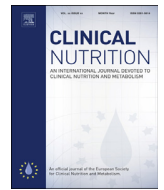




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ESPEN endorsed recommendation

Diagnostic criteria for malnutrition – An ESPEN Consensus Statement



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SUMMARY

Objective: To provide a consensus-based minimum set of criteria for the diagnosis of malnutrition to be applied independent of clinical setting and aetiology, and to unify international terminology.

Method: The European Society of Clinical Nutrition and Metabolism (ESPEN) appointed a group of clinical scientists to perform a modified Delphi process, encompassing e-mail communications, face-to-face meetings, in group questionnaires and ballots, as well as a ballot for the ESPEN membership.

Result: First, ESPEN recommends that subjects at risk of malnutrition are identified by validated screening tools, and should be assessed and treated accordingly. Risk of malnutrition should have its own ICD Code. Second, a unanimous consensus was reached to advocate two options for the diagnosis of malnutrition. Option one requires body mass index (BMI, kg/m²) <18.5 to define malnutrition. Option two requires the combined finding of unintentional weight loss (mandatory) and at least one of either reduced BMI or a low fat free mass index (FFMI). Weight loss could be either >10% of habitual weight indefinite of time, or >5% over 3 months. Reduced BMI is <20 or <22 kg/m² in subjects younger and older than 70 years, respectively. Low FFMI is <15 and <17 kg/m² in females and males, respectively. About 12% of ESPEN members participated in a ballot; >75% agreed; i.e. indicated ≥7 on a 10-graded scale of acceptance, to this definition.

Conclusion: In individuals identified by screening as at risk of malnutrition, the diagnosis of malnutrition should be based on either a low BMI (<18.5 kg/m²), or on the combined finding of weight loss together with either reduced BMI (age-specific) or a low FFMI using sex-specific cut-offs.

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1. Introduction

Malnutrition due to starvation, disease or ageing can be defined as “a state resulting from lack of uptake or intake of nutrition leading to altered body composition (decreased fat free mass) and body cell mass leading to diminished physical and mental function

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and impaired clinical outcome from disease” [1]. Although this definition is well-accepted, the condition lacks clear and generally accepted diagnostic criteria.

During the famine catastrophes in Africa during the 1960s, WHO brought attention to the medical aspects of starvation [2]. The concepts of kwashiorkor and marasmus were introduced to define a particular protein deficient condition characterized by hypoalbuminemic peripheral edema and ascites, i.e. kwashiorkor, and a particular energy deficient state characterized by severe weight loss due to mainly fat store depletion, i.e. marasmus. This classification did not turn out as relevant for the recognition and diagnosis of malnutrition that was increasingly observed in hospitals in the Western countries during the later decades of the last century. Since depletion is usually a combined deficiency and loss of protein and energy, the general term of protein-energy malnutrition (PEM) became widely accepted [3]. Clinical characteristics used to define PEM have varied over time, but there was never a consensus on diagnostic criteria. Various combinations of clinical, anthropometrical, biochemical and immunological measures were used (e.g. Refs. [4,5]).

The last decades have seen the advent of several malnutrition screening tools that have reached increased acceptance due to their clinical feasibility. These screening tools combine about the same variables, i.e. weight loss, body mass index (BMI), signs of eating difficulties (e.g. appetite loss or reduced food intake) and a grading of on-going disease severity. ESPEN recognizes the following risk screening tools to be used in the hospital, elderly care and community settings; Nutritional Risk Screening 2002 (NRS-2002), Mini Nutritional Assessment-Short Form (MNA-SF) and Malnutrition Universal Screening Tool (MUST) [6]. The major use of these tools is to screen for malnutrition risk. The subsequent clinical actions should be assessment of underlying mechanisms and type of nutritional problems, in order to design personalized nutritional therapies. The diagnostic procedure usually ends there. The reasons for this are many-fold. One may be the imperative to focus on the implementation of the malnutrition risk screening procedures over the past years. Another apparent reason is the lack of consensus over diagnostic criteria. In the absence of such criteria, it is difficult to distinguish the effectiveness and efficacy of nutritional therapies when applied in different phases of the patients decline into malnutrition. The effects of nutritional therapy given at an early stage, before body protein and energy stores have been depleted, might differ as compared to when given at a late stage with overt depletion.

