The Economic, Medical/Scientific and Regulatory Aspects of Clinical Nutrition Practice: What Impacts What?

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The Economic, Medical/ Scientific and Regulatory Aspects of Clinical Nutrition Practice: What Impacts What?

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Foreword

Malnutrition is an under-recognized problem in hospitalized, home and community patients. It has been identified as an issue for more than 30 years, but has struggled to be recognized as an important issue by healthcare clinicians, administrators and government officials. Recent data show that at least 30% of hospitalized patients are malnourished, with a large majority of the cases unrecognized and untreated. Although awareness of the situation is increasing, there remains a great deal of work that must be done to educate healthcare professionals on the value of nutrition intervention as an integral part of medical therapy. Along with this is the need to educate administrators and regulators of the cost benefits of nutrition care. Recent studies have shown that disease-related malnutrition increases healthcare costs by 30–70%. In the UK it has been demonstrated that the costs for hospital malnutrition are greater than that for obesity. Nutritional interventions, representing only a small cost, may result in substantial absolute savings.

It is with these facts that the Nestlé Nutrition Institute organized this 12th Clinical and Performance Workshop with the title 'The Economic, Medical/Scientific and Regulatory Aspects of Clinical Nutrition Practice: What Impacts What?' in Peebles, Scotland.

Learnings from this workshop include the need to more clearly define malnutrition. There is a strong need to effectively educate physicians on the importance of nutrition in medical therapy – something currently lacking in most medical education. Additional work is needed to define outcomes impacted by nutrition intervention. The results of this work need to be clearly and effectively communicated to both healthcare administrators and government and regulatory officials. The identification, prevention and treatment of malnutrition need to be seen by all as an integral part of medical management, thus should not be excluded from reimbursement programs.

We want to thank the chairmen, Prof. Marinos Elia from the University of South Hampton, UK and Prof. Bruce Bistrian from Harvard Medical School, USA both experts in the field of clinical nutrition and the economics of malnutrition for putting together the excellent program of this workshop. We also thank our expert speakers for their valuable contribution. Finally, our thanks go to the team from Nestlé UK for their wonderful organization.

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The Magnitude of the Problem of Malnutrition in Europe

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Abstract

A review of the publications on hospital malnutrition in Europe over the last 5 years shows that the incidence and prevalence of malnutrition are still very high: 21 and 37%, respectively. The process of structured nutrition support is still far from being generally implemented, as based on the few studies available. As a result, malnutrition diagnosed on admission to hospital is still associated with adverse clinical outcome (increased length of stay and higher rates of complications).

Introduction

The epidemiology of malnutrition in European hospitals has not been well described as there have been no studies with a random sample of hospitals, departments and patients to allow a true epidemiological picture.

Most studies have been performed 'spontaneously' in individual departments and may not reflect the typical picture. These departments are probably a priori interested in clinical nutrition due to a high number of malnourished patients, or because they belong to a specialty already dealing with nutritional problems such as gastroenterology. The existing data will be reviewed here due to the lack of better data.

In addition, the epidemiology of nutrition care will be covered as this will reflect the potential for improvement.

It is also important to distinguish between studies of incidence versus studies of prevalence. Here incidence will mean malnutrition diagnosed on admission to hospital, reflecting the rate of new cases entering the hospital, and prevalence will mean malnutrition encountered among patients in the

departments at a given time. Prevalence will usually be higher than incidence as malnourished patients usually stay in hospital longer.

Prevalence and Incidence of Malnutrition in Hospitals

Here an overview of studies of incidence and prevalence in European hospitals over the last 5 years will be presented. Only studies applying a formally validated nutritional screening or assessment tool in >100 patients has been included. Studies using only P-albumin or other nonspecific plasma 'pseudo-nutrition markers' are excluded.

The abbreviations used are: SGA = Subjective Nutritional Assessment [1]; NRS-2002 = Nutrition Risk Screening-2002 [2, 3]; MUST = Malnutrition Universal Screening Tool [4], and SNAQ = Short Nutritional Assessment Questionnaire [5].

A proper epidemiological study of prevalence was attempted in Denmark [6], albeit restricted to specialties with a suspected high rate of malnourished patients: internal medicine, gastric and orthopedic surgery. Among 33 hospitals with >200 beds, 5 hospitals were randomly selected for each of the specialties mentioned. The end result was 15 randomly selected departments in 12 hospitals. After prior consent, the departments were visited on a day unknown to the staff, and all records (n = 590) were audited for information of nutritional status and care. The prevalence of nutritional risk according to NRS-2002 was 40% in all patients and in individual specialties: 42% (internal medicine); 57% (gastric surgery), and 37% (orthopedic surgery).

In another quasi-epidemiological study in Denmark, the incidence of nutritional risk was described in a random sample of all newly (<24 h) admitted patients (n = 750). The study took place in 3 hospitals selected because of known interest in disease-related malnutrition at the managerial level, and for being either a local, a regional or a university hospital, respectively. The incidence of nutritional risk on admission was 19% according to NRS-2002 [7].

In a study in 12 Western and former Eastern European countries, and also including a few Middle East countries (Lebanon, Egypt and Libya), 26 departments were selected based on their interest in but limited experience with nutrition care [8]. In this study 5,051 patients were selected randomly on admission among all newly (<24 h) admitted patients. A total of 33% were at-risk according to NRS-2002. The incidence in individual specialties can be seen in table 1.

In a university hospital in Geneva [9], 995 mixed medical and surgical patients were screened. The patients were selected as every 10th patient admitted over a 3-month period and were screened on admission by 3 different tools: SGA, MUST and NRS-2002. By these methods, the incidence of malnutrition was 29, 37 and 28%, respectively. Discussion of the validity and other aspects of the methods applied is beyond the scope of the present paper.

Table 1. Incidence of nutritional risk according to NRS-2002 in various specialties in hospitals in Western and former Eastern Europe

Specialty	Western Europe		Eastern Europe	
	%	n	%	n
Internal medicine	28	187	46	302
Gastroenterology	27	54	36	122
Geriatrics	52	108	–	–
Surgery	19	244	18	110

Data from Sorensen et al. [8].

In a study in the UK [4], a prevalence of malnutrition of 39% according to MUST was found in a total of 346 patients. In individual specialties, it was 30% (general medicine), 46% (elderly), 60% (gastrointestinal surgery) and 19% (other surgery). The purpose of the study was to compare different screening tools and therefore the epidemiological relevance of the study was not given a high priority.

In a study in Germany and Austria [10], 1,886 patients were screened consecutively on admission by SGA in 13 hospitals (7 university, 6 teaching/community hospitals). Data collection took place over 3 years and it was not specified how the hospitals or time periods of data collection were selected. A total of 27% of the patients were malnourished (SGA B or C), and in individual specialties it was 33% (gastroenterology), 22% (cardiology), 38% (oncology), 56% (geriatrics), 27% (other medical specialties), 15% (urology), and 14% (surgery).

In a study in Poland [11], every 10th patient admitted to 12 hospitals (4 university, 4 provincial and 4 community hospitals) over a 2-year period was screened for nutritional problems. Among the 3,310 patients studied, 10% had a BMI of <20 on admission.

In Austria [12], 640 patients were examined for nutritional status. Ten percent of the patients had a low BMI. We only had access to the abstract, so further details cannot be given.

A study in Glasgow screened all patients for malnutrition on admission for 1 week in each of 6 specialties, according to MUST [13]. The incidence of malnutrition was 42% among 242 patients. In individual specialties it was 73% (oncology), 58% (geriatrics), 52% (general medicine), 28% (orthopedics), 26% (surgery) and 34% (plastics).

In the Spanish region of Galicia, a random sample of 376 patients in all hospitals in the region was examined on a specific day for the presence of malnutrition [14]. According to SGA, the prevalence of malnutrition was 47%. Divided into age groups (<65 and ≥65 years), the prevalence in individual diagnostic groups was: 9 and 18% (cardiology); 7 and 20% (respiratory); 18

and 8% (cancer); 8 and 7% (digestive); 7 and 4% (sepsis); 18 and 16% (surgery), and 26 and 17% (others).

In 1 hospital in London [15], all 817 patients in the hospital had nutritional screening performed within 2 weeks, showing a prevalence of malnutrition of 19% according to a local assessment tool employing actual/usual body weight, recent dietary intake changes and recent weight loss.

In a university hospital in Amsterdam [16], 297 patients with mixed diagnoses were screened on admission by the SNAQ questionnaire and 32% of these were found to be malnourished.

In addition, two small studies, each with about 130 patients, have been performed among medical patients in Madrid, Spain [17], and among orthopedic geriatric patients in Oporto, Portugal [18]. The studies showed an incidence of malnutrition of 45 and 28%, respectively. Both studies were carried out with SGA and NRS-2002 (results here for NRS-2002 only).

These data are summarized in table 2 together with results from abstracts from the congresses of the European Society for Clinical Nutrition and Metabolism (ESPEN) in 2005 [19] and 2006 [20]. The abstracts from 2005 and 2006 are marked by 05 and 06, respectively.

In total, results from nearly 60,000 patients over the last 5 years are available, showing an average of 30% of the patients being malnourished. The weighted average is 22%, heavily influenced by the large Turkish study. Excluding this study, the weighted average is 24%. The weighted average for all incidence studies is 21% and for all prevalence studies it is 37%. The latter figure is higher that the incidence rate, as would be expected, but the difference must be taken with great caution since neither the same patient populations nor the same methods were used in the 2 data sets.

These rates of malnutrition seem not to have changed considerably compared to earlier periods [21]. In fact, a tendency to the opposite would be expected since admittance to hospital has been restricted to more severe cases in recent years in most European hospitals, but the data available do not allow analysis of such time-dependent changes.

Epidemiology of Nutritional Care

In recent years there has been an increasing awareness about disease-related malnutrition in Europe. This is illustrated by the Resolution from the Council of Europe on Food and Nutritional Care in Hospitals [22]. Before the resolution was adopted by the European foreign ministers, the Council performed a survey among the European health authorities in 2001 [23]. The responses showed that in most European countries, nutritional screening on admission to hospital is not performed, food supply simply consists of 3 meals served per day (i.e. very few snacks between the main meals), nutritional support is scarce, inconsistent and usually restricted to special patient groups,

and about half of the countries could not provide any information on the existence of nutrition support teams. Among those who could, about 10–15% of the hospitals were believed to have nutrition support teams. The survey also showed that doctors in, e.g., Denmark, Germany, Italy, the Netherlands, and Switzerland, only have a few lessons in clinical nutrition during their university training, whereas doctors in Finland, France, Norway, and Sweden have >15 lessons. For nurses, it was a few lessons in Italy, France, and Portugal, and >15 lessons in Denmark, Finland, Netherlands, Norway, Slovenia, and Sweden.

The council of Europe also identified 5 barriers reported by all European health authorities: lack of sufficient education with regard to nutrition among all staff groups; lack of cooperation between different staff groups; lack of clearly defined responsibilities in planning and managing nutritional care; lack of involvement from the hospital managers, and lack of influence and knowledge of the patients [23].

There is therefore a major task to educate doctors and nurses. The first step is to define the process of nutrition care, serving as the curriculum to be taught and also serving as a basis for quality management in hospitals. Such a process was described as a guideline by ESPEN [2]. Figure 1 shows the essentials: all patients should be screened for nutritional risk; those not at-risk should be re-screened at weekly intervals; those at-risk should have a nutrition plan worked out, consisting of an estimate of requirements, a prescription of feeding mode (food, supplements, tube feeding or parenteral feeding) and a plan for monitoring, and then, the planned monitoring should be performed. At each of these steps, there may be complex problems which do not allow a standard process to be carried out. In these cases, the process is aided by experts undertaking a more detailed assessment.

With this scheme in mind, we can now turn to some information available about nutrition care in European hospitals.

Of the patients identified as being at-risk in the Danish study mentioned above [6], the records contained information on BMI, recent weight loss or recent dietary intake (i.e. screening information) in 64, 7 and 10%, respectively. Only 8% of the at-risk patients had a nutrition plan in their records.

Of the 750 patients examined in the other Danish study [7], only 315 (42%) had any form of nutrition screening performed. Only 64 of 137 at-risk patients (47%) had any form of nutrition plan made, and of 87 at-risk patients remaining in the hospital ≥1 week only 26 (30%) reached a minimum of 75% of their estimated requirements. In this study, the staff taking care of the patients was also asked about the causes of inadequate care when this was identified for an individual patient. The main causes were: lack of managerial instructions to take care of nutrition problems; lack of education in estimating nutritional requirements and knowledge of energy and protein contents of hospital foods, and the patients' reduced appetite. Such questionnaires done in direct relation to failures of well-defined steps in the nutrition care process are prob-

Table 2. Incidence (I) or prevalence (P) of malnutrition in European hospitals, published 2002–2007

Category	n	Method	Type	Malnourished %	Location	Authors	Source
Cancer	2,060	BMI <18.5 or weight loss >5%/month or >10%/6 months	P	39	24 cities, France	Hebuterne et al.	06/P0051
Cancer	232	NRS-2002	P	49	Ljubljana, Slovenia	Kozjek et al.	06/P0284
Gastroenterology	944	NRS-2002	I	16	Izmir, Turkey	Oruc et al.	06/P0084
Geriatics, elderly, >65 years	233	NRS-2002	I	67	3 cities, Scandinavia	Holst et al.	06/O022
Geriatrics	520	MUST	?	43	Berlin, Germany	Hengstermann et al.	05/P039
Geriatrics	110	NRS-2002	I	40	Nurnberg, Germany	Bauer et al.	05/P046
Head and neck cancer	407	Wt loss >5%/1 mths or >10%/6 mths	I	19	Groningen, Netherlands	Jager-Wittenaar et al.	05/P002
ICU	291	NRS-2002	I	37	Prague, Czech Republic	Charvat et al.	06/P105
Internal medicine/ surgery	588	SNAQ	I	29	Amsterdam, Netherlands	Kruizenga et al.	05/P009
Internal medicine/ surgery	400	NRS-2002	I	35	3 cities, Spain	Velasco et al.	06/P0279
Internal medicine	135	NRS-2002	I	48	Madrid, Spain	Valero et al.	[17]
Mixed	9,139	NRS-2002	I	19	19 cities, Turkey	Korfali et al.	06/O011
Mixed	3,310	BMI <20	I	10	5 cities, Poland	Dzieniszewski et al.	[11]
Mixed	2,566	NRS-2002	I	11	Ankara, Turkey	Selcuk et al.	06/P0119
Mixed	1,886	SGA	I	27	10 cities, Germany and Austria	Pirlich et al.	[10]
Mixed	995	SGA	I	29	Geneva, Switzerland	Kyle et al.	[9]
Mixed	817	Local tool	P	19	London, UK	O'Flynn	[15]

Mixed	750	NRS-2002	I	19	3 cities, Denmark	Kondrup et al.	[7]
Mixed	590	NRS-2002	P	40	12 cities, Denmark	Rasmussen et al.	[6]
Mixed	376	SGA	P	47	Galicia, Spain	Martinez Olmos et al.	[13]
Mixed	346	MUST	P	39	Southampton, UK	Stratton et al.	[4]
Mixed	297	SNAQ	I	33	Amsterdam, Netherlands	Kruizenga et al.	[16]
Mixed	202	MUST	?	24	Glasgow, UK	Gerasimides	[14]
Mixed	189	SGA	I	33	A Caruña, Spain	Vidal et al.	06/P0104
Mixed	5,051	NRS 2002	I	30	26 hospitals, 12 European countries	Sorensen et al.	[8]
Mixed?	640	Low BMI	?	10	Austria	Galvan et al.	[12]
Mixed?	258	NRS-2002	I	34	Porto, Portugal	Tavares et al.	05/P051
Mixed?	255	NRS-2002	I	31	Malaga, Spain	Garcia-Almeida	06/P289
Mixed?	101	SGA	I	44	Madrid, Spain	González-Madrono et al.	05/P047
Stroke	176	MUST	I	10	3 cities, Norway	Ha et al.	06/P0273
Surgery, abdominal	753	NRS-2002	I	19	Ankara, Turkey	Ozogul et al.	06/P0096
Surgery, abdominal	171	MUST	I	57	Leeds, UK	Sarveswaran et al.	06/P0080
Surgery, elective	720	NRS-2002	I	19	Ezurum, Turkey	Erdem et al.	06/P0085
Surgery, elective	696	NRS-2002	I	6	Izmir, Turkey	Gur et al.	06/P0081
Surgery, general	793	NRS-2002	I	10	Ankara, Turkey	Gundogdu et al.	06/P0283
Surgery, general	723	SGA	I	17	Manisa, Turkey	Gûler et al.	06/P0093
Surgery, orthopedic	256	NRS-2002	I	28	Izmir, Turkey	Ozkalnakli et al.	06/P0257
Surgery, orthopedic	135	NRS-2002	I	28	Oporto, Portugal	Martins et al.	[18]

05 and 06 indicate abstracts from that year's ESPEN congress.

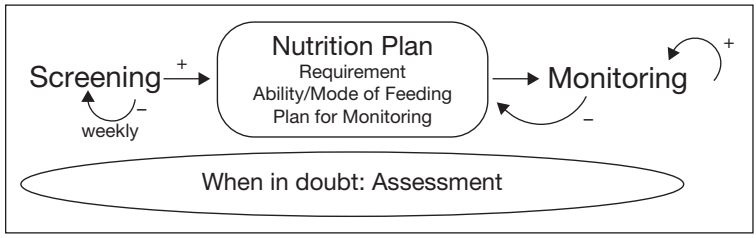

Fig. 1. The structure of the nutrition care process. All patients should be screened for nutritional risk. Those not at-risk should be re-screened at weekly intervals. Those at-risk should have a nutrition plan worked out, consisting of an estimate of requirements, a prescription of feeding mode (food, supplements, tube feeding or parenteral feeding) and a plan for monitoring. Then, the planned monitoring should be performed. At each of these steps, there may be complex problems which do not allow a standard process to be carried out. In these cases, the process is aided by experts undertaking a more detailed assessment. Based on Kondrup et al. [2].

ably more likely to accurately reflect the causes of inadequate intake than stand-alone questionnaires given to staff groups without relation to specific patients.

In a study in Geneva, Switzerland, of 1,707 patients, it was found that the energy and/or protein intakes of 70% of the patients were below reasonable recommended needs. In only 26% of the underfed patients did the disease and/or treatment play a predominant role in the insufficient intake. This study also indicates a considerable lack of nutrition care.

Lastly, data from audits in the Copenhagen hospitals are presented in figure 2. These audits are performed as part of the accreditation by the Joint Commission International. The hospitals underwent accreditation in January 2002 and January 2005. Documentation of nutrition care is obligatory to obtain the accreditation. It can be seen that the rates of screening and weekly re-screening are reasonably high at 60–70%, while the rates of making a nutrition plan and meeting a minimum of estimated requirements are lower, and even decreasing, after the last accreditation. These results illustrate the difficulty in reaching the final goal in the process, i.e. adequate intake, and also underline the importance of continued attention at the managerial level.

Malnutrition and Clinical Outcome

With a continued high incidence and prevalence of malnutrition on admission to hospitals and a nutrition care process which is far from being generally implemented, it would be expected that clinical outcome continues to be related to nutritional status on admission.

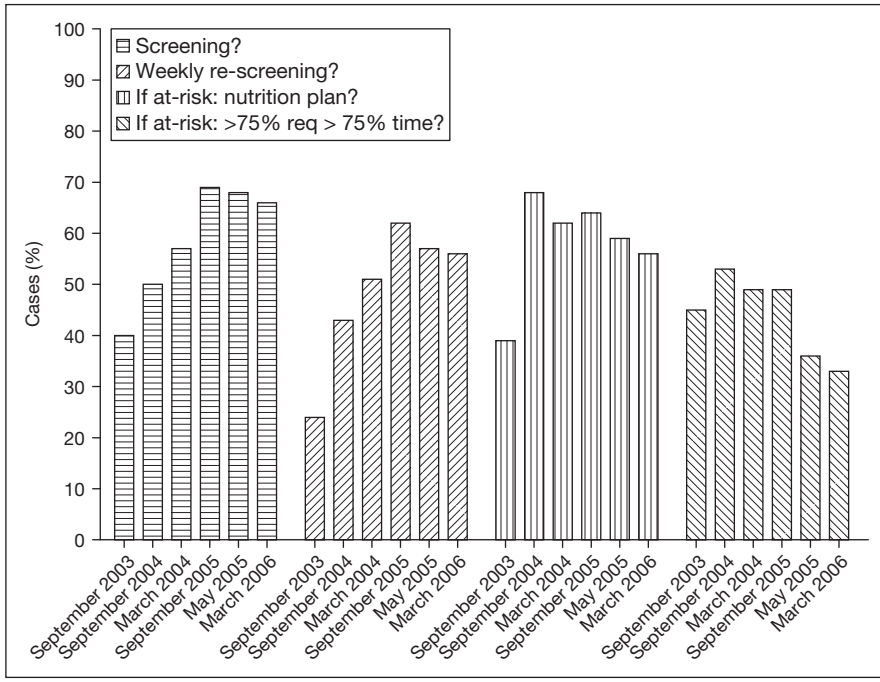

Fig. 2. Audit of nutrition care in Copenhagen hospitals. Semi-annual audits were performed in approximately 1,500 randomly selected records among patients discharged from the 4,500 beds in the 6 Copenhagen hospitals. >75% of req >75% time = intake was >75% of estimated requirement in >75% of the days when the patient was at nutritional risk.

In the study in Geneva [9], it was found that the odds ratio for a prolonged length of stay (>11 days) was 2.5–3.0 in patients identified as malnourished. In the German/Austrian study [10], the average length of stay was 4.6 days longer in malnourished patients compared to well-nourished patients. In the EURO-OOPS study [8], the median length of stay was 3 days longer in patients at nutritional-risk and the rate of complications was 3 times higher. With the large number of patients studied, it was possible to demonstrate that these associations were also highly significant when adjusted for a large number of obvious confounding variables (age, sex, surgery, cancer, diagnoses, comorbidity, specialties and geographical region).

