

Minimum Data Set for Nutritional Intervention Studies in Elderly People

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Malnutrition, considered for the purpose of the present data set as undernutrition, is a major risk factor of mortality in elderly people. Such protein-energy malnutrition should be detected as soon as possible. Once established, this malnutrition state must be corrected by appropriate diet, supplementation, artificial nutrition, or therapeutic treatment. If carried out well, these interventions should reduce the risk of mortality and, for some diseases such as degenerative diseases, may postpone morbidity and dependence. The efficiency of nutritional interventions has already been evaluated by different means including the measurement of anthropometric and laboratory parameters. However, in the absence of a consensus on the use of these parameters, comparison between studies and even effectiveness of the proposed treatment are frequently unconvincing. The relevance of the most common markers used in epidemiologic studies on malnutrition and nutritional interventions in elderly persons was studied for establishing a minimum data set. The aim of this task force was to provide investigators and operators in the field of clinical nutrition with clear and expert validated clinical outcomes allowing them to design and set up conclusive trials.

MALNUTRITION, considered for the purpose of the present data set as undernutrition, is a major risk factor of mortality in elderly people (1–4). It may also worsen the progression of several age-related diseases. Data from the different surveys recently conducted in Europe reveal that over 25% of the noninstitutionalized population has a lower-than-recommended intake, corresponding to 1700 kcal/day for women and 2100 kcal/day for men. When Mini Nutritional Assessment (MNA) is used, low percentages of malnutrition (1%, range 0%–2% with MNA < 17) are found among the general population, but 29% (range 15%–44%) present nutritional risk criteria (23.5 > MNA > 17) (4–7). In hospitals or nursing homes, such nutritional risk may affect 20% to 60% of the residents; and 25% (range 10%–32%) are considered as undernourished (MNA < 17). Comparable conclusions were reached using the criteria of the Malnutrition Advisory Group in the United Kingdom (8).

Such protein-energy malnutrition should be detected as soon as possible to initiate interventions to prevent any further decrease in weight (2,9,10). Once established, this malnutrition state must be corrected by appropriate diet, supplementation, artificial nutrition, or therapeutic treatment. If carried out well, these interventions should reduce the risk of mortality and, for some diseases such as degenerative diseases, may postpone morbidity and dependence (11,12).

The efficiency of nutritional interventions has already been evaluated by different means including measurement of anthropometric and laboratory parameters. However, in the absence of any consensus on the use of these parameters, comparison between studies and even effectiveness of the proposed treatment are frequently unconvincing. It may be that an apparent absence of effect in some studies was

merely linked to an inappropriate choice of parameters—with confusing results.

To overcome this lack of standardization in protocols and outcomes in nutritional interventions in elderly people, a minimum data set should be proposed. This was the goal of the present Task Force of international experts from Europe, the United States, and Japan, joined by the International Association of Gerontology and International Academy of Nutrition and Aging. Analysis of the literature was performed to identify the most common markers used in epidemiologic studies on malnutrition and nutritional interventions in elderly persons. The relevance of these parameters for establishing a minimum data set was detailed during three consecutive meetings with experts over a period of 3 months to reach a consensus (the conclusions are reported in this article).

The final aim of this task force was to provide investigators and operators in the field of clinical nutrition with clear and expert validated clinical outcomes allowing them to design and set up conclusive trials.

METHODS AND RESULTS FROM BIBLIOGRAPHIC ANALYSIS

The literature was analyzed from three different sources. The first source was the *Cochrane Library* review “Protein and energy supplementation in elderly people at risk from malnutrition,” published in 2002 and including 31 studies with 2464 participants randomized therein (13). The second was a qualitative analysis of bibliographic references from 1966 to April 2003 found on MEDLINE (National Library of Medicine, Bethesda, Maryland). It started from 7241 abstracts extracted using the keywords “elderly people and nutrition,” “undernutrition,” “nutritional status,” “nutritional assessment in elderly people,” and “geriatric assess-