Previous important consensus initiatives have been attempted [7–9], and the outcomes have reflected the complexity of the issue and the difficulties to reaching consensus. It was considered that these results “... may fuel the discussion within the nutritional societies, which will most ideally lead to an international consensus on a definition and operationalism of malnutrition” [7].

There is moreover a confusion of terminology. Malnutrition, protein-energy malnutrition, undernutrition, depletion, wasting, cachexia are some of the terms used to denominate the condition that ensues deficiencies of macro- and micronutrients and catabolism of protein and energy stores due to disease and ageing. The malnutrition-related concepts cachexia [10,11], sarcopenia [11,12] and frailty [13] are today well-established. The current initiative doesn't challenge their definitions.

This statement is aimed at helping clinicians to effectively provide therapeutic nutritional interventions, and accordingly, to document clinically relevant malnutrition, and moreover to facilitate documentation in the Disease Related Group (DRG) and International Classification of Diseases (ICD) systems.

Malnutrition should be recognized as a serious clinical risk factor. In real clinical settings this is not the case, partly due to the

lack of simple and unequivocal diagnostic criteria. It is crucial to reach consensus on diagnostic criteria for malnutrition in order to unify the terminology (e.g. for ICD-10), to enhance the legitimacy of nutritional practices, to improve clinical care and to move the clinical and scientific nutrition field forward. For this purpose the European Society of Clinical Nutrition and Metabolism (ESPEN) appointed a consensus group with a clear mission to provide criteria for the diagnosis of malnutrition.

1.1. The consensus group objectives

The primary objective was to reach consensus for simple, clear and generally applicable diagnostic criteria of malnutrition in the sense of energy and protein store depletion. The intention was to provide criteria that are independent from etiologic mechanisms, and that can be used for all patients and in all clinical settings.

Secondary objectives were to try to bring clarity to the nutritional terminology, and to provide a general nutritional disorders concept tree.

2. Methods

2.1. Design of the delphi process and selection of the expert group

ESPEN decided in late 2012 to launch the initiative. In January 2013 representatives of more than 40 member countries of ESPEN outlined the initiative and acknowledged the process. An international expert group consisting of experienced clinical scientists was gathered to perform a modified Delphi process. The consensus group participants, i.e. the authors behind this report, were chosen to represent the clinical fields of medicine, surgery, intensive care, oncology and geriatrics.

It was agreed within the group to base the process on open e-mail communications, face-to-face meetings and on open as well as closed ballots within the group. The intention was to maintain the communication at each step until consensus for each milestone (see below) was reached among all participants before the next step was taken. Furthermore, the group agreed to seek the opinions of the ESPEN members before deciding on the statement. Finally, it was decided to perform validation studies of the final statement. This paper reports the process and outcome of the Delphi process, i.e. the consensus based malnutrition diagnostic criteria, while the validation studies are on-going and will be presented separately.

2.2. Defined milestones of the process

Overall there were five major milestones defined for the project. These were to

- decide the interrelationship between the screening and the diagnostic process.
- identify the individual criteria that cover the crucial components of the condition for all patients in all settings. For the sake of feasibility, the goal was to use as few criteria as possible.
- decide on whether and how the individual criteria should be combined to provide an expected high specificity of the diagnosis.
- come up with clinically relevant cut-off values based on relevant reference populations for the chosen individual criteria.

Finally, an independent milestone was to decide whether the term of undernutrition or malnutrition is to be preferred.