References

1 Detsky AS, McLaughlin JR, Baker JP, et al: What is subjective global assessment of nutritional status? JPEN J Parenter Enteral Nutr 1987;11:8–13.

2 Kondrup J, Allison SP, Elia M, et al: ESPEN Guidelines for Nutrition Screening 2002. Clin Nutr 2003;22:415–421.
3 Kondrup J, Rasmussen HH, Hamberg O, et al: Nutritional risk screening (NRS 2002): a new method based on an analysis of controlled clinical trials. Clin Nutr 2003;22:321–336.
4 Stratton RJ, Hackston A, Longmore D, et al: Malnutrition in hospital outpatients and inpatients: prevalence, concurrent validity and ease of use of the 'malnutrition universal screening tool' ('MUST') for adults. Br J Nutr 2004;92:799–808.
5 Kruizenga HM, Seidell JC, de Vet HC, et al: Development and validation of a hospital screening tool for malnutrition: the short nutritional assessment questionnaire (SNAQ). Clin Nutr 2005;24:75–82.
6 Rasmussen HH, Kondrup J, Staun M, et al: Prevalence of patients at nutritional risk in Danish hospitals. Clin Nutr 2004;23:1009–1015.
7 Kondrup J, Johansen N, Plum LM, et al: Incidence of nutritional risk and causes of inadequate nutritional care in hospitals. Clin Nutr 2002;21:461–468.
8 Sorensen JM, Kondrup J, et al: EuroOOPS: an international, multicenter study to implement nutrition screening and evaluate clinical outcome. Clin Nutr 2008;27:340–349.
9 Kyle UG, Kossovsky MP, Karsegard VL, et al: Comparison of tools for nutritional assessment and screening at hospital admission: a population study. Clin Nutr 2006;25:409–417.
10 Pirlich M, Schutz T, Norman K, et al: The German hospital malnutrition study. Clin Nutr 2006;25:563–572.
11 Dzieniszewski J, Jarosz M, Szczygiel B, et al: Nutritional status of patients hospitalised in Poland. Eur J Clin Nutr 2005;59:552–560.
12 Galvan O, Joannidis M, Widschwendter A, et al: Comparison of different scoring methods for assessing the nutritional status of hospitalised patients. Wien Klin Wochenschr 2004;116:596–602.
13 Martinez Olmos MA, Martinez Vazquez MJ, Martinez-Puga Lopez E, et al: Nutritional status study of inpatients in hospitals of Galicia. Eur J Clin Nutr 2005;59:938–946.
14 Gerasimidis K, Drongitis P, Murray L, et al: A local nutritional screening tool compared to malnutrition universal screening tool. Eur J Clin Nutr 2007;61:916–921.
15 O'Flynn J, Peake H, Hickson M, et al: The prevalence of malnutrition in hospitals can be reduced: results from three consecutive cross-sectional studies. Clin Nutr 2005;24:1078–1088.
16 Kruizenga HM, Van Tulder MW, Seidell JC, et al: Effectiveness and cost-effectiveness of early screening and treatment of malnourished patients. Am J Clin Nutr 2005;82:1082–1089.
17 Valero MA, Diez L, El Kadaoui N, et al: Are the tools recommended by ASPEN and ESPEN comparable for assessing the nutritional status? Nutr Hosp 2005;20:259–267.
18 Martins CP, Correia JR, do Amaral TF: Undernutrition risk screening and length of stay of hospitalized elderly. J Nutr Elder 2005;25:5–21.
19 Abstracts from 27th ESPEN Congress. Clin Nutr 2005;24:535–710.
20 Abstracts from 28th ESPEN Congress. e-SPEN, the European e-journal of Clin Nutr Metab 2006;1:12–200.
21 Stratton RJ, Green CJ, Elia M: Prevalence of disease-related malnutrition; in Disease-Related Malnutrition: An Evidence-Based Approach to Treatment. Wallingford: CABI, 2003, pp 35–92.
22 Ministers Council of Europe Resolution ResAP(2003)3 on Food and Nutritional Care in Hospitals. Strassbourg, Council of Europe; 2003.
23 Beck AM, Balknas UN, Camilo ME, et al: Practices in relation to nutritional care and support–report from the Council of Europe. Clin Nutr 2002;21:351–354.

Discussion

Dr. Elia: On the issue of process and outcome, it is interesting that you have reported an improvement in process but not necessarily in outcome and that raises a number of questions. Is it, for example, that the process is only partially implemented

but the whole process should be implemented? Is the premise on which the causal pathway has been established in the first place correct or is it something else?

Dr. Kondrup: In this study in the Copenhagen hospitals on 480 patients, we also tried to compare how the departments were performing the individual steps of the process. It does seem that the more they adhered to the structured process, the higher the chances of successfully feeding the patients. It is a good argument that the process is at least a large part of the solution to the problem. During the last survey in Copenhagen, we asked why there was inadequate intake. Again, we found that those without artificial feeding had a much lower chance of being adequately fed. We also left out the question of poor appetite because we realized that it is similar to saying that people do not get fluid in the hospital because they are not thirsty. When we, as professionals, say that the reason the patient is not eating is because he doesn't have an appetite, it really means that we are incompetent in dealing with this problem. So, we took away the appetite question. The most frequent reasons that we found were nausea and vomiting, and the patient was too tired to eat and was not motivated. I think education is a major issue. Once the education question has been solved, other issues become more important and we are now working on nausea, patients being too weak to eat and motivation. We will see if it changes things.

Mrs. Howard: One of the points that struck me was that you picked up on the conflicting agendas in hospital. Our experience has shown that nurses can be educated at the local level, but taken that in the wider context of everything else, doctors have different priorities as do the general managers and senior nurses, who may be responsible for resource allocation and do not see nutrition as a priority. This means that action isn't followed through and isn't valued. This is where one of the major educational drives has to happen. One of the problems we have had has been demonstrating outcome, and the lack of large, conclusive studies which obviously can't be carried out. Have you encountered a similar problem with other disciplines impacting on what you are doing in Copenhagen?

Dr. Kondrup: Yes, of course, there is a lot of competition, but we also had the congratulations of the hospital manager for being successful in putting this topic in the media and the political agenda. In other words, he had completely surrendered to our political lobbying. Now, that is not the final word or victory but it does show that if you can ally with the politicians and the quality management system, then the managers will have to follow. Of course, some resources are needed to get the nurses interested in education. If you start with some interested and positive key nurses, they will spread the message in their organizations. I do not go to the nurse manager asking for some of her nurses to work on this. That would never work. I work with some nurses on the floor who are interested in nutrition and they put pressure on the nurse management system.

Mrs. Reich: Which process will you follow? Say that a new department has started in a large hospital and the doctors or nurses have no knowledge of nutrition, what are the steps to start in order to improve that in practice?

Dr. Kondrup: That is a difficult question to answer but I can share my experience with you. When we formed the nutrition unit, we kept track of all our patients, our success in feeding the patients with food or artificial nutrition, and how the bodyweight changed. We only did this with patients who had been in our care for more than a week, so we had some data. When we had collected information on the first 500 patients, we published an article in the Danish Medical Journal [1]. In about 90% of the patients that were referred we were successful in meeting their dietary requirements and preventing them from losing further weight. When this had been published, we also made a small press release saying that this problem could be solved. I think

this is a very good way to gain a clinical reputation, and showing your colleagues that you can do the job. This is a good way to start.

Dr. Van Emelen: You have done a lot of work in the hospital ward; is the situation the same in the homecare environment or worse?

Dr. Kondrup: Unfortunately, I have worked very little with homecare, but I think Dr. Elia has some experience so perhaps he can answer that question.

Dr. Elia: There are different types of care homes, ranging from those that do not require nursing support and those that are nursing homes requiring care support. In general, the more support the individuals require, the more disease is present, and the higher the prevalence of malnutrition. It can be as high and, in some cases, even higher than in some types of hospital wards.

Dr. Silver: A couple of things struck me while you were speaking: one is the availability of food, at least three meals per day, and also the palatability of food is a key factor in whether people consume the food that is available. I know from the United States that hospital food is often very unpalatable and I wonder if you might consider that factor?

Dr. Kondrup: One of the reasons we decided on these questionnaires in this way was to get an impression of the relative roles of a number of different factors. Until now, we have had hospital food palatability, consistency, and how it is served incorporated into all our questionnaires, but they still only add up to less than 10% of the total reasons given. At present, I think that the quality of hospital food is not a rate-limiting step. Of course, when everything else is solved with education and nausea, etc., then the food itself will be the rate-limiting step. At present other ingredients of this complex are more important. The food should be edible but I do not think that it is a rate-limiting step.

Dr. Silver: The other thing that struck me is the role of dieticians in the hospitals and healthcare facilities. If a healthcare professional is waiting for a referral or waiting to take action, there is a significant time before a nutrition intervention actually occurs. One of the things you talked about was the need for an educational process, to have active screening assessments. Mrs. Howard brought up reintervention, reassessment and follow-up. One of the problems with healthcare systems universally is that the dietician plays a more subservient role, waiting for a referral or information rather than actively becoming involved as an independent practitioner.

Dr. Kondrup: We have chosen the strategy to make the screening, the planning and the monitoring as simple as possible so the departments can do it on their own. Of course, they have to be educated in the principles of this but they should have a standard care plan and be able to deal with most of their at-risk patients themselves. Only when they need assessment, when they doubt something, should they call a dietician or another expert. It is a very important key element for its success that we train the nurses and doctors of the department and give them ownership of the process. If you want people to work for you, you have to give them ownership of what they are doing and find other ways of getting into the process. In my hospital, the chairman of our nutrition committee is a nurse and all the members are nurses from individual centers. I am just there as a consultant and have no formal decisive power. It works very well.

Dr. Bistrian: I have a slightly provocative question. Among the huge number of people who are at-risk and are not being treated adequately, would it be important to identify those for whom nutritional support would make a difference? The infection rates and complication rates are higher in the at-risk but much of that could be the result of their disease and not the nutritional state. Wouldn't it be very useful to have information to identify those people who would particularly benefit from nutritional support because they would be the ones for whom the failure to do so would be most problematic and most worthy of comdemnation.

Dr. Kondrup: That is a very good question with no simple answer. It leads into a discussion of which screening or diagnosis system to use. For the NRS 2002, we developed it based on all available intervention studies. When does it work and when does it not work? We also tried to independently validate it in a new prospective study where half of the patients identified with this tool were the control patients and the other ones were treated. Those who had the team effort in the subgroup of patients who had complications, their length of stay was shorter. So, I think that we need a tool like this based on when does it work and when it doesn't work, and validate it in a separate prospective study. I think that there is a high chance of these patients benefiting from nutrition support. That is the whole idea of that screening tool.

Dr. Jensen: Throughout the United States, we have mandated screening within 24 h of hospital admission by a joint commission. It is actually not clear what that has translated into, other than unbelievable consumption of resources to achieve this screening throughout the United States. Initially, all the dieticians would literally spend half their time running around screening every single hospital admission for risk for complications of malnutrition. Of course, that was not a very effective use of skilled dietician consultant time. Since then, most of the big teaching hospitals now use nurse's aides or technicians to do this process and collect great volumes of information, some of which may or may not be of some use. It is not entirely clear who is being identified as at-risk, there is no standardization of tools between institutions, who is actually receiving interventions, and whether it is translating into a meaningful difference in outcome. Ultimately, there should be an opportunity to identify a specific subgroups of patients, that could be readily identified by screening, who might be amenable to nutrition support intervention that translates into improved outcomes. Many of the people that we are identifying as at-risk are people with very advanced chronic disease, people with significant underlying inflammatory processes, some of whom may or may not benefit from intervention. It is a great challenge, and mandatory screening in the United States has probably been done for a decade. It is not entirely clear what this has translated into, other than a tremendous use of resources to achieve that.

Dr. Kondrup: You should use a screening tool that, as part of its validity, has predictive validity. Not only can it predict complications but also that clinical outcome will change. As far as we know, our screening tool, NRS 2002, fulfils that criterion. We would also much rather have dieticians working with complicated cases and that is why we try to train the nurses not only in screening but also in the nutrition therapy part of it because, as you see in the quality management system, we keep track of whether patients are getting food or not. So, it is not only the screening but the whole process. When the nurses screen and need assistance from dieticians, we go there and talk to management.

Mrs. Anthony: It is very interesting that you talk about validated tools. I have been working with the American Dietetic Association a little on validating screening tools and one of the problems that we have in the US is that most hospitals are not using a validated tool. They are changing their tool based on resources or whatever. Do you think that any of us are measuring the same thing?

Dr. Kondrup: I agree that, if you look at it from the outside, it is a messy area. There was a study in Switzerland which compared the NRS 2002 with the SDA [2], and they did not result that far from each other. Of course, there was not 100% concordance but it was not that far off. The SDA is a little complicated as a screening tool for admitting staff because it takes some training. I think we need something lighter than the SDA if we want the nurses to do this. I think the NRS 2002 compares pretty well with the SDA.

Dr. Labadarios: Must we go on with malnutrition in hospitals? It has been around for so long as a concept and has not really brought us very far. Isn't it time to redefine

not necessarily the name but what exactly we are talking about? My concern is also on the point that Dr. Elia raised on the process and outcome. The process improved but the outcome didn't. That, of course, is a concern. Regarding the length of stay, you did a correlational analysis on nutritional status and disease severity. Was that a bivariate analysis or did you analyze individually per parameter? Is the severity of the disease the cause of the association, because it then muddles things up a little bit?

Dr. Kondrup: It was a multivariate analysis, so the components of the NRS 2002, nutritional status, severity of disease, which are meant to reflect increased requirements, were entered into the equation with all the other variables shown. Such an analysis shows us the independent influence of each of these variables on the length of stay, and the nice thing is that nutritional status survived in spite of all these other variables. There was a similar analysis done years ago with the SGA and they included a lot of other severity of disease variables seen as prognostic variables, then the SGA disappeared out of the prediction of the length of stay. We were happy that nutritional status and the requirements for the patients survived in the equation.

Mrs. Gailing: This is more a comment than a question. Beyond the benefits for the patient this screening tool will be very useful in the discussion regarding the reimbursement system because it will help to have uniform criteria to support reimbursement in different countries. It is quite messy now because we don't have a simple answer to get these variables right. Definitively, we have to work on a validated screening tool in the future.

References

1 Kondrup J, Beck AM, Hansen BS, et al: Nutrition therapy in 542 hospitalized patients (in Danish). Ugeskr Laeger 1996;158:893–897.
2 Kyle UG, Kossovsky MP, Karsegard VL, Pichard C: Comparison of tools for nutritional assessment and screening at hospital admission: a population study. Clin Nutr 2006;25:409–417.

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Malnutrition in North America: Where Have We Been? Where Are We Going?

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Abstract

Malnutrition was first highlighted as a prevalent concern in hospital care more than 30 years ago. In response the nutrition support field grew precipitously but changes in the healthcare environment have culminated in a period of accountability and consolidation in nutrition support practice over the past decade. Evolving regulatory environment and reimbursement policies have had a profound impact upon nutrition support and these trends are likely to continue. Both undernutrition and overnutrition (obesity) remain prevalent concerns in North America. In particular the growing prevalence of overweight/obesity will have far-reaching implications for nutrition support practitioners and will require the development, testing, and validation of new standards of assessment, intervention, and monitoring. Adoption of common language and definitions by practitioners will facilitate standardized interventions, outcome measures, and high quality research. The future remains bright with tailored nutrition interventions poised to become a part of the individual medical treatment plan for specific patient conditions and genotypes. Future research priorities should include studies of nutritional modulation of inflammatory conditions with specific nutrients and functional foods and the testing of individualized nutritional interventions tailored to gene polymorphisms.

Introduction

In 1974 Butterworth [1] raised awareness of the ‘skeleton in the closet’, the problem of iatrogenic malnutrition among hospitalized patients in the United States. That same year, Bistrian et al. [2] first described the high prevalence of low albumin among hospitalized patients. These alarming reports regarding the high prevalence of malnutrition combined with the recognition that malnutrition is associated with adverse patient outcomes and the

growing availability of enteral and parenteral feeding interventions laid the foundation for the rapid emergence of nutrition support in North America. Multidisciplinary nutrition support teams, professional nutrition societies, training programs, and professional certifications blossomed in relatively short order. Within just two decades the surge in nutrition support enthusiasm reached a peak; all to be tempered by evolving changes in the healthcare environment that have culminated in a period of accountability and consolidation in nutrition support over the past 10 years. Suddenly practitioners were asked to show that what they do in nutrition support actually makes a difference in patient outcomes. It was no longer enough to say, 'It is nutrition, it must be good for you'. This challenge to the field has helped to drive a much needed priority for well-conceived outcome research and a movement toward the adoption of evidence-based practices. In addition, changes in reimbursement policies have impacted the healthcare environment dramatically, such that if you are a nutrition support practitioner who is not a source of revenue, then you are perceived as an expense. Many nutrition support practitioners found themselves expendable. One consequence is that the number of fully multidisciplinary nutrition support programs has declined, and in particular the numbers of physicians and nurses actively participating in nutrition support programs has fallen precipitously. Many variants of nutrition support teams now exist and dietitians and pharmacists continue to be represented. Efforts at nutrition licensure and certification have generally not been as rewarding as had been hoped for nutrition support professionals in North America. These credentials have not been necessary for employment and they have not translated into enhanced recognition or compensation.

Prevalence

Nutritional concerns span the spectrum of community, hospital, and chronic care settings in North America. The prevalence of malnutrition depends upon the criteria that are used. There are relatively few undernourished people in community settings, generally <10%. These are usually individuals with serious underlying disease, mental illness, substance abuse, eating disorders, or homeless or homebound status. Particularly vulnerable community populations include those of low socioeconomic status, certain racial/ethnic groups, and the elderly. The growing population of older persons will have a tremendous impact upon resource consumption across the spectrum of healthcare and will necessitate the broad availability of nutrition practitioners with expertise in the assessment and care of these individuals. Despite the availability of food programs for those in need, food security issues remain relatively common for vulnerable populations [3–5].

In hospital and chronic care settings the prevalence of undernutrition is much higher, generally on the order of 30–50% [2, 6–8]. These are often indi-

viduals with acute illness, injury or surgery as well as those with significant underlying disease or disability. With an aging population the acuity and disease burden of those who are hospitalized continues to climb.

The tremendous growth in the prevalence of overweight/obesity observed in North America is also having a profound impact upon public health, disease burden, and healthcare. Based upon NHANES 2003–2004 [9] some two thirds of American adults are classified as overweight/obese and one third as obese (32.2%). Among children and adolescents 17.1% are classified as overweight/obese. The growing prevalence of overweight/obesity has far-reaching implications for nutrition support practitioners and will require the development, testing, and validation of new standards of assessment, intervention, and monitoring. It is important to note that one can be obese and undernourished at the same time. Micronutrient deficiencies have been associated with poor quality diets in obese older persons [10, 11]. Sarcopenic obesity may be associated with disease, injury, or functional compromise [12, 13]. Multiple nutrient deficiencies may be observed in persons who have undergone bariatric surgeries [14, 15].

Definition

Traditionally malnutrition has been used to mean undernutrition, but this may be appropriately expanded to include other deviations from sound nutritional status, including micronutrient deficiencies and overnutrition (obesity). The lack of shared definitions is problematic, for example cachexia means different things to different practitioners. This confusion makes standardized interventions, outcome measures, and high quality research much more difficult.

Roubenoff et al. [16] proposed a practical approach to categorizing undernutrition syndromes that takes inflammatory response into consideration. Five syndromes are described: cachexia, wasting/marasmus, protein-energy undernutrition, sarcopenia, and failure to thrive. Since inflammation and compromised dietary intake or assimilation are often present at the same time, there frequently is overlap among undernutrition syndromes and a given underlying condition may precipitate more than one type of syndrome. Key features for each syndrome are summarized in table 1. By adopting such an approach a common language for nutrition support practitioners can be promoted.

Regulatory Environment/Reimbursement

Regulatory environment and reimbursement policies have had a profound impact upon healthcare in North America and nutrition support has not escaped these evolving trends. Managed healthcare capitation and

Table 1. Key characteristics of undernutrition syndromes

Undernutrition syndrome	Characteristics
Wasting	Loss of body cell mass without underlying inflammatory condition. Visceral proteins preserved. Extracellular fluid not increased
Sarcopenia	Aging-related muscle loss without other precipitating causes
Cachexia	Loss of body cell mass with underlying inflammatory condition. Decline in visceral proteins. Increased extracellular fluid
Protein-energy undernutrition	Clinical and laboratory evidence for reduced dietary intake of protein and energy. Reduced visceral proteins
Failure to thrive	Weight loss and decline in physical and/or cognitive functioning with signs of hopelessness and helplessness

Adapted with permission from Jensen GL: Nutritional Syndromes. http://pier.acponline.org/physicians/diseases. Date accessed February 24, 2007. In PIER (online database). Philadelphia, American College of Physicians, 2007.

reimbursement based upon diagnosis-related groups, have driven far-reaching cost-containment efforts. Lengths of hospital stay have decreased such that outpatient and home-based nutrition services have assumed greater importance. Many persons do not have insurance coverage for such services. Not only has pressure to increase revenue and decrease expense resulted in fewer physicians and nurses with active involvement in nutrition support, but enteral and parenteral nutrition formularies are also increasingly restricted. Practitioners often cannot access the desired specialty products for the indicated patient conditions. It is often particularly difficult to secure insurance coverage in the outpatient setting for oral nutritional supplements or tube feeding equipment/supplies.

