
Guidelines

Home Artificial Nutrition: national Guidelines of reference*

DEVELOPMENT COMMITTEE, AGENZIA PER I SERVIZI SANITARI REGIONALI – ASSR (AGENCY FOR REGIONAL HEALTHCARE SERVICES - ARHS)

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ABSTRACT: *The present regulations on home artificial nutrition (HAN) in Italy resemble leopard spots, with remarkable differences even in its organization. At present time, in 10% of our country (Piemonte, Veneto, and Molise) there is a specific regional law for HAN, in 65% there are general regional resolutions (Campania, Emilia Romagna, Friuli Venezia Giulia, Marche, Lazio, Liguria, Lombardia, Puglia, Toscana, Trentino Alto Adige, Umbria, and Val d'Aosta), and more than 25% of the country (Abruzzo, Basilicata, Calabria, Sardegna, and Sicilia) lacks efficient prescriptive instruments, which are necessary to appropriately start a HAN treatment with promptness. A difference in procedures can be found also within the same region. A significant problem is represented in general by a lack of a clinical-institutional point of reference assuming responsibility for the treatment. The sum of these aspects inevitably leads to protracted hospitalization with an increase in national health care costs, and most notably the worsening of the patient's quality of life and that of his family. HAN, owing to the possibility of treating at home, clinically stable patients who would need to be hospitalized only for nutritional treatment, allows us to avoid a prolonged hospitalization, makes the patient's total family, social, and working reintegration easier and considerably reduces health care costs. After Decreto Delegato of 3 June 2003, a development committee was set up at the Direzione generale della valutazione dei Medicinali e della Farmacovigilanza of the Department of Health for formulation of the present document on HAN. Subsequently, the Agenzia per i Servizi Sanitari Regionali was entrusted by the Department of Health to formulate the clinical and organizational guidelines for HAN in order to include them in the "Manuale della Buona Pratica Clinica" (Manual of Good Clinical Practice) and to use them to promote a more homogeneous realization of HAN in the Italian Regions. The development committee, comprising specialists appointed by the Regions, decided on the elaboration of the present recommendations handbook. Now, in light of our work so far and being aware of the necessity for further efforts, we believe that this document can be presented in the relevant institutions to help toward reaching the declared targets in real terms and to represent a point of reference and a clinical and organizational direction for nutritional staff in the field. (Nutritional Therapy & Metabolism 2008; 26: 1-14)*

KEY WORDS: *Home Artificial Nutrition, Guidelines, HAN management*

PRELIMINARY REMARKS

The present situation regarding home artificial nutrition (HAN) in Italy, as it appears from the document "Relazione sulla situazione attuale della Nutrizione Artificiale domiciliare in Italia", drawn up by the development committee for HAN set up after Decreto Delegato of 3 June 2003 at the Direzione generale della valutazione dei Medicinali e della Farmacovigilanza of the Department of Health (formerly the Direzione generale dei Farmaci e dei dispositivi medici, previous D.P.R. no. 129/2003), is very heterogeneous, resembling leopard spots in many aspects and with remarkable organization-

al differences in every single Region. According to the information collected by the Italian Demographic Institute, which was updated for the resident population up to 31 December 2004, still today in only 10% of our country and for only 1.6% of the Italian population there is a specific law for HAN, whereas in 65% of the country and for 78.6% of the population there are general regional resolutions often very different from each other. Finally, in about 25% of the country and for about 20% of our population, there is no available prescriptive rule for guaranteeing the prompt starting of HAN, when indicated. After setting up the above-mentioned document, the Agenzia dei Servizi Sanitari Regionali (ASSR) was en-

trusted by the Department of Health with drafting clinical and organizational guidelines for HAN in order to include them in “Manuale della Buona Pratica Clinica” (Manual of Good Clinical Practice) and to use them to promote a more homogeneous HAN practice within the Italian Regions. The ARHS development committee for elaboration of the “Guidelines on Home Artificial Nutrition” worked, actively following the National System for Guidelines, from 16 March 2005 to 15 May 2006, and concluded its task by drawing up the document “Guidelines on Home Artificial Nutrition” presented here. Now, in the light of the work carried out so far and aware of the necessity of a further effort, this document should be further presented in the relevant institutions to help in reaching the declared targets, taking into account the following possibilities:

- inserting artificial nutrition in the ELA (essential levels of assistance): cooperating with the Direzione Generale del dipartimento della Qualità e Programmazione Sanitaria dei Livelli di Assistenza of the Department of Health, to consider the possibility of including of artificial nutrition as an ELA in the new list for home care;
- involving Regions in order to reach an agreement in the national regional conference field, to guarantee HAN supplementation in all of the Regions, fully respecting their acknowledged autonomies but also satisfying the necessary needs of the patient, that is to say, for medical care;
- organizing an epidemiological registry and, eventually, records of patients undergoing HAN, for monitoring the adequacy of the indication and the correctness of the treatment and for preventing complications.

INTRODUCTION

Artificial nutrition (AN) is a therapeutic procedure that can satisfy the nutritional needs of those patients who are unable to feed themselves naturally and adequately.

AN includes parenteral nutrition (PN) and enteral nutrition (EN). With PN, nutrients are delivered directly into blood circulation through a peripheral vein (i.e., cephalic, basilic, etc.) or a central vein of large caliber (i.e., jugular, subclavian, etc.), by means of venipuncture (cannulation) or venous catheters. With EN, nutrients are delivered directly into the stomach or gut by means of an appropriate tube into the gastrointestinal tract (nasogastric, nasoduodenal, nasojejunal tube and stoma). Both PN and EN require specific therapeutic protocols and monitoring according to the metabolic condition and nutritional requirements of each patient.

