular mode of providing parenteral nutrition feeding formulations. The underlying judgment regarding the propriety for any specific practice guideline or procedure shall be made by the attending health professional in light of all the circumstances presented by the individual patient and the needs and resources particular to the locality. These guidelines are not a substitute for the exercise of such judgment by the health professional, but rather are a tool to be used by the health professional in the exercise of such judgment. These guidelines are voluntary and should not be deemed inclusive of all proper methods of care or exclusive of methods of care reasonably directed toward obtaining the same result.
- Unfortunately, there is little, if any, published evidence to support good practices in the area of parenteral nutrition ordering and administration. Although data from randomized clinical trials of nutrition support are ideal for developing clinical practice guidelines, this type of information is not widely available. Several factors inherently limit the use of prospective randomized clinical trials in the evaluation of nutrition support. Those most likely to benefit from the treatment (e.g., severely malnourished patients) cannot be randomized to an unfed control group due to ethical dilemmas. Other limitations include outcome results influenced by clinical variables independent of nutrition support and inability to recruit large numbers of eligible individuals from 1 medical center, contributing to the enrollment of marginal candidates for nutrition support.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Patient Resources
Resources

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

End of Life Care
Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Mirtallo J, Canada T, Johnson D, Kumpf V, Petersen C, Sacks G, Seres D, Guenter P, Task Force for the Revision of Safe Practices for Parenteral Nutrition. Sterile compounding of parenteral nutrition formulations. In: Safe practices for parenteral nutrition. JPEN J Parenter Enteral Nutr 2004 Nov-Dec;28(6):S57-61. [11 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004 Dec

GUIDELINE DEVELOPER(S)

American Society for Parenteral and Enteral Nutrition - Professional Association

SOURCE(S) OF FUNDING

American Society for Parenteral and Enteral Nutrition

GUIDELINE COMMITTEE

Task Force for the Revision of Safe Practices for Parenteral Nutrition

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Task Force Members: Jay Mirtallo, MS, RPh, BCNSP, Chair; Todd Canada, PharmD, BCNSP; Deborah Johnson, MS, RN; Vanessa Kumpf, PharmD, BCNSP; Craig Petersen, RD, CNSD; Gordon Sacks, PharmD, BCNSP; David Seres, MD, CNSP; Peggi Guenter, PhD, RN, CNSN

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available to subscribers of the American Society for Parenteral and Enteral Nutrition (ASPEN) Guideline and Standards Library.

Print copies: Available from the American Society for Parenteral and Enteral Nutrition (ASPEN), 8630 Fenton St, Suite 412, Silver Spring, MD 20910-3805; (800) 727-4567.

AVAILABILITY OF COMPANION DOCUMENTS

The following background documents are available:

- Preface. Safe practices for parenteral nutrition. 4 p. 2004 Dec.
- Introduction. Safe practices for parenteral nutrition. 2 p. 2004 Dec.

The following documents are also available:

- Standards of practice. Definition of terms, style, and conventions used in A.S.P.E.N. guidelines and standards. 2005 Apr. 5 p.
- Parenteral nutrition safe practices: results of the 2003 American Society for Parenteral and Enteral Nutrition Survey. 2006 Jun. 7 p.
- American Society for Parenteral and Enteral Nutrition (ASPEN), Parenteral Nutrition Standardization Task Force: Kochevar M, Guenter P, Holcombe B,

Malone A, Mirtallo J. ASPEN statement on parenteral nutrition standardization. J Parenter Enteral Nutr 2007;31(5):441-8.

Print copies: Available from the American Society for Parenteral and Enteral Nutrition (ASPEN), 8630 Fenton St, Suite 412, Silver Spring, MD 20910-3805; (800) 727-4567.

A CD-ROM tutorial: Writing PN orders is available for purchase from the American Society for Parenteral and Enteral Nutrition Web site.

PATIENT RESOURCES

The following is available:

- The A.S.P.E.N. nutrition support patient education manual. Silver Spring (MD): American Society for Parenteral and Enteral Nutrition, 2007. 427 p.

Print copies: Available for purchase from the American Society for Parenteral and Enteral Nutrition Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI Institute on July 8, 2008. The information was verified by the guideline developer on July 30, 2008.

COPYRIGHT STATEMENT

DISCLAIMER

NGC DISCLAIMER

The National Guideline Clearinghouse™ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public

or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at http://www.guideline.gov/about/inclusion.aspx .

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

Date Modified: 11/3/2008