3. Results

3.1. How are screening and the diagnostic procedures interrelated?

There was a strong consensus from e-mail communications, a one-day face-to-face meeting, and an anonymous group ballot that the diagnostic procedure has to be based on the outcome of a screening evaluation. Nutritional screening is always mandatory in all clinical and care settings, since it is unanimously recognized that patients affected by acute and chronic diseases are at high risk of developing nutritional impairment. Diagnostic measures are only needed for those cases that score positive for nutritional risk by any of the validated screening tools. This consensus group does not recommend any specific of the validated tools, as long as the tool is validated for the setting where it is applied. Screening should be sensitive, whereas diagnosis is specific. Thus, fewer will be diagnosed as suffering from malnutrition than the number of subjects that are identified as being at risk. It was acknowledged that measurements that were performed during the screening process could potentially be used also for the diagnostic decision.

“Risk of malnutrition” was suggested to be as a diagnosis with its own ICD Code. The general acceptance of the prevailing malnutrition screening tools relies on the fact that fulfilling the criteria for risk of malnutrition imposes negative clinical outcomes, including death. Therefore it is crucial to commence nutritional therapy as early as possible. Such intervention generates costs. Therefore, the diagnosis of being “at risk of malnutrition” needs to be coded and reimbursed in the ICD and DRG systems.

3.2. Which individual criteria do best capture the state of malnutrition?

Nutritional variables are traditionally categorized as measures of anthropometry, including body composition, biochemical indicators and data related to eating capability. The latter include history as well as recording of actual food intake, or information on factors for potential limitations of food intake like anorexia, dysphagia or chewing problems.

A one-day face-to-face meeting was organized to scrutinize these potential diagnostic criteria. Functional measures of strength or power were soon dismissed as part of the diagnosis since they were consensually viewed as not nutrition specific enough. Thus, the following variables, or group of variables, were discussed as potential criteria.

3.2.1. Anthropometry

BMI and leg and arm anthropometry, e.g. calf circumference, arm muscle circumference and triceps skinfold, are clinically available objective variables with a fairly wide-spread use.

3.2.2. Body composition

Fat free mass (FFM) and fat mass (FM) can objectively be measured by technical devices like bioelectrical bio-impedance analyses (BIA), dual energy x-ray absorptiometry (DXA), computed tomography (CT), ultrasound or magnetic resonance imaging (MRI).

3.2.3. Weight loss

This reflects a dynamic process that requires a negative energy balance; i.e. a reduced food intake or increased energy expenditure.

3.2.4. Anorexia

Loss of appetite is a common complication to disease, medication and ageing. It is one of the most important mechanisms behind weight loss.

3.2.5. Reduced food intake

Self-reported or quantified reduction of the food intake is a feature of most of the screening tools.

3.2.6. Biochemical indicators

Markers of visceral protein status, like serum concentrations of albumin have a tradition of being used as markers of nutritional status. Inflammation, due to disease or ageing, is likely the most common cause underlying the development of malnutrition. Thus, inflammation is an important etiologic factor for malnutrition.

3.2.7. Subjective professional evaluation

After the screening procedure has identified subjects at nutritional risk, a subjective evaluation of body composition and physical function performed by experienced health professionals could indicate the diagnosis of malnutrition.

3.3. The result of the criteria ballot in the consensus group

As a result of the consensus group face-to-face meeting, a questionnaire was constructed and provided to all group members where they were asked to grade their degree of acceptance from 1 to 6 to include the following variables as one of the diagnostic criteria; i.e. weight loss, reduced BMI, reduced fat free mass index (FFMI), reduced fat mass index (FMI), reduced food intake, reduced appetite, a biochemical marker (visceral proteins or inflammatory markers), or a subjective evaluation of a professional. The response of the questionnaire was anonymous for all but the facilitator (TC). The scores of 1–2, 3–4 and 5–6 were denoted against, middle and pro, respectively. Figure 1 shows the result of the ballot. A fairly clear pattern emerged, as there was a preference in the group for the use of weight loss, reduced BMI and reduced FFMI.

