



INTRODUCTION PART TO THE ESPEN GUIDELINES ON ENTERAL NUTRITION

Methodology for the development of the ESPEN Guidelines on Enteral Nutrition

T. Schütz^{a,*}, B. Herbst^b, M. Koller^c

^aMedizinische Klinik mit SP Gastroenterologie, Hepatologie und Endokrinologie, Charité Universitätsmedizin Berlin, Berlin, Germany

^bDGEM-Infostelle, Berlin, Germany

^cZentrum für Klinische Studien, Klinikum der Universität Regensburg, Regensburg, Germany

Received 13 January 2006; accepted 13 January 2006

KEYWORDS

Clinical practice guidelines;
Guideline development;
Evidence-based;
Recommendations

Summary Under the auspices of the European Society for Clinical Nutrition and Metabolism (ESPEN) clinical practice guidelines on enteral nutrition were systematically developed between spring 2004 and winter 2005 in a both evidence and consensus based process.

A steering committee implemented 13 disease-specific working groups with a total of 88 experts in clinical nutrition from 20 countries. Evidence was gathered by conducting a structured literature search applying a defined search strategy, inclusion criteria and specified keywords. The quality and strength of the supporting evidence was then graded according to published standards. On this basis recommendations were spelled out which were not only based on the evidence levels of the studies but also on the judgement of the working groups concerning the consistency, clinical relevance and validity of the evidence. Preparation of the drafts was accomplished in interactive small group work processes. The voting of statements took place in a consensus conference and final refinements and voting were done using the Delphi technique.

The ESPEN guidelines enteral nutrition reflect the current medical knowledge in the field of enteral nutrition therapy and summarize the evidence when enteral nutrition is indicated and which goals can be reached in regard to nutritional state, quality of life and outcome.

The full version of this article is available at www.espen.org.

© 2006 European Society for Clinical Nutrition and Metabolism. All rights reserved.

*Corresponding author. Tel.: +49 30 450 514 059; fax: +49 30 450 514 923.
E-mail address: elke-tatjana.schuetz@charite.de (T. Schütz).

Definition and aims

The European Society for Clinical Nutrition and Metabolism (ESPEN) is an organisation which is dedicated to all issues concerning enteral and parenteral nutrition and metabolism and promotes among other aims the development of clinical practice guidelines. Clinical guidelines are defined as systematically developed statements to assist practitioner and patient decisions about appropriate health care and for specific clinical circumstances.¹

The ESPEN guidelines enteral nutrition aim to assist clinical practitioners, dietitians and nurses who provide enteral nutrition support to patients in all care settings as well as to give information to decision-makers in the health care system. They

reflect the current medical knowledge in the field of enteral nutrition therapy and summarize the evidence when enteral nutrition is indicated and which goals can be reached in regard to nutritional state, quality of life and outcome.

Basis of guideline development

The ESPEN guidelines enteral nutrition were developed between spring 2004 and winter 2005 on behalf of ESPEN. Starting point of the ESPEN guidelines was the guideline on enteral nutrition of the German Society for Nutritional Medicine (DGEM), which followed the time schedule depicted in Table 1 and which was published in two parts in February 2003² and August 2004.³ The recently

Table 1 Time schedule of guideline development.

German guidelines on enteral nutrition—parts 1 and 2

2001

January–May

Project planning, establishment of the steering committee and the organising office, constitution of 10 working groups

9 November–10 November

Consensus conference for part 1 in Berlin (working group meeting and plenary meeting)

2003

January

Publication part 1²

6 November

11, Annual meeting of the German Geriatrics Society in Berlin Presentation of part 2 and voting during the symposium "enteral nutrition in old age"

2004

August

Publication part 2³

ESPEN guidelines on enteral nutrition

2003

Decision to start the guideline development process on basis of the German guidelines on enteral nutrition
Establishment of the Steering Committee

2004

February

Establishment of the Central Organizing Office

March–April

Establishment of 12 working groups with members of 20 predominantly European countries

Until April

Translation of the German guidelines on enteral nutrition parts 1 and 2

April–May

Review of the translated manuscripts by the group chairs

May–August

Search for current literature, systematic evidence review, modification of the translated manuscripts

10 September

Consensus conference in Lisbon

Presentation of the drafts in the plenary meeting, discussion, revisions and voting

2005

September 2004–March 2005

Revision of the drafts, final voting by Delphi technique via internet

April–June

Three editorial meetings; recirculation of the drafts within the groups

August

Publication of the final drafts on the ESPEN website for discussion

October–December

One editorial meeting, finalizing of the drafts

2006

May

Publication in *Clinical Nutrition*

published German guidelines gave the opportunity to facilitate and shorten the time-consuming development process on a European level. They were made available in English translation and then updated and revised by the working groups.

