

Introduction and methodology – Guidelines on Parenteral Nutrition, Chapter 1

Einleitung und Methodik – Leitlinie Parenterale Ernährung, Kapitel 1

Abstract

Guidelines for Parenteral Nutrition were prepared by the German Society for Nutritional Medicine (<http://www.dgem.de/>), in collaboration with other medical associations to provide guidance for quality assurance for parenteral nutrition (PN) practice, and to promoting health and quality of life of patients concerned. A coordination team proposed topics, working group leaders who along with working group members performed systematic literature searches and drafted recommendations in a nominal group process. Recommendations were discussed and agreed upon in a structured consensus conference process, followed by a Delphi consensus. The current English version of the guidelines was written and updated during the period between the last quarter of 2007 and the first quarter of 2009. The recommendations of the guidelines should be reviewed, and if necessary updated five years after publication.

Keywords: guideline, parenteral nutrition, nominal group process, degree of adequacy, recommendation categories

Zusammenfassung

Die „Leitlinie Parenterale Ernährung“ wurde unter Federführung der Deutschen Gesellschaft für Ernährungsmedizin e.V. (<http://www.dgem.de/>) in Zusammenarbeit mit weiteren medizinischen Fachgesellschaften erstellt mit den Zielen einer Qualitätssicherung der Praxis der Parenteralen Ernährung (PE) und der Förderung von Gesundheit und Lebensqualität der betroffenen Patienten. Das Koordinationsteam entwarf einen Projektplan für die einzelnen, zu behandelnden Themen und schlug Arbeitsgruppenleiter vor. Diese führten zusammen mit ihren Arbeitsgruppenmitgliedern eine systematische Literaturrecherche durch und erarbeiteten in einem nominalen Gruppenprozess Kernaussagen und Empfehlungen. Die Empfehlungen wurden diskutiert und in einem strukturierten Konsensuskonferenzprozess abgestimmt, gefolgt von einer Delphi-Runde. Die derzeitige englische Fassung der Leitlinie wurde zwischen dem letzten Quartal 2007 und dem ersten Quartal 2009 geschrieben und aktualisiert. Die Empfehlungen der Leitlinie sollten fünf Jahre nach Publikation geprüft und gegebenenfalls aktualisiert werden.

Schlüsselwörter: Leitlinie, parenterale Ernährung, nominaler Gruppenprozess, Evidenzhärtegrade, Empfehlungsklassen

Introduction

Parenteral nutrition (PN) is, for many patients, not only an important but also a life-saving therapeutic measure. These “Guidelines for Parenteral Nutrition” were prepared with the aims of providing guidance for quality assurance for PN practice, and of promoting the health and quality of life of the patients concerned. The guidelines are inten-

ded to provide a reference for professional groups involved in the application of PN, based on either scientific evidence or, in case of inadequate scientific evidence, on expert consensus.

The guidelines were prepared under the direction of the German Society for Nutritional Medicine (Deutsche Gesellschaft für Ernährungsmedizin e. V., <http://www.dgem.de/>), in collaboration with specialist medical

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associations named in the overview. The principles in preparing guidelines provided by the Joint Committee for Scientific Specialist Medical Associations (AWMF) and the Agency for Quality in Medicine (AQuMed/AEZQ) were followed [1], [2], [3], [4].

Methodology

The DGEM appointed Professor Dr. Berthold Koletzko, M.D. and Professor Dr. Karl-Walter Jauch, M.D. (Table 1) to be the managers of the guideline development project. They formed a coordination team together with Sabine Verwied-Jorky, Ph.D. (responsible for the organisation of the project), Kathrin Krohn, M.D. and Maria-Angelica Trak-Fellermeier, M.Sc., who were joined by Rashmi Mittal, M.D. during the preparation of english version of the guideline. The coordination team drew up a project plan which included the individual topics to be covered, proposed leaders of the working groups (WG) for these topics, and also compiled an initial list of possible working group members. The project plan was reviewed and approved by the DGEM council (Table 1).

In order to finance the expenses incurred during the development of the guidelines (organisational costs and costs of consensus conferences), requests were made for financial grants to the German Federal Ministry for Health and Social Security, as well as to various health insurance companies. All of these requests were rejected and some insurance companies did not even answer. Subsequent to negotiations by the DGEM council, agreements were signed on the donation of external funds to the University Hospital of Munich by various manufacturers of PN products (Baxter Germany GmbH, B. Braun Melsungen AG, and Fresenius Kabi Germany GmbH). The donors of the funds agreed to bear the logistic and organisational costs for the development of the guidelines, including travelling expenses to meetings and consensus conferences by the working group leaders. In these contracts, it was explicitly stated that the companies donating these funds would not in any way influence topics, structure and content of the guidelines. Accordingly, no representative of these companies took part in any of the meetings or conferences of the working groups.