Medicare regulations serve as the template for many other commercial insurers in the United States. These regulations were critically reviewed by the Food and Nutrition Board Committee on Nutrition Services for Medicare Beneficiaries in 2000 [17]. It was recommended that nutrition therapy be a reimbursable benefit upon referral by a physician for those conditions for which nutrition therapy is found to be of benefit. Legislation has subsequently endorsed reimbursement for nutrition therapy for management of diabetes and for pre-dialysis renal failure. Other recommendations have not been adopted. The regulation that excludes coverage for enteral and parenteral nutrition unless they are anticipated to be required for at least 90 days was questioned. This unfortunate requirement persists such that patients may be discharged without the indicated nutrition support interventions or may remain in the hospital longer than necessary to receive the indicated nutri-

tion support interventions. The Joint Commission requirement for nutrition risk screening within 24 h of hospital admission was found to not be evidence-based and to possibly produce inaccurate and misleading results. A call was made for further testing of screening methodologies as well as the optimal timing of nutrition screening. Appreciable resources currently continue to be devoted to systematic nutrition risk screening of all hospital admissions that has not been validated.

Research Priorities

Ultimately it will be necessary to demonstrate that nutrition screening can identify malnourished individuals at-risk of adverse outcomes that are amenable to favorable nutrition interventions. Some of the most extensively tested nutrition screening/assessment tools have been developed for older persons. An example is the Mini-Nutritional Assessment (MNA), an 18-item tool that includes BMI, mid-arm and calf circumferences, weight loss, living environment, medication use, dietary habits, clinical global assessment, and self-perception of health and nutrition status [18–20]. Also available as a screening tool is the 6-item MNA Short-Form that includes food intake, weight loss, mobility, acute disease or psychological stress, dementia or depression, and BMI [19]. It is important to recognize that screening/assessment tools cannot be adapted for populations or settings for which they were not developed without appropriate validation testing. For example, there is a pressing need to develop, test, and validate screening/assessment tools for obese persons.

Underweight and weight loss are clearly valid clinical indicators of undernutrition [21, 22], but fundamentally we lack sound laboratory indicators of nutritional status. Research is needed to validate new reliable indicators. One approach to overcoming these limitations has been to combine multiple variables using multivariable regression modeling. An example that includes both nutritional and inflammatory indices is the Prognostic Inflammatory and Nutritional Index (PINI) = (α1-acid glycoprotein) × CRP/(albumin) × (prealbumin) [23].

Some of the hopes for nutrition support in promoting improved patient outcomes have gone unfulfilled in early studies, but often the outcomes of interest like length of stay, complications, and mortality, are also impacted by multiple other non-nutritional variables. Limitations have included poor study design, inadequate sample size, heterogeneous subjects, variable nutritional status, and inappropriate outcome measures. There must be priority for the support of strongly designed multicenter studies that are adequately powered with appropriate entry/exclusion criteria, standardized nutrition interventions, and well-defined outcome measures.

A particularly noteworthy theme for further investigation is the nutritional modulation of inflammatory conditions with specific nutrients and functional

foods [24]. For example, there has been considerable interest in the application of n-3 fats to modulate inflammatory response in clinical settings like arthritis and inflammatory bowel disease [25, 26]. Use of enteral feedings enriched with eicosapentaenoic acid (20:5n-3), γ-linolenic acid (18:3n-6), and antioxidants has been associated with improved gas exchange, respiratory dynamics, and requirements for mechanical ventilation among patients with adult respiratory distress syndrome [27]. As understanding of the fundamental role of inflammation in medical conditions continues to grow, it is likely that there will be opportunity for a variety of therapeutic nutritional interventions that will become an integral part of the individually tailored medical treatment plan. Extending this vision of individualized treatment, one of the highest priorities for research must be the application of gene polymorphisms to tailored nutritional interventions. For example, it appears likely that there are single nucleotide polymorphisms that predispose an individual to a more robust inflammatory response and greater risk for developing adult respiratory distress syndrome in critical illness [28, 29]. Such individuals might be targeted for aggressive early intervention with anti-inflammatory nutrients. Another example is the identification of single nucleotide polymorphisms of the methylenetetrahydrofolate reductase gene. The C677T allele is associated with the highest levels of homocysteine and lowest levels of folate [30]. Such individuals could be targeted for more aggressive folic acid replacement therapy, because elevated homocysteine is associated with increased risk for cardiovascular disease, stroke, dementia, and osteoporosis.

Conclusion

Undernutrition remains a significant concern in North America, especially in hospital and chronic care settings. Overweight/obesity continues to grow in prevalence and will require the development, testing, and validation of new standards of assessment, intervention, and monitoring for nutrition support practitioners. Adoption of common language and definitions by practitioners will facilitate standardized interventions, outcome measures, and high quality research. Evolving trends in the healthcare regulatory environment and reimbursement have culminated in a period of accountability and consolidation in nutrition support over the past 10 years. The future is bright with tailored nutrition interventions poised to become a part of the individual medical treatment plan for specific patient conditions and genotypes.

Future Research Priorities Include:

- Further development and testing of screening/assessment tools
- The identification and validation of new laboratory indicators of nutritional status

- The conduct of well-conceived nutrition intervention studies tied to relevant clinical outcome measures
- Studies of nutritional modulation of inflammatory conditions with specific nutrients and functional foods
- Testing of individualized nutritional interventions tailored to gene polymorphisms

References

1 Butterworth CE: The skeleton in the hospital closet. Nutr Today 1974;9:4.
2 Bistrian BR, Blackburn GL, Hallowell, et al: Protein status of general surgical patients. JAMA 1974;230:858–860.
3 Stuff JE, Casey PH, Szeto KL, et al: Household food insecurity is associated with adult health status. J Nutr 2004;134:2330–2335.
4 Meyers A, Cutts D, Frank DA, et al: Subsidized housing and children's nutritional status: data from a multisite surveillance study. Arch Pediatr Adolesc Med 2005;159:551–556.
5 Quandt SA, Shoaf JI, Tapia J, et al: Experiences of Latino immigrant families in North Carolina help explain elevated levels of food insecurity and hunger. J Nutr 2006;136:2638–2644.
6 Bistrian BR, Blackburn GL, Vitale J, et al: Prevalence of malnutrition in general medical patients. JAMA 1979;235:1567–1570.
7 Abbasi AA, Rudman D: Observations on the prevalence of protein-calorie undernutrition in VA nursing homes. J Am Geriatr Soc 1993;41:117–121.
8 Sullivan DH, Sun S, Walls RC: Protein-energy undernutrition among elderly hospitalized patients: a prospective study. JAMA 1999;281:2013–2019.
9 Ogden CL, Carroll MD, Curtin LR, et al: Prevalence of overweight and obesity in the United States, 1999–2004. JAMA 2006;295:1549–1555.
10 Ledikwe JH, Wright HS, Mitchell DC, et al: Nutrition risk assessment and obesity in rural older adults: a gender difference. Am J Clin Nutr 2003;77:551–558.
11 Ledikwe, JH, Smiciklas-Wright H, Mitchell DC, et al: Dietary patterns of rural older adults are associated with weight and nutritional status. J Am Geriatr Soc 2004;52:589–595.
12 Baumgartner RN, Wayne SJ, Waters DL, et al: Sarcopenic obesity predicts instrumental activities of daily living disability in the elderly. Obes Res 2004;12:1995–2004.
13 Jensen GL: Obesity and functional decline: epidemiology and geriatric consequences. Clin Geriatr Med 2005;21:677–687.
14 Clements RH, Katasani VG, Palepu R, et al: Incidence of vitamin deficiency after laparoscopic Roux-en-Y gastric bypass in a university hospital setting. Am Surg 2006;72:1196–1202.
15 Xanthakos SA, Inge TH: Nutritional consequences of bariatric surgery. Curr Opin Clin Nutr Metab Care 2006;9:489–496.
16 Roubenoff R, Heymsfield SB, Kehayias JJ, et al: Standardization of nomenclature of body composition in weight loss. Am J Clin Nutr 1997;66:192–196.
17 Committee on Nutrition Services for Medicare Beneficiaries, Food and Nutrition Board, Institute of Medicine: The Role of Nutrition in Maintaining Health in the Nation's Elderly. Washington, National Academy Press. 2000.
18 Vellas B, Guigoz Y, Garry PJ, et al: The Mini Nutritional Assessment (MNA) and its use in grading the nutritional state of elderly patients. Nutrition 1999;15:116–122.
19 Rubenstein LZ, Harker JO, Salva A, et al: Screening for undernutrition in geriatric practice: developing the short-form mini-nutritional assessment (MNA-SF). J Gerontol A Biol Sci Med Sci 2001;56:M366–M372.
20 Vellas B, Guigoz Y, Baumgartner M, et al: Relationships between nutritional markers and the mini-nutritional assessment in 155 older persons. J Am Geriatr Soc 2000;48:1300–1309.
21 Stanley KE: Prognostic factors for survival in patients with inoperable lung cancer. J Natl Cancer Inst 1980;65:25–32.
22 Dewys WD, Berg C, Lavin PT, et al: Prognostic effect of weight loss prior to chemotherapy in cancer patients. Eastern Cooperative Oncology Group. Am J Med 1980;69:491–497.

23 Ingenbleek Y, Carpentier YA: A prognostic inflammatory and nutritional index scoring critically ill patients. Int J Vitam Res 1985;55:91–101.
24 Jensen GL: Inflammation as the key interface of the medical and nutrition universes: a provocative examination of the future of clinical nutrition and medicine. JPEN J Parenter Enteral Nutr 2006;30:453–463.
25 Pattison DJ, Symmons DP, Young A: Does diet have a role in the etiology of rheumatoid arthritis? Proc Nutr Soc 2004;63:137–143.
26 Maclean CH, Mojica WA, Newberry SJ, et al: Systematic review of the effects of n-3 fatty acids in inflammatory bowel disease. Am J Clin Nutr 2005;82:611–619.
27 Singer P, Theilla M, Fisher H, et al: Benefit of an enteral diet enriched with eicosapentaenoic acid and gamma-linolenic acid in ventilated patients with acute lung injury. Crit Care Med 2006;34:1033–1038.
28 Paoloni-Giacobino A, Grimble R, Pichard C: Genomic interactions with disease and nutrition. Clin Nutr 2003;22:507–514.
29 Minnich DJ, Moldawer LL: Anti-cytokine and anti-inflammatory therapies for the treatment of severe sepsis: progress and pitfalls. Proc Nutr Soc 2004;63:437–441.
30 Bathum L, Bomemenn JV, Christiansen L, et al: Evidence for an association of methylene tetrahydrofolate reductase polymorphism C677T and an increased risk of fractures: results from a population-based Danish twin study. Osteoporos Int 2004;15:659–664.

Discussion

Mrs. Anthony: In talking about your research priorities, you mentioned the need for different outcome measures and the such. Can you comment a little on the recent use of meta-analysis in the nutrition literature?

Dr. Jensen: Mrs. Anthony is touching on an interesting and controversial point. Of course, meta-analysis and evidence-based review are beginning to drive practice worldwide. Getting back to our discussion of the need for high-quality outcome studies, the reality is that existing studies are small and underpowered. One approach to dealing with this is to try to combine the analyses of multiple studies. The problems with this are myriad and they relate to everything we highlighted on study limitations: disparate populations, disparate interventions, disparate conditions, and disparate levels of undernutrition. All that said, it is a way to explore this type of data and some people are very focused on doing this. I think the practical reality, and what I would recommend, is that meta-analyses are meant to be hypothesis-generating, to drive the next phase of research. They are not meant to develop clinical practice guidelines and to drive standards. My personal approach to this would be to use them to generate hypotheses that can be tested prospectively. It doesn't mean that we can't use them to guide us in the meantime but some of these studies are very difficult to do and very costly. That would be my current vision of how to use meta-analyses.

Dr. Sanz: Meta-analyses collate studies with their own hypotheses. They are already hypothesis-driven. It is like a circle where, based on studies with clear hypotheses, we perform the analysis. What is the advantage is of restarting the circle?

Dr. Jensen: No matter how you cut it, it is not a prospective, randomized, blinded trial. Even when you set up as rigid criteria as possible, there is no way that you can say that the patients are all the same, the procedures are all the same, and the outcome measures were done in exactly the same way. It simply is not comparable to a large, well-conceived prospective trial. Obviously, there will be differences of opinion about how one wants to use this. It is problematic, though I am not saying that we can't use them. They can be very helpful but I am just suggesting that the

best way to use them is to design appropriate clinical trials in the meantime to help guide us.

Dr. Kondrup: Sometimes, I feel that we are medieval age monks whipping ourselves whenever we talk about obesity and obesity surgery. In Denmark I have teased our National Board of Health on why they waste so much money on treating obesity because there is no documentation that this will improve survival, reduce morbidity or be cost-efficient in any way. But this locomotive is still pulling ahead and we keep whipping ourselves that we don't have the evidence.

Dr. Jensen: It's interesting to see that, in the United States, there is very compelling surgical literature saying that, for severely obese patients, bariatric surgery can be cost-effective by documenting improvements in diabetes, dyslipidemia and hypertension, and then projecting that over years of healthcare utilization. The one thing I would point out, which is not often highlighted, is that, for example, you are a very skilled bariatric surgeon, doing 100 cases, and only 1 or 2 of those 100 cases have serious complications; the cost associated with those 1 or 2 patients' serious complications can outweigh the net benefit of almost all the others. You rarely see that addressed.

Dr. Kondrup: We can also easily demonstrate that malnutrition leads to immobilization and muscle weakness and, if treated we can improve it, just like we can improve the blood sugar of patients losing a lot of fat. What authorities want from us is really the cost-effectiveness of the long-term outcome, and they don't require the same evidence for obesity surgery.

Dr. Labadarios: Dr. Kondrup, the comment you made about us whipping ourselves makes me wonder if we have enough advocacy for this cause in hospital management. Looking at undernutrition, there are UNICEF, WHO and millions of other NGOs who actually push a mandate systematically. These NGOs do very important work in general terms, depending how you look at it, but they want nothing to do with ill people. They only use ill people to the advantage of prevention, which is correct, rather than treatment. So, as part of my previous comment, do we use the right words to promote or highlight a particular issue? I don't know of any NGOs in the clinical area who actually push medical aides. Perhaps some of my colleagues here can share some their ideas.

Dr. Jensen: I would agree that we have a tremendous need for advocacy worldwide for our cause. If you want to talk about difficult causes, look at my work with obesity and ageing. It was hard enough to go to Washington and get money for work with obesity, though now you can. NIH and some other agencies are throwing some tremendous funding especially at adolescent and pediatric obesity and prevention. But, at the other end of the spectrum, you wouldn't get the time of day. Now, to make it even more difficult, we are talking about being obese, older and undernourished at the same time. Part of this is that we need to get our message across at the government and public health levels, and very much to the healthcare environment itself, from insurers, reimbursers and our fellow practitioners. Certainly in North America, many physicians remain unconvinced that nutrition support is a major player that can impact their patient outcomes. This is where using nutrients pharmacologically may go a long way for us as part of the medical treatment of their patients.

Dr. Bistrian: When you mentioned serum albumin and prealbumin and other secretory proteins, isn't the presence of inflammation and its severity an important variable on whether someone needs nutritional support? Don't serum albumin and white count number and differential do that effectively?

Dr. Jensen: I think that they are tremendously useful, and in the way that you are alluding to. They help identify people under inflammatory stress, from which it is a very logical leap to say that they are at nutritional risk. The flipside of this is that in

intensive care we see people with low visceral protein status who are not malnourished at that time. It does not mean that they are not at risk; they certainly will be. If you see a multi-trauma case and 24 h later their albumin is 2.5, it is a question of semantics and what you want to call undernourished? To me, it is an appropriate massive inflammatory response which places them at risk of adverse nutritional outcomes.

Dr. Bistrian: Yes, but in the US, wouldn't by definition everyone in the ICU have an inflammatory response and a low serum albumin? The nutrition of everyone in an ICU needs to be addressed because there is clear evidence that early invasive nutrition support in the critically ill within the first 3 days is an important variable in determining morbidity and mortality.

Dr. Jensen: Sure, I am not quibbling with that. All I am saying is that, at that point in time, it is a very potent inflammatory indicator. It has tremendous prognostic import specifically for that reason. It doesn't mean that they are undernourished at that point in time but they are at great risk. Aside from a few acute drug overdoes, virtually anyone in an ICU in America is going to be at significant nutritional risk.

Dr. Kondrup: I would see low albumin as part of the indication for nutritional support but not part of the diagnosis. I think we have to distinguish between them. In the ICU, if you want to diagnose malnutrition when the patient arrives, you need 24-hour urinary nitrogen excretion. We just did a study on that with 60 patients and there is no correlation between the urinary nitrogen loss and their COP levels for instance. Urinary nitrogen must be measured in all patients in the ICU as this is really a sign of malnutrition. While low albumin adds to the indication for treatment.

Dr. Bistrian: Are you not suggesting then that one of the indications for nutritional support is someone who is malnourished and who might benefit from nutritional support, but another indication is someone who is injured and calling that malnutrition is probably what got us into the trouble that we are in. People who were well-nourished to begin with and become critically ill, at least for a week or longer, have no classification. We could call them protein-calorie malnourished and yet, quite clearly, it is one of the most common indications for nutritional support. Is that not what people believe?

Dr. Kondrup: We would have to turn some switches in the brains of our colleagues because if you have a patient who is not yet dehydrated but has a fistula or something like that, and is losing liters per hour or per day, you would start treating him with fluid therapy because otherwise he would die from dehydration within a few days. So, there is an indication for fluid therapy, although he is not yet dehydrated. Of course, the problem is the same, you want to prevent severe dehydration. We need to train our colleagues to see that we have two main groups: those who are already malnourished and those at risk of becoming so. This is similar to fluid therapy.

Dr. Elia: You can have a person in the ICU who is likely to be unconscious for a long time and likely to be on a respirator with acute respiratory distress syndrome. He may not be malnourished at that time but he is at risk. I think that part of our clinical practice is to try and prevent the development of malnutrition and the perceived adverse consequences from an early stage if you know that the patient will be out of action and unable to eat for many days or weeks.

Dr. Jensen: This ultimately gets back to something we have highlighted repeatedly, which is the need for some definitions that we can use systematically throughout the world. In the United States, part of what drives this is that, for reimbursement purposes, to administer nutrition support to an acutely ill trauma patient, for example, we have to label him as something. The DRG code for some of those people would be protein-energy malnutrition. While, strictly speaking, that may or may not be what they have; they certainly have a robust inflammatory response that puts them at great risk. None of us would propose to starve them for a week, but it does highlight the need for some common definitions.

Dr. Elia: It is also a matter of whether a DRG requires the condition to have developed. Do you wait a week, when you know that it will develop, and then call them malnourished, or do you say that this individual is at risk or there is a probability that this condition will develop if you don't do something?

Dr. Jensen: Practically speaking, we label them with this condition upfront, even though we know that is not what it is.

Dr. Bistrian: For these reasons wouldn't it be helpful for the future to identify indications for nutritional support without having malnutrition as one of the diagnoses, or even being at risk? In other words, nutritional support is indicated for someone who is going to be in the ICU for 7 days with a head injury or burns or trauma of a certain severity. Wouldn't that be more reasonable? Otherwise, we pay for things for reasons that are not what they should be.

Dr. Elia: Absolutely, if you identify a condition that you can't do anything about, it is a waste of time, money and effort. The whole art of clinical nutrition is to identify individuals who are likely to respond to treatment. If you don't have that, then you don't have a discipline.

Dr. Bistrian: I don't want to take away from your talk but, Dr. Hoffer, you have thought long and hard about some of these issues, do you have any comments?

Dr. Hoffer: I was thinking about the practice in the ICU of my hospital. I am not familiar with the American DRG system as we have a universal healthcare system in Canada. I am not trying to be too sanguine but that is the policy in place right now in our ICU. All patients are immediately followed by a well-qualified expert dietician and all patients who cannot be fed adequately are fed by one route or another. It is just the existing state of care in our institution, and it surprises me that this would not be the case in all of them. Perhaps I am wrong, perhaps we are not so unique in our hospital but perhaps we are.

Dr. Jensen: Practically speaking, in any leading institution in the United States, everyone is very aggressively screened within 24 h, and intervention happens very rapidly. The DRG part is the flip side, which is where reimbursement comes from. If you are giving an ICU patient aggressive early tube feeding, for example, they will need a nutrition DRG code attached to that. So by and large they will be labelled protein-energy malnutrition for reimbursement reasons. We are not talking about what they have but it depends on what protein-energy malnutrition means. What they really have is a very appropriate and massive manifestation of inflammatory response that has tremendous prognostic import to us. Part of it may well be, as Dr. Bistrian stated, that we are misstating what we are doing.

Dr. Labadarios: What you are actually suggesting is taken from one of the ASPEN recommendations. There is no need to wait for 5–7 days. Isn't that so? There is that one last thing, if the patient is well-nourished.

Dr. Jensen: The ASPEN guidelines are in a state of evolution and review as we speak. Certainly, I would think that the standard of care in many ICUs in the United States for patients at risk is not to wait 5–7 days. People are being intervened very acutely, often within 24 h.

Dr. Labadarios: I am agreeing and highlighting something that needs to be addressed in exact terms because it has implications. For instance, the feeling of 5–7 days goes around. If you talk to management money-wise, there are some things that seem to suit them, but other things that don't suit them they prefer to ignore. This has practical implications. My question, or perhaps comment, relates to an earlier point that you made regarding inflammation. What ever happened to the PINI index? Everyone asks you what to measure and, you are right, we don't know. We did have the PINI index, and there were some initial data. What is the experience of the people here about the PINI index?

Dr. Jensen: That is a timely observation. Since we lack single good indicators of nutritional status, it is an interesting approach to combine multiple variables and multi-variable analysis to develop predictive equations. The PINI is a good example as it has a mix of nutritional and inflammatory indicators that has validity in terms of predicting adverse outcomes. This may well be a very practical approach.