Home artificial nutrition (HAN), including home parenteral nutrition (HPN) and home enteral nutrition (HEN), embraces all of the methods of organization of AN carried out at home, whenever the clinical and sociofamilial conditions of the patient can secure the safety and effectiveness of the treatment outside the hospital.

AN, whether enteral or parenteral(1), is an essential therapeutic device as it allows us to maintain or reintegrate the nutritional state of those patients for whom oral feeding is contraindicated, impossible, or inadequate. Treatment with AN is considered to be essential for: (a) malnourished patients who are not able to satisfy their energetic requirements through oral feeding (D[GPP]); (b) patients at risk of malnutrition: i.e., normal-nourished patients who have been unable to satisfy their energetic requirements through oral feeding for 5 days (D[GPP]); (c) patients at risk of malnutrition: i.e., normal-nourished patients who are not going to be able to satisfy their energetic requirements through oral feeding for the next 5 days or longer (D[GPP]); (d) patients in need of major surgery who are malnourished or at risk of malnutrition to treat preoperatively (B); (e) age and basic pathology should not represent a limitation for HAN (D[GPP]).

Nutritional therapy, in enabling the treatment of malnutrition, allows a permanent improvement in the clinical course (2), the quality of life (3), and the prognosis of many pathologies, thus significantly influencing morbidity and mortality (4, 5).

AN is a chronic treatment that can very often be life-saving (6, 7) and is thus useful to ensure the patient's survival. Its employment may therefore require treatment through HAN. HAN thus represents a necessary extra-hospital therapy for helping with further positive outcomes for patients, such as: (a) general reintegration of the subject into his/her family social, and working context (de-hospitalization); (b) improvement of the quality of life of the patient and of his/her family; (c) a reduction of health care costs, due to a shorter hospitalization and a reduction in subsequent rehospitalizations (8).

Indication to HAN is given on a clinical, ethical, and environmental basis and according to the patient and/or caregiver's willingness to provide home management of the treatment. In case of environmental or patient and/or caregiver's inadequacy, AN should be provided anyway to the patient in a nonhospital environment, which can be adequate to correct treatment management. Management of HAN needs specific expertise that provides the knowledge of prevention and treatment of the most frequent technical and metabolic complications (9-11) and that can make it an essential tool for a complete family and

social reintegration of the patient. Its realization is therefore very complex, and it requires an operational standard of adequate level.

HAN EPIDEMIOLOGY

From the epidemiological data available so far (12, 13), the prevalence of HAN (number of patients in treatment per million inhabitants) subdivided according to age and typology is as follows: adults: HEN: 120; oncological HPN: 13.6; BCIF (Benign Chronic Intestinal Failure) HPN: 3.7; other HPN: 5; and children: HEN: 8.4; oncological HPN: 0.3; BCIF HPN: 0.7; other HPN: 0.4.

In a study made in April 2005 by the Italian Society of Artificial Nutrition and Metabolism (SINPE) in Italy, it was demonstrated that global average prevalence of HAN is 152.6 cases/million inhabitants of which 83.9% involves HEN and 16.1% HPN. There are, however, remarkable differences between the Italian Regions, both in terms of prevalence and in terms of indications for suitability and protocols of realization.

Necessity of HAN Guidelines

The necessity of guidelines for HAN is highlighted by the points that follow.

Considerable heterogeneity of the law within the different Italian regions

The situation regarding HAN in Italy (14) resembles leopard spots, with remarkable differences even in its organization. At the present time, in 10% of our country (Piemonte, Veneto, and Molise) there is a specific regional law for HAN. In 65% there are general regional resolutions (Campania, Emilia Romagna, Friuli Venezia Giulia, Marche, Lazio, Liguria, Lombardia, Puglia, Toscana, Trentino Alto Adige, Umbria, and Val d'Aosta). More than 25% of the country (Abruzzo, Basilicata, Calabria, Sardegna, and Sicilia) lacks efficient prescriptive instruments, which are necessary to appropriately start a HAN treatment with promptness. Finally, organizational differences are evident also within the same Region, with further inconvenience both for health care and for HAN (15) users.

This variation could eventually lead to a lack of organization that may prolong the waiting period for domiciliation for those patients undergoing artificial nutrition and a consequent complicated therapeutic course.

A further negative element is represented by the lack of any clinical and institutional reference that is supposed to be responsible for the treatment.

All of these inconveniences contribute to an increase in hospitalization time and in national health care costs

and to a worsening in the quality of life of the patient and his/her relatives.

Work of a specific Ministerial Committee

In consideration of the above-mentioned situation, the Health Department, *Direzione Generale della Valutazione dei Medicinali e della Farmacovigilanza*, with a ministerial ordinance of 3 June 2003, appointed a Ministerial Guideline Development Committee for HAN that worked out the first document, the "**Report of the Current Situation of Home Artificial Nutrition in Italy**" (12), in which indications, appropriateness, efficacy, and safety of HAN are defined and the further following aims are identified:

- to insert AN into the essential levels of assistance (ELA);
- to further a national and regional agreement on HAN;
- to organize a ministerial epidemiological registry for patients undergoing HAN.

Indications from the Minister of Health

The above-mentioned document was approved by the Minister of Health in 2004. As directed by from the Minister of Health, it was passed to the Agenzia dei Servizi Sanitari Regionali (ASSR) with a suggestion to establish a development committee for elaboration of guidelines for HAN, these being necessary to establish, together with regional technicians, standard references for clinical control in the different divisions and for organization of the services in the Regions.

METHODOLOGY

The method followed for elaboration of the "*Guidelines for HAN*" was developed in the National Program for Guidelines (NPGL) (16). For a wider understanding of the task, we are going to report the essential points as follows:

Choice of the issues

Epidemiological method (relevance in terms of incidence, mortality, etc.), availability of evidence (analyzing the availability of recent data on intervention efficacy in specific health care problems in the data base) and operators' opinions are combined together in a semi-structured way.