The German guidelines were developed in accordance with the German Manual for Clinical Practice Guidelines⁴ of the German Association of the Scientific Medical Societies (AWMF) and the Agency for Quality in Medicine (AquMed).^{5,6} This manual describes in detail the national methodology for development and implementation of clinical practice guidelines and is based upon the international state of the art and in particular upon the methodology of the Scottish Intercollegiate Guidelines Network (SIGN). The German guidelines met all criteria for a so called S3 guideline, i.e. it is systematically developed and is both evidence and consensus based. The guideline can be accessed via the website of the Association of the Scientific Medical Societies in Germany (www.leitlinien.net).

Responsibilities

Steering committee/editors

Herbert Lochs, Luzia Valentini, Tatjana Schütz, all Germany; Pat Howard, United Kingdom; Simon Allison, United Kingdom; Claude Pichard, Switzerland.

The tasks of the steering committee comprised strategic decisions such as the number of working groups and the time schedule, the nomination of the working group members, the final agreement on each chapter, the checking of the intersection coherence, and finally the editing of the manuscript.

Editorial group

All members of the Steering Committee and in addition Brigitte Herbst, Johann Ockenga, and Matthias Pirlich (all Germany) who had also been members of the steering committee of the German guidelines.

The editorial group formatted and harmonized all chapters, and prepared the summary of recommendations for each chapter in a standardized way.

Central organizing office

Luzia Valentini; Brigitte Herbst; Tatjana Schütz; Kristina Norman; all Germany.

The central organizing office coordinated the translation of the original guideline text from German into English, communicated with the working groups and thus intensified the contact between the groups and the steering committee. Its main responsibilities were the keeping of the time schedule throughout the guideline development process, the organisation of the consensus conference and assistance in formatting and finalising the drafts.

Methodological adviser

Michael Koller, Germany.

The progress of the guideline development and the course of the consensus conference were supervised by the same guideline methodologist who had also acted as competent adviser for German guidelines on enteral nutrition.

Working group chairs and members

Thirteen working groups with a total of 88 members from altogether 20 countries, predominantly from Europe, were constituted. They consisted of experts in clinical nutrition working in the fields of medicine, dietetics, nursing, or pharmaceuticals. Representatives of the companies were not eligible to participate in the working groups. These multidisciplinary groups were responsible for the literature search, the preparation, discussion and revisions of the drafts according to evidence-based criteria (Tables 2 and 3) and were invited to actively participate in the consensus conference.

Due to their knowledge of the original text and their experience with the guideline development process, the group chairs of the German guidelines acted also as group chairs for the ESPEN guidelines. Group members were proposed either by the steering committee or the group chairs, and after agreement they were nominated by the steering committee. Authors for the introductory parts of the guidelines were appointed by the steering committee. All experts worked on an honorary basis.

The authors for each chapter are listed starting with the working group leader and followed by the members of the ESPEN working group. In a second line the original authors of the German guidelines are mentioned.

Conflict of interest disclosure

All 89 experts participating in the guideline development process (members of the steering

Table 2 Criteria for systematic search for literature—databases and keywords.

	German guidelines on enteral nutrition	ESPEN guidelines on enteral nutrition
Publication date	From 01.01.1985 to 01.10.2001 (part 1) to 01.02.2003 (part 2)	From 01.10.2001 (geriatrics from 01.02.2003) to 01.08.2004
Languages	English, German, French	English
Databases	Medline, EMBASE, Pubmed, Cochrane	
Filter	Human	
Publication type	Original publications, guidelines, recommendations, meta-analyses, systematic reviews, randomized controlled trials, observational studies	
Default keywords	Enteral nutrition, tube feeding (in combination with chapter specific keywords)	
Optional keywords	Enteral feeding, enteral diet, enteral nutritional support, enteral nutritional supplementation, enteral nourishment, formula diet, feeding tube	