Dr. Bistrian: To address your question, Dr. Labadarios, I believe the 5- to 7-day rule came from a Swedish study on previously well-nourished subjects who underwent major thoraco-abdominal surgery and other experiences. Most of those individuals do not have a major inflammatory response postoperatively and 80–90% of them would have oral intakes within 5 days. It was thought then, rather than feed everyone having major surgery, to wait 5–7 days, depending on the quality of the nutrition support service, before initiating nutritional support. It was thought to be beneficial because those for whom the time was 14 days or more before initiation of nutritional support, the outcome was severely impaired. That is where it comes from and it is probably common among surgical services to give a period of 5–7 days for initially well-nourished subjects. That period is dramatically shortened if the patient is moderately or severely malnourished. Dr. Kondrup, is that the practice in Denmark?

Dr. Kondrup: I think so. This is one of the issues that we have not solved yet. As a rule of thumb, 5–7 days are reasonable. We would though advocate enteral feeding from day 0.

Dr. Bistrian: On average, in surgical patients when you start enteral feeding on day 0, the first 3 days are essentially grossly inadequate feeding.

Dr. Kondrup: This is not to keep their nutritional status but to keep the bowels functioning and to prevent the translocation of all those problems. There was a study done in Denmark where well-nourished colectomy patients were started with enteral feeding 4 h after the operation. The tube was left there only for 3 days, when the patients could start eating themselves. This gave 85% reduction in wound infections. The control group was a placebo with a tube and colored water.

Dr. Bistrian: There is always a concern that the routine use of nasogastric feeding tubes in otherwise well-nourished patients is that the tubes have complications associated with them, including aspiration pneumonia. In addition, there is good evidence that they impair ventilatory function. So, their use is not benign and you need to be certain of benefit in order to justify their routine application. That is why they aren't routinely used in most American hospitals.

Dr. Jensen: In the United States, there is fair consensus in the standard of care over not waiting 5–7 days in a critical care setting. As we discussed, these people are in such proinflammatory states and are perceived to be at great nutritional risk. In general, certainly at our ICUs at Vanderbilt, these people are being tube fed within 24–36 h.

Dr. Elia: In coming to this 5- to 7-day rule, you have taken a clinical perspective. One can also take a physiological perspective. A typical person with a BMI of 20–25, who fasts and eats nothing for 5 days, would lose about 5% of their body weight or more. Admittedly some of that is water. If an entirely healthy individual has a BMI of 35 and fasts for 5 days, they would lose about 5% of body weight. If someone has an initial BMI of 18 and fasts for 5 days, they will lose close to 10% of body weight. This is without disease, so imagine a catabolic process as well that could add to the loss of lean tissue as well. The issue of 5–7 days is a convenient cutoff point but it also depends on the patient's initial status. The percentage loss in an underweight patient is so much greater that we ought to start thinking about a shorter time without feeding for those already compromised nutritionally.

Dr. Jensen: We already do, and having a BMI of 18 would be considered initially malnourished, so it is dramatically shortened. For those initially severely malnourished,

we begin feeding immediately postoperatively; for those moderately to mildly malnourished, within 3 days. The timing of intervention depends on the baseline assessment of the individual status. If someone is (1) at great nutritional risk because of their inflammatory status, that moves them ahead, and (2) if they are significantly undernourished at baseline, we are not going to starve them for a week and then intervene. This is where we get back to Dr. Kondrup's observation that people who are moderately obese may have more metabolic reserve in some fashion and better outcomes.

Mrs. Anthony: I would like to talk a little more about guidelines per se. With two very predominant sets of guidelines right now, the new ESPEN ones and the ASPEN ones, and I am happy to hear that ASPEN is redoing them. One of the goals of this workshop is to talk about how we communicate to the non-nutrition people, whether they be legislators, regulators or other healthcare professionals. They look to these guidelines very strongly for practice and I have always struggled with this 5–7 days. For a well-nourished, non-stressed patient it makes perfect sense, but I am not sure how the guidelines are interpreted by others. This is why this discussion has been generated. ESPEN seems to have come up with specific guidelines for specific disease states, and the ICU ones say start as early as possible and talk about early enteral nutrition. ESPEN and ASPEN are now talking about collaborating on international guidelines, which is a huge amount of work but would be a useful tool as we try to communicate to the others with a unified voice. This needs to be made really clear. Even in the Canadian critical care guidelines, the talk is about evidence-based guidelines. While we support them, we need to know that the average clinician or non-nutrition person only reads the one page of guidelines and not everything behind them. We need somehow to make those guidelines clear now. I know that is easier said than done.

Dr. Jensen: A major initiative has been kicked off with ESPEN and other organizations to begin a dialog that will ultimately result in some coherent international nutrition guidelines in relation to nutrition support. The title of my talk in Phoenix was 'International Nutrition Guidelines: Global Consensus or Chaos?' You can imagine taking all of these disparate entities and their advocates and guidelines and attempting to make some sense of this. From our initial meetings in Phoenix and beforehand, it is clear that this is great opportunity to find some common ground and move ahead. There are some areas of strong consensus and we need some clear language that the consumers and practitioners worldwide will find clinically useful. For example, we are not going to take critically ill people and starve them for a week and then intervene. It is going to be a great challenge. The initial approach we are taking is to focus on a couple of guideline initiatives at a time. For example, for Prague, the agenda has a guideline in relation to supporting burn patients and another in relation to pancreatitis. There is also some clear language in trying to define malnutrition and the risk of adverse outcomes. It is going to be tremendously challenging but there will be great benefit from pooling all the different parties. Of course, a host of countries and nutrition entities have already developed some wonderful guidelines that make a nice starting point.

Dr. Roessle: I wanted to touch on a point that has not been discussed so far. You said that in the last decade the role of the nutrition support team has decreased due to cost containment. I would be interested in any data on how the relative cost of nutritional support has evolved from 10 years ago to the present. Pharmaceutical costs are going up and I would bet that nutrition support costs, in relative terms, is decreasing.

Dr. Jensen: That is a great question. It is very difficult to demonstrate because the outcomes that we would like to look at in relation to that are multifactorial. The healthcare costs of a given patient have multiple variables impacting on them. Part of the challenge is that we have always tried to sell nutrition support to hospital

administrations in the United States by saying that we are going to improve patient outcomes, shorten lengths of stay, decrease ventilator days and decrease mortality. In certain instances well-defined outcome studies can be done, but it is very challenging because you are talking about outcome variables with multiple impact variables besides nutritional status. Disease burden is a simple example. One of the easier ways that we have been able to sell nutrition support to hospital administrations in the US has been to say that we will reduce inappropriate use of nutrition support modalities. Especially when you consider the misuse of parenteral modalities, there can be great costs involved and that has been one of the easier ways to demonstrate the benefit of a nutrition support team per se. There are also studies showing that a nutrition support team creates a lot more laboratory work, which has significant costs. It is a tricky issue.

Dr. Labadarios: What the situation now with the international guidelines? There are the ESPEN, the ASPEN and the Canadians guidelines too. Are we going for a unified, international set of guidelines and under whose auspices will they be issued?

Dr. Jensen: Between ESPEN and ASPEN, we have sent out a call to all the worldwide nutrition societies to convene in Prague at the next ESPEN meeting to discuss this initiative. Indeed, the goal is to develop some common guidelines that can be readily disseminated to nutrition practitioners throughout the world.

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The Economics of Malnutrition

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Abstract

Despite extensive information on the adverse physical and psychological consequences of malnutrition, there is little information on its economic consequences. International studies suggest that disease-related malnutrition increases hospital costs by 30–70%. In the United Kingdom the Malnutrition Universal Screening Tool (MUST) was used as the basis for identifying the prevalence of malnutrition in various care settings. Malnutrition increased both the frequency of admissions and length of stay in hospitals, as well as the frequency of visits to a general practitioner and hospital outpatient visits, and residency in care homes. After assigning nationally representative costs to the utilization of these services, the public expenditure on disease-related malnutrition in the UK in 2003 was estimated to be more than GBP 7.3 billion. The large cost of disease-related malnutrition means that small fractional cost savings from intervention can result in substantial absolute cost savings. A summary of nutritional intervention studies with cost analyses (including meta-analyses) and cost-effectiveness analyses are presented, and some of the clinical and ethical implications discussed.

Introduction

Despite extensive information on the prevalence of malnutrition and its clinical and public health consequences, there is comparatively little information on its economic consequences [1]. One of the reasons for this is the difficulty in equating the adverse consequences of malnutrition with monetary values. These values can vary widely according to disease status, socioeconomic status, life expectancy, and the cultural background of the individuals making judgments. They also depend on whether the individual is a patient, a health professional, or a healthy member of the general public. Another problem is that there are different types of economic analyses which may

be confused with each other or poorly understood. Therefore, most studies on malnutrition have not incorporated a formal economic analysis into their study design, and although some retrospective analyses can be undertaken, this is far from ideal. In addition, as malnutrition often coexists with disease, separating their independent effects can be difficult, especially as each can predispose to the other. For this reason the costs of malnutrition and associated disease (disease-related malnutrition) have usually been considered together. The section that follows discusses the cost of disease-related malnutrition, but as this does not reflect the extent to which interventions can result in cost savings, the value of other types of economic evaluations are also briefly considered.

Estimating the Cost of Disease-Related Malnutrition

There is virtually no information about the national cost of malnutrition in developed countries. However, the cost might be expected to be substantial because malnutrition predisposes to disease, delays recovery from illness, and increases use of healthcare resources [2]. Some insights into the magnitude of such costs can be obtained from cross-sectional cost analyses of malnutrition in both the hospital and community.

In a study involving two acute hospitals in Pennsylvania, USA, a retrospective review was undertaken of 771 patient charts to assess hospital costs and the likelihood of malnutrition on admission [3]. Those at risk of malnutrition (assessed using objective or subjective criteria) incurred greater costs than those without malnutrition (USD 5,519 vs. 3,372/patient; pre-1988 prices; 67% greater costs and 46% greater charges). A more recent prospective study in Ohio, USA [4], reported that individuals classified as being at risk of malnutrition (56 of 172 patients; assessed using weight status, weight loss or hypoalbuminemia as criteria) had significantly higher hospital costs than those not at risk (USD 6,196 vs. 4,563/patient; pre-1998 prices; 36% greater costs). The at-risk patients were also more likely to use home healthcare services. In yet another study in the USA (Illinois) [5], patients who stayed in hospital for more than 7 days and declined nutritionally (assessed using subjective global assessment) had significantly higher hospital charges compared to those who remained normally nourished (USD 45,762 vs. 28,631/patient; pre-2000 prices; 62% greater charges). A review from the USA suggested that hospital costs for undernourished patients were generally 35–75% greater than for well-nourished patients [6]. A broad estimate of annual hospital costs in the USA incurred by malnourished patients (based on costs of USD 5,000/malnourished patient), was USD 18 billion (pre-1993 prices) [7].

The increased hospital costs associated with disease-related malnutrition have also been reported in European [2, 8–10] and other countries, including

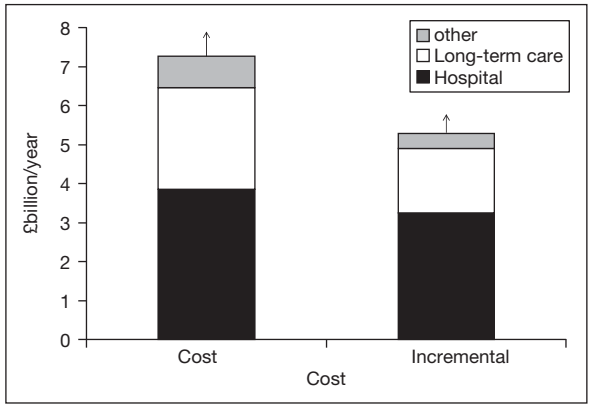

Fig. 1. The estimated annual cost and incremental cost (public cost only) of disease-related malnutrition in the UK in 2003. The incremental cost is the additional cost of treating patients with malnutrition compared to treating the same number of patients without malnutrition (low risk of malnutrition according to MUST). The arrows at the top of the bars indicate that the costs represent minimum values as they do not include all services. Based on Elia et al. [8].

Brazil [11]. For example, in a UK hospital the cost of disease-related malnutrition, identified with the Malnutrition Universal Screening Tool (MUST), was found to be 40% higher in patients with medium plus high risk of disease-related malnutrition compared to low risk patients ($p < 0.001$, $n = 857$). However, this extra cost varied from 11% in surgical wards, 36% geriatric wards, 44% orthopedic wards and 71% in medical wards [10]. In Brazil [11], a survey was undertaken in 709 patients randomly selected from 25 hospitals using subjective global assessment to categorize patients into malnutrition risk. The hospitals were part of a larger hospital survey of hospital malnutrition, which was carried out in 1996. The malnourished patients had a mean daily expenditure of USD 228/patient compared to USD 138/patient in the well-nourished, an increase of 65%. No estimates were made of community costs.

Some insights into community costs can be obtained from a retrospective analysis of the 1987 National Medical Expenditure Survey (Household Survey) in the USA [12]. There was a progressive increase in the annual healthcare expenditure in men from USD 1,300 in those with a body mass index (BMI) of 21 to USD 3,250 in those with a BMI of 15 (2003 prices) [12]. Expenditure below a BMI of ~18.5 was greater than for obese men (e.g. only USD 1,700 in those with a BMI of 39). The increased cost for underweight women was less pronounced than that for men, and at a BMI of 15, it was lower than at a BMI of 39. This analysis did not take into consideration recent weight loss or the magnitude of weight loss, which may also indicate malnutrition or risk of developing malnutrition. In addition, the study could not estimate the total

community cost of malnutrition because it did not include subjects older than 65 years which account for a major proportion of total national expenditure on health.

It seems that the information on the cost of disease-related malnutrition is patchy, collected in various countries at different times, and sometimes based on rudimentary calculations that involve different criteria for identifying malnutrition. This makes it difficult to establish a single accurate national estimate of the total expenditure on disease-related malnutrition arising from various care settings at a point in time. However, an attempt to do this has recently been made in the UK using consistent criteria for detecting malnutrition across care settings [8].

Estimating the Cost of Disease-Related Malnutrition in the UK

In 2001, a paper briefly reported that the cost of disease-related malnutrition in the UK was as high GBP 15–20 billion/year [13], corresponding to 20–27% of the total expenditure on health (a total of GBP 74,883 billion in the same year according to the Organisation of Economic Co-operation and Development (OECD) [14]). Unfortunately, the estimated cost of disease-related malnutrition was very informal, with no information as to the basis of the calculations.

A more formal analysis of the cost of disease-related malnutrition in the UK (2003 prices) was undertaken by the Health Economic Group of the British Association for Parenteral and Enteral Nutrition [8]. It brought together information on the prevalence of malnutrition in the hospital and community in people above and below 65 years (e.g. in their own homes and different types of residential accommodation), and the rate of utilization and cost of healthcare resources. Each of these is discussed below, but special attention is given to malnutrition in older individuals in the community. This is not only because little information is available in this age group and setting, but also because it illustrates important health inequalities, which are relevant to economic models of care and social justice.

The Prevalence of Malnutrition in the Community (Outside Hospital)

The prevalence of malnutrition was established using MUST [15] or MUST-type criteria, which were applied to secondary analysis of a National Diet and Nutrition Survey [16] and studies involving various hospital wards and alternative care settings.

The overall prevalence of malnutrition in the community in the UK (medium and high risk according to MUST-type criteria) increased with age, so that in those aged 65 years and over it exceeded 10%. This result reflects the overall combined prevalence of malnutrition among a representative sample of people living in their own homes and in residential accom-

modation in the UK. The prevalence in those aged 65 years and over was as high as 19.4% in northern England compared to 12.3% in central England and 11.3% in southern England ($p < 0.001$). These differences are mirrored by a north–south divide in the prevalence of vitamin C deficiency, and differences in circulating vitamin C, carotenoids and vitamin D concentrations [17]. Such inequalities in malnutrition are linked to a cluster of other inequalities, including inequalities in educational and economic status, which can only explain part of the geographic differences in the prevalence of malnutrition.

A separate study using MUST examined inequalities in malnutrition within the same geographic area [18]. One thousand subjects admitted to hospital were assigned a multiple deprivation index based on national criteria that were applied to the local community wards in which the patients lived. Those with malnutrition (medium and high risk using MUST) had more deprivation than those without malnutrition (low risk), after adjusting for age and sex. In addition, those who were more deprived and more malnourished were more likely to die in hospital. The economic implications of these inequalities are briefly discussed below, after consideration of the national expenditure on disease-related malnutrition.

Cost of Services

In the health economic report on malnutrition [8], the rate of utilization of healthcare services was established and their costs estimated using information from the Department of Health (www.dh.gov.uk) and Netten and Curtis [19]. It was found that many services were utilized more frequently by malnourished than non-malnourished individuals. For example individuals aged 65 years and over had 82% more hospital admissions (0.503 vs. 0.276/year), with about 30% longer length of stay per admission, 65% more GP visits to a general practitioner (GP; 7.096 vs. 4.307/person and year), and 33% more hospital outpatient visits (1.355 vs. 1.019/person and year). They also had more admissions to care homes.

Estimated Public Health Expenditure on Health

The estimated public health expenditure on disease-related malnutrition in the UK was estimated to be at least GBP 7.3 billion in 2003, of which about half was due to hospital care and the other half to community care, predominantly for older individuals. In the community, the costs were mainly due to long-term care (~GBP 2.6 billion) and GP visits (>GBP 0.5; probably GBP 0.5–1 billion). The annual expenditure on artificial nutrition and oral nutritional supplements in the community was only about GBP 0.15 billion, and in the hospital setting it was even less (GBP 0.054 billion; table 1). Five points can be made about these findings.

First, the overall expenditure on disease-related malnutrition is large. In 2003, the OECD estimated that the total expenditure on health in the UK

Table 1. **The estimated annual cost of parenteral nutrition, enteral tube feeding and oral nutritional supplements in hospital and the community in the UK in 2003**

	Hospital GBP millions/year	Community GBP millions/year	Total GBP millions/year
Parenteral nutrition	47.5	17.6	65.1
Enteral tube feeding[1]	3.2	66.4[1]	69.1
Oral nutritional supplements[2]	2.8	65.3	68.1
Total	53.5	149.3	202.8

Based on Elia et al. [8].

[1] The commonest indication for home enteral tube feeding (own homes + care homes) is cerebrovascular accident, accounting for about a third of the total point prevalence.

[2] These supplements only refer to those containing a mixture of macronutrients and micronutrients.

was GBP 87.647 billion, of which GBP 74.872 billion was public expenditure, and GBP 12.775 billion private expenditure [14]. This means that public expenditure on disease-related malnutrition (>GBP 7.3 billion) accounted for about 10% or more of the total expenditure on health. Since the public expenditure on health in 2003 was 6.8% of the gross domestic product (GDP; ~GBP 1,257/capita), malnutrition accounted for more than 0.68% of the GDP.

Second, the public health expenditure on malnutrition appears to exceed that on obesity, which was estimated to be GBP 3.4–3.7 billion/year by a House of Commons Health Committee (2002 prices) [20]. The cost of malnutrition was similar to the combined cost of obesity and overweight, which was estimated to be GBP 6.6–7.4 billion/year by the same House of Commons Health Committee. The media seem to focus more on overweight/obesity than malnutrition. However, both are important, both have large economic implications, and both deserve appropriate preventive and therapeutic measures. It is perhaps surprising that only 0.5–5.9% of the total expenditure on health was estimated to be on prevention and public health in 18 OECD countries in 2005 [14].

Third, a disproportionately large fraction of the expenditure on disease-related malnutrition in both the hospital and community involves older people. Thus, well over half of the public expenditure on disease-related malnutrition involves people aged 65 years and over (mainly for hospital and long-term care), who account for only about 15% of the general population. This expenditure may increase in the future, as the older population represents one of the fastest growing segments of the general population. The United Nations estimated that in the more developed regions of the world the proportion of people aged 65 years and over will have increased from 14% in 2000 to 21% in 2025.

Fourth, one of the general aims of guidelines targeted at healthcare workers [21–23] is to improve health inequities by promoting a better, more uniform approach to treatment. However, since most healthcare workers typically only deal with individuals that access the healthcare system, this approach does not address many of the underlying causes of health inequalities, some of which lie outside the healthcare sector. A different approach is required to deal with individuals who do not access healthcare services, or who access them late, so that their malnutrition becomes more severe. One approach to this problem is to increase awareness amongst patients and the public, and direct this awareness into practical pathways of prevention and care. Such recommendations were the focus of a recent report on malnutrition in older people in the community, which was launched in the House of Commons (UK) in 2006 by a group of non-governmental organizations [24]. However, improvement in health among poorer [25], less privileged people may cost more than improvement of the same amount of health in more educated and more privileged individuals. There are many reasons for health inequities, including better compliance to treatment and better access and use of healthcare services by the more privileged and educated individuals. What is the most appropriate balance between the efficiency of a healthcare system on the one hand, and equity and fairness on the other? When there is a conflict between the two, to what extent should health inequalities be sacrificed at the expense of efficiency [26]? What exactly is equity and fairness? More detailed discussions on the ethics and philosophy of issues concerning health inequalities/inequities can be found elsewhere [25, 27–29].

Fifth, one of the limitations of simply estimating the cost of disease-related malnutrition is that it does not reflect cost savings associated with interventions, which are of particular interest to managers and health planners. Since the overall cost of disease-related malnutrition is large, a small fractional cost saving will result in a large absolute cost saving, e.g. a 1% cost saving from the annual expenditure on malnutrition in the UK corresponds to >GBP 73 million. Intervention studies of oral nutritional supplementation in hospital have shown that they can save up to 10% or more of the total cost of care [8], depending on the type of patient, as well as the type and duration of the intervention. Specific examples of nutritional interventions are considered next to illustrate the advantages and limitations of different types of economic evaluations, and how they can be used together with cross-sectional evaluations in order to inform policy.

Economic Evaluations of Nutritional Interventions

Cost Analyses

Some examples of cost-analyses involving randomized controlled trials of nutritional support are enumerated below:

Hospital

(1) An analysis of 7 randomized controlled trials comparing the effects of oral nutritional supplements vs. routine care in hospital (1 surgery, 1 elderly, 1 stroke, 1 fracture neck of femur and 4 abdominal surgery patients) revealed a cost saving of GBP 320–5,040/patient in favor of supplementation, which was associated with a reduction in length of hospital stay [9].