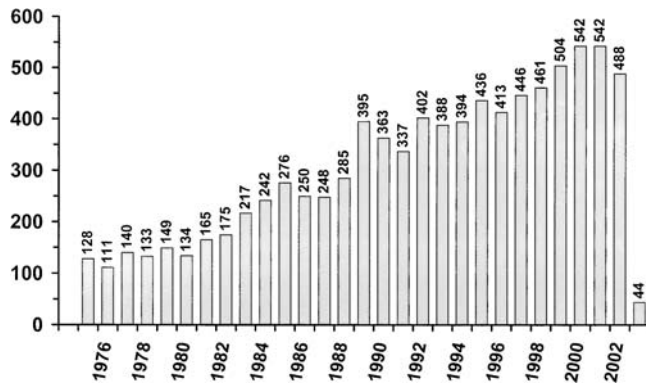


Figure 1. The number of articles published each year on malnutrition in elderly people, from 1975 to March 2003.

ment.” From these, 132 articles concerned with randomized interventional studies in healthy people aged older than 65 years, with control groups and defined nutritional status, were selected. In the third bibliographic analysis, references published between 1975 and March 2003 were extracted from MEDLINE using the following criteria “malnutrition or undernutrition or parenteral nutrition or enteral nutrition or nutritional status not obesity” limited to “65 years and over; published in English; only those articles with abstracts.” The result was a total of 8815 references. The titles, keywords, authors, affiliations, and abstracts were quantitatively analyzed by text-mining according to the methodology developed by the Successful Aging Database and colleagues (the whole report of this third analysis is available by request at info@successaging.com).

The rate of publications on nutrition in elderly people is illustrated in Figure 1.

Analysis of the key concepts emerging from the present database reveals those seeking potential nutritional markers and those related to various diseases, treatments, or physiological conditions associated with the nutritional parameters. The most representative concepts relative to nutritional markers are listed in Table 1, with their respective number of references in the database.

Co-occurrences between the different items in each reference (title, keywords, abstract) were then determined by text-mining. A representative map of such an analysis is shown in Figure 2 for the central concept “Nutritional status.” The 20 more frequent co-occurrences between nutritional status and other concepts have been determined through the 8815 references relative to malnutrition in elderly people, which have been sorted out from MEDLINE.

METHODOLOGICAL RECOMMENDATIONS

In addition to definition of a minimum data set, guidelines and optional parameters were proposed by the Task Force for interventional studies.

The *type of intervention* will be clearly stated. This is related to the kind of diet supplementation or medical treatment and the route of administration: normal food, changes in dietary habits, natural enrichment, nutritional

Table 1. Items Related to Putative Nutritional Markers (Number of Quoted References in the Database)

Items
<i>Biological markers</i>
Serum albumin (355)
Amino acid (183)
Nitrogen balance (179)
Retinol-binding protein (100)
C-Reactive protein (100)
Serum vitamin (97)
Alkaline phosphatase (92)
Rest energy expenditure (84)
Total lymphocyte count (77)
Growth factor (68)
Serum creatinine (58)
Fatty acid (54)
Serum transferrin (49)
Serum calcium (47)
Trace element (46)
Total cholesterol (41)
Creatinine clearance (40)
Methylmalonic acid (40)
Total iron-binding capacity (36)
Free fatty acid (36)
Branched chain amino acid (35)
Growth hormone (33)
Medium-chain triglycerides (33)
TNF alpha (33)
Essential amino acid (29)
HDL cholesterol (29)
Serum cholesterol (28)
Serum alkaline phosphatase (27)
Serum iron (25)
Blood urea nitrogen (24)
Total homocysteine (24)
Linoleic acid (23)
Long-chain triglyceride (23)
<i>Anthropometric markers</i>
Body weight (338)
Body mass index (326)
Weight loss (255)
Anthropometric measurement (128)
Body composition (105)
Arm muscle circumference (91)
Triceps skinfold thickness (82)
Lean body mass (62)
Fat-free mass (48)
Bone mineral density (60)
Weight gain (48)
Body fat (47)
Fat mass (38)
Muscle mass (32)
Muscle strength (25)
Handgrip strength (24)
<i>Composite index</i>
Mini Nutritional Assessment (44)
<i>Vitamins</i>
Folic acid (102) or serum folate (29)
Parathyroid hormone (52)
Beta carotene (40)
Alpha tocopherol (39)
Ascorbic acid (39)
Hydroxy vitamin (32)

Note: TNF = tumor necrosis factor; HDL = high-density lipoprotein.