Setting up of the working groups; declaration of conflict of interest

The coordination team and the working group leaders selected by voting the other members of the working groups. The voting aimed to ensure that each team was multidisciplinary and included members from various professional groups such as doctors from various specialities, pharmacists, nutrition scientists, dietitians, professional carers and legal experts. Experts from the industry were excluded from being members of the working groups. The authors working together on the guidelines are named in the list of authors provided at the beginning of these guidelines, with the list indicating both, the

leaders of the working groups and the affiliations of the experts involved. All working group members worked on a voluntary basis, and received no fees. Travelling expenses were reimbursed in line with the guidelines for travelling expenses according to the usual guidelines for public institutes of higher education.

During the meetings between the coordination team and working group leaders, possible conflicts of interest were discussed. In the interest of transparency, it was decided to request a completed declaration of potential conflicts of interest from participant (Table 2). These were reviewed by the coordination team who concluded that none of the experts working on the development of these guidelines were either a representative or spokesperson for any particular company or range of products.

Literature searches and evaluation

The individual working groups carried out a comprehensive literature search of scientific publications since 1990 in English or German (Table 3). Some relevant publications, which had been published prior to 1990, were also considered, if deemed necessary by the concerned working group. The publications relevant to the proposed questions were evaluated, with regards to the degree of adequacy as scientific evidence, by at least two working group members, independently of each other (Table 4). The recommendations were then derived, in a stepwise manner, from this information as recommended by the Scottish Intercollegiate Guidelines Network (Figure 1) [5].

Nominal Group Process

The various working groups made core statements and recommendations on the basis of the systematic literature searches. The working groups were encouraged to follow the 'Nominal Group Process' method, i.e. the individual members of the working groups were expected to develop their own proposals, which were then combined to form a group consensus [4]. Individual working groups were responsible for processing the texts using the Delphi method (written questions and answers in several rounds). The final version was accessible for comments and criticisms, via a password-protected home page, by members of all working groups and representatives of other specialist medical associations. The suggested amendments were considered by the pertinent working group as well as the coordination team. The initial recommendations were discussed, amended if considered necessary, and voted upon by the working groups in separate rooms at the working group meetings held before the first consensus conference. This method of working in small groups was in accordance with the Nominal Group Process, which ensured that all members of the groups made their opinions clear, and had the chance to influence the group voting. However, as the number of groups (18) was large, with each group having only a maximum of six members, it was decided not to carry out a formal Nominal Group Process. The experts in the methodology

Table 1: Timeline and steps involved in the planning, organisation and execution of the project plan for the production of the guidelines (DGEM = The German Society for Nutritional Medicine)

July 2002	1.	DGEM	Appointment of managers for the guidelines development project.
July 2002	2.	Project managers	Setting up of the project office. Formation of a coordination team.
August 2002	3.	Coordination team	Devising 18 individual topics, and proposing a working group leader for each topic.
August 2002	4.	DGEM Presidium	Preview and agreement of the project plan.
August to October 2002	5.	Coordination team	Letters to potential working group leaders and recording of their answers.
25 October 2002	6.	Coordination team and working group leaders	First meeting of the working group leaders to discuss the topic for each working group, the interdisciplinary make-up of the working groups, methodology, and searches in the literature.
until November 2002	7.	Working group leaders	Appointing the members of the working groups (WG).
until December 2002	8.	Working groups	Devising the key questions for core statements of the guidelines; circulating these to the main coordinators.
until January 2003	9.	Working groups	Discussion and agreement on the contents of the various topics, and determining keywords of literature search.
January to June 2003	10.	Working groups	Literature search and evaluation, drawing up the first proposals and circulating them.
12.-15.06.2003	11.	Working groups	Exchanging the first proposals.
till February 2004	12.	Working groups	Amending the proposals, circulating the amendments to all working groups, receiving the first comments.
12/13. March 2004	13.	Working groups and coordination team	First consensus conference: 1. Amending the proposals and voting on the amended proposals in the working groups; 2. Presenting the proposals to the whole conference, discussion, amending and voting.
13.03. - 06. 08. 2004	14.		Internet-based Delphi consensus.
08. 05. 2004	15.	Working groups and coordination team	Second consensus conference: presentation of the amended proposals to the whole conference, discussion, further amendments and voting.
till July 2004	16.	Working groups	Further amendments of the proposals and passing them on to the coordination team.
	17.	Coordination team	Information regarding the amended proposal sent to all working groups (Delphi round).
March 2005	18.	Coordination team and working group leaders	Information to the Association of Medical Specialty Societies (AWMF) on the preparation of the guidelines. Agreement on formal collaboration of the following associations in the preparation of the guidelines: The German Society for Anaesthesiology und Intensive Medicine, The German Society for Surgery, The German Society for Paediatrics, The German Society for Internal Medicine, The German Society for Internal Intensive Medicine und Emergency Medicine, The German Society for Digestive and Metabolic Diseases, The German Diabetes Society, The German Interdisciplinary Alliance for Intensive and Emergency Medicine, and the Society for Paediatric Gastroenterology and Nutrition.
August 2004 to December 2006	19.	Coordination team and working group leaders	Final editing of the proposals, and completion of the final German version ready for publication.
October 2007 to May 2008	20.	Coordination team	Translation into English, and editing and updating of the final English version ready for publication.