Table 3 Grades of recommendations and levels of evidence.^{7,8}

Grades of recommendations	Levels of evidence	Requirement
A	Ia	Meta-analysis of randomized controlled trials
	Ib	At least one randomized controlled trial
B	IIa	At least one well-designed controlled trial without randomization
	IIb	At least one other type of well-designed, quasi-experimental study
	III	Well-designed non-experimental descriptive studies such as comparative studies, correlation studies, case-control studies
C	IV	Expert opinions and/or clinical experience of respected authorities

committee, the working groups, authors of the introductory chapters, and the methodological adviser) as well as the authors of the editorial, the introduction and the methodology chapters disclosed any potential conflicts of interests on a form which was created according to ESPEN specifications. The following items had to be answered by no or yes, and if yes the name of the company had to be declared, and conflicts of interest arising from item 1 or 2 were disclosed:

1. consultancy or advisory agreement ($n = 13$ (4 had more than one entry); names of companies: Abbott (2), Baxter (3), B. Braun (2), Fresenius-Kabi (1), Nestlé (5), Novartis (4), Nutricia (1), Otsuka (2), Serono (1)),
2. stock share holder with a company in the field of nutrition ($n = 1$; name of company: Numico),
3. receipt of research grant for work in basic science or for clinical trials,
4. receipt of fees / honoraria for lectures,
5. other sources of conflict of interest (e.g. patent holders).

It was made sure that individuals who reported potential conflicts of interest had a full-time academic position and were not representatives of medical companies. Therefore, these individuals were not retained from contributing to the guidelines. All forms are held on file at the ESPEN steering committee.

Funding

ESPEN paid the cost for the guideline development, i.e. the translation of the German guidelines into English, the central organising office (L.V.) and the editorial meetings. Only the consensus conference was supported by an unrestricted fund allocated to ESPEN by the Industry Liaison Group for renting the conference room and technical equipment, catering of coffee and lunch breaks, dinner, hotel accommodation for one or two overnight stays and travel expenses for the members of the central organising office and for working group chairs and

members who came to Lisbon only for the consensus conference and not for the ESPEN congress. No member of the Industry Liaison Group took part in the consensus conference nor exerted influence on the process of guideline development, the topics or the content of the guidelines.

Search for literature and literature review

Evidence was gathered by each working group by conducting a structured literature search which was adapted to the German guidelines. A defined search strategy, inclusion criteria and specified keywords (in combination with appropriate disease-specific keywords) were used to retrieve literature from the Medline, EMBASE, PubMed and Cochrane databases (Table 2).

The quality and strength of the supporting evidence was graded according to the criteria of the SIGN⁷ and the Agency for Health Care Policy and Research (AHCPR).⁸ This grading system relies primarily on studies of high quality, i.e. prospective randomized controlled trials. Evidence levels were then translated into recommendations according to Table 3 taking into account study design and quality as well as consistency and clinical relevance (Fig. 1). The highest grade (A) is assigned to recommendations which are based on at least one randomized controlled trial whereas the lowest recommendation (C) is based on expert opinion, including the view of the working groups. These two grading systems were chosen because they were used in the German guideline development and were proposed in the German Manual for Clinical Practice Guidelines.⁴

Those areas where guidelines are being classified as being based on class IV data reflect an attempt to make the best recommendations possible within the context of the available data and expert

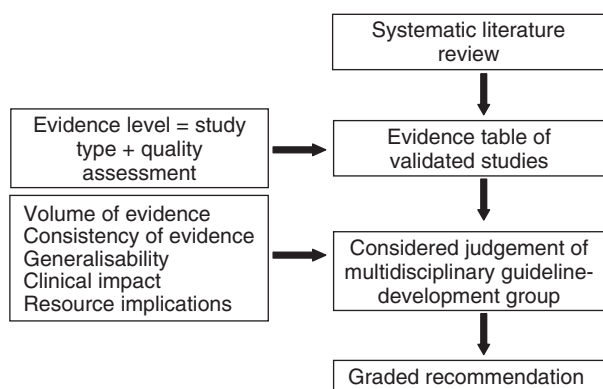


Figure 1 Derivation of guideline recommendations.⁹

clinical experience. Some of the statements of these guidelines were developed on the basis of expert opinion because of the ethical dilemma of conducting prospective randomized trials involving patients at risk for starvation.