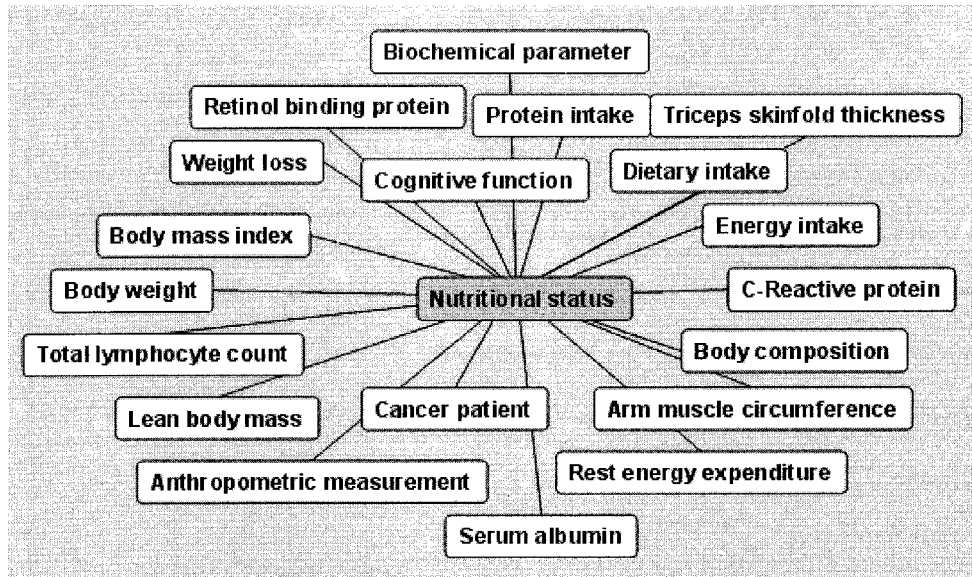


Figure 2. Example of co-occurrence map between nutritional status and the main associated concepts.

supplement, liquid or solid food, enteral or parenteral nutrition, active feeding, therapeutic protocol, and so forth.

As far as possible, evaluation of nutritional intervention will be performed in randomized controlled trials. The inclusion and exclusion criteria of the initial population will be well defined, taking into account characterization of the coassociated diseases. When possible, a placebo group will be set up, especially for trials dealing with medical interventions of malnutrition. Ethical considerations, availability of patient consent, impact of diet monitoring on nutritional status of placebo arm patients will all be considered in definition of such a control group.

Stratification of the population by age groups will be recommended to evaluate possible differences in the effectiveness of nutritional interventions. The definition of these age groups will be up to the investigators according to the protocol design, age of the patients, sample size, and adequate statistical power.

Duration of treatment is crucial. In protein-energy malnutrition, a 3-month treatment appears to be the minimum for any effect on body weight to be measurable, and a 6-month to 12-month intervention with periodic and accurate weight monitoring should be preferred when clear outcomes have to be drawn.

The Task Force members are aware that feasibility of determinations of *body weight*, and changes in body weight, are often questionable. This is the case in several pathological conditions such as stroke, hip fracture, dementia, or for patients under intensive care. However, when feasible, baseline body weight at the beginning of the study will be instrumental to the harmonization of the initial population and randomization, although it will not be an indication of nutritional status by itself. In addition, weight should be measured at different times during the study to determine the trend and the impact of the intervention.

Measurement of *serum albumin* is common in studies on malnutrition but is not mandatory. Most of the Task Force members agree that serum albumin reflects diseases rather than nutritional status. In addition, the values may be related to the level of hydration and dehydration. However, serum albumin remains useful for a description of the initial population. Should laboratory data be introduced, serum albumin monitoring must be standardized and performed under well-controlled conditions of hydration and nutrition always given at the same time of the day. *C-reactive protein* (CRP) determination will be performed as well. Plasma CRP is a marker of inflammation that is frequently associated with malnutrition and hypercatabolism. Its determination may support interpretation of albumin data. All biological assays from a given multicentric trial will be centralized in the same laboratory.