Table 2: Declaration of conflict of interest by members of working groups for preparing the Guidelines for Parenteral Nutrition (according to the guidelines manual provided by the AWMF and the AQuMed/AEQZ [4])**Declaration of conflict of interest by members of the working groups for preparing the guidelines for Parenteral Nutrition**

According to the manual of the AQuMed (Agency for Quality in Medicine) and the AWMF (Joint Committee for Scientific Specialist Medical Association) recommend that the members of working groups set up for preparing guidelines, in our case for parenteral nutrition, be free from any conflict of interest. Therefore, we ask you to answer the following questions. All information will be treated confidentially.

1. Possible personal conflicts of interest:

Have you, in connection with the topics of the working group, parenteral nutrition, carried out any consulting, expert witness or contractual activity that was connected with financial or other personal advantages, or any comparable activity?

yes no

If so, in which way?

2. Possible professional conflicts of interest:

Does the institution with which you are employed or your employer, receive any financial or other benefits for projects or measures which are connected with the topics of the working groups?

yes no

If so, what are they?

Signature _____ Date _____

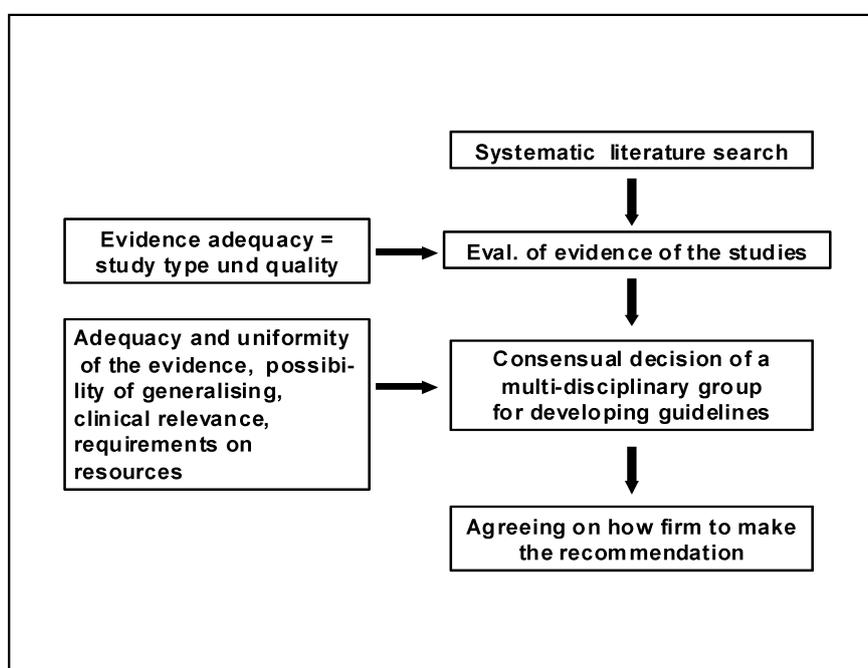
With your signature you confirm that there are no conflicts of interest between your activity in a working group, for preparing guidelines for parenteral nutrition, and your personal or professional commitments.

