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## **Clinical Guidelines for the Use of Parenteral and Enteral Nutrition in Adult and Pediatric Patients, 2009**

American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) Board of Directors

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# Clinical Guidelines for the Use of Parenteral and Enteral Nutrition in Adult and Pediatric Patients, 2009

American Society for Parenteral and Enteral Nutrition  
(A.S.P.E.N.) Board of Directors

## Introduction

The American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) is an organization comprised of healthcare professionals representing the disciplines of medicine, nursing, pharmacy, dietetics, and nutrition science. The mission of A.S.P.E.N. is to improve patient care by advancing the science and practice of nutrition support therapy. A.S.P.E.N. vigorously works to support quality patient care, education, and research in the fields of nutrition and metabolic support in all healthcare settings.

Promotion of safe and effective patient care by nutrition support practitioners is a critical role of the A.S.P.E.N. organization. To this end, in 1993 and 2002, the A.S.P.E.N. Board of Directors published "Guidelines for the Use of Parenteral and Enteral Nutrition in Adult and Pediatric Patients."<sup>1,2</sup> The Guidelines were created in accordance with Institute of Medicine recommendations as "systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances."<sup>3</sup> These Guidelines, designed for use by healthcare professionals who provide nutrition support services and their patients, offer clinical advice for managing adult and pediatric (including adolescent) patients in inpatient and outpatient (ambulatory, home, and specialized care) settings. The utility of the Guidelines is attested to by the frequent citation of this document in peer-reviewed publications, and their frequent use by A.S.P.E.N. members and other healthcare professionals in clinical practice, academia, research, and industry. They guide professional clinical activities, they are helpful as educational tools, and they influence institutional practices and resource allocation.<sup>4</sup>

The A.S.P.E.N. Board of Directors has developed a mechanism to be applied in future guideline development. The objectives for this updated version (now titled as "Clinical Guidelines") are:

1. The Clinical Guidelines must be factually up-to-date to reflect a current, evidence-based, best approach to the practice of nutrition support.
2. The Clinical Guidelines must support the clinical and professional activities of nutrition support practitioners by articulating evidence-based recommendations upon which to base personal and institutional practices and resource allocation.
3. The Clinical Guidelines should serve as a tool to help guide policy makers, healthcare organizations, insurers, and nutrition support professionals to improve the systems and regulations under which nutrition support therapy is administered.
4. The Clinical Guidelines must show clearly how the supporting medical literature was gathered and analyzed to make these recommendations.

Patients may be treated with nutrition support therapy in any care setting, including hospitals, nursing homes, rehabilitation facilities, and at home. For most patients, the duration of nutrition support therapy is relatively short (less than 6 weeks); for others, dependence upon parenteral or enteral nutrition may be lifelong. These Clinical Guidelines are intended to assist clinical practitioners who provide nutrition support therapy to patients in all care settings.

## How to Use These Clinical Guidelines

These Clinical Guidelines offer clinical advice for managing adult and pediatric patients receiving nutrition support

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therapy in the hospital or home. In order to meet the objectives set forth for this revision, the following reorganization of the Clinical Guidelines was developed. Unlike the 2002 Guidelines which were developed and published as one document, new versions of the Clinical Guidelines will be published in *JPEN J Parenter Enteral Nutr* and on the A.S.P.E.N. website under Clinical Guidelines ([www.nutritioncare.org](http://www.nutritioncare.org)) with open access to the public. These Clinical Guidelines will be published as separate “chapters.”

Because guidelines cannot account for every variation in circumstances, the practitioner must always exercise professional judgment in their application. These Clinical Guidelines are intended to supplement, but not replace, professional training and judgment.

## Background

“Clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances.”<sup>3</sup> The principles upon which good practice guidelines are created include the following: Clarity, Compatibility, Clear rationales or justifications, Practicality, and Transparency.

**Clarity** is important to facilitate ease of use. Guidelines should be stated in a manner that is both understandable and applicable.

**Compatibility** is also important. These Clinical Guidelines should be compatible with the other A.S.P.E.N. related documents listed at the end of this document unless specifically noted.

**Rationale or justification should be evidence based.** It must be **valid** (lead to desired health and cost outcomes), **reliable** (the data should be subject to review by an independent set of experts who would be likely to reach the same conclusions), **applicable** (stated in a fashion that defines the target patient population and the explicit manner in which the recommendations are to be applied), **flexible** (account for clinical variability and exceptional cases), **clear, generated in a multidisciplinary manner**, and thoroughly **documented** as described under grading the evidence and use of references.