Choice of development committees

The choice is made according to specific expertise of professionals, of their curricula, and of their representativeness on the issue.

Definition of scientific enquiries and working plan

Scientific enquiries to be answered are defined by the development committee during the first experts panel meeting, in which the main issues for the management of the clinical problem are also defined.

TABLE I - LEVELS OF EVIDENCE

LEVELS AND TYPE OF EVIDENCE

1++ High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias

1+ Well conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias

1 – Meta-analyses, systematic reviews or RCTs, or RCTs with a high risk of bias

2++ High quality systematic reviews of case-control or cohort studies *or*

High quality case-control or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal

2+ Well conducted case-control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal

2 Case-control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is causal

3 Non-analytic studies, (eg case reports, case series)

4 Expert opinion, formal agreement

TABLE II - GRADING OF RECOMMENDATIONS

GRADES AND EVIDENCE

A At least one meta-analysis, systematic review, or RCT rated as 1++ and directly applicable to the target population *or*

A systematic review of RCTs or a body of evidence consisting principally of studies rated as 1+ directly applicable to the target population and demonstrating overall consistency of results

Evidence defined by an evaluation of NICE technology

B A body of evidence including studies rated as 2++ directly applicable to the target population and demonstrating overall consistency of results *or*

Extrapolated evidence from studies rated as 1++ or 1+

C A body of evidence including studies rated as 2+ directly applicable to the target population and demonstrating overall consistency of results *or*

Extrapolated evidence from studies rated as 2++

D Evidence level 3 or 4 *or*

Extrapolated evidence from studies rated as 2+ *or*

Consensus conference

D(GPP) represents a recommendation for a good practice point (GPP) based on the experience of the Guideline Development Group for elaboration of Guidelines

Trials collection

The NPGL adopted a research hierarchic structure and procedure for evidence evaluation. Efficacy and safety trials are first of all searched in the Cochrane Library (Clib), and in greater detail in the systematic revision database (CDSR) produced by Cochrane Groups or others (DARE). In case of an unsuccessful first attempt, a new search of Clib and other bibliographical databases is recommended to identify single trials and nonrandomized comparative studies.

Editing and development of guidelines draft

Once collected and assessed, trials are considered by the editorial board and a first draft of the guidelines and recommendations is edited. The draft is then handed out to all those contributing to the project (panel, representatives of scientific societies, and the NPGL editorial board) for any further comment. The draft is again revised and modified according to comments; problems and further opinions are examined during the second and last plenary group meeting with representatives of scientific societies.

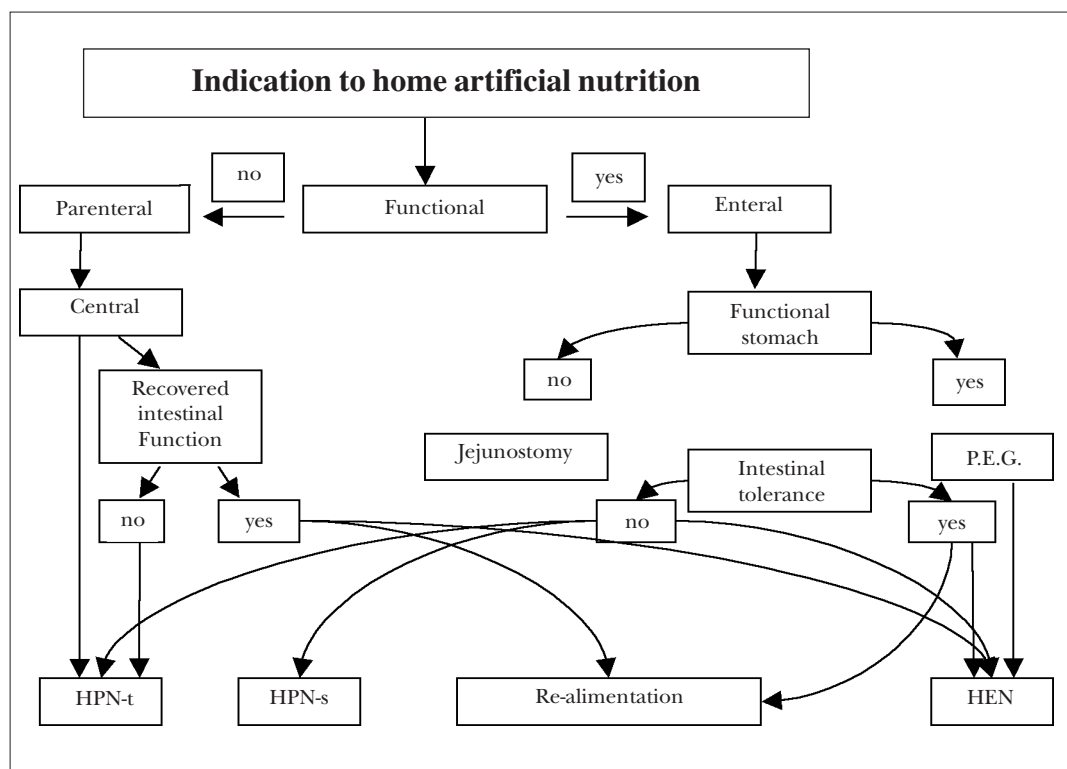
Grading assignment

In the guidelines, recommendations are qualified with a certain grade of evidence level and grades of recommendation, expressed, respectively, with numbers (from 1 to 4) and letters (from A to D[GPP]) as reported in Tables I and II. Level of evidence refers to the probability that some discoveries may derive from planned studies, these being carried out to produce valid information without bias. Grades of recommendation refers to the probability that the practical application of a recommendation may improve the health of a target population to whom the recommendation is addressed. Among the different grading systems reported in the literature to record the level of evidence and grades of recommendation, we used here the Scottish Intercollegiate Guidelines Network modified appropriately (17).