Table 3: Minimum requirements for literature searches to be carried out by the individual working groups

Period:	from 01.01.1990 onwards
Languages:	German, English
Filter:	Human
Databases:	Pubmed/Medline, EMBASE, Cochrane
Literature:	Original work, guidelines, recommendations, meta-analyses, systematic reviews of literature, randomised control studies, observational studies
Prescribed keyword for all working groups	parenteral nutrition (in combination with keywords from each individual topic)

Table 4: Degree of adequacy as scientific evidence for evaluating studies according to ZQ (in accordance with the guidelines manual from the AWMF und AQuMed/AEZQ [4])

Degree of adequacy	Evidence on the basis of ...
Ia	meta-analyses of randomised control studies
Ib	at least one randomised control study
IIa	at least one well designed control study without randomisation
IIb	at least one other type of well designed quasi-experimental study
III	well designed, non-experimental, descriptive studies, e.g. comparative studies, correlation studies and case control studies
IV	reports of expert committees or expert opinions and/or clinical experience of recognised authorities

**Figure 1: Derivation of degrees of adequacy as scientific evidence (modified according to [5])**

of guideline development, Koller M und Celik I, assisted the process by visiting the individual working groups, and performing the role of methodology enforcers and observers.

Consensus conferences, Delphi consensus and the final editing

A first consensus conference was held in Munich in March, 2005 with 29 working group members, at which the members of the individual working groups presented their recommendations. These provisional recommendations were discussed, if necessary revised, and then voted upon. The recommendations were allocated into categories according to the guidelines provided by the AWMF and AQuMed/AEZQ (Table 5). The results as well as an

account of the proceedings of the consensus conference were recorded in writing.

The suggested amendments, discussed in the consensus conference, were incorporated into the recommendations using another round of the Delphi method. A password-protected home page was set up by the DGEM, was made accessible to all working group members, who then voted on the amendments.

At a second consensus conference in May, 2004, also held in Munich, the amended manuscripts were again discussed, amended where necessary, and voted upon. The working group Ethics and Law presented only an interim report as they were unable to complete their work by that time. After further amendments, the working group leaders posted their manuscripts in the section 'completed manuscripts' or, in the case of suggestions which had not yet been voted upon, in the section 'Delphi round' of the password-protected home page, so that the parti-

Table 5: Allocation to recommendation categories (in accordance with the guidelines manual from the AWMF und AQuMed/AEQZ [5])

Category	Degree of adequacy	Explanation is substantiate by:
A	Ia, Ib	Convincing literature of high quality that contains at least one randomised study (recommended without reservations)
B	IIa, IIb, III	Well performed, non-randomised studies (recommended)
C	IV	Reports and opinions of expert groups and/or clinical experience of recognised authorities. Indicates a lack of directly applicable clinical studies of good quality (recommended with reservations)

Participants could once again review and comment upon the proposals. The final group consensus emerged in this way from several rounds of proposals, reviews and amendments. During the process, the coordination team met several times to review and edit all contributions. The English version of the guidelines was written and updated during the period between the last quarter of 2007 and the first quarter of 2009.

Use and implementation of the guidelines

The aim of the current guidelines is to improve the quality of applying PN in practice. It must, however, be noted that the guidelines are not mandatory directives or procedural regulations, but they are intended to provide guidance to the medical and nursing profession on how to deal with specific situations. Special circumstances pertaining to an individual patient, progress in medical knowledge, and development of new techniques may justify a deviation from the recommendations included in these guidelines.

The implementation of guidelines is often difficult. It involves taking into consideration the infrastructure and the personnel available, and the availability of experts in the field in one's own settings. Many times, although the guidelines are available, it is not feasible to implement them either due to lack of resources or information.

The Leeds Castle conference on implementation of guidelines recommended against individual and isolated methods of implementation [6]. It concluded that implementation must be carried out as a strategy with several steps, with the aim of changing the attitudes and behaviour of those affected. Accordingly, it was important that a plan which incorporated both dissemination of information as well as encouraged a change in bedside practice, according to the guidelines, was formulated.

At the second consensus conference, the following steps for an implementation strategy were decided upon:

- Publication in German language magazines like the 'Nutrition Medicine Today'.
- Publication in English to enable dissemination in non-German-speaking countries.
- Publication in an abridged form – small enough to slip into the pocket of a doctor's white coat – increas-

ing the availability and the possibility of practical implementation of the guidelines, where they are needed, i.e. at the bedside.

- Dissemination at various meetings and congresses of medical specialists
- Production and distribution of training CDs with practical examples.
- Identification of nutrition support teams in hospitals and outpatient settings, and of the information they might need.
- Identification of hospitals that will commit themselves to implementation of the guidelines, and also will give feedback regarding the implementation process (duplicator effect).
- Awarding CME points to doctors within the framework of training activities.

Updating of the guidelines

The recommendations of the guidelines should be reviewed, and if necessary updated five years after publication by the DGEM e.V.

Notes

This article is part of the publication of the Guidelines on Parenteral Nutrition from the German Society for Nutritional Medicine (overview and corresponding address under <http://www.egms.de/en/gms/2009-7/000086.shtml>).

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