**Practicality** refers to the need to articulate practice guidelines so that they may be implemented appropriately.

**Transparency** allows the reader to judge clinical guidelines by observing how the authors assessed the evidence; thus, enhanced transparency has the potential to promote acceptance of the guidelines. The reader can determine how the recommendation was derived and trace the recommendation directly back to the supporting literature. The grading for these 2 pivotal components of the document will coincide with one another. In addition, the summary statement of the evidence (referred to as the rationale) and tables used to describe the literature will clearly summarize the design and findings such that the users of the Clinical Guidelines will be able to obtain

the primary literature and corroborate the findings of the chapter authors. Finally, professional affiliations and potential conflicts of interest of the authors will be provided in the document so that users can understand the potential for the introduction of bias into the Clinical Guidelines.

## Format of Clinical Guidelines

The revised Clinical Guidelines were formatted to promote the ability of the reader to understand the strength of the evidence used to grade each recommendation. Each recommendation continues to be presented as a definitive statement of care. (Note: The terms *literature* and *evidence* are synonymous as are the terms *guideline* and *recommendation*.)

Each Clinical Guideline will be comprised of 7 parts:

- Background
- Methodology
- Practice Guidelines and Rationales (plus tables, if any)
- References
- Algorithm (optional)
- Notice
- Acknowledgment (optional)

Each set of Clinical Guidelines will consist of a series of recommendations that are related by virtue of their relationship to a single disease, condition, or topic. Each recommendation will be related to a body of evidence (a set of research studies).

The content of each part is described below.

**Background.** This part provides a brief review of the disease, condition, or topic. In contrast to the 2002 Guidelines, the background statement will consist of a brief preamble to the chapter and will refer the reader to citations on the topic for more detailed information on the topic or disease. The references will be recent and, if appropriate, from A.S.P.E.N. publications.

**Methodology.** This section will be the same for all Clinical Guideline chapters and includes a table which will contain the process for determining levels of evidence and grading of the recommendations.

**Practice Guidelines, Rationales, and Tables.** Practice Guidelines consist of a series of recommendations listed prior to a discussion of the literature that supports that recommendation. Each recommendation is graded according to the level of the evidence.

Each recommendation or set of recommendations is followed by the rationale used to support and grade the recommendation. The rationale consists of a concise description of the existing literature along with the level of the evidence. The type of patients and circumstances to which a given recommendation applies is stated.

The literature is presented in a table which serves as a summary of the design and results of each study. The information provided in the table depends on what the study was designed to investigate.

**References.** Primary references are to be used for this version of the Clinical Guidelines. This new format will place a priority on listing randomized controlled trials (RCTs) followed by non-randomized controlled studies. All available RCTs and systematic reviews (SRs) that are used to develop a guideline are referenced. Nonrandomized controlled trials are used if RCTs are not available to develop a recommendation. It is not necessary to use all available nonrandomized controlled trials; rather, studies with the highest quality should be selected to develop a recommendation statement.

**Algorithm.** An algorithm can be used to emphasize a recommended approach to a commonly encountered clinical circumstance. This section is optional.

**Notice [standard content for all Clinical Guidelines].** "These A.S.P.E.N. Clinical Guidelines are general. They 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 medical therapy against certain risks inherent with such therapy. However, the professional judgment of the attending health professional is the primary component of quality medical care. The underlying judgment regarding the propriety of any specific procedure must 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."

**Acknowledgment [optional].** This section is completed by the primary author and editor to recognize individuals who made significant contributions without meriting authorship.

### Levels of Evidence

- I. Large randomized trials with clear-cut results; low risk of false-positive (alpha) and/or false-negative (beta) error.
- II. Small, randomized trials with uncertain results; moderate-to-high risk of false-positive (alpha) and/or false-negative (beta) error.
- III. Nonrandomized cohort, contemporaneous controls.
- IV. Nonrandomized cohort, historical controls.
- V. Case series, uncontrolled studies, and expert opinion.