(2) An analysis of 7 randomized controlled trials and 1 cross-over trial based on length of stay costs in patients undergoing abdominal and orthopedic surgery (oral nutritional supplements, ONS, vs. no ONS) [8] revealed a consistent net cost saving in favor of supplementation (mean of GBP 1,166/patient; GBP 966 for the lower quartile and GBP 1,368 for the upper quartile). A separate economic model based on complication costs using specific unit costs provided by the Department of Health of England for 2003, also revealed significant cost savings in favor of supplementation (average cost saving of GBP 321/patient; GBP 392/patient for the upper quartile and GBP 233/patient for the lower quartile).

(3) A meta-analysis of 6 studies of patients undergoing abdominal surgery (n = 418 subjects; ONS vs. no ONS) showed a significant net cost saving in favor of supplementation [8]. When only the 5 studies carried out in the UK were considered in the meta-analysis (n = 358 subjects), the results remained significant [8].

(4) A meta-analysis of enteral nutritional support prevented the development of pressure ulcers [30], which translated into significant economic benefits [31].

(5) Cost analyses are also reported in studies of patients receiving 'immunonutrition' perioperatively (a feed containing n-3 fatty acids, RNA and arginine; Impact, Sandoz) [32–34], with overall results in favor of 'immunonutrition'.

Community

(1) Three studies involving preoperative supplementation for about 2 weeks before admission to hospital for surgery were associated with a significant net cost saving in favor of supplementation (GBP 688/patient; $p = 0.008$; lower quartile GBP 497/patient, upper quartile GBP 828/patient) [8].

(2) A longer term randomized controlled trial involving oral nutritional supplementation or no supplementation of malnourished patients discharged from hospital prospectively examined the costs of hospital admissions, prescriptions, and both GP and hospital outpatient visits. No overall economic benefits were found during 6 months of supplementation in this mixed group of patients [35]. However, the largest expenditure in both groups was on hospital admissions, which accounted for over 70% of the total expenditure.

Cross-sectional studies in the UK indicate that although less than about 3% of malnutrition is found in hospital, about half the estimated expenditure on malnutrition involves hospital care. Interventions that reduce this large

expenditure would obviously be welcomed. However, potential conflicts could arise when there are separate funding streams for community and hospital care. For example oral supplements prescribed in the community add to the costs there, but may reduce hospital admissions and hospital costs [8].

Cost-Effectiveness Analysis

Cost-effectiveness analysis (CEA) involves a comparison of the relative expenditure (costs) and outcomes (effects) associated with two or more alternative treatments. Cost-effectiveness is typically expressed as an incremental cost-effectiveness ratio: the ratio of change in costs (treatment A – treatment B):change in effects (treatment A – treatment B). The unit of effectiveness may vary from study to study, making comparisons between studies difficult. However, in cost-utility analysis, which can be regarded as a special type of CEA, the same unit of effectiveness is often used (e.g. quality adjusted life years, (QALY), which combines both quality and quantity of life), making it possible to compare a range of different treatments in different fields of medicine. Few CEAs have been undertaken in the field of nutritional support, but some examples are given below.

(1) CEA studies (using cost per complication-free patient as the measure of effectiveness) involving 'immunonutritional' feeds have reported with some favorable results [32–34].

(2) A CEA was undertaken by the National Institute of Clinical Excellence (NICE; www.nice.org.uk) in the UK to evaluate the impact of a nutritional screening program for individuals over 65 years, which included treatment with ONS [21]. It concluded that the intervention was cost-effective, producing a favorable incremental cost-effective ratio which was as low as GBP 5,000–10,000/QALY, when the baseline mortality was 3–5% and prevalence of malnutrition 4–8%. The results of this CEA should be interpreted with caution as several unsubstantiated assumptions were made, including assumptions about the long-term mortality of the control group.

(3) A cost-utility analysis of home parenteral nutrition (PN), undertaken in the UK in 1995 and reported in 1996 [36], estimated that the cost/QALY was GBP 69,000 (almost GBP 100,000 in 2007, if the result is discounted at a rate of 3%/year).

(4) A CEA was undertaken of patients with stroke receiving home enteral tube feeding (ETF) [37]. The cost (GBP)/QALY for patients receiving ETF in their own home was GBP 12,816 (95% CI, GBP 10,351–16.826). In the nursing home the costs ranged from GBP 10,304 to 68,064, depending on the contribution of the state to healthcare (private expenditure is often taken into account in CEA).

Two important modifications to CEA have recently been introduced in the UK.

(1) Restricted practice: this involves selective withdrawal of treatment in those who do not respond. This improves the cost-effectiveness amongst

those who comply and respond to treatment. An example of this concerns the use of the drug xenical for the treatment of obesity [38].

(2) Risk sharing – the concept of outcomes guarantee: in this scheme the National Health Service (NHS) pays for the cost of treatment only when there has been a response. If a drug fails to meet expectations, industry will refund the NHS the cost of the drug. Such a scheme was established in 2002 for the use of interferon-β (and glutamine acetate) in multiple sclerosis, with a computed cost per QALY of GBP 36,000 for those who responded to treatment (GBP 70,000; GBP 35,000–104,000/QALY if all patients receiving treatment are considered). A progress report on the 5,000 patients recruited by 2005 is awaited [39].

The above data can be used to illustrate two issues. First, CEA does not indicate whether a condition is common or rare, and the incremental cost-effectiveness ratio does not reflect the overall cost of treatments. For example, CEA on home ETF and PN does not reflect the 50-fold greater use of home ETF than home PN in the UK or the costs of these treatments (table 1), which in combination account for only about 1% of the public expenditure on disease-related malnutrition. Therefore, in making policy decisions about the distribution of limited finances, it seems reasonable to take into account more than one type of economic analysis, including cross-sectional analysis. Second, regulatory agencies using CEA to help them to decide how to distribute limited financial resources may face problems because the philosophy of CEA may be at odds with practice and societal values. In 1999, NICE was established as a special Health Authority in the UK, with the mission of providing patients, health professionals and the public with authoritative, robust and reliable guidance on current practice. Since it brought CEA into one of the largest European markets, its decisions have been monitored by the Treasury. Treatments that cost more than about GBP 30,000/QALY are unlikely to get approval from NICE, whilst treatments that cost <GBP 20,000/QALY are much more likely to be approved [39, 40]. The value for home PN is well above the 'threshold' of about GBP 30,000/QALY and well above the most expensive cost/ QALY approved by NICE. The continued funding of home PN by government challenges the principle of using CEA alone as a measure of social justice, since it denies other patients more cost-effective treatments, which have been declined by NICE. The use of ETF outside hospital is also problematic because when the treatment is provided at home the cost/QALY is well below the threshold of GBP 30,000, whereas in nursing homes it ranges from well below to well above the GBP 30,000 'threshold'(GBP 10,000–70,000) depending on the contribution of the state. The calculations do not take into consideration the burden of care that falls on relatives who are often elderly with health problems which are made worse through caring. Such issues need to be discussed openly and take into account general societal values. Cost containment in a NHS through restricted practice and risk sharing also needs to be openly discussed.

Concluding Remarks

Since 1990 expenditure on health has grown faster that the GDP in most developed countries [14]. Such countries aim to improve the efficiency of their health services and to reduce health inequities, although these two aims may conflict on financial grounds. In the UK social and geographic inequalities exist in obesity as well as malnutrition. The cost of malnutrition is high and appears to exceed that of obesity, accounting for about 10% of the total public expenditure on health. Economic evaluations, such as CEA, are important but they have been little used in studies of prevention and treatment of malnutrition. Controversies continue to exist as to the best method to distribute limited resources, and although CEA has found considerable application in some countries (e.g. UK), it has not in others (e.g. USA). Differences in attitudes, culture and history may explain at least some of the differences.

References

1 Elia M: Nutrition and health economics. Nutrition 2006;22:576–578.
2 Stratton RJ, Green CJ, Elia M: Disease-Related Malnutrition. An Evidence-Based Approach to Treatment. Oxford, CABI, 2003.
3 Reilly JJ, Hull SF, Albert N, et al: Economic impact of malnutrition: a model system for hospitalised patients. JPEN J Parent Enteral Nutr 1988;12:371–376.
4 Chima CS, Barco K, Dewitt MLA, et al: Relationship of nutritional status to length of stay, hospital costs, and discharge status of patients hospitalised in the medicine service. J Am Diet Assoc 1997;97:975–978.
5 Braunschweig C, Gomez S, Sheean PM: Impact of declines in nutritional status on outcomes in adult patients hospitalized for more than 7 days. Am J Diet Assoc 2000;100:1316–1320.
6 Gallagher-Allred CR, Voss AC, Finn SC, McCamish MA: Malnutrition and clinical outcomes: the case for medical nutrition therapy. J Am Diet Assoc 1996;96:361–366, 369; quiz 7–8.
7 Meguid MM: An open letter to Hillary Rodham Clinton. Nutrition 1993;9:ix–xi.
8 Elia M, Stratton R, Russell C, et al: The Cost of Disease-Related Malnutrition in the UK and Economic Considerations for the Use of Oral Nutritional Supplements (ONS) in Adults. A Report by the Health Economic Group of the British Association for Parenteral and Enteral Nutrition (BAPEN). Reddich, BAPEN, 2006.
9 Stratton RJ, Green CJ, Elia M: Simple cost-analysis of changes in hospital length of stay with oral nutritional supplements (ONS) from randomised controlled trials (RCT) (abstract). Clin Nutr 2004;23:906.
10 Stratton RJ, King C, Stubbs S, et al: Cost of disease-related malnutrition (DRM) in hospital according to 'must' and specialty (abstract). Clin Nutr 2004;23:918.
11 Correia MI, Waitzberg DL: The impact of malnutrition on morbidity, mortality, length of hospital stay and costs evaluated through a multivariate model analysis. Clin Nutr 2003;22:235–239.
12 Heithoff KA, Cuffel BJ, Kennedy S, Peters J: The association between body mass and health care expenditures. Clin Ther 1997;19:811–820.
13 Wynn M, Wynn A: Reducing waiting lists for hospital admission: community nutrition services reduce the need for hospital beds. Nutr Health 2001;15:3–16.
14 Organisation for Economic Co-Operation and Development: OECD Health Data 2006. Eco-Sante OCD software (www.oecd.bookshop.org). Statistics and indicators for 30 countries, 2006.
15 Elia M: The 'MUST' Report. Nutritional Screening for Adults: A Multidisciplinary Responsibility. Development and Use of the 'Malnutrition Universal Screening Tool' ('MUST') for Adults.

A Report by the Malnutrition Advisory Group of the British Association for Parenteral and Enteral Nutrition, 2003. ISBN 1 899467 70X.
16 Finch S, Doyle W, Lowe C, et al: National Diet and Nutrition Survey: People Aged 65 Years and Over. London, Stationery Office, 1998.
17 Elia M, Stratton RJ: Geographical inequalities in nutrient status and risk of malnutrition among English people aged 65 y and older. Nutrition 2005;21:1100–1106.
18 Stratton RJ, Elia M: Deprivation linked to malnutrition risk and mortality in hospital. Br J Nutr 2006;96:870–876.
19 Netten A, Curtis L: Unit Cost of Health and Social Care. Canterbury, University of Kent, 2003.
20 House of Commons Health Committee: Obesity, vol 1. London, Stationery Office, 2004.
21 National Institute of Health and Clinical Excellence: Nutrition Support in Adults. Clinical Guideline 32. London, NICE, 2006.
22 Council of Europe – Committee of Ministers: Resolution ReAP (2003)3 on Food and Nutritional Care in Hospitals, Strasbourg, Council of Europe, 2003.
23 NHS Quality Improvement Scotland. Food, Fluid and Nutritional Care. Edinburgh, NHS, 2003.
24 European Nutrition for Health Alliance, British Association for Parenteral and Enteral Nutrition ILC-U, in collaboration with the Associate Parliamentary Food and Health Forum: Malnutrition among Older People in the Community. Policy Recommendations for Change. London, European Nutrition for Health Alliance, 2006.
25 McPake B, Kumaranayake L, Normand C: Health Economics. An International Perspective. London, Taylor & Francis (Routledge), 2002.
26 Lindholm L, Rosén M, Emmelin M: How many lives is equity worth? A proposal for equity adjusted years of life saved. J Epidemiol Community Health 1998;52:808–811.
27 Anand S, Fabienne P, Sen A: Public Health, Ethics, and Equity. New York, Oxford University Press, 2006.
28 Bartley M: Health Inequality. Cambridge: Polity Press/Blackwell, 2004.
29 Neuman PJ: Using Cost-Effectiveness Analysis to Improve Health Care. Oxford, Oxford University Press, 2005.
30 Stratton RJ, Ek AC, Engfer M, et al: Enteral nutritional support in prevention and treatment of pressure ulcers: a systematic review and meta-analysis. Ageing Res Rev 2005;4:422–450.
31 Elia M, Stratton RJ: A cost-benefit analysis of oral nutritional supplements in preventing pressure ulcers in hospital (abstract P210). Clin Nutr 2005;24:640.
32 Gianotti L, Braga M, Frei A, et al: Health care resources consumed to treat postoperative infections: cost saving by perioperative immunonutrition. Shock 2000;14:325–330.
33 Braga M, Gianotti L, Vignali A, et al: Hospital resources consumed for surgical morbidity: effects of preoperative arginine and omega-3 fatty acid supplementation on costs. Nutrition 2005;21:1078–1086.
34 Senkal M, Zumtobel V, Bauer KH, et al: Outcome and cost-effectiveness of perioperative enteral immunonutrition in patients undergoing elective upper gastrointestinal tract surgery: a prospective randomized study. Arch Surg 1999;134:1309–1316.
35 Edington J, Barnes R, Bryan F, et al: A prospective randomised controlled trial of nutritional supplementation in malnourished elderly in the community: clinical and health economic outcomes. Clin Nutr 2004;23:195–204.
36 Richards DM, Irving MH: Cost-utility analysis of home parenteral nutrition. Br J Surg 1996;83:1226–1229.
37 Elia M, Stratton RJ: A cost-utility analysis in patients receiving enteral tube feeding at home and in nursing homes. Clin Nutr 2008;27:416–423.
38 Foxcroft DR: Orlistat for the treatment of obesity: cost utility model. Obes Rev 2005;6:323–328.
39 Raftery J: Review of NICE's recommendations, 1999–2005. BMJ 2006;332:1266–1268.
40 Towse A, Pritchard C: Does NICE have a threshold? An external view?; in Towse A, Pritchard C, Devlin N (eds): Cost-Effectiveness Thresholds: Economic and Ethical Issues. Proceedings of a Workshop Jointly Organised by the Office of Health Economics and the King's Fund on 1 March 2002. London, King's Fund, 2002.

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The Need for Consistent Criteria for Identifying Malnutrition

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Abstract

The lack of consistent criteria for diagnosing malnutrition and protein-energy malnutrition (PEM) creates problems in educating medical students and physicians, setting the parameters for observational and controlled clinical trials, and formulating clinical guidelines. There is no validated formal definition of malnutrition (or PEM), and the tools that have been developed to screen for it, or diagnose it, vary in their agreement. I make the following suggestions. First, avoid unqualified use of the term 'malnutrition', as it is ambiguous. Second, carefully distinguish between screening and diagnosis, which have different aims and implications. Third, consider the notion that in medicine the diagnosis of PEM is reached by 'narrative-interpretive' reasoning, which regards the disease as a pathophysiological entity in a specific clinical context. I recommend that the concept of PEM as a disease (not a score) be imbedded in teaching and the practice of medicine, and in the design of clinical trials and the setting of guidelines. Fourth, disagreements in screening-derived risk scores and uncertainty in diagnosis are difficult to avoid, but only in the grey zone. It would be prudent, at least until the greater medical world considers the nutritional paradigm plausible enough to invest in it, to enroll only patients who have unambiguously diagnosed PEM in prospective trials with hard clinical endpoints.

Approximately one quarter of the patients occupying hospital beds in the wealthy countries of the world have protein-energy malnutrition (PEM), but the disease is largely unacknowledged by doctors, nurses and administrators, and ignored or inadequately treated when the diagnosis is made [1–5]. Here I consider how the lack of consistent criteria for diagnosing malnutrition and

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PEM creates problems in educating medical students and physicians about them, setting the parameters for observational and controlled clinical trials, and formulating clinical guidelines. I also offer suggestions for improving the situation, in the hope they will stimulate a fruitful exchange of ideas during this workshop.

There is no validated formal definition of malnutrition or PEM. The many tools that have been developed for this purpose are uncertain in their validity and reliability, and vary in ease of use and acceptability [6–9]. But the problem is not simply one of definition and measurement. The identification of in-hospital PEM is hindered by its overlap with the muscle wasting that occurs with normal aging ('sarcopenia') and the metabolic-inflammatory state commonly engendered by the patient's primary medical or surgical disease ('cachexia'). There is even evidence that some of the changes of old age are proinflammatory [10] and that simple starvation may at certain stages induce a secondary inflammatory reaction [11]. The interrelationships among PEM, sarcopenia, and cachexia are intimate and inextricable [12]. How is it, then, that in 5 or 10 min a capable clinical dietitian or knowledgeable physician can usually diagnose medically important PEM, determine what further information should be obtained about its causes and trajectory, and formulate a tentative treatment plan? Roubenoff et al. [13] and Cheskin et al. [14] taught medical house officers the skill in a few hours. What simple method do knowledgeable clinicians use to diagnosis and assess PEM that is not being accurately or consistently identified by their unaware compatriots or by formulas and algorithms?

Some Nutritional Assessment Tools

Subjective Global Assessment (SGA) was first described in 1982 as a formalization of the process used by skilled clinicians to diagnose PEM [15]. The method involves a consideration of five elements in the medical history (dietary intake, weight change, gastrointestinal symptoms, functional capacity, and identification of the primary disease and any associated metabolic stress) and a targeted physical examination. After contemplating the 'whole picture,' the assessor intuitively diagnoses the patient as having: no malnutrition; questionable or mild malnutrition (PEM), or severe malnutrition (PEM) [16]. (In the present era of evidence-based medicine the word 'subjective' has become tainted; it should probably be replaced by 'interpretive', as explained later.)

The Mini Nutritional Assessment® (MNA) calculates a nutritional status score from the weighted answers to 18 questions about food intake, prior weight change, functional and medical status, body mass index (BMI) and anthropometrics. A score of >24 rules out malnutrition; a score of 17–23.5 indicates a risk of malnutrition, and a score of <17 classifies the patient as malnourished. The test has been used since 1989 [17].

In a frequently cited paper published in 1994, McWhirter and Pennington [18], referring to PEM, operationally defined 'undernutrition' as mild when the BMI was <20 and triceps skinfold thickness (TST) or mid-arm muscle circumference (MMC) was below the 15th centile; moderate when the BMI was <18 and TST or MMC were below the 5th centile, and severe if the BMI was <16. A history of weight loss in the recent past was considered confirmatory evidence [18].

The Malnutrition Universal Screening Tool (MUST) is a short scoring system described in detail in 2003 [4, 19]. It categorizes a patient's risk of malnutrition (and directs the management response) as low, medium, or high on the basis of a score of 0, 1 or 2 assembled from a BMI of <18.5, prior important weight loss, and predicted starvation in the near future. The maximum possible score is 6.

The Nutrition Risk Screening 2002 (NRS-2002) aims to identify hospitalized patients who are either malnourished at the time of assessment or at imminent risk of it because of their primary disease, and hence predicted to benefit from nutritional intervention [6, 20]. Described in detail in 2003, this test assigns a maximum of 3 points for a BMI of <18.5, important recent weight loss, and inadequate intake or poor functional status, plus a further maximum of 3 points for mild, moderate or severity of their primary disease, plus a bonus point for age >70, for a maximum possible score of 7. Unlike previous tools, the NRS-2002 was painstakingly developed by searching the clinical trial literature for parameters that predict a clinical benefit from nutritional intervention [20]. According to this construct analysis, a patient whose total score is 3 or greater stands to benefit from nutritional intervention.

All the tools except the NRS-2002 – and it, too, indirectly – are products of the pooled intuition of experts. They mostly address the same parameters but apply different weights to calculate the final score. For each of them a 'grey zone' lies between the well-nourished and the definitely malnourished. However, whereas the SGA refers to its grey zone as 'mild' or 'possible' malnutrition (referring to PEM), the MNA and MUST refer to their grey zones as 'risk' categories. The NRS-2002, which targets 'undernutrition', lumps people diagnosed as having PEM and people at imminent risk of developing it in the same category. No test discriminates among PEM, sarcopenia, and cachexia, nor aims to. What the tools do, and what their validation is based on, is predict the likelihood of an adverse clinical outcome (and, in the case of the NRS-2002, a *preventable* adverse outcome). In the end, of course, outcome is what matters. A test serves its purpose if it accurately predicts an adverse outcome that can be prevented by therapeutic intervention.

When contemplating the differences among these assessment tools it is worth appreciating that the more severe a patient's PEM, the more the tests agree. No one would dispute the diagnosis of PEM when the BMI is 16, and any test that fails to yield this result is a bad test. Actually, BMI is only one of many parameters in the MNA and is not even mentioned in the SGA, but

by the time the BMI has fallen to16 most of the other parameters (nutritional and weight history, intercurrent disease, physical function and physical examination) will have fallen in line with the diagnosis. When the BMI is 18.5, however, one tool could indicate no nutritional problem, a second one identify a patient 'at risk' of mild malnutrition, a third one a patient who is 'at risk' of severe malnutrition, and a fourth declare that the patient has the disease, PEM, which is mildly severe or severe.