Editorial presentation of guidelines

Authoritativeness and clarity of recommendations, the use of unambiguous language, and well-defined terms (also by means of a “Glossary”), are necessary conditions to ensure the success of a tool which aims at assisting and directing clinical decisions. Recommendations should also be presented in a form that is quick and easy to look up and facilitates learning and memorization. It is therefore suitable to define the document’s general structure as well as its form and style (from a textual and graphical point of view) as it should always be followed, even with any variation that might be suggested by the specifics of the topic.

Fig. 1 - Algorithm for the choice of type of artificial nutrition in patients with an indication to home artificial nutrition.



HAN GUIDELINES

Indications to HAN are the same as those for AN in the hospital, as provided in all the previous national and international guidelines (18-29). HAN allows us to treat clinically stable patients at home, who otherwise would need hospitalization only for nutritional treatment. HAN avoids long hospitalization and facilitates total family, social, and working reintegration of the patient and considerably reduces health care costs (30). Old age and malign basic pathology should not be considered contraindications to HAN.

HAN is indicated in these specific clinical and environmental conditions, taking into account ethical evaluations (D[GPP]):

- **Impossibility of maintaining or reintegrate, when necessary, the nutritional status of the patient with only oral intake, because of altered functioning of the gastrointestinal tract, or the patient's inability to eat normally;**
- **Stability of the patient's case history and possibility of basic pathology to be treated and nutritional management to be completed at home;**
- **The patient's residence should be healthy to ensure**

a suitable HAN management;

- **Patients who are not self-sufficient should be entrusted to an eligible carer, or, when there is no one, the treatment should be integrated into a local assistance home service.**

In general, HAN is not indicated when the treatment is supposed to last less than 90 days (31).

Anyway, it should be said that because of the lack of randomized studies and the considerable variety of both patients and pathologies compatible with HAN, an individual clinical evaluation of each specific case and a knowledge of specific guidelines (such as the Italian Society of Artificial Nutrition and Metabolism guidelines [SINPE GL]) are required.

When there is an indication to HAN but no suitable environmental conditions, the patient should receive the same treatment in a health care or assistance institution. These should be contacted by the HAN specialist unit and by the home health care service of the relative district.

The choice of the appropriate form of nutritional support, among HAN, HEN, and HPN, should be made using the algorithm shown in Figure 1, based on residual intestinal function.

Clinical indications to HAN

Indications to HAN reported here are taken from the SINPE guidelines, thus they have been formulated according to a broader national scientific and qualified agreement. They include all the situations when the patient's clinical conditions are stable so that hospital discharge and/or home care is possible, but they cannot satisfy their nutritional requirements naturally. When clinical conditions are no longer critical and an indication to HAN persists, a multidimensional assessment for suitability of carrying on with the treatment in the patient's usual environment is needed. HAN allows for treating patients at home who otherwise would need hospitalization solely for nutritional treatment. One of the main elements of eligibility for home treatment is the ability of nutritional recovery to improve both quality of life and clinical conditions without any risk. In any case, an indication to HAN should be periodically checked.

During the age of development, in the presence of a chronic pathology such as Crohn's disease, there is a stronger indication to HAN, as it allows us to ensure growth during the period when it is quicker and it would suffer more from cortisone therapy (B).

Specific indications to HEN

Whenever there is an indication to HAN and the gastrointestinal tract is functional and accessible, enteral tube feeding will be the first choice of treatment (B).

This rule is supported by a great deal of available scientific data from the literature. In Europe, HEN represents 80%-90% of all home nutritional treatments. Basic reasons for enteral choice are:

- its more physiologic nature;
- its minor risk of complications;
- its easier management;
- its minor costs compared with HPN.

The main indications to home enteral nutrition in adults are swallowing disorders of neurological origins (i.e., due to cerebrovascular diseases, degenerative diseases of the central nervous system, etc.) and obstructions of the upper gastrointestinal tract and of the cervicocephalic area (frequently in neoplastic diseases).

Contraindications to HEN

HEN is generally contraindicated in patients with intestinal subocclusion, untreatable vomiting, paralytic ileum, and/or severe diarrhea making metabolic management of the patient difficult, proximal ("high") and/or large-caliber intracutaneous fistulas, and chronic intestinal ischemia.

Specific indications to HPN

HPN is indicated in situations of chronic intestinal failure that cause a reduction of intestinal functional mass so that an adequate absorption of nutrients is not ensured. Because of what has previously been said about HEN, it is fundamental, in order to judge the indication to HPN as appropriate, that any oral nutrition or HEN is first considered, and that the patient has reported any altered nutritional condition and weight loss. Eligibility also requires a minimum length of time of some months and stability of hemodynamic and metabolic condition. Home parenteral nutrition involves some risks and implies in any case the recruitment of more human and economic resources in comparison with HEN.

As for the most frequent indications to HPN, there are first neoplastic diseases, whereas among nonneoplastic diseases we find most frequently mesenteric vasculopathy (24%), intestinal inflammatory diseases (20%), actinic enteritis (17%), intestinal pseudo-obstruction (7%) and other (32%). As already said, in the case of short bowel syndrome, HPN entirely replaces the functions of the intestine, can be continued indefinitely, and represents a life-saving treatment.

Contraindications to HPN

HPN is contraindicated whenever there is an indication to enteral AN, in those cases where it can fully satisfy the patient's nutritional requirements. Relative contraindications may be severe coagulopathies or thrombophilic syndromes, where risks and benefits should be assessed for each individual case.