An RCT, especially one that is double blind in design, is considered to be the strongest level of evidence to support

decisions regarding a therapeutic intervention in clinical medicine.<sup>5</sup> A level of I, the highest level, will be given to reports of large RCTs where results are clear and the risk of alpha and beta error is low. A level of II will be given to RCTs that include a relatively low number of patients or are at moderate-to-high risk for alpha and beta error. A level of III is given to cohort studies with contemporaneous controls, while cohort studies with historic controls will receive a level of IV. Case series, uncontrolled studies and expert opinion will receive a level of V. Narrative reviews can introduce bias into the recommendations and should not be used as a primary reference source. On the other hand, narrative reviews can be used to help perform a comprehensive review of the literature, as previously mentioned. It should be noted that RCTs comparing parenteral to enteral nutrition can not be blinded and that this fact can introduce bias in the collection of outcome data. Having said this, these studies are still of a higher quality than nonrandomized studies.

RCTs that do not adequately report the methods and results surrounding the design and execution of the study have been associated with bias in estimating the effectiveness of intervention.<sup>6</sup> To improve the transparency of manuscripts where RCTs are presented, the CONSORT (Consolidated Standards of Reporting Trials) statement was developed by an international group of clinical trialists, statisticians, epidemiologists and biomedical editors to help standardize the methodology used to report these trials.<sup>7</sup> You may find that RCTs published before the creation of the 2001 CONSORT statement do not provide sufficient information to classify the study at a level I.

An SR is a specialized type of literature review that analyzes the results of several RCTs. A high quality SR usually begins with a clinical question and a protocol that addresses the methodology to answer this question. These methods usually state how the literature is identified and assessed for quality: (a) what data are extracted, (b) how they are analyzed, and (c) whether there were any deviations from the protocol during the course of the study. In most instances, meta-analysis (MA), a mathematical tool to combine data from several sources, is used to analyze the data. However, not all SRs use MA. SR is considered among the most important level of evidence in the field of Evidence Based Medicine. An SR may receive a grade level of I or II, depending on the overall quality of the report.

One should keep in mind that the result of an SR may favor or reject the use of an intervention. SRs that are not optimally performed or that do not contain all appropriate RCTs should be mentioned in the Rationale section for a recommendation statement. The comment can either focus on how results from more recent or excluded RCTs affect the conclusions of the SR or that an SR was not used to formulate a recommendation for a particular reason.

**Table 1.** The Relation Between Grades of Recommendations and Levels of Evidence

Grades of Recommendations	
A	Supported by at least two level I investigations
B	Supported by one level I investigation
C	Supported by at least one level II investigation
D	Supported by at least one level III investigation
E	Supported by level IV or V evidence
Levels of Evidence	
I	Large randomized trials with clear-cut results; low risk of false-positive (alpha) and/or false-negative (beta) error
II	Small, randomized trials with uncertain results; moderate-to-high risk of false-positive (alpha) and/or false-negative (beta) error
III	Nonrandomized cohort with contemporaneous controls
IV	Nonrandomized cohort with historical controls
V	Case series, uncontrolled studies, and expert opinion

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### Grading of Clinical Guideline Recommendations

The grading system for Clinical Guidelines is outlined in Table 1.

This system has been adapted from several methods used to grade guidelines. It has been designed to clearly state when there is agreement and disagreement in the literature on a particular topic. A grade of A is given to a recommendation that is supported by at least two level I RCTs or an MA with clear-cut results. A grade of B is given to a recommendation that is supported by one level I RCT or an MA of heterogeneous trials. A grade of C is given to a recommendation that is supported by at least one level II investigation. A grade of D is given to a recommendation that is supported by at least one level III investigation. A grade of E is given to a recommendation supported by evidence that received a level of IV or V.

### Use of Tables and Figures

Tables are used to highlight the finds of controlled trials. A standardized table assures that essential information is displayed in a consistent fashion throughout the Clinical Guidelines document. This table is present unless it is felt that a table is not the most optimal way to present the evidence that supports a recommendation statement.

Because Clinical Guidelines should rely on the best available literature, tables will either contain the results of RCTs or nonrandomized trials. In other words, when RCTs are available to support a guideline statement, nonrandomized trials will not be used (or displayed in a table) for that recommendation since they are superseded by RCTs.

Information which is important in the interpretation of a trial but that does not fit in the standardized table may be discussed in the Rationale section. This information may include duration of intervention or observation, use of surrogate markers as outcomes measures, or whether post-hoc analyses were performed. A table may be used to list information obtained from case series and uncontrolled studies, but it is preferred that a summary statement be given in the Rationale section since this will often suffice for evidence that receives a level of V.