When two tests differ in their assignment of a patient's nutritional status it could be that one, or both, of them is not telling us enough about what we want to know for clinical decision making. Alternatively, it may be that mild PEM just isn't important enough to worry about or act upon because intervening in this situation is unlikely to change clinical outcome for the better. Consider PEM in its pure manifestation, minus sarcopenia and minus inflammation; for example, PEM as it occurs in human starvation research [21], in famine areas or concentration camps, or in anorexia nervosa or intestinal angina. How confident can one be at quantifying the near-term medical risk of a medically stable patient who has pure starvation disease and a BMI of, say, 17.5? This BMI is not uncommon in the ambulatory population of many countries of the world, and on the runways at fashion shows in the wealthiest of them.

Since the discrepancies occur in the grey zone, the obvious way to deal with them is to ignore the grey zone. That is, stop worrying about the grey zone insofar as diagnosing PEM, teaching medical students and physicians about it, and enrolling patients in hard-endpoint randomized clinical trials are concerned. Such a policy would lead to some PEM being missed, but there is plenty of work to be done in the hospital setting to come to grips with clinically manifest PEM. This is not to advocate a cessation of activities aimed at detecting patients 'at risk' of PEM, but rather to advocate focusing teaching and the design of pivotal prospective clinical trials, at least for the present time, on patients who definitely have the disease, as opposed to patients who could have it or could develop it.

In an important clinical trial, Johansen et al. [22] randomized hospitalized patients whose NRS-2002 score was 3 or greater or anticipated to reach 3 or greater in the near future to standard in-hospital nutrition or an intervention consisting of intense nutritional motivation and monitoring. The intervention improved nutritional status in the intervention group, but, disappointingly, it did not lead to any important overall benefit. This negative result was not necessarily due to inadequacies in the NRS-2002. The average BMI in the intervention and control groups was 21.5, and the average NRS-2002 score was 3.5. A z-score calculation indicates that some – theoretically, one third – of the patients enrolled in the study could have had scores of <3.0. According to the criteria the assessment tool is based upon, these patients were unlikely to benefit from nutritional intervention. Their inclusion in the analysis could lead to an underestimation of the adverse consequences of PEM in the control group and an underestimation of the benefits of nutritional intervention

in the treatment group. One suggestion that emerges from that study is that in future clinical trials only patients with a score of 4 or greater be selected for intervention. Recently developed statistical techniques for subgroup analysis could be brought to bear here [23].

Terminology

It is not easy to develop valid, reliable, acceptable and convenient screening tools. Most of the nutritional screening procedures in common use have been criticized for a lack of attention to these matters [8, 9, 24–26]. The greatest challenge for developing nutritional screening tools is in the domain of content validity. Content validity is defined as a tool's relevance and completeness, its suitability in relation to its intended purpose [9]. The process used to develop the content of the NRS-2002 is an important example of establishing content validity [6, 20]. The name given to this test implies a laudable openness to future, improved versions. There is also merit in exploring validity by formally comparing the reports of different screening tools [4]. I suggest that clearer terminology would also help considerably.

More clarity will be achieved if workers in this field draw a clearer distinction than has heretofore been done, between screening for malnutrition and diagnosing PEM. Others may take a different view [6], but I regard the aims of screening, as it pertains to PEM, as (1) the efficient identification of situations, such as poor diet, in which PEM is likely to arise, and (2) the identification of plausible candidates for the diagnosis of PEM. Diagnosis has quite different aims. They are (1) to name, and (2) to serve as the key ingredient in the process of justifying and formulating the patient's treatment plan. The distinction between identifying a risk of PEM and diagnosing it has previously been pointed out [27].

A related suggestion is to avoid unqualified use of the term 'malnutrition', which can refer to all manner of nutritional problems, including 'overnutrition', but especially confusingly, is frequently used to refer to a diet which creates a risk of PEM. Poor diet is not the same as malnutrition-the-disease (PEM), and does not always lead to it. (The term 'undernutrition' is prone to the same confusion.) Another, more subtle confusion can arise from the unqualified use of terms such as 'risk' and 'risk score', which belong to the language of screening but not that of diagnosis. Thus, poor diet creates a (potentially quantifiable) risk of developing PEM, as does metabolic stress, but neither of these risk factors is the disease. Reports of the prevalence of 'malnutrition' would be easier to understand, and PEM would be easier to teach to medical students and residents, if the language of screening was kept separate from the language of diagnosis.

I take this view because PEM is not a risk, but a pathophysiological entity: a diagnosable disease that is best understood in its pure form as the disease

which results from prolonged simple starvation [28, 29]. I have found that once PEM is understood as a disease, like other diseases, the student gains the ability to discern (or at least infer) its outline and appreciate its repercussions within the mixture of sarcopenia and cachexia that is now the norm in the hospitals of the world's wealthy nations. The experience of Roubenoff et al. [13] and Cheskin et al. [14] would seem to bear this impression out.

The way PEM is defined is important for all of the activities necessary to foster a proper role for nutrition in clinical medicine: education, clinical research, administrative change, and the publication and effective dissemination of clinical practice guidelines. The definition ought to be recognizably the same in every domain. This leads me to suggest the desirability of formally incorporating the conceptual process skilled clinicians use to diagnose PEM into teaching and the design of clinical trials.

Narrative-Interpretive Medicine

This process is now understood as narrative-interpretive reasoning, and is well explained by the English physician-researcher, Trisha Greenhalgh [30]. Greenhalgh [31] explains that the business in any field of endeavor is conducted according to a set of rules and standards, referred to metaphorically as a paradigmatic 'lens', which is accepted by the workers in the field but not by people outside it. Quoting the Harvard psychologist, Jerome Bruner, Greenhalgh [32] claims that all reasoning can be divided into logico-deductive (rational, objective, scientifically verifiable; the business of evidence-based medicine) and narrative-interpretive (which has the elements of a good story). Both types of reasoning are necessary in medicine, the second no less than the first. A narrative is a sequence of events in time that is presented in such a way that a 'plot' emerges from within which discoveries and insights occur (and lead to further discoveries and insights) [31]. Narrative-interpretive understanding is what makes medicine 'sensible', and this sensibility fuels motivation and guides practice [30].

Statements of fact can be interpreted differently in different paradigms and direct the reasoner to different conclusions. This phenomenon can be illustrated by reference to two rationales for disregarding in-hospital PEM. The first argument is that when PEM develops as a consequence of a primary disease (as is almost always the case in the developed world), the physician's chief obligation is to ameliorate the disease, see that there is food on the table, and let the patient (and 'the system') take care of the rest. The second argument flows from the first, and is rather more difficult to refute; I am not even sure how often it is wrong. This argument points out that the relationship between more severe PEM and a worse clinical outcome is not necessarily causal. Sicker patients do not eat well and are catabolic, so it is almost self-evident that PEM is a marker of more serious disease, not its cause. Therefore

(in this view), except for clear-cut, extreme and unusual cases, it is a waste of time, energy and resources to make special efforts to treat PEM. By contrast, the nutritionally sophisticated paradigm appreciates that PEM is a disease in its own right: one whose pathogenesis, pathophysiology and natural history are known from a wealth of basic and clinical knowledge that goes back centuries. Workers who view medicine through this paradigmatic lens are not surprised that the known adverse consequences of PEM are the ones experienced by patients whose primary disease is complicated by PEM [1]. But logico-deductive reasoning, as portrayed in some versions of evidenced-based medicine, either will not regard this way of reasoning as valid or regards it as irrelevant, not based on 'evidence' [33, 34].

These remarks are not intended to downplay the importance of evidence of the kind that is the fodder of evidence-based medicine. Clinical trial evidence is crucial [19, 33]. Physicians, nurses and administrators will change their attitude and behavior about PEM only when they begin to regard the paradigm of PEM-as-a-disease as both acceptable (plausible) and accepted (proven).

Scoring systems may be necessary for screening, but clarity of meaning can be lost and confusion can arise when it is affirmed or implied that screening and scoring systems diagnose PEM. A scoring system should be regarded as provisional. When used for diagnosis it strips the disease of its clinical, narrative-interpretive context. A score is not a disease. Greenhalgh [30] cites the English philosopher, Alfred North Whitehead, who described the practice of regarding summary statistics as realities as 'the fallacy of misplaced concreteness'. Sixty-four years before Whitehead, the French physiologist Claude Bernard [35] was unimpressed by a contemporary scientist's announcement that he had determined the composition of 'the average European urine' by sampling the urinal of a railroad station where the citizens of all nations passed. When scores are used in the realm of diagnosis, I suggest they be used to grade the severity of the disease, or as an indicator of the need for therapeutic intervention, not to decide whether the diagnosis is correct.

Consider two hypothetical patients. The first one has severe PEM (based on physical examination) which is successfully adapted (constant body weight, no inflammation) and food intake that is reasonable for his or her estimated energy expenditure. The second patient has moderately severe PEM, active inflammation, and is not eating. A logico-deductive formalism could reduce these narratives to the same number. But the first patient probably does not require treatment as urgently as the second one, and I could foresee problems enrolling both of them in the same randomized clinical trial.

I suspect that many nutritional consultants formulate PEM diagnosis and assessment as follows: diagnosis of PEM (none, mild, serious); successful adaptation (yes/no); cachexia-inflammation (yes/no); needs intervention (yes/no); can treat (yes/no); should treat (yes/no). From the answers to these narrative questions, the consultant determines the need for intervention. Perhaps one can teach and design clinical trials along these lines.

Conclusions

In summary, the following suggestions are offered to increase the clarity of thinking about, teaching, and acting upon issues related to the screening and diagnosis of malnutrition and PEM. First, avoid unqualified use of the word 'malnutrition'; it has too many meanings. Second, although screening and diagnosis have many things in common, they have different aims. Thinking about them becomes clearer if they are explicitly distinguished from one another in teaching, observational studies and clinical trials. Therefore, distinguish between screening to detect situations which create a risk of poor diet from screening to detect a potential candidate for the diagnosis of PEM, and distinguish both of these from the act of confirming the diagnosis. Third, thoughtfully consider the claim that the diagnosis of PEM is based on narrative-interpretive reasoning. The concept of PEM as a disease (not a score) should be imbedded in teaching and the practice of medicine, and in the design of clinical trials and the setting of guidelines. Fourth, disagreements in screening-derived risk scores and uncertainty in diagnosis are difficult to avoid, but only in the grey zone. It would be prudent, at least until the greater medical world considers the nutritional paradigm plausible enough to invest in it, to enroll only patients who have unambiguously diagnosed PEM in prospective trials with hard clinical endpoints.

References

1 Corish CA, Kennedy NP: Protein-energy undernutrition in hospital in-patients. Br J Nutr 2000;83:575–591.
2 Beck AM, Balknas UN, Furst P, et al: Food and nutritional care in hospitals: how to prevent undernutrition – report and guidelines from the Council of Europe. Clin Nutr 2001;20:455–460.
3 Kondrup J, Johansen N, Plum LM, et al: Incidence of nutritional risk and causes of inadequate nutritional care in hospitals. Clin Nutr 2002;21:461–468.
4 Stratton RJ, Hackston A, Longmore D, et al: Malnutrition in hospital outpatients and inpatients: prevalence, concurrent validity and ease of use of the 'malnutrition universal screening tool' ('MUST') for adults. Br J Nutr 2004;92:799–808.
5 Mowe M, Bosaeus I, Rasmussen HH, et al: Nutritional routines and attitudes among doctors and nurses in Scandinavia: a questionnaire based survey. Clin Nutr 2006;25:524–532.
6 Kondrup J, Allison SP, Elia M, et al; Educational and Clinical Practice Committee ESo: ESPEN guidelines for nutrition screening 2002. Clin Nutr 2003;22:415–421.
7 Elia M, Zellipour L, Stratton RJ: To screen or not to screen for adult malnutrition? Clin Nutr 2005;24:867–884.
8 Jones JM: The methodology of nutritional screening and assessment tools. J Hum Nutr Diet 2002;15:59–71.
9 Jones JM: Validity of nutritional screening and assessment tools. Nutrition 2004;20:312–317.
10 Roubenoff R: Catabolism of aging: is it an inflammatory process? Curr Opin Clin Nutr Metab Care 2003;6:295–299.
11 Ling PR, Smith RJ, Kie S, et al: Effects of protein malnutrition on IL-6-mediated signaling in the liver and systemic acute phase response in rats. Am J Physiol 2004;287:R801–R808.
12 Weinsier RL, Heimburger DC: Distinguishing malnutrition from disease: the search goes on. Am J Clin Nutr 1997;66:1063–1064.

13 Roubenoff R, Roubenoff RA, Preto J, Balke CW: Malnutrition among hospitalized patients: a problem of physician awareness. Arch Intern Med 1987;147:1462–1465.
14 Cheskin LJ, Fontaine KR, Lasner LA, et al: Improved detection of malnutrition by medical housestaff following focused-teaching intervention. J Gen Intern Med 1996;11:548–550.
15 Baker JP, Detsky AS, Wesson DE, et al: A comparison of clinical judgment and objective measurements. N Engl J Med 1982;306:969–972.
16 Jeejeebhoy KN: Clinical and functional assessments; in Shils ME, Olson JA, Shike M (eds): Modern Nutrition in Health and Disease. Philadelphia, Lea & Febiger, 1994, pp 805–811.
17 Vellas B, Villars H, Abellan G, et al: Overview of the MNA – its history and challenges. J Nutr Health Aging 2006;10:456–463.
18 McWhirter JP, Pennington CR: Incidence and recognition of malnutrition in hospital. BMJ 1994;308:945–948.
19 Stratton RJ, Green CJ, Elia M: Disease-Related Malnutrition: An Evidence-Based Approach to Treatment. Cambridge, CABI, 2003.
20 Kondrup J, Rasmussen HH, Hamberg O, Stanga Z; Ad Hoc ESPEN Working Group: Nutritional risk screening (NRS 2002): a new method based on an analysis of controlled clinical trials. Clin Nutr 2003;22:321–336.
21 Keys A, Brozek J, Henschel A, et al: The Biology of Human Starvation. Minneapolis, University of Minnesota Press, 1950.
22 Johansen N, Kondrup J, Plum LM, et al: Effect of nutritional support on clinical outcome in patients at nutritional risk. Clin Nutr 2004;23:539–550.
23 Kent D, Hayward R: When averages hide individual differences in clinical trials. Am Sci 2007;95:60–68.
24 Jones JM: Development of a nutritional screening or assessment tool using a multivariate technique. Nutrition 2004;20:298–306.
25 Jones JM: Reliability of nutritional screening and assessment tools. Nutrition 2004;20:307–311.
26 Corish CA, Flood P, Kennedy NP: Comparison of nutritional risk screening tools in patients on admission to hospital. J Hum Nutr Diet 2004;17:133–139.
27 Elia M, Stratton RJ: How much undernutrition is there in hospitals? Br J Nutr 2000;84:257–259.
28 Hoffer LJ: Clinical nutrition: protein-energy malnutrition in the inpatient. CMAJ 2001; 165:1345–1349.
29 Hoffer LJ: Metabolic consequences of starvation; in Shils ME, Shike M, Ross AC, et al (eds): Modern Nutrition in Health and Disease. Philadelphia, Lippincott Williams & Wilkins, 2006, pp 730–748.
30 Greenhalgh T: Narrative based medicine: narrative based medicine in an evidence based world. BMJ 1999;318:323–325.
31 Greenhalgh T, Robert G, Macfarlane F, et al: Storylines of research in diffusion of innovation: a meta-narrative approach to systematic review. Soc Sci Med 2005;61:417–430.
32 Greenhalgh T: Can 'anecdote' ever be research? Fam Pract 2005;22:1.
33 Greenhalgh T: Intuition and evidence – uneasy bedfellows? Br J Gen Pract 2002;52:395–400.
34 Heaney RP: Nutrition, chronic disease, and the problem of proof. Am J Clin Nutr 2006;84:471–472.
35 Bernard C: An Introduction to the Study of Experimental Medicine. New York, Dover, 1865.

Discussion

Dr. Elia: You talked about disease going to malnutrition, but I would argue that it is not unidirectional. Malnutrition can also predispose to disease and one can feed from the other. If a patient has a pathological process he might have malnutrition just from lack of food, predisposing to disease. Is that pathology? Essentially, malnutrition may initially not be complicated by disease; it can predispose to disease because all bodily functions are impaired. It is a slight variation. I want to know if that is what most people believe here? I'd be interested in some feedback on this because a few of us might feel differently about this.

Dr. Hoffer: I have tried to mimic what the clinician goes through, and there are two questions that everyone who does nutritional consultations asks, and the answers do not appear in any of the nutritional assessment tools that I have described. One is can this malnutrition be treated, and the second is should this malnutrition be treated? The answers to these questions will change the profile.

Dr. Elia: I think that is absolutely vital because if you have a unidirectional flow, with no impact of malnutrition on the pathway leading to death, then the potential for intervention and the response to intervention are likely to be small and therefore of little value. Therefore, the discipline just doesn't evolve. If, on the other hand, there is some role in the causal pathway, then there is some potential for interventions. It is absolutely crucial.

Dr. Hoffer: I would go further and say that people have fixed beliefs, and these are based on what they were taught, often forgotten, but their beliefs remain embedded. For me, the mission is educational and education is crucial to change. Not just educating medical people but also administrators who care about nutrition. If you ask administrators in hospitals what they would like done with regard to their own care or that of a loved one who develops illness and weight loss, that is a narrative question, it is the story of their lives. It is crucial and we can't abandon the power of that.

Dr. Bistrian: Because it is so important we had all those trials in diet, nutrition and cancer, where nutritional support had no effect at all. It added fat but had no effect on prognosis. The problem is that this paradigm is used against us, saying, obviously, these people are malnourished and nutrition does no good. We have to say that there are certain instances where the pathological process of the disease will produce malnutrition as a byproduct but this is not why death occurs. They will die malnourished and feeding them will not do much in terms of repair. We have to accept that there are conditions for which we have no effective nutritional therapy, even though protein-energy malnutrition (PEM) is a consequence of a disease process, e.g. HIV, heart therapy, etc. But there are many other diseases for which PEM is a component and it can be effectively dealt with by nutrition. We are aware of this and need to distinguish between the two.

Dr. Hoffer: That is exactly my view. Because of some of the things that I have heard about nutrition around the world, I think we have to be careful not to take too big a bite in terms of malnutrition or we will enter into global sociopolitical issues. Nutrition and nutrition intervention have to have some humility. We can't solve all of the problems of nutrition, which is why I am suggesting focusing on the most important problems, and then I'd like a more explicit categorization there. The patients who should be treated are the ones who should be studied. Demonstrations are necessary, clinical trial results are necessary, but don't design clinical trials unless you have a really impressive outcome. Just don't do the trial if you are not going to have an impressive outcome.

Dr. Kondrup: Where did you get the idea that NRS 2002 is built on the Malnutrition Universal Screening Tool (MUST)? That is a mistake.

Dr. Hoffer: I misunderstood; the first three points, scores 0–3 are MUST. *Dr. Kondrup:* There is a similarity. We started using the NRS 2002 in Denmark in 1997 long before MUST appeared, and it took some years before ESPEN got the work done.

Dr. Elia: It is quite possible for concepts to develop in parallel ways from a different source. Although there are common elements, I don't think that one really evolved from the other. There are common conceptual elements but the reasoning taken for each was based on different principles. They used the evidence-based approach and

we used a physiological type of approach with outcome measures, but the two did develop independently.

Dr. Elia: There are a lot of other nutrition screening tools that still have common elements. The trouble is that, when I reviewed the situation a few years ago, there were at least 70 published nutrition screening tools and probably many other unpublished nutrition screening tools. Although you focused on some of the most commonly used ones, there are a lot of others that really might not perform as well. In fact, some of them differ not only in their agreement but the prevalence of malnutrition detected by two different tools in the same patient, which can sometimes differ 2-, 3- and even 4-fold. That is quite a sobering thought. That is one potential problem from the uncritical use of nutrition screening tools. The other thing to consider is that these nutrition screening procedures could be carried out by a variety of different healthcare workers, and how they use and apply it may differ depending on the training they have had. Nutritional education is important for almost any tool.

Dr. Hoffer: I want to make a tactical point. By saying ignore the grey zone, I meant that if we talk about the prevalence of malnutrition as 70–80%, it will not be believed. If one wants to be tactical, one has to focus. Administrators might think that nutritionists want to take over their office and run the hospital. We have to ask if this is a rational, reasonable and persuasive number; it is just so outlandish, and it may be correct, but it cannot be. It cannot be applied to the real world of clinical practice.

Dr. Elia: I agree, but of course the prevalence of malnutrition may vary considerably from ward to ward: in a terminal care cancer ward or an elderly ward or a ward of anorectics, it may be close to 80%. Comparisons that have been made using the same tool, and one person may diagnose 20% malnutrition compared to 80% by another. Other tools would be closer to 20%. I think that rationality is so important. These tools must not be used uncritically.

Dr. Labadarios: For arguments sake, what is to prevent administrators from saying, our statistics look alright so it is not important to treat? If it is not a serious problem but a consistent one recurring over many years, and nothing is done about it, how important is it?

Dr. Elia: It can be argued that almost everyone who comes to hospital has a disease, so it is a recurring consistent problem, that is the baggage that comes with it.

Dr. Kondrup: How do you define the PEM? We need some rather strict objective criteria both for the purpose of making controlled studies and for initiating this quality management process.

Dr. Hoffer: There are two answers. First, ignore the grey zone, in which case many of the problems disappear. I am not saying forever, but I think nutrition's credibility/visibility is in jeopardy. So, ignore the grey zone. My preference as a physician, who thinks like a physician and teaches medical students, is to prefer a process that diagnoses the existing disease. I like subjective global assessment, which I intuitively use, or something similar. The MUST comes very close to that for me, and the method of McWhirter and Pennington [1] is not too bad actually, as long as you do away with the grey zone. With subjective global assessment, there are lots of problems and wishy-washiness in the grey zone. Jeejeebhoy et al. [2] thought that the grey zone need not be considered malnutrition. If the grey zone is not considered malnutrition, then we don't have to worry about it too much. I think that if you ignore the grey zones, you could use many of these tools; they would converge and you would have your cases. Anyone practicing clinical medicine would know within 5 min of coming to the bedside. You know what the disease is and you don't have to be embarrassed about it, it is not unscientific or evidence-free, it is the practice of clinical medicine.