MANAGEMENT OF HAN

In Italy there are many different organizational models for HAN. It is therefore appropriate for each model to follow some minimal criteria, while respecting the autonomy of each Region.

The scientific societies in the field (the Italian Dietetic and Clinical Nutrition Association [ADI] and SINPE) elaborated guidelines in 2000 for approval by the Centers of Home Artificial Nutrition (32), and in March 2004, the HAN development committee together with the Direzione Generale dei Farmaci e dei Dispositivi Medici of the Department of Health, drafted a document titled "Proposta di accordo NAD" (Proposal for HAN agreement), stating further management aspects. The development committee entirely agrees with the recommendations presented.

Management model from Guidelines for approval of Centers of Home Artificial Nutrition ADI/SINPE (D[GPP])

1. Treatment responsible structure

HAN should be prescribed, carried out, and monitored by dedicated units, preferably by those services currently operating in each Region, for as long as they have a clinical role in the patient's treatment. These could be

- already operating specialist units or services or health care facilities with documented experience in HAN, and in close interaction with ADI services and the Districts.
- specialist units or dietetics and clinical nutrition services; clinical nutrition and HAN specialist units in close interaction with ADI and the District authorities.

The activity of the specialist unit, which will always be defined as the HAN specialist unit in the present document, should be recognized by the Azienda Sanitaria according to the current law and clearly identifiable by users. Every Region will be able to decide the criteria of identification of HAN specialist unit including also inter-corporation structures or structures resulting from homogeneous areas, according to the law. The activity should be officially acknowledged by the Azienda Sanitaria (HAN specialist center) and clearly identifiable by users.

2. Human resources

Every HAN specialist unit should be managed by a physician with documented clinical experience in artificial nutrition. He or she is going to be the person responsible for HAN treatment. Every HAN specialist unit should have dedicated personnel, whose roles will be defined according to corporate criteria, taking into consideration the fact that management of HAN requires a team of professionals – dietitians, nurses, pharmacists, psychologists, social workers, secretarial personnel, and others (33).

For the management of HAN in pediatrics, specific expertise is required. In hospital, the referral will always be to a pediatrics OU or a pediatric hospital in coordination with HAN specialist unit, and at a regional level, any pediatrician. Every Region should establish a specific organization to function as a pediatric HAN specialist unit for direct and/or indirect management of pediatric patients in its district.

3. Functions of the HAN specialist unit responsible for HAN

In response to a request by a hospital or district doctor, the HAN specialist unit decides if there is any indication to HAN and takes responsibility for the whole diagnostic-therapeutic course, cooperating with the general practitioner and the pediatrician and, where provided, with the district services of home care.

The HAN specialist unit initiates communication to guarantee a quick sharing of information with the general practitioner, the pediatrician and the district workers involved in patient management. The HAN specialist unit guarantees quick and complete information and training of the patient, relatives, or caregivers. The HAN specialist unit is responsible for management of the treatment in all its steps and makes use of clinical and organizational protocols to complete the following steps:

Step 1: Start

- Indication and choice of the access for infusion.
- Clinical and management aspects of HAN.
- Organization of equipment, materials, and products delivery. The HAN specialist unit is responsible for the correct products and equipment delivery and their substitution, when necessary. Delivery should follow certain procedures and duration.
- Training of patients and relatives (caregivers).
- Delivery of an instruction handbook (with images) to patients, relatives, or caregivers with all procedures for nutrient preparation, infusion pump employment, possible risks, frequently asked questions, and instructions in case of emergency.
- Delivery of an address book with telephone numbers (routine or emergency) for contacting health care personnel who understand HAN patient needs and problems. Health care personnel are available:
 - For at least 8 hours a day, for at least 5 days a week (HEN);
 - For at least 8 hours a day, for 7 days a week (HPN, non-IICB);
 - For 24 hours a day every day (HPN-IICB).

For days and times when personnel are not available, the OU responsible for HAN delivers instructions about type of access, nutritional therapy, and treatment for access complications, so that other health care facilities can intervene safely. The HAN specialist unit also delivers an assistance protocol to patients and relatives which includes a monitoring program. Suitable documentation about necessity and modality of nursing assistance, materials delivery and home medical control – possibly arranged – is delivered to the general practitioner, the pediatrician, and to the respective district services.

Step 2: Cure and clinical monitoring

- The HAN specialist unit ensures ordinary admission to hospital and day hospital (DH), ambulatory or home assistance, decided according to the clinical characteristics of the individual case.
- The HAN specialist unit, in response to a request from a general practitioner or a pediatrician or other health care staff member, or after a request from the

patient or caregiver, ensures that, within an adequate time to fulfill the clinical needs of the patient, a clinical assessment is made regarding ordinary admission, DH, or ambulatory or a home assistance, of those cases that may require a slight variation of nutritional and therapeutical regimen.

- The HAN specialist unit ensures ambulatory, DH, Hospitalization or home assistance of those cases requiring a diagnosis and/or treatment of complications.

The patient should be supported by a relative or caregiver and the general practitioner during diagnosis and treatment of any eventual problem.

Other possible management models (D[GPP])

1. The hospital OU manages and takes responsibility for the whole diagnostic-therapeutic procedure. Equipment and materials delivery can be directly managed by the hospital OU or by other district services of home care and home assistance companies.
2. The district OU manages and takes responsibility for the whole diagnostic-therapeutic procedure. Equipment and materials delivery can be directly managed by the OU or by other district services of home care and external home assistance companies. The district OU should formally cooperate with specialistic hospital wards for ensuring the patients priority for all interventions related to HAN, that should necessarily take place in hospital – DH or Hospitalization:
 - Positioning and eventual repositioning or revision of enteral and parenteral accesses.
 - Diagnosis and treatment of HAN complications, when these are the duty of the hospital.