In the case of inconsistent data the following approach was chosen (Fig. 1). The recommendations were not only based on the evidence levels of the studies but also on the judgement of the working group concerning the consistency, clinical relevance and validity of the evidence.⁹

General structure

The disease-specific working groups were encouraged to adopt the structure of the German guidelines on enteral nutrition which were developed according to the following clinical questions:

- Which influence does the disease exert on nutritional state and energy and substrate metabolism?
- Which influence does nutritional state exert on outcome?
- Which are the goals of enteral nutritional therapy?
- When is enteral nutrition indicated? Is enteral nutrition superior to normal food?
- In which way is enteral nutrition practically implemented?
- Are there disease specific contraindications for enteral nutrition?
- Are there disease specific complications of enteral nutrition?
- When is oral feeding initiated?

At the beginning of each chapter a summary of recommendations and their grades is provided in table form. This structure does not apply to the introductory part of the guidelines (introduction, ethics, methodology).

Preparation of the drafts

Using the reviewed literature the working groups prepared first drafts which were discussed and finalized in intensive small group sessions. Thereby it was made sure that each individual group member could express his/her viewpoint and contributed to the final product, thus following the philosophy of the nominal group process. The drafts were then made available to all other

working groups on a specifically created, password protected internet platform.

Consensus conference

The consensus conference took place in the Lisbon Congress Centre on 10 September 2004, one day before the annual ESPEN congress. A total of 36 group chairs and members representing each of the working groups took part in the consensus process. All drafts were provided in printed form to each participant. Statements were presented mostly by the group chairs and were discussed in the plenary meeting before voting.

The voting options were to (1) completely agree, (2) agree, but include suggestions discussed in the sessions, or (3) revise guideline, incorporate sug-

gestions discussed in the consensus conference and incorporate additional written comments. All suggestions were documented online and summarised in the minutes.

Further procedure for finishing the drafts (Fig. 2)

Revisions of the first drafts incorporating the discussed points were prepared by the working groups and were made available to the other working groups on the internet platform for commenting and final voting (Delphi technique). At this stage 41 modifications were proposed by the working group members. Afterwards the second drafts were published on the ESPEN website giving the future users the opportunity to give a feedback.