It may seem obvious that complete *dietary intake* will be determined in interventional studies, with a special interest in total calorie and protein intakes. The Task Force members acknowledged that the queries and recording of dietary habits may positively influence the diet of enrolled patients. The records of dietary habit will therefore be driven in a way to avoid artefactual impact on nutritional status, when possible. At least three methods are suitable in interventional studies. The single 24-hour dietary recall, used if memory allows, will be repeated throughout the intervention. The 3-day record, preferably used for prospective studies, offers a mean value that buffers day-to-day variations, but can also introduce specific bias such as changes in habits of the placebo group. The food frequency questions are particularly suited to lower day-to-day intervariability in long-term studies. Whatever the method, caregivers as dieticians in charge of the patients will be involved in these determinations. In multicenter studies, the selected methodology for dietary intake determinations will

Table 2. Relevant Current Medical Conditions (Comorbidity)

Comorbidities
Cancer and malignancy
Chronic renal failure
Postoperative and intensive care
Liver disease
Anemia
Infectious disease
Bowel disease
Diabetes mellitus
Respiratory disease
Vascular and heart disease
Cognitive impairment
Hip fracture
Arthritis
Depression
Dementia
Cerebrovascular diseases and stroke
Other

be carefully taught to people responsible for records in order to standardize the procedures. As far as possible, it will be better to stop any personal over-the-counter administration.

Compliance should be assessed with great care as the intention for caregivers to treat. It includes several aspects: a) the number of patients who actually comply with the treatment throughout the study will be checked; b) how the supplementation was fully or partially accepted will be recorded, with scale or cut-off exclusion criteria expressed as a percentage of the proposed intervention; c) how compliance relative to baseline food intake ensured that nutritional intervention did not have side effects on previous dietary habits. The recommendation would establish whether an interventional study is inefficient due to lack of compliance or to a real lack of effectiveness of the tested treatment.

Social and economic outcomes, including use of health, social services, and cost effectiveness, could be used to evaluate the success of an intervention. As far as possible, these outcomes would be evaluated with criteria that will not depend too much on the national healthcare system. The number and the type of contacts (nurse, physician, dietician) would be a possible parameter. The type of organization contacted, the use of community services, and whether the patient was admitted to an institution could also be recorded. In terms of hospitalization, the length of stay, emergency room consultation, and day hospital visits should be evaluated. More specific scales may be used such as the Resource Utilization in Dementia (14).

MINIMUM DATA SET

A majority of the Task Force members stated that parameters for a minimum data set have to fulfill a number of criteria taking into account the feasibility of measurements under most conditions, low time-consuming or resource-consuming, and a high probability of being affected by nutritional intervention. In addition, the population of patients at the beginning of the intervention

must be carefully described to allow further comparisons between studies and allow meta-analysis.

- *Birth date* and *gender* will be recorded.
- *Education* will be characterized by the number of years at school or university.
- *Social status* (live alone or with family) as well as income may also be relevant to describe the initial population. These parameters are likely to interfere with nutritional habits and compliance with interventions.

Anthropometry

The body measurement protocol must be standardized using accepted World Health Organization criteria measurements. Equipment accuracy and sensitivity should be recorded. Baseline body weight should be recorded before starting the intervention to allow stratification of further evolution including stable body weight, weight loss, or weight gain. Weight will be measured at timely intervals during the study to determine the trends.

Body Mass Index (BMI)

The body mass index (weight/height squared) suffers from the same difficulties as the measurements previously mentioned for body weight assessment (15,16). Height measurements may be difficult in elderly people and can be calculated from the height from the heel to the knee. Knee-heel length (knee-height) has been suggested as a surrogate measurement by using the equation of Chumlea and Guo (16) to calculate standing height. However, these equations were derived from healthy North American people. Attention will be paid to the variability of BMI standards according to ethnic and social subset of populations.