Figures may also be used to illustrate study findings such as with an MA or practice algorithm. If these figures are from another publication they must be submitted as camera ready and permission to reprint the figure must be obtained.

### Development of the Clinical Guidelines

The revised A.S.P.E.N. "Clinical Guidelines for the Use of Parenteral and Enteral Nutrition in Adult and Pediatric Patients" are being developed in response to the need to factually update the 2002 Guidelines in light of new evidence and a new process. This opportunity was also used to improve the Clinical Guidelines' presentation and transparency. The A.S.P.E.N. Board of Directors developed a Clinical Guidelines Editorial Board. This Editorial Board is responsible for working with authors to develop the Clinical Guidelines according to the A.S.P.E.N. Board of Directors' objectives and the designated processes. The Clinical Guidelines Editorial Board includes the following individuals:

#### Editor in Chief:

Charlene Compher, PhD, RD, FADA, CNSD  
University of Pennsylvania School of Nursing  
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#### Associate Editors:

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Patricia A. Worthington, MSN, RN, CNSN  
Thomas Jefferson University Hospital  
Philadelphia, PA

The Clinical Guidelines Editorial Board selected chapter authors and supervised the authors' efforts. The authors were selected for their detailed knowledge and expertise in a chosen area. These authors deserve the credit for reviewing the primary literature, synthesizing and summarizing it, and formulating the recommendation statements. Without their detailed knowledge of the literature and current best practice, these documents could not have been completed. When the authors' drafts were completed, they were reviewed by the associate editors, edited and/or rewritten, and then sent out for internal review by the Clinical Practice Committee and for external reviews by content experts. These reviewers were specifically asked to check each recommendation statement for appropriateness, accuracy, and strength of evidence. The A.S.P.E.N. Clinical Practice Committee reviewed the document as well for clarity and internal consistency with other A.S.P.E.N. documents. The final document was then approved by the A.S.P.E.N. Board of Directors and submitted to *JPEN* for publication.

The members of the Clinical Guidelines Editorial Board, the A.S.P.E.N. Board of Directors, and the authors feel that these documents represent the current state of the science in the provision of nutrition support therapy to adult and pediatric patients and provide an evidence-based rationale for the recommendations, to be used in conjunction with professional judgement as circumstances warrant. The members of the Clinical Guidelines Editorial Board and the A.S.P.E.N. Board of Directors express their deep gratitude to all of the volunteers who contributed their time and expertise to make these Clinical Guidelines possible.

### Acknowledgment

The A.S.P.E.N. Board of Directors wishes to acknowledge the efforts of the following members who assisted in development of this guideline process over the past several years: Douglas Seidner, MD; Jane Gervasio, PharmD; Praveen Goday, MD; Kathleen Gura, PharmD, Robert Martindale, PharmD; Carol Rollins, PharmD; Timothy Sentongo, MD; David Seres, MD; Peter Wasserman, RD; and Jane Anne Yaworski, RN.

### Related Documents

The A.S.P.E.N. Board of Directors has published a series of related documents that may be referred to when using these guidelines. The following documents can be obtained on the A.S.P.E.N. website at: <http://www.nutritioncare.org/Library.aspx>.

- Definition of terms, style, and conventions used in A.S.P.E.N. guidelines and standards. *Nutr Clin Pract.* 2005;20:281–285. (under revision)
- Standards of practice for nutrition support physicians. *Nutr Clin Pract.* 2003;18:270–275.
- Standards of practice for nutrition support pharmacists. *Nutr Clin Pract.* 2008;23:189–194.
- Standards of practice for nutrition support nurses. *Nutr Clin Pract.* 2007; 22:458–465.
- Standards of practice and standards of professional performance for registered dietitians (generalist, specialty, and advanced) in nutrition support. *Nutr Clin Pract.* 2007;22:558–586.
- Standards for specialized nutrition support: adult hospitalized patients. *Nutr Clin Pract.* 2002;17:384–391. (under revision)
- Standards for specialized nutrition support: home care patients. *Nutr Clin Pract.* 2005;20:579–590.
- Standards for specialized nutrition support for adult residents of long-term care facilities. *Nutr Clin Pract.* 2006;21:96–104.
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