The ensuing e-mail discussion confirmed that the term *weight loss* would encompass significant reductions in food intake, appetite loss, and for any imbalance between nutrient requirements and intake. Thus, evaluations of food intake and appetite will not add further information beyond weight loss. Nevertheless, data on intake and appetite are important for screening for malnutrition risk.

Next *BMI* was discussed. Low BMI is commonly accepted in the medical community, and received support from the majority of the consensus group to be one criterion. However, BMI can be misleading as the growing obesity epidemic renders a number of seriously ill and malnourished patients in the normal BMI range although they may have lost a considerable and clinically relevant

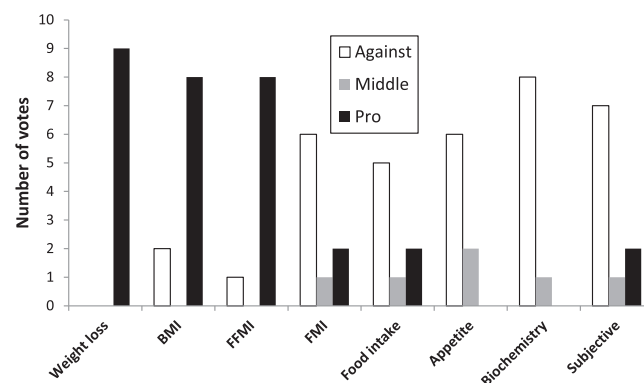


Fig. 1. Outcome of the questionnaire on the preference of the individual criteria. Group members were asked to grade from 1 to 6; 1 = total disagreement and 6 = total agreement, on the use of each criterion. Scores of 1–2 was aggregated to being against, scores of 5–6 as being for (pro) and 3–4 as in between (middle).

amount of body mass. Due to several question marks on the use of BMI for malnutrition diagnosis some of the consensus group members suggested to omit BMI as a potential criterion. Nevertheless in the final analysis it was unanimously decided to keep BMI for the final selection, due to the fact that BMI has a well-validated outcome predictive value.

For *body composition*, the pros and cons of fat mass and fat free mass to reflect nutrition status was discussed. One incentive for ESPEN to launch this malnutrition diagnosis initiative was to test the grounds for promoting body composition measures for diagnostic purposes. Information on relative amounts of fat mass and fat free mass provides far more valuable information than BMI alone, both from functional and metabolic points of view. FFM, i.e. mainly the muscle mass was considered to provide the most relevant information. Muscle confers ability to activity, acts as the amino acid pool and is important for energy expenditure and glucose metabolism [14].

According to *biochemical indicators*, the perception was that visceral proteins like serum albumin concentrations are good indicators of disease severity and outcome. Inflammation is today considered the major reason for reduced serum levels of visceral proteins. Thus, visceral proteins should not be used for either screening or diagnosis of malnutrition. The low grade of nutrition specificity was the major reason for this decision. The question of integrating a biochemical indicator of inflammatory activity, e.g. C-reactive protein, into the diagnostic format raised another discussion. Inflammation has a central etiologic role for catabolism and is an integral feature of cachexia. Thus, inflammation is rather to be regarded as an etiologic factor than a diagnostic feature of malnutrition. The same reasoning goes for indicators of potential anabolic activity, e.g. insulin-like growth factor-1.

The Consensus group decided that all criteria should be objective as far as possible. Diagnosis by *subjective evaluation* by an experienced health professional did not meet this criterion.

3.4. Is there an optimal combination of criteria?

Thus, three variables were chosen to most accurately reflect malnutrition, namely weight loss, reduced BMI and reduced FFMI. The next question was whether and how to combine the variables to best capture the diagnosis.