Minimal organizational characteristics for a HAN-OU (D[GPP])

- a) Identification of the company where it is set, with related cost center.
- b) Doctor-manager, with specific knowledge and experience in clinical/HAN/AN nutrition.
- c) Presence of dietitians, nurses, and advising pharmacists.
- d) Presence of facilities, human resources, and organizational links for correctly accomplishing the whole diagnostic-therapeutic procedure of HAN:
 - Start;
 - Cure and clinical monitoring;
 - Products delivery.

HAN-OU tasks (D[GPP])

- a) Evaluation of eligibility for HAN;
- b) Acquisition of the patient's or relative's informed consent;

- c) Contact and full sharing of the case with GP (General Practitioner);
- d) Preparation and prescription of the nutritional program;
- e) Training to home management;
- f) Periodic programmed monitoring;
- g) Prevention, diagnosis, and management of treatment complications;
- h) Decisions regarding ending of treatment;
- i) Initiation and control of equipment and materials delivery;
- j) Initiation and control of home service;
- k) Management of clinical folder.

Basic features to be ensured in a course of HAN treatment (D[GPP])

- Home delivery of products, equipment, devices, and related assistance.
- Nursing home assistance as required by the OU (in cases where patients are not self-sufficient and/or caregivers are not competent).

Recommendations regarding modality and instruments for realization of HAN

We will here report specific recommendations for each of the possible home artificial nutrition treatments.

HEN

Percutaneous endoscopic gastrostomy (PEG) is indicated in patients who need treatment for more than 4 weeks (D[GPP]).

All patients undergoing home enteral treatment should be assisted by multidisciplinary professionals including dietitians, nurses, and other professionals linked to home care (rehabilitation and speech therapists). Diagnosis and treatment of any potential problems should be discussed with the patient together with a relative and the general practitioner or the pediatrician (D[GPP]).

Discharged patients continuing enteral nutrition at home (or their relatives) should receive a protocol of assistance including a monitoring program. Patients should also receive adequate training and an information handbook from health care professionals who are qualified in nutritional support (nurses and dietitians specializing in nutrition), which includes the following (D[GPP]):

- Management of the infusion system for the enteral nutrition and supplementation regimen, information about procedures for preparation of nutrients, use of the infusion pump and its possible risks, methods for solving the most frequent problems, shown in an adequately illustrated handbook.
- Telephone numbers (emergency and routine) for con-

tacting health care professionals who are able to deal with the needs and problems of HEN-treated patients.

- Organization regarding delivery of equipment, materials, and nutrients that should be carried out with an appropriate specific contact with the external provider of home care eventually involved.

HPN

All patients undergoing HPN treatment should be assisted by a team of multidisciplinary professionals including dietitians, nurses, and others linked to home care. Diagnosis and treatment of any potential problems should be discussed with the patient together with a relative and the general practitioner or the pediatrician (D[GPP]) (Tab. II).

Discharged patients continuing HPN (or their relatives) should receive a protocol of assistance including a monitoring program. Patients should also receive ade-

quate training and an information handbook from health care professionals who are qualified in nutritional support (nurses and dietitians specializing in nutrition), which includes the following (D[GPP]):

- Management of the infusion system for the parenteral nutrition and supplementation regimen, information about procedures for preparation of nutrients, use of the infusion pump and its possible risks, methods for solving the most frequent problems, shown in an adequately illustrated handbook.
- Telephone numbers (emergency and routine) for contacting health care professionals who are able to deal with the needs and problems of HPN-treated patients.
- Organization regarding delivery of equipment, materials, and nutrients that should be carried out with an appropriate specific contact with the external provider of home care eventually involved.

INDICATIONS TO HEN

1) Impossibility or contraindication to oral feeding due to:

a. Obstructive Dysphagia:

i. Neoplastic diseases in therapeutical phase and not (head-neck tumours, esophagus, stomach, duodenum);

b. Functional Dysphagia:

i. Neurological pathologies (cerebral coma, outcomes of acute cerebrovascular events and cerebral traumas, progressive chronic diseases: dementia, Alzheimer, Parkinson, multiple sclerosis, motoneuron disease).

ii. Alteration of motility of the upper digestive tract (achalasia...)

2) Need of oral feeding integration due to:

a. Anorexia or hyporexia due to different reasons

b. Hypercatabolic chronic pathologies

c. Sequelae of severe pathologies (ex: Chron's disease)

INDICATIONS TO HPN

For short-term HPN:

a) *Neoplastic diseases during the following conditions:*

i. severe nutritional vs digestive deficits, sequelae of aggressive oncologic treatments without evidence of ongoing disease.

ii. in outpatients with ongoing neoplastic disease where poor nutritional conditions compromise an adequate oncologic therapy.

iii. patients with advanced disease whose final prognosis is more influenced by malnutrition/hypophagia than by the disease progression, as long as the patient's quality of life is acceptable.

b) *Other more rare diseases with indication to short-medium term Parenteral Nutrition:*

i. severe temporary malabsorption.

ii. gastric fistulas.

iii. hyperemesis gravidarum.

iv. immune pathologies.