Mini Nutritional Assessment (MNA) and Its Short Form (MNA-SF)

The MNA was developed to assess the nutritional status of the at-risk elderly population (15,17–20). This scale includes 18 items covering anthropometric measurements, risk situation, dietary survey, and self-perception of health. The maximum score is 30, and the threshold for normality is 23.5. A score below 17 is indicative of malnutrition, and intermediate values between 17 and 23.5 are indicative of nutritional risk. It is a relatively simple and quick test that is not time consuming. Over the past few years, several studies with different levels of care and clinical conditions have included the MNA and have validated its reliability by comparison with other nutritional markers. The results of the shortened version with 6 of the 18 initial items were highly correlated with those of the full MNA (21). A score of 12 or more on the MNA-SF reflects a satisfactory nutritional status. A score of 11 or less suggests a risk of malnutrition and calls for full assessment. If not all of the anthropometric parameters are available, we recommend at least the MNA-SF.

Functional Status

Different available scales will be used to define the population under study and to test possible changes in functional status due to nutritional interventions:

Table 3. Examples of Critical Classes of Medication Related to Common Diseases in Elderly People

Disease	Medication
Depression	Antidepressive drugs
Behavioral troubles	Antipsychotic drugs
Arthritis	NSAIDs/AS/TNF blockers
Hip fracture	Calcium/vitamin D/alendronate-type drugs
Diabetes	Insulin/oral hypoglycemic medications
Postoperative and intensive care	Antibiotics
Anemia	Supplemental iron
Respiratory disease	Steroids
Vascular heart disease	Statins, other hypolipidemic drugs, diuretics, ACE inhibitors, beta-blockers
Dementia	AChE, memantine

Note: NSAIDs = nonsteroidal antiinflammatory drugs; AS = anabolic steroids; TNF = tumor necrosis factor; ACE = angiotensin-converting enzyme; AChE = acetylcholinesterase.

- Instrumental and basic Activities of Daily Living (IADL and ADL, respectively) measure the ability to perform daily life activities such as feeding, washing, dressing, walking, and determining mobility and the occurrence of incontinence (22,23).
- Geriatric Depression Scale (GDS), a 15-item test for screening depressive symptoms and their severity in elderly persons (24–26).
- Folstein's Mini-Mental State Examination (MMSE) is used to evaluate cognitive function and to identify dementia and Alzheimer's disease (27). Impaired cognitive function, which is quite frequent in elderly people, is a clear risk for malnutrition.
- Gait and balance will be additional parameters. Within a study, investigators will choose to use consistently either "the timed chair stand" or a "timed 4-meter walk" (28,29). They should use standardized measurements from a written protocol, whichever measurement they choose, and should plan to do periodic quality controls during the study.

Relevant Current Medical Conditions (Comorbidity)

Every acute and chronic disease that constitutes a malnutrition risk in elderly people or that would impair the effectiveness of any nutritional intervention will be recorded. Comorbidity can be set up from the most common diseases according to the results of database analysis, presented in Table 2.

Care and Medication

Different levels of care may be defined. It is recommended to stratify patients on the basis of their health status and their residence at the initiation of the study.

Any medical cotreatment will be recorded, with the number and kinds of major prescribed drugs. This also applies to over-the-counter or enriched foods, which could interfere with nutritional assessment, such as vitamin or other self-administered oral supplements. The medications can be classified in different categories including those

critical for disease severity, for impact on nutrition, and for aging processes (Table 3).

Summary

The present Task Force proposes a limited number of items to be used in every study on nutritional intervention in elderly people. These are synthesized in the Appendix. Optional parameters will be chosen, depending on the investigators, the design of the study, the question under investigation, or the nature of the associated diseases. Care will also be taken to follow methodological recommendations in order to facilitate comparison and meta-analysis between studies.

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APPENDIX

- Birth date
- Gender
- Education (number of years)
- Place of residence (at home, in hospital, nursing homes)
- Anthropometry
 - Weight
 - Body mass index (BMI)
- Mini Nutritional Assessment (MNA) or its short form (MNA-SF)
- Functional status
 - Basic Activities of Daily Living (ADL)
 - Instrumental Activities of Daily Living (IADL)
 - Geriatric Depression Scale (GDS)
 - Folstein's Mini-Mental State Examination (MMSE)
 - Timed chair-stand or timed 4-meter walk
- Comorbidity
- Current medications
- Optional items
 - Biological markers (serum albumin, C-reactive protein)
 - Daily dietary intake in the case of interventional study