For this purpose the group performed a second anonymous ballot based on a questionnaire that comprised nine options. For each option, any of the three favored variables was suggested to be mandatory and combined with one or both of the other two variables. Eight out of ten answers were positive for the option where unintentional weight loss should be mandatory, and weight loss should be combined with either reduced BMI or with reduced FFMI. Consensus was reached to suggest both alternatives, i.e. either weight loss and reduced BMI, or weight loss and reduced FFMI, should give the diagnosis of malnutrition. In real clinical life access to body composition measurements is limited, which justifies keeping both alternatives.

3.5. Which are the clinically relevant cut-off values for the chosen individual criteria?

The next challenge was to find valid and clinically relevant cut-off values for weight loss, BMI and FFMI.

3.5.1. Weight loss

Weight loss trajectories differ with clinical condition. Nevertheless, involuntary weight loss is a strong predictor of negative outcomes irrespective of magnitude, speed and underlying cause. Naturally, a massive and fast weight loss due to an aggressive

cancer disease imposes a higher risk than a smaller and slower weight loss due to ageing.

Thus, consensus was reached to propose two optional cut-offs for unintentional weight loss; i.e. either >5% over the last 3 months to cover for acute illnesses, or >10% of habitual weight indefinite of time to be relevant for chronic conditions.

3.5.2. BMI

WHO advocates BMI <18.5 kg/m² as a general cut-off for underweight. This cut-off is justified at a public health population level [15], whereas its relevance for clinical and care settings may be questioned. As already mentioned the trend of increasing BMI in all populations world-wide make this acknowledged BMI cut-off value difficult to use for the purpose of defining malnutrition. Patients struck with highly catabolic diseases may in 3–6 months lose substantially more than 10% of their weight and still have BMI values well above “normal” ranges. Another issue to consider is that epidemiological evidence indicates that older populations display higher optimal BMI intervals (e.g. for survival) than younger people.

Partly due to the strong global acceptance of the WHO cut-off of 18.5 kg/m² it was decided unanimously to accept the WHO recommended cut-off of as a criterion that in its own right will be enough to diagnose malnutrition.

With this latter decision it was easy to come to consensus for a complementary suggestion for relevant BMI cut-off values; namely <20 kg/m² for subjects <70 years of age, and <22 kg/m² for subjects 70 years and older, remembering the fact that these BMI levels need to be linked to weight loss as defined above. The choices of 20 and 22 kg/m², respectively, were based on consensus in the group. Ethnic and regional variability in BMI may need to be considered.

3.5.3. FFMI

Cut-offs for FFMI need to be linked to the decided cut-offs for BMI on one hand, and to the fact that women have lower FFMI (and higher FMI) than men on the other hand. Based on Swiss reference material [16] it was decided to suggest FFMI <15 and <17 kg/m² in women and men, respectively. It has to be emphasized that reference values, like for BMI, should be relevant for the specific ethnic and cultural context that is at hand.

The result of this process is summarized in the Fact box.

Fact box: Two alternative ways to diagnose malnutrition. Before diagnosis of malnutrition is considered it is mandatory to fulfil criteria for being “at risk” of malnutrition by any validated risk screening tool.

Alternative 1:

- BMI <18.5 kg/m²

Alternative 2:

- Weight loss (unintentional) > 10% indefinite of time, or >5% over the last 3 months combined with either
- BMI <20 kg/m² if <70 years of age, or <22 kg/m² if ≥70 years of age or
- FFMI <15 and 17 kg/m² in women and men, respectively.