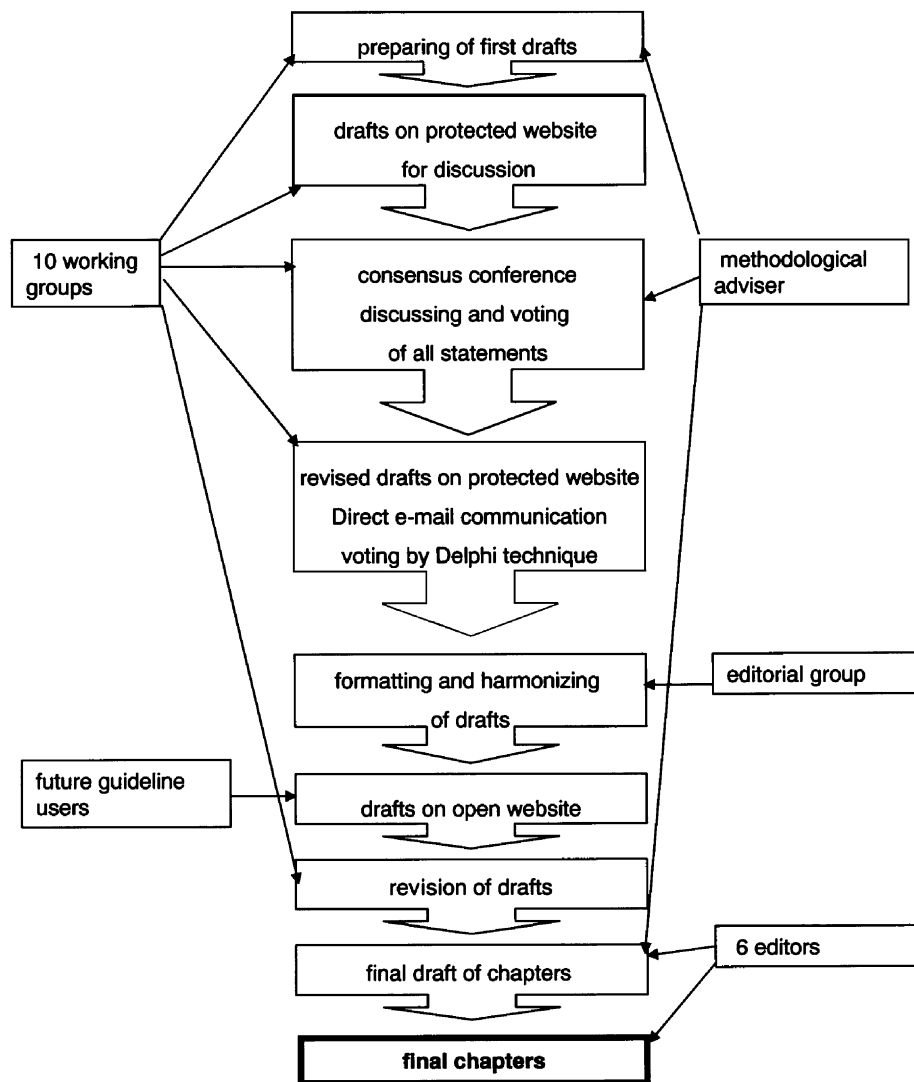


Figure 2 Procedure for finishing the drafts.

Comments were forwarded to the group chairs and discussed within the working groups. The third drafts were then circulated in each respective group, approved and finally forwarded to the steering committee. Altogether the drafts were revised and recirculated 8.5 times on average. The final versions were reviewed and approved by the editors.

Publication and dissemination

In addition to the publication in *Clinical Nutrition* the chapters of the ESPEN guidelines on enteral nutrition can be downloaded as PDF-files from the ESPEN homepage (www.espen.org/education/guidelines.htm). The guidelines were also offered to the national societies of clinical nutrition for approval, distribution, and implementation. Moreover the guidelines were presented to a broad audience at the ESPEN congresses 2004 and 2005 in special sessions. It is recognized that implementation is a highly important but also a particularly difficult task.¹⁰

Scheduled review

Two years after publication each chapter of the guidelines will be reassessed for validity by an ESPEN panel and adapted to new scientific evidence if indicated.

References

1. Field MJ, Lohr KN. *Clinical practice guidelines—directions for a new program*. Washington: National Academy Press; 1990.
2. Lochs H, Lübke H, Weimann A, editors. *Leitlinie Enterale Ernährung*. *Aktuel Ernaehr Med* 2003;**28**(Suppl. 1): S1–S121.
3. Lochs H, Volkert D, Krys U, editors. *Leitlinie Enterale Ernährung Teil 2*. *Aktuel Ernaehr Med* 2004;**29**:187–232.
4. Arbeitsgemeinschaft der wissenschaftlichen medizinischen Fachgesellschaften (AWMF), Ärztliche Zentralstelle für Qualitätssicherung (ÄZQ), editors. *Das Leitlinien manual. Entwicklung und Implementierung von Leitlinien in der Medizin*. *ZaeFQ* 2001; 95 (Suppl. I): 1–84.
5. Kopp I, Encke A, Hartig S, Müller W, Lorenz W. Zur Empirie hochwertiger Leitlinien im System der Arbeitsgemeinschaft Wissenschaftlicher Medizinischer Fachgesellschaften (AWMF): Gibt es sie und wie viele? *Deut Gesell Chir—Mitt* 2005;**1/05**:21–9.
6. Kopp I, Encke A, Lorenz W. Leitlinien als Instrument der Qualitätssicherung in der Medizin—das Leitlinienprogramm der Arbeitsgemeinschaft Wissenschaftlicher Medizinischer Fachgesellschaften (AWMF). *Bundesges—Gesundheitsforsch—Gesundheit* 2002;**45**:223–33.
7. Scottish Intercollegiate Guidelines Network. SIGN guidelines—an introduction to SIGN methodology for the development of evidence-based clinical guidelines, Edinburgh, SIGN Publication No. 39, SIGN Secretariat, Royal College of Physicians of Edinburgh, 1999.
8. Agency for Health Care Policy and Research. *Clinical practice guideline No. 1*. AHCPR Publication No. 92-0023, 1993.
9. Miller J, Petrie J. Development of practice guidelines. *Lancet* 2000;**355**:82–3.
10. Koller M. Beiträge der Sozialpsychologie zur Analyse und Lösung von Problemen im deutschen Gesundheitssystem. Das Beispiel Leitlinien. *Z Sozialpsychol* 2005;**36**:47–60.

Available online at www.sciencedirect.com