Dr. Jensen: I thought the narrative description you gave was fascinating. I want to be a little provocative and describe an approach to screening that I have been dying

to try that really encompasses what you describe. Understand that much of this joint commission-mandated screening in the United States is done without even seeing the patient. It is very common for nurse extenders or other staff to go to a computer and the patient's chart and try to abstract an albumin from it that may be unrelated to what is going on, use unreliable weights, and basically of little validity. I propose that it would be fascinating to test the following as an intake screening tool: simply send a physician extender into the patient's room, they should ask three questions, look at the patient, and walk out. The first question to the physician extender is: does the patient appear malnourished; does the patient look undernourished? Two, is the patient underweight? Three, is the patient losing weight? Four, is the patient having difficulty? This interpretive information that the extender walks out with, I would contend, could be as reliable, if not more so, than many of the elaborate tools that we have been testing and developing.

Dr. Hoffer: I agree with you and that is probably how you and I practice medicine. We get a feeling very quickly. I am not trying to demean screening, it is crucial; screening tells you which room you should walk into.

Dr. Jensen: Specifically, I am not proposing to use skilled clinicians for this, a nurse's aide is adequate. We are already screening all over the place. The level of expertise that we are talking about here is not substantial.

Dr. Hoffer: It has been shown that it is very easy to teach this skill.

Dr. Labadarios: These pictures are not difficult to describe but there is always the grey area, which we must get rid of. I was rather fascinated by a statement you made, 'all nutrition problems will not be solved'. Now I ask you why, and is one of the reasons that we don't know what we are doing?

Dr. Hoffer: What is being lauded as a great accomplishment of 21st century medicine is the reduction in cardiovascular disease risk. We are reducing the burden of disease by something like 25%. What about the other 75%? Nobody is saying that cardiology has failed because it didn't eliminate heart disease. Nutrition is even harder. Malnutrition was what the human race evolved to survive and, with some confidence, I predict that when the human race is extinguished, there will be massive malnutrition. Malnutrition is with us to stay, and all we can do is pick out the aspects where we can make an impact. We have to be somewhat humble here. First, you have to treat and correct to persuade the non-paradigmers. Once they are persuaded and have accepted your paradigm, you can move to prevention. This isn't a golden rule or a dictatorial statement but a suggestion for a strategy.

References

1 McWhirter JP, Pennington CR: Incidence and recognition of malnutrition in hospital. BMJ 1994;308:945–948.

2 Jeejeebhoy KN, Detsky AS, Baker JP: Assessment of nutritional status. JPEN J Parenter Enteral Nutr 1990;14(suppl):193S–196S.

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Enteral Nutrition Reimbursement – The Rationale for the Policy: The US Perspective

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Abstract

Enteral nutrition (EN) is generally defined by third party payers as tube feeding for patients who cannot take food orally. EN is widely accepted in the United States as an effective, often life-sustaining therapy. Coverage and payment policies for EN differ among payers and settings. These differences often may depend on whether EN is reimbursed as a discrete therapy or subsumed into a larger benefit. In the US, the Medicare and Medicaid programs are the major public payers for EN. EN may be susceptible to overuse, especially in the long-term care setting. The trends in coverage and payment for EN suggest tighter reimbursement; competitive bidding between suppliers and data-driven performance measurement and payments may be in the future for EN reimbursement.

Introduction

Enteral nutrition, generally defined by third party payers as tube feeding for patients who cannot take food orally, has been covered in the United States by public and private payers for several decades in a variety of care settings. This paper provides an overview of how these payers cover and pay for enteral nutrition, the factors that influence their policies, and trends that could affect these policies in the future.

The topic of enteral nutrition coverage is often not very straightforward because in several important instances enteral nutrition is not covered for what it is. Rather, it often has been shoe-horned into an ill-fitting coverage niche that creates confusion and uncertainty. In addition, while enteral nutrition is increasingly seen as a cost-effective alternative to parenteral nutrition, policymakers' general

concerns about possible fraud and abuse activities within the Medicare program have affected their perceptions of enteral nutrition (and many other product and therapy areas) and will undoubtedly continue to do so in the future.

Public Payers: Coverage and Reimbursement for Enteral Nutrition under Medicare

Introduction to Medicare

Medicare, the federal health insurance program for individuals over 65 and the permanently disabled administered by the Centers for Medicare and Medicaid Services (CMS) within the Department of Health and Human Services (DHHS), is a critical and influential source of coverage for enteral nutrition. Given the size and scope of the Medicare program, it influences coverage and reimbursement policies of other public and private payers. Medicare now covers nearly 43 million beneficiaries [1].

Medicare has several programs of relevance to enteral nutrition: Part A, Part B, and Part C. Part A covers inpatient hospital costs, excluding physicians services (which are covered under Part B), as well as costs of skilled nursing facilities and home healthcare under certain conditions. Part B is the medical insurance portion of Medicare, which covers the cost of physician services, outpatient hospital care, and medical supplies and equipment. Under Part C, known as the Medicare Advantage (MA) program, privately managed care companies contract the federal government to offer inpatient and outpatient benefits to Medicare beneficiaries through their own policies.

Inpatient Hospital Coverage for Enteral Nutrition through Medicare Part A

Enteral nutrition provided in an inpatient hospital setting may be covered under Medicare Part A. Medicare coverage extends to medications, medical supplies and equipment that are determined to be reasonable and medically necessary.

Medicare Part A reimburses providers of inpatient hospital services through an inpatient hospital prospective payment system (PPS) that sets a single payment amount for a type of patient case based on the patient's primary diagnosis [2]. Psychiatric, rehabilitation, children's, long-term care and certain cancer hospitals and units, among others, are excluded from the inpatient hospital PPS. Generally, Medicare reimburses these excluded hospitals based on reasonable costs. However, recent legislation has called for the implementation of PPS in rehabilitation, long-term care, and psychiatric hospitals.

Under the inpatient hospital PPS, each patient's case is categorized into one of approximately 530 diagnosis-related groups (DRGs) in 25 diagnostic categories [3]. Each DRG has a payment weight assigned to it, based on the average resources used to treat Medicare patients in that group. Beginning in

2007, DRG weights will be based on hospital costs rather than hospital charges, leading to potentially lower reimbursement rates [4]. There are a number of DRGs that may be used to classify patients receiving enteral nutrition.

While the DRG system sets predetermined payment rates for all cases within a DRG, additional payments are possible for exceptionally costly cases, known as outliers, to protect hospitals from potentially large financial losses in these cases and to ensure that hospitals have the appropriate financial incentive to accept such patients. An outlier must have costs that exceed prospective Medicare payments by a fixed amount [5]. (Previously, a case could also qualify for outlier payments if the patient had an exceptionally long length of stay compared to other patients in that DRG, but these 'day outlier' payments were phased out ending in 1998.) In addition, reimbursement may be altered based on the presence of a secondary condition at the time of admission (comorbidity) or which develops after admission (complicating condition) that results in a longer hospital stay. Secondary diagnoses of malnutrition or other nutrition-related conditions can qualify as comorbidities or complicating conditions, potentially allowing for additional reimbursement.

Medicare Part A does not dictate precisely how enteral nutrition must be provided for a hospital to receive payment. As Medicare pays hospitals a fixed prospective rate based on patient diagnosis rather than for the individual treatments provided, hospitals have incentives to contain costs while providing appropriate care. Each hospital thus has discretion as to the proper use of nurses, dietitians, and other health professions in the provision of enteral nutrition. Medicare has established federal quality standards for hospitals known as Conditions of Participation, but these conditions do not specifically address enteral nutritional therapy. The current condition related to nutrition services requires hospitals to meet the nutritional needs of patients 'in accordance with recognized dietary practices . . . and orders of the practitioner or practitioners responsible for the care of patients' [6].

CMS is beginning a Hospital Quality Initiative, wherein hospital reimbursement eventually will be linked to performance on designated quality measures. The clear trend in Medicare is to link payment to performance, whereby payments may be modified (up or down) based on compliance (or lack of compliance) with certain measurements. CMS recently published regulations requiring hospitals to collect and submit data on 21 clinical quality measures related to acute myocardial infarction, heart failure, pneumonia, and surgical care improvement. Hospitals that do not submit data will not receive a full update in the inpatient PPS rates for fiscal year 2008. Eventually, quality measures could be expanded to include nutrition care.

Medicare Part B Coverage and Reimbursement for Home Enteral Nutrition

As described above, Medicare Part B is the medical insurance portion of Medicare that covers the cost of physician services, outpatient hospital care,

and medical supplies and equipment. This coverage may be increasingly important to the enteral nutrition community, as patients and government programs are increasingly moving in the direction of home care as a cost-effective alternative to inpatient hospital care. Medicare Part B covers enteral nutrition in the home and in nursing homes for patients who do not qualify for Part A skilled nursing care. Historically, the majority of Part B enteral patients have resided in nursing homes, although the division of enteral patients between home care and nursing home care is approaching 50–50. Part B enteral suppliers primarily are durable medical equipment (DME) companies or infusion pharmacies.

Coverage

Since 1981, Medicare Part B has covered enteral nutrition in the home and alternate care settings under the prosthetic device benefit. How this came about is an interesting example of creative policymaking. Medicare coverage for an item or service can be established in one of two ways: Congress can mandate coverage through legislation which CMS then implements through regulation or Medicare manual instructions, or CMS can establish coverage without an authorizing statute through regulations or manuals by establishing coverage for an item or service within an existing coverage policy. CMS decided to cover enteral nutrition based on a House Ways & Means Committee report from the 1980 Omnibus Budget Act suggesting that DHHS should consider covering enteral nutrition in the home setting as a cost-effective alternative to inpatient care. However, as report language simply indicates congressional intent but does not have the force of law, CMS had to find an existing niche into which it could fit enteral nutrition. CMS considered several options, including the home health benefit, the DME benefit, and the prosthetic device benefit.

To qualify for the home health benefit, patients must be homebound, i.e., be in such a condition that 'there exists a normal inability to leave home and, consequently, leaving their homes would require a considerable and taxing effort usually requiring the use of supportive devices such as crutches, cranes, wheelchairs, walkers, or the assistance of another person' [7]. Most home enteral patients would not meet this criterion, and thus CMS rejected this option. CMS also considered using the DME benefit because a significant number of enteral suppliers would likely be DME companies. However, Medicare does not cover DME in nursing homes, where close to 80% of the enteral patient population was located at the time, so this option was discarded.

Ultimately, CMS determined that the prosthetic device benefit would enable Medicare to reach the highest number of beneficiaries without the limitations of the other options. CMS reasoned that the tube can be likened to a replacement for a body part – in this case, a part of the digestive tract – thus meeting the literal definition of a prosthetic device. And, to make coverage of the tube meaningful, CMS also decided to cover the nutrients that flow through the

tube as well as the enteral pumps that may be used in the provision of the therapy. However, as a result of this decision, enteral nutrition must satisfy the coverage requirements of the prosthetic device benefit.

Clinical Conditions

CMS has developed detailed requirements related to the clinical conditions for which enteral therapy is covered. Under Medicare guidelines, all enteral nutrition claims must be approved on a case-by-case basis. The prosthetic device benefit requires that the patient has 'a permanently inoperative internal body organ or function thereof' [8]. CMS further defines this requirement as follows:

> Enteral nutrition is considered reasonable and necessary for a patient with a functioning gastrointestinal tract who, due to pathology to, or nonfunction of, the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general condition [8].

The requirement that there be a permanent injury or malfunction received a lot of attention when enteral nutrition was first placed in the prosthetic device benefit. In selecting the prosthetic device benefit as the coverage niche for enteral nutrition, CMS realized that this requirement, taken literally, made little sense for a patient who may need enteral nutrition for some period of time after surgery. CMS ultimately decided the issue by ruling that permanent injury means being of a long and indefinite duration, which was further refined for enteral nutrition to mean at least 90 days. Thus, enteral nutrition for a prescribed period that is less than 90 days is not covered under Part B.

Medicare Part B does not cover enteral nutrition for patients who have a functioning gastrointestinal tract but nevertheless have nutritional needs due to cognitive disorders such as anorexia, mood disorders, Alzheimer's disease, etc. Though these conditions can make chewing and swallowing difficult, the malfunctioning organ or body part under these circumstances is not the gastrointestinal tract. There may, however, be specific instances in which documentation of a patient's functional inability to swallow can satisfy the coverage requirements.

Importantly, Medicare Part B does not cover enteral nutrition that is orally administered. At the time that CMS decided to cover enteral nutrition in 1981, it was thought that if a formula could be consumed orally, then it was simply food and not a medical treatment. In addition, there were concerns that continue to be present about high costs and potential abuse if the formulas could be taken orally.

The Medicare program carefully monitors the use of enteral nutrition in nursing homes to protect against overuse and possible abuse. The concerns center around the possibility that a thinly staffed nursing home may opt to put some of their residents on tube feeding rather than bring them to the dining halls and assist in their oral feeding.

Enteral Pump Coverage

If patients require the use of a pump due to complications with a syringe or gravity method of administration, the medical necessity of the pump must be justified and documented or coverage will be denied as not medically necessary [9]. In actual practice, however, especially in light of the more sophisticated enteral formulas introduced into the market over the past decade, enteral pumps are considered to be medically necessary in most situations.

Product Coding

For the purpose of standardizing claims processing, Medicare suppliers must classify the enteral nutrient, supply, or pump provided using the appropriate Healthcare Common Procedure Coding System (HCPCS) code. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) made the use of HCPCS mandatory for transactions involving healthcare information. Enteral nutrition codes are grouped into codes B4000 through B9999, with enteral nutrition formula products into seven codes or product categories. Medicare recently expanded the number of codes available for classifying enteral nutrition to better group products of similar composition and like ingredients. However, it is important to note that some codes continue to group non-substitutable products. For example, B4154 is used to classify nutritionally complete formulas for special metabolic includes diabetes, hyperglycemia, renal failure, pulmonary disease, and respiratory illness.

Reimbursement

Equipment

Patients may rent or purchase enteral nutrition pumps and intravenous poles. Medicare pays for rental pumps on a monthly basis [10], but for no more than 15 months. Suppliers are also entitled to periodic maintenance and servicing payments on rental equipment, even after the 15th month of use [11].

Formulas and Supplies

From 1981, when Medicare Part B coverage for enteral nutrition began, through 2001, enteral nutrition was reimbursed on the basis of reasonable charges submitted by enteral suppliers. Beginning January 1, 2002, Medicare changed from a reasonable charge-based payment methodology for enteral nutrition to a fee schedule, as authorized by Section 4315 of the Balanced Budget Act of 1997. At the time, enteral nutrition was one of the few remaining therapies reimbursed on the basis of reasonable charges. In actual effect, the change to a fee schedule has not modified reimbursement to a great extent because the first year of the fee schedule was required to be budget neutral. CMS basically used the prior reasonable charge amounts as the initial fee schedule.

The fee schedule provides a single payment amount per HCPC code. For formulas, the amount reimbursed is then determined based on the number

of units of formula used, with a unit defined as 100 kcal. Fee schedules are updated annually by the change in the CPI-Urban Index, unless Congress enacts a payment freeze or reduction (enteral nutrition payments have been frozen by Congress on several occasions since the 1980s).

Medicare Competitive Acquisition Program

In the Medicare Modernization Act of 2003, Congress directed CMS to develop and phase-in a national competitive acquisition program for most Part B therapies, items and services. The first phase of this new program will begin during the fourth quarter of 2007 in 10 metropolitan statistical areas (MSAs). The program must be expanded to 80 of the largest MSAs in 2009 and to additional MSAs thereafter.

This competitive acquisition program is a significant departure from the traditional Medicare program in that it will purposely limit the number of Part B suppliers available to provide Part B-covered therapies, items and equipment in competitive bidding areas. Importantly, Congress also mandated that CMS develop quality standards that would apply to virtually all Part B items and services, regardless of whether the particular items or services are subjected to the competitive acquisition program. Congress clearly thought that the application of quality standards to the competitive acquisition program would ensure that beneficiaries would receive care in compliance with the standards, despite the financial pressures on suppliers to bid lower than current payment levels.

As of this date, the final regulation implementing the competitive acquisition program has not been issued. It is not clear at this juncture whether enteral nutrition will be included in the first phase of the program. There are reasons to suspect that enteral nutrition could be included in the first phase, principal among them being that Medicare expenditures for enteral nutrition rank fourth among expenditures for all items potentially subject to the competitive acquisition program. On the other hand, there are strong arguments why enteral nutrition should be exempted from the competitive acquisition program. Enteral nutrition is the only area possibly subject to competitive acquisition where the majority of the patients reside in long-term care facilities rather than in their homes. This creates a complicating dynamic and involves integrating another setting and a different type of provider (long-term care facilities) into what is already a complex and largely untested new system. CMS is expected to clarify which items will be subject to competitive acquisition within the next month of this writing.

Medicare Reimbursement for Enteral Nutrition Provided in Skilled Nursing Facilities

The Medicare program pays for care provided in a skilled nursing facility (SNF) under Part A according to a PPS in which providers are reimbursed on a per diem basis for covered services. Prior to the enactment of the SNF PPS,

Medicare reimbursed facilities based on a retrospective reasonable cost basis. To account for differing patient needs under this prospective system, per diem payments are case-mix adjusted based on assignment of patients to 1 of 53 Resource Utilization Groups III (RUG-III). RUG-III further organizes these patient types into 9 broader categories: Rehabilitation, Rehabilitation plus Extensive, Extensive Services, Special Care, Clinically Complex, Impaired Cognition, Behavior Problems, and Reduced Physical Function, and designates groups of patients for whom SNFs should receive higher payment. The medical need for enteral nutrition may allow patients to be classified in the Extensive Services, Special Care, and recently added Rehabilitation plus Extensive categories for which higher payments are available to better account for higher costs of medically complex patients [12, 13]. Thus, assuming that a patient meets the conditions for Medicare coverage of SNF services, the provision of enteral nutrition could lead to higher reimbursement for the SNF. To receive payment for SNF coverage, the 'beneficiary must have been an inpatient of a hospital for at least 3 consecutive calendar days … and must have been transferred to a participating SNF within 30 days after discharge from the hospital[;] the SNF care services must be needed for a condition that was treated during the hospital stay, or for a condition that arose while in the SNF for treatment of a covered condition[;] and the services must be reasonable and necessary to diagnose or treat the beneficiary's condition' [14].

Coverage of Enteral Nutrition by Medicare Advantage Plans

The vast majority of MA plans are based on the Medicare Part A and Part B coverage policies. However, there is some variation in plans, particularly in instances when a payer tacks a MA plan on to a commercial product. While some MA plans strictly follow Medicare's requirements for medical necessity, a general selling point of the MA program is that plans can cover more than traditional Medicare. The MA plans provide at least the same coverage for enteral nutrition as are provided under Parts A and B of the program, and plans have the flexibility to provide more expansive coverage.

Public Payers: Coverage of Enteral Nutrition under State Medicaid Programs

The other major source of public coverage for enteral nutrition is the Medicaid program. Medicaid provides healthcare coverage for over 55 million low-income people. It is also a primary source of financing for long-term care services, with the majority of Medicaid spending (70%) attributable to the elderly and people with disabilities [15].

Medicaid is jointly administered and funded by the states and the federal government. The states administer Medicaid within broad federal guidelines

and subject it to oversight by CMS. The Medicaid statute sets out certain minimum services that state programs must provide and populations that must be covered. Within these broad guidelines, states have considerable discretion regarding eligibility, benefits, and provider payments, leading to variation in coverage of enteral nutrition among Medicaid programs. In addition, states can offer additional benefits, such as a drug benefit, at their discretion. Increasingly, DHHS is granting waivers to the states that allow further flexibility to deviate from federal guidelines, in some instances to provide coverage beyond federal limits and in others to implement more efficient programs.

Variation in Medicaid Coverage Standards for Enteral Nutrition in Outpatient and Home Care Settings

Not surprisingly, coverage of enteral nutrition varies across states. State Medicaid programs generally cover and reimburse enteral nutrition in inpatient hospital settings as they pay for inpatient benefits. With respect to enteral nutrition provided in an outpatient or home setting, although Medicare coverage standards have influenced coverage in Medicaid, states deviate in important ways from some Medicare requirements. Some states have relaxed restrictive requirements linked to Medicare coverage of enteral nutrition as a prosthetic device, and states may cover enteral nutrition as part of a DME benefit, a pharmacy benefit, or a standard medical benefit [16].

A recent survey of State Medicaid programs by the Government Accountability Office (GAO) [17] compared coverage standards of Medicaid programs with Medicare's main coverage requirements, using the following criteria:

- Pathology: The patient has to have a pathology or nonfunction of the structures that normally permit food to reach the small bowel (e.g., inability to swallow), which impairs the ability to maintain weight and strength;
- Permanent Condition: The impairment has to be considered a permanent condition, (i.e., lasting at least 3 months);
- Tube Feeding: The patient's condition must necessitate tube feedings to provide sufficient nutrients to maintain weight and strength (i.e., the patient must be unable to obtain adequate nutrition through dietary adjustment and/or oral supplements);
- Partial Impairments: The program will cover enteral nutrition for patients with partial impairments, as Medicare does, and
- Documentation: Specific documentation has to be provided in the patient's medical record.

The GAO also obtained information on whether the state covers orally administered enteral nutrition products, which Medicare Part B does not (table 1; see column indicating that states cover orally administered 'products and supplies').