3.6. ESPEN membership ballot

For transparency, implementation and awareness purposes the final consensus group suggestion for the malnutrition diagnostic

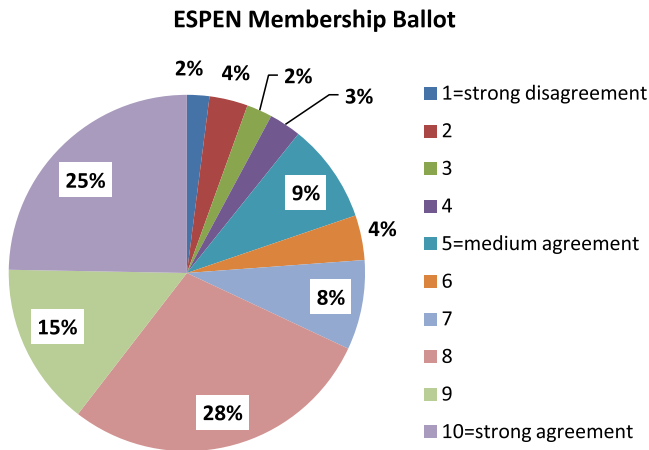


Fig. 2. ESPEN membership ballot. Vote count on the question “We want you to indicate on a scale from 1 to 10 whether you agree strongly = 10, or disagree strongly = 1, with this suggestion” (see Fact box).

criteria was presented to the membership of ESPEN to vote for. The ESPEN Newsletter provided the questionnaire by e-mail to all members (~around 3000 world-wide). Members were asked to grade their acceptance of the suggestion, as presented in the Fact box, on a scale from 1 (very low) to 10 (very high). Altogether 344 members gave their vote. Figure 2 shows the result of the poll; i.e. >75% of the voting members gave a score of 7 or more in agreement of the suggestion. A score of 4 or less indicating disagreement was given by 10% of the voters. According to the given comments from the members that gave low scores, the absence of functional measures was the major reason for disagreement.

3.7. Terminology of malnutrition or undernutrition and the conceptual tree of nutritional disorders

The general perception of the group was that malnutrition and undernutrition is about equally used in the scientific literature and in clinical practice, with a slight preponderance for malnutrition. A potential problem with the term malnutrition is that it literally covers all deviating nutritional states. In the first in-group ballot performed, the group members were asked to anonymously state their preference. The two terms received an equal number of votes, i.e. 5 vs 6. The pro and con arguments were not strongly in favor of any of the terms and it was decided to leave the question open for the ESPEN member ballot to give a stronger advice.

Thus, in the same ESPEN Newsletter that encouraged ESPEN members to vote for or against the suggested diagnostic criteria (see above), the members were also asked to give their opinion on whether they preferred the term of malnutrition or of undernutrition. The vote came out as indecisive and split as in the smaller

poll among the consensus group. Malnutrition had a slight preponderance with 53% of the votes as compared to 47% in favor of undernutrition. Due to this uncertain result the consensus group doesn't advocate any specific term, but has chosen to use malnutrition for this paper.

Finally, a conceptual tree of prevailing nutritional disorders was constructed (Fig. 3), acknowledging the complex interactions between the conditions. The structure of Fig. 3 was discussed as some in the consensus group preferred a less hierarchical arrangement of the conditions.

4. Discussion

This ESPEN Consensus Statement provides a novel, comprehensive, yet simple, format for the diagnosis of malnutrition. The statement acknowledges the well-accepted BMI cut-off of 18.5 kg/m² provided by WHO. In addition, it introduces an alternative and partly new format based on the combination of unintentional weight loss, and low BMI or low FFMI, where the latter drives the necessity to use modern techniques for body composition measurements. Regarding BMI, there was unanimous consensus that, in the presence of significant weight loss, BMI levels higher than 18.5 kg/m² may also reflect sufficiently altered nutritional state to warrant the diagnosis of malnutrition. The proposed cutoff values of 20 (<70 y) and 22 (≥70 y) kg/m² was the result from consensus within the group. Validation studies have been launched to possibly confirm these indications.