For long-term HPN:

a) *Short Bowel Syndrome (wide intestinal resections outcomes due to mesenteric infarctions, Chron's disease, actinic enteritis, volvulus, aderenal syndrome...).*

b) *Alterations of intestinal motility (pseudo-obstruction, late sequelae of actinic enteritis, toxic and ischemic neuropathies).*

c) *Severe, non treatable malabsorption (non-responder celiac disease...).*

d) *Rare pathologies (congenital metabolic disorders inducing malabsorption, scleroderma, lymphangiectasia, amyloidosis, VIP syndrome).*

HEN and HPN

Home health care professionals should make sure that patients on home artificial nutrition or their relatives (D[GPP]):

- Are completely informed and have access to appropriate information sources regarding the patient's individual characteristics with regard to the form, language, and structure of the information. Plenty of attention should be given to adapting to each patient's cognitive capacities, sex, physical and cultural needs, and stage of life;
- Have the possibility of discussing diagnosis, treatments, and physical, psychological, and social problems;
- Receive addresses of religious support groups of volunteers, if available and required.

COSTS OF TREATMENT

HAN does not imply any costs for patients either for products and equipment purchase, or for their delivery and related professional services.

Each local health care company (Azienda Sanitaria Locale [ASL]) should completely cover treatment costs and supply all-inclusive daily coverage – in relation to the treatment activated – to Clinical Nutrition and the HAN-OU supplying home treatment. The ASL also provides for ambulance transport costs to the OU and/or for referral to a hospital at the request of the HAN-OU (D[GPP]).

ENVIRONMENTAL CHARACTERISTICS NOT SUITABLE TO TREATMENT

When environmental characteristics are not suitable, the patient should receive HAN treatment in alternative conditions. Patients with an indication for HAN, but who are not suitable for home treatment, should receive artificial nutrition treatment – with the same qualitative adequacy features mentioned above – from a residential or health care facility, according to the patient's typology (D[GPP]). Treatment charges (nutritional assistance and supply of equipment and materials) should obviously be provided according to each regional law.

SAFETY OF HAN

Safety is the basis for carrying out home treatment where possible, most of all in HPN, where, as it is known, septic complications related to the central venous catheter can be very high (34) and may considerably influence morbidity and mortality with treatment. Prevention requires the use of specific and standard protocols of initiation and monitoring to ensure a significant reduction (35) of infective risk and/or other procedural risks.

The HAN specialist unit should organize a training service; home delivery of solutions, materials, and equipment for HAN; materials for dressings and disinfection; together with ensuring clinical procedures and monitoring and clinical efficacy analysis. This can be organized directly, or indirectly with the use of specific providers (36) (D[GPP]).

STATE OF MOOD

The impact of HAN on the emotional state of the patient is a very interesting issue that in the last few years has received attention from the scientific world, most of all regarding patients undergoing HPN. On this topic some authors have shown that HPN treatment negatively

influences the patient's emotional state (37) and that assistance from dedicated organizations could represent the most adequate strategy to reduce these effects and to improve the patient's general condition.

QUALITY OF LIFE

Quality of life of patients undergoing HAN basically depends on their basic pathology and on the procedures necessary to carry out the treatment. Quality of life is obviously reduced in those patients, compared with a control group of the same age and sex, but it remains unchanged in long-term treatments (38). Technical and administrative aspects of HPN treatment interfere with the patient's quality of life especially in those suffering from depression or showing signs of drug dependence (39). Thus HPN induces a significant worsening of the patient's quality of life compared with that of a normal individual and this effect is greatest in depressed and drug-dependent patients (B).

ETHICAL ISSUES REGARDING HAN

The literature on this issue is wide-ranging and many of the opinions voiced there are recent (40-58). It is useful to reaffirm that in the light of the documents produced by the National Committee for Bioethics (59) and the Department of Health (60), and the above-mentioned guidelines of the Italian Society of Artificial Nutrition and Metabolism, and according to the indications from the Oviedo Convention (49):

- AN, often a lifesaving device, should be guaranteed as prevention and therapy of secondary protein-calorie malnutrition and should be prescribed by specialists throughout the country to the advantage of those patients suffering from either neoplastic diseases – even the incurable – or nonneoplastic diseases, where normal oral feeding with natural food is impossible permanently or for a limited period (D[GPP]).
- It is considered appropriate to wean the patient off HAN when a condition of overtreatment is identified (D[GPP]).
- It is important for a medical commission to identify any overtreatment status in a patient and thereafter to discuss the eventual suspension of medical care and of artificial nutrition with patients and their legal advisers (D[GPP]).
- An appeal to an ethics committee from an Azienda ospedaliera or Azienda sanitarie related to the patients and their doctors, is highly recommended and encouraged (D[GPP]).
- In cases where AN represents a therapy until the end of life or involves a permanent vegetative state, it should take into account some of the palliative criteria of medicine or compassionate medicine; that is to say, it

should ensure or end life respecting the documented ethical beliefs of the patients and their family circumstances (D[GPP]).

INDICATORS OF EFFICACY AND SAFETY

To monitor the therapeutic effects and organizational level of HAN it is necessary to promote the collection of those parameters enabling an evaluation of the process's efficacy and safety.

Indicators of efficacy and safety that are largely considered to be adequate for HAN:

- I. assessment of technical, septic, and metabolic complication incidence correlated to HAN;
- II. questionnaires for evaluation of the training program efficacy;
- III. assessment of nutritional parameters;
- IV. questionnaires for evaluation of the quality of life (D[GPP]).

GLOSSARY

Anthropometry: All measurements of the body that allow us to evaluate the nutritional status of the patient. This is carried out by means of a scales, stadiometer, tape measure, and "skinfold calipers". The most common parameters are weight, height, waist and hip circumference, and skinfolds (tricipital, bicipital, subscapular, and suprailiac).

Artificial accesses: All the methods used to bring nutrients to their digestive, absorptive, and metabolic site. Artificial accesses to the alimentary canal include the positioning of nasoenteric tube (nasogastric, nasoduodenal, or nasojejunal tube), stomas realization through a gastric or jejunal endoscopic examination (percutaneous endoscopic gastrostomy [PEG] or percutaneous endoscopic jejunostomy [PEJ]), or through a surgical intervention in the abdomen. Artificial accesses to blood circulation include central venous catheters with direct access through venipuncture or with access through a peripheral vein (peripherally inserted central catheter, PICC).