Table 1. Reported Enteral Nutrition therapy coverage standards by the state Medicaid program. [a] Patient has to have a severe pathology or non-function of the structures that normally permit food to reach the small bowel, which impairs the ability to maintain weight and strength. [b] The impairment has to be considered a permanent condition, i.e., lasting at least 3 months. [c] The patient's condition must necessitate tube feedings to provide sufficient nutrients to maintain weight and strength. [d] Enteral nutrition for patients with permanent impairments is possible. [e] The state covers enteral nutrition products and related supplies that are administered orally. [f] Specific documentation related to enteral nutrition has to be provided in the patient's medical record. [g] For acute care adult patients, enteral nutrition must be the sole source of nutrition. [h] For adults, enteral nutrition is covered only if it is the sole source of nutrition. [i] For adults and children, enteral nutrition must provide 51% or more of caloric intake. [j] For adults, the tube feeding criterion is only applicable in home health delivery settings. [k] The state does not require documentation for adults. Excerpt from GAO-06-63, pp 38–39. Source: GAO survey of state Medicaid programs

State	Pathology[a]	Permanent condition[b]	Tube feeding[c]	Partial impairment[d]	Products and supplies[e]	Documentation required[f]
Alabama	⊗	⊗	●	⊗	○	●
Alaska	●	●	●	●	●	●
Arizona[a]	●	⊗	●	●	●	●
Arkansas[h]	◉	⊗	⊗	○	○	●
California	●	⊗	⊗	●	●	●
Colorado	●	⊗	●	●	●	●
Connecticut	●	⊗	●	●	●	⊗
Delware	⊗	⊗	●	●	●	●
District of Columbia	●	●	●	●	○	●
Florida	●	⊗	◉	●	●	●
Gerorgia	●	●	●	●	⊗	●
Hawaii	●	⊗	◉	●	●	●
Idaho	⊗	⊗	●	●	●	●
Illinois	●	⊗	⊗	●	●	●
Indiana	●	⊗	●	⊗	●	●
Iowa[i]	●	●	●	●	●	●
Kansas	◉	●	●	○	○	●
Kentucky[j]	⊗	⊗	◉	●	●	●
Louisiana[k]	⊗	⊗	⊗	●	●	⊗
Maine	●	●	●	●	●	●
Maryland	⊗	⊗	◉	⊗	⊗	●
Massachusetts	⊗	⊗	●	●	●	●
Michigan	●	⊗	●	●	●	●
Minnesota	●	⊗	⊗	●	●	●
Mississippi	◉	◉	◉	○	○	●
Missouri	⊗	⊗	●	⊗	◉	◉
Montana[l]	●	●	●	●	○	●
Nebraska	●	⊗	●	●	●	⊗
Nevada	●	⊗	●	●	⊗	●
New Hampshire	⊗	⊗	⊗	●	●	●
New Jersy	⊗	⊗	⊗	●	●	●
New Mexico[m]	●	⊗	●	●	●	●
New Youk	⊗	⊗	⊗	●	●	●
North Candina	⊗	⊗	●	●	⊗	●
North Dakota	●	●	●	●	●	●
Ohio	●	●	⊗	●	●	●
Oklahoma[n]	○	○	○	○	○	○
Oregon	●	⊗	⊗	●	●	●
Pennsylvania	⊗	⊗	⊗	⊗	●	●
Rhode Island	◉	◉	⊗	●	●	●
South Carolina[o]	●	●	●	●	●	●
South Dakota	◉	◉	●	●	●	●
Tennessee	●	◉	●	●	●	●
Texas	●	●	●	●	●	●
Utah	●	⊗	●	●	⊗	●
Vermont	●	●	●	●	●	●
Virginia	●	○	●	●	○	●
Washington	●	⊗	⊗	●	●	●
West Virginia	⦸	⦸	⦸	⦸	⦸	⦸
Wisconsin[o]	●	⊗	●	●	●	●
Wyoming	●	◉	●	◉	⊗	●

● Applies to both adults and children
◉ Applies to adults only
○ Applies to children only
⦸ State does not cover therapy
⊗ Coverage standard or requirement does not apply

This survey clearly illustrates the variation among states and between the Medicaid and Medicare programs (table 1). As of 2005, all state Medicaid programs, except West Virginia's, provided some coverage for enteral nutrition. The greatest deviation from Medicare standards centers on the requirements that the condition be permanent (last more than 3 months) and the lack of coverage for orally administered nutrition.

- Thirty states do not require that the impairment be a permanent condition in order to cover enteral nutrition, with an additional 4 applying this requirement only to adults, and 2 applying it only to children. For example,
- More than half of all states choose to cover orally administered nutrition therapy, with 34 covering it for both adults and children, and 8 states covering it for children only.

To a lesser extent, states also deviate from the required Medicare pathology, with 12 states not requiring this pathology, 5 requiring it only for adults and 2 only for children. On the other hand, like Medicare, nearly all states require specific documentation of enteral therapy in the medical record. Twelve states tend to have less restrictive coverage standards for children [15].

The GAO also found that state Medicaid programs vary in coverage of enteral nutrition supplies in home health and outpatient delivery settings (table 2). As the GAO concluded:

> Based on our survey, state Medicaid programs' payment for seven of the most commonly used enteral nutrition supplies varies depending on the type of product, delivery setting, and whether the patient is an adult or a child. Table 2 shows that states reported that their Medicaid programs pay for enteral feeding supply kits and tubing more than other therapy supplies. In addition, more states pay for enteral supplies for children than adults and more states pay for supplies in outpatient delivery settings than in home health delivery settings.
>
> Further analysis revealed that 15 states pay for all 7 supplies listed in our survey in both home health and outpatient delivery settings for adults and children. Thirty states pay for five or more enteral nutrition supplies for adults and children in these same settings. We also found that additives for enteral formula, such as fiber, are the least covered product, with only 21 states covering it in both home health and outpatient delivery settings for adults and children [17].

Coverage and Reimbursement of Enteral Nutrition by Private Third-Party Payers

Private payer coverage of enteral nutrition varies depending on the particular benefit. While Medicare Part B covers enteral nutrition under the prosthetic device benefit, private payers may cover enteral nutrition as part of an infusion benefit, a home medical equipment benefit, or even under a drug benefit.

Table 2. State Medicaid programs that reported payment for common enteral nutrition therapy supplies for adults and children in home health and outpatient delivery settings

Supplies	Adults		Children	
	home health	outpatient	home health	outpatient
Enteral formula	35	42	37	44
Enteral feeding supply kit	40	45	43	46
Tubing	41	48	42	46
Additive for enteral feeding	22	28	24	30
Enteral nutrition infusion pump	38	40	40	42
Intravenous pole	38	40	40	42
Percutaneous catheter/tube	30	33	31	38

Excerpt from GAO 06-63, p 21. Source: GAO survey of state Medicaid programs.

Product Coding

Most private sector payers must use Medicare HCPCS codes to classify products for claims processing. Private payers, like Medicare, have adopted HCPCS codes in an attempt to standardize the codes used by different payers and providers and to comply with HIPAA standards for healthcare-related transactions. When CMS added additional HCPCs for enteral nutrition to separate adult formulas from pediatric and children's formulas, private payers followed suit.

Private sector payers also employ 'per diem' S-codes, created 'to report drugs, services and supplies for which there are no national codes; but for which codes are needed by the private sector to implement policies, programs, or claims processing' [18]. The per diem code includes enteral formula as well as supplies and equipment (pumps and poles are not coded separately). Some Medicaid programs have adopted these codes as well for reporting purposes, although 'they are not payable' [18].

Reimbursement

Private payers usually negotiate reimbursement rates with enteral nutrition suppliers through a process that has some elements of competitive bidding. In bidding for these contracts, suppliers often offer to provide enteral nutrition supplies and equipment among a range of other infusion drug therapies. In return for accepting the negotiated rates, suppliers often are ensured a certain level of business and prompt payment.

The majority of private insurers reimburse suppliers using the negotiated rate for the particular HCPC code on a per 100-calorie unit basis for enteral formulas. Whether the reimbursement rate varies between different

codes as it does in Medicare (for example, for a more complex nutrition formula) depends entirely on the negotiated contract. Private payers may also provide opportunities for enhanced reimbursement for particularly expensive products within a code through the use of a modifier if special medical needs are present. This has been particularly important for nutritionally complete formulas that were previously included with other less expensive products and were often not profitable to provide at reimbursement levels under the former HCPC code. As in Medicare Part B, pumps and poles are separate rental products for which providers receive payment on a monthly basis.

Private payers that use 'S' codes reimburse providers on a per diem basis using rates based on the average wholesale price. The per diem rate includes payment for pumps and poles.

Medical Necessity

Private payers may not follow the stringent Medicare requirements for medical necessity for Medicare reimbursement, though specific coverage again varies from payer to payer. Generally, if a physician prescribes enteral nutrition, it will be reimbursed.

Coverage for oral nutrition varies depending on the payer. Increasingly, the trend is not to pay for oral administration. Payers are generally looking to control expenditures and believe that they should not be paying for enteral nutrition in circumstances where the patient can purchase food and blend it if necessary. For certain products, however, such as elemental products for patients who have an absorption impairment, payers are still likely to cover and reimburse. There is a HCPC modifier, BO, to indicate orally administered nutrition not by feeding tube.

Conclusion

- Enteral nutrition is widely accepted as an effective mainstream, often life-sustaining, therapy
- Coverage and payment policies for enteral nutrition differ among payers and settings. These differences largely depend on whether enteral nutrition is covered and reimbursed as a discrete therapy or whether it is subsumed into a larger benefit
- There is some concern among policymakers that enteral nutrition is susceptible to overuse, particularly in the long-term care setting
- The trends in coverage and payment for enteral nutrition suggest
  - Tighter reimbursement
  - Introduction and expansion of competitive bidding approaches
  - Data-driven performance measurement and payments

References

1 Kaiser Family Foundation: Medicare at a Glance Fact Sheet. Menlo Park, Kaiser Family Foundation, 2006.
2 Section 1886(d) of the Social Security Act.
3 Medicare and Medicaid Guide 2007, ¶8.5.
4 71 Fed. Reg. 47870 (Aug. 18, 2006) (Final rule Medicare IPPS FY2007).
5 68 Fed. Reg. 34494 (June 9, 2003).
6 42 C.F.R. § 482.28 (Condition of participation: Food and dietetic services).
7 Medicare and Medicaid Guide, ¶1.56.
8 Medicare National Coverage Determinations Manual, § 180.2.
9 Medicare NCD Manual, § 180.2; Medicare and Medicaid Guide, Coverage and Payment Rules.
10 42 C.F.R. §§414.104 (a) (PEN Items and Service, Payment Rules).
11 Jurisdiction B DME MAC Supplier Manual, Revision 51 – December 2006, Ch. 15, pp 2–3.
12 Medicare and Medicaid Guide ¶8.120.
13 AAHSA, Summary of AAHSA's Comments on CMS's Revisions to Medicare Payment System for Skilled Nursing Facilities, Aug. 2005.
14 Medicare and Medicaid Guide ¶8.120.
15 Kaiser Family Foundation: The Medicaid Program at a Glance Fact Sheet. Menlo Park, Kaiser Family Foundation, 2006.
16 HHS Office of the Inspector General, Coverage of Enteral Nutrition Therapy: Medicare and Other Payers, OEI-03–94–00020, May 1995.
17 GAO, Medicaid and Medicaid Coverage: Therapies and Supplies for Inflammatory Bowel Disease, GAO-06–63, Dec. 2005.
18 Palmetto GBA, Region C Council Q & A, Jan. 19, 2005, at http://www.palmettogba.com/palmetto/providers.nsf/44197232fa8516898525719600693 9dd/85256d580043e75485256fd60054bbeb?OpenDocument.

Discussion

Dr. Elia: I have a question about disease-specific formulas. How does the reimbursement process works here? By and large, disease-specific formulas are more expensive than standard formulas. What kind of information or evidence needs to be acquired to inform the reimbursement process? For example, is it sufficient to demonstrate safety and a rational concept or do you require formal evidence that the disease-specific formula is superior to a standard formula, and does that determine the reimbursement rate?

Mr. Parver: That's a good question and the short answer is if the disease-specific formula is more costly than the standard formula, they will look for more evidence. There was a phase for a while when patients were being put on special metabolic formulas all over the place, and some of these formulas did not look as though they were supported by a lot of clinical evidence. Reimbursement was materially higher for disease-specific formulas, and the industry was not able to say why these patients were all of a sudden being switched to these disease-specific formulas, other than reimbursement. So, reimbursement levels came down for those formulas and they are all now at the same level. That is going to be one of the challenges; we will have to be able to give better justifications for the use of such formulas than may have been provided in the past. What also affects the issue is that there are some disease-specific formulas in the codes and categories with the other formulas. There are categories for other disease-specific formulas that are reimbursed at a higher level and there are almost similar disease-specific formulas in the cheaper category. So, policymakers are justified in asking if industry can provide this one for that price, why are we asked to pay at this higher level? We need something besides 'we make more money from it'.

Mrs. Gailing: I have a question on the difference between the reimbursement and putting the product on the market. Are all food products eligible for reimbursement or do they first have to go through medical food clearance in the US?

Mr. Parver: Be careful with medical food. Some enteral products are regulated as medical foods by the Food and Drug Administration, but a lot aren't. They are just regulated as food. Your price is not that relevant, as Medicare does it. They already have their particular codes, and will take your product based on how you describe it and will put it in the code. Once it is in the code, that is the reimbursement rate for that product. Your own costs are interesting, but not that relevant to that decision.

Dr. Bistrian: There is fairly good evidence that oral supplements in many disease states can, when added to regular food intake, increase the total caloric intake and be beneficial. If it were not covered in a particular state, could you say that it would have to be provided by tube and that would be more expensive?

Mr. Parver: That would be a dangerous route unless the person is already receiving tube feeding. Tube feeding is only implicated when they cannot take food orally. You can't just do that to get coverage. It would not be a proper way to gain coverage.

Dr. Hoffer: Thank you for a very clear presentation for material which is completely new to me. It was a real eye-opener. You said that there is some concern among policymakers that enteral nutrition is susceptible to overuse in long-term care. That sounds very plausible to me because it would be economically beneficial to a facility to insert a tube and get a packet of money for it as opposed to paying someone to hand-feed a person, even though the second would be far preferable from every aspect of medical and social wellbeing. I wouldn't say that there is concern, but it is a recipe for that sort of abuse to take place.

Mr. Parver: There is a concern that thinly staffed nursing homes would find it easier to stick a tube into someone than wheel them down to the dining hall and feed them by hand, no question. The nursing homes have to meet quality standards and the surveyors are supposed to be watching for this. They are supposed to be concerned if there are too many patients on enteral feeding. Keep in mind that most facilities only have a handful of patients who are getting tube feeding. So, if there is a large number, the surveyors are suspicious, unless the home is competing for sicker patients. If their staffing doesn't reflect that, the surveyors will probably conclude that they are gaming the system and doing exactly what you said. Certainly, there are a lot of biases about that and they have to be very careful. My wife is a nursing home administrator and they always see it as a failure if they have to put someone on tube feeding. It should only be under the most rigorous criteria. The surveyors are trained to look for that.

Dr. Seidner: I would assume that the reimbursement process works quite easily for the patient with a degenerative disease or head-neck cancer who can't swallow and needs a tube. What are your views on the patient who is able to eat but has severe malabsorption and has a tube for supplemental feeding while they are not eating over the evening? I would assume that those are the patients with some hurdles to cross.

Mr. Parver: This issue came up a lot in the beginning, but I don't see it as much any more. First of all, they will not pay for patients who are just recalcitrant. If people refuse to eat, they will not be covered by Medicare in most cases. Tube feeding as a supplemental benefit is not covered either. Let me read this sentence, 'Enteral is considered reasonable and necessary for a patient with a functioning gastrointestinal tract, who, due to pathology or non-function of the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general condition'. CMS has interpreted this to mean total nutrition. They want the tube feeding and they want parenteral feeding to be the great percentage of the feeding the patient gets. I understand that parenteral patients are told to

keep eating because they need to keep the systems working. The fact that you can take some food orally but not enough to survive is the issue. There is a line some place, they say it is total but there are coverages for people who have something less than total but it has to be a small portion of that. Again, tube feeding has to be the dominant means of keeping the patient thriving.

Mrs. Anthony: You said that enteral nutrition has not been cut heavily so far by Medicare. Why do you think it is protected?

Mr. Parver: One of the things that worked in our favor is the absolute confusion about what it is and how it is covered. The fact that it is in the prosthetic device benefit is not something people get their minds around easily. Medicare doesn't work well when things fall across different spectra, when you have nutrients, equipment, supplies and different players working; there are dieticians and different settings. They are uncomfortable with it and the fact is that, for a while, they were targeting enteral feeding every year, and we were relatively successful in pushing that back. Now, they see enteral as a cost-effective alternative to parenteral feeding. One of the things that has helped the enteral area is that many patients who would have been on parenteral are now on enteral feeding, at much greater savings to the program. So, they see this as a good story; though, if you talk to anyone at CMS, they really have a hard time understanding what they are doing, and why their predecessors created this thing. It is not a model for future policy development. They use this area as an example of being a little too creative and this may not have been the way to do it. In other areas, they looked for more linear ways as opposed to what they came up with for us.

Mrs. Anthony: I would like you to comment on the advocacy. I am fairly familiar with your work which you have been doing for a long time, and you get a lot of credit for letting the CMS realize how complicated it is. Could you to comment on the advocacy for enteral nutrition? Are there other groups that, if we need to be more aggressive advocates, we could model ourselves after or look to as examples?

Mr. Parver: The best advocacy is one that involves patient organizations and patient groups right up front. The Oley Foundation in the United States represents patients. The best advocacy involves patient groups, suppliers, providers, distributors, manufacturers and physicians all saying the same thing and for the same reasons. We are not quite there, we can do better. The manufacturers have been one of the principle advocates for enteral policy. The enteral suppliers have grown reliant on manufacturers such as Nestlé to carry the ball here. One of the things we have been doing is to get the suppliers more active in their own right. We have done alright, but we can do better if we get more of the stakeholders at the table being aggressive and articulating their concerns. In terms of whom to pattern ourselves after, I don't know how to answer that. There are a lot of groups that we emulate. The best example of how to do advocacy in Washington DC in healthcare is the oncology community. Cancer is something that policymakers know, they understand it and have seen how it affects their families. Crohn's disease does not have that same identification. The cancer community has done a fantastic job of organizing beneficiaries and physicians. Congress knows that the cancer community can generate 60–70,000 letters in a week protesting something a month before the election. So they are extremely good at what they do. I am not sure if we will ever be at that level but I think we should strive for better grassroots; have the patients and physicians involved and understand what the consequences are. One of the good things about what we have done is that we have had to invent our benefit under Medicare, as silly as it may sound. In terms of the evolving Medicare structures, we are probably better positioned than some to reinvent it and readjust it to what the new realities are. Some groups that have just been handed a coverage scheme may feel that is the way life is and should always be. We have never

been that sanguine about it and understand that we have always had to fine-tune it in very technical ways to make it work. I think that will help us in the future.

Dr. Kondrup: I can't help thinking that, in the end, the system that is most profitable for lawyers and accountants will win and the patients will not benefit very much from that. In Denmark, we have reimbursement for 60% of the cost of enteral feeding in the homecare setting. The reason why it is not 100% is that these people will spend money on food anyway. The only thing that it requires is a prescription written by the doctor that there is a medical indication for this, and the prescription has to be renewed every 3rd month. This system was introduced about 10 years ago. We had an expectation about the cost, and it has increased over the years to 50% more than the expected, but still it's accepted. This is a very non-bureaucratic way of running things.

Mr. Parver: Medicare is the opposite of a non-bureaucratic way of running things. To quote Rumsfeld, 'this is the system you have, not the system you want'. We also need a physician to write the prescription and it has to be renewed every 90 days. It is quite bureaucratic but not just in this area, it is bureaucratic across the board. All of our advocacy efforts were not to enrich ourselves but to benefit our clients, the manufacturers, the providers, and it only works for them if it works for the beneficiaries. The reason Medicare has been good about leaving us alone, relatively speaking, is because they see it working for the beneficiary. The bottom line is if the beneficiaries were not getting access to quality care, this thing would be a lot different.

Dr. Labadarios: My questions may be seen a little naive but I want your opinion. To what extent do you think all of this rigmarole inhibits professional development? Who are these people actually and do they interfere with my professional rights as a practitioner? Who put them there in the first place and why are they there? This next question is addressed to everybody: have we lost control of our profession? If we have, what are we doing about it?

Mr. Parver: That it is not naive at all. It is not limited to nutrition; it runs across the board. Most physicians and health practitioners who have to do business with this program feel that they are being turned into clerks and, to some degree they are; they spend far too much time dealing with the program than dealing with their patients. There is no question about it, and it is not limited to nutrition. Who put them there? When you talk to policymakers about Medicare, they will use two words and you know immediately where the conversation will go after that; those words are 'trust fund'. When they mention trust fund, those are public dollars that are put into this fund for the Medicare program, which is going to go bankrupt in 11 years by the way, unless something is changed. Once they mention trust fund, they ask what we have to do to protect the sanctity of the fund. The fact is that a lot of public money is involved in this. Medicare treats 43 million beneficiaries annually and the cost is astronomical. People have criticized the American system for being so expensive and not producing results commensurate with those expenses. One of the ways Medicare works, this might be a bit of an aside, is they will often tell you that their administrative costs are 2%, which is terrific. The reason they are 2% is that they shift the administrative burden to everybody else so that the practitioners and the institutions are saddled with all these coding documentation issues and just the daily business of the program. That is where the costs are too. Who put them there? The system grew that way because so many public dollars were involved and it was increasing at a tremendous rate. Here is the rub, to fix it, if it can be fixed, it's not going to mean less bureaucracy but more, at least in the short-term, to deal with those issues. Medicare has to evolve into something else. It will not happen from our vantage point but from the governmental perspective, and it will require a lot of those people.

Mr. de Man: In terms of bureaucracy, does the contracting out to managed care organizations decrease the bureaucracy to a certain extent?

Mr. Parver: Absolutely, yes. The managed care operation does not work like a Swiss watch either. Right now, Medicare pays managed care more than it pays fees for service. So how did this happen? I thought that managed care was supposed