Recent years have seen the development of several malnutrition screening tools, for example NRS-2002, MNA-SF and MUST, which should be used for everybody that comes in contact with health and elderly care. The purpose is to identify the individuals that will need further nutritional assessment and that will need nutritional therapy, in order to prevent the further nutritional deterioration into malnutrition. To be defined as “at risk” for malnutrition according to any of the validated screening tools should render its own ICD Code. Many of the validated screening tools in clinical use today also provide grading into manifest malnutrition as well, which is somewhat beyond their primary purpose. Since NRS-2002, MNA-SF and MUST use different criteria and cut-offs, and were designed for different purposes and populations [17], the prevalence of malnutrition in a specific population will differ with the screening tool used. Moreover, as indicated the appropriate evaluation of nutritional therapy effects is affected by when the therapy is applied, i.e. in late or early phases of malnutrition, as well as by variations in the diagnostic criteria [18]. These examples illustrate how acknowledgment and development of clinical nutrition may suffer from the lack of clear diagnostic criteria for malnutrition.

As indicated the purpose of this initiative was to provide a general diagnosis that is relevant for all subjects in all clinical settings. Recent years have seen the advent of improved conceptualization and better understanding of different forms of nutritional disorders and malnutrition (Fig. 3). Nevertheless, the definition is meant to be valid for all individuals no matter if starvation, acute or chronic disease or ageing is the dominant underlying cause of the state of malnutrition. As with all general diagnoses (compare anemia) they need to be elaborated into sub-diagnoses which indicate their etiologies to facilitate the best treatment. Thus, this ESPEN statement also provides a conceptual tree where pure starvation, disease-related malnutrition (cachexia) [10,11], and the concepts of sarcopenia [11,12] and frailty [13] are related to, and at least partly over-arched by the general term of malnutrition.

The concepts of cachexia and sarcopenia pinpoint the importance of variations in body composition, i.e. fat and muscle mass, as predictors of clinical outcome. The two-compartment model for body composition, i.e. FMI and FFMI, offers a more precise

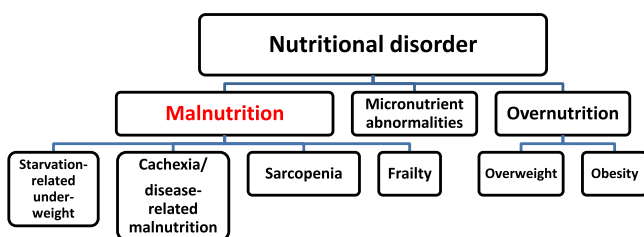


Fig. 3. A conceptual tree of nutritional disorders.

description of the investigated subject than for example BMI, and is thus providing a clearer justification for clinical decisions. Therefore, it was encouraging to see the strong consensus of the group to advocate the potential requirement of FFMI for the diagnosis of malnutrition. Devices for body composition measurements, e.g. bioelectrical impedance analyzers and DXA machines, are not readily available for daily routine care. Thus it was crucial to not to mandate FFMI for the diagnosis of malnutrition. This Consensus Statement will hopefully drive and promote the need to develop accessible techniques for body composition measurements in all health care settings, i.e. at hospital wards, in primary care, in nursing homes as well as in home elderly care.

Beyond the identification of diagnostic criteria this initiative also aimed to clarify whether the term malnutrition or undernutrition is to be preferred. As reported above the vote, in the consensus group as well as among the voting ESPEN membership, was more or less split in two halves. For the moment there is a small preponderance for the use of malnutrition in the nutrition community. The uncertain outcome of this issue doesn't justify any strong recommendation.

In conclusion, this ESPEN Consensus Statement has rendered a clear and simple format for the diagnosis of malnutrition. Parallel initiatives are on-going. The strong objective of the current ESPEN statement is to provide malnutrition diagnostic criteria that are independent of etiology, whereas other initiatives state that they aim to provide etiology-driven criteria [8,9]. The various global initiatives need to be linked and in the long run it is crucial to reach a global consensus on this important issue. On-going and future validation studies will provide data that may confirm the feasibility of, or be used to update, the malnutrition criteria of this ESPEN Consensus Statement.

Conflict of interest

None of the authors display any CoI in the production of this manuscript. Travel expenses for the one-day meeting were reimbursed by ESPEN. No other grants from any funding agency were offered.

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