Central venous catheter (CVC): A device that can be inserted through a central vein for the supplementation of nutritional blends or other infusions. There are long-term and short-term CVCs, according to the expected time length (see also "Artificial accesses").

Enteral nutrition: Nutrition administered through the gastrointestinal tract. The term is usually used for nutrition by means of a tube or a stoma, passing through the mouth and directly reaching the bowel.

External provider: Company trained in the realization of home artificial nutrition; that is to say, methodical nutri-

tional blend supply, equipment for dressings and CVC heparinization, patient's and caregiver's training regarding treatment, nurse monitoring – all provided according to specifications from the local HAN specialist unit.

Infusion Pump: A device for controlled supplementation of a nutritional blends flux. It is used both for enteral nutrition (nutripump) and parenteral nutrition (volumetric pump).

Gastrostomy: A stoma created through the abdominal wall directly into the stomach to empty it (gastric decompression) or to administer nutrients by means of a tube. Gastrostomy tubes are usually placed endoscopically (percutaneous endoscopic gastrostomy [PEG]) or surgically (see also "Artificial accesses").

HAN Équipe: In conformity with Deliberation no. 920, 2002, of the Lazio Region, the Équipe should operate in every ASL (Azienda Sanitaria Locale [local health care company]) and should be composed of a clinician, a pharmacist, and a care assistant. It has the task of working together to assist the patient during the whole treatment with HAN, giving an effective and ready response to requests for attendance. The Équipe HAN is to be replaced by the HAN specialist unit.

HAN specialist unit: A specialist unit provided for by Deliberation no. 920, 2002, of the Lazio Region. This unit can be based at ASL hospitals, Aziende Ospedaliere, or Distretti Sanitari, and it has the necessary expertise and human resources to carry out HAN treatment, particularly artificial access packing, planning, and monitoring of the nutritional plan, admissions to day hospitals, or hospitalization if necessary, and availability.

Hypercatabolism: Prevalence of catabolic processes, demolition of tissues in anabolic processes.

Intestinal failure, acute or chronic: When a certain tract of the bowel (of varying length) is unable to accomplish its function of digestion or absorption. It occurs because of a partial surgical removal of intestine, or for a more or less severe damage to its mucosal surface due to acute or chronic pathologic phenomena, or finally because of an acute or chronic seriously impaired intestinal motility.

Jejunostomy: A breach through the abdominal wall made to reach the jejunum in the intestinal tract, to empty it (decompression), or to supply nutrients by means of a tube. Jejunostomy can be performed surgically or through endoscopy (percutaneous endoscopic jejunostomy [PEJ]) (see also "Artificial accesses").

Malabsorption: An impaired absorption of food and liquids of the gastrointestinal tract. Its etiology may vary: intestinal tissue structure alteration, deficiency of contact between nutrients and absorptive surface, or alteration of digestion and of the period of nutrient transit within the bowel.

Malnutrition: Any condition caused by a deficiency

in food intake, or an impaired intestinal absorption or metabolism. In the broad sense, any limitation to nutrient assumption can be considered as malnutrition.

Nasogastric (nasoduodenal, nasojejunal) tube: A tube of different diameters, lengths, and materials, inserted through the nose to reach the stomach, duodenum, or jejunum.

Nutritional assessment: A method of defining the nutritional status of a patient based on a series of collected anamnestic, clinical, dietary, anthropometric, and laboratory data.

Nutritional bag, enteral or parenteral: A bag made of different biocompatible materials and containing blends for EN or PN. Bag content may be a fixed formulation (blends prepared by a pharmaceutical company) or be derived from a certain prescription (galenic preparations realized according to a medical prescription from an accredited hospital pharmacy).

Nutritional plan: Prescription of the type of nutritional intervention, its modalities and necessary products for assuring nutrient assumption. It should also include a monitoring program. It follows a nutritional assessment (see "Nutritional assessment").

Nutritional team: Provided for by a regional law (Veneto), it should operate in every ASL and should be composed of a clinician, a pharmacist, and a care assistant. It has the task of working together to assist the patient during the whole treatment with HAN, giving an effective and ready response to requests for attendance. The nutritional team is to be replaced by the HAN specialist unit.

Parenteral nutrition: Nutrition administered through a central vein of adequate diameter (usually by placing a catheter in the subclavian vein, internal jugular or femoral running up to the superior or inferior vena cava).

Pharmaconutrition: This refers to the use of those active ingredients naturally contained in food, which have a documented pharmacologic action and that can improve pathological processes or reduce the risk of relapse.

DEVELOPMENT COMMITTEE

Dott Bruno Rusticali Coordinatore Linee guida AS-SR; Dott.ssa Loredana Gili ASSR; Dott. Antonio Addis Ministero della Salute. AIFA; Prof. Marco Braga Ateneo Vita-Salute San Raffaele, Ospedale San Raffaele Milano; Prof. Franco Contaldo Università degli Studi di Napoli Federico II; Prof. Antonino De Lorenzo Università degli studi di Roma "Tor Vergata"; Dott. Dino Faraguna, Regione Friuli V. Giulia Azienda ASS n. 2 Gorizia; Dott. Alessandro Ghirardini Ministero della Salute, Direzione

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Address for correspondence:
Prof. Francesco William Guglielmi
Section of Gastroenterology & Day Hospital of Artificial Nutrition
"San Nicola Pellegrino" Hospital
70059 Trani (Bari), Italy
e-mail: guglielmifw@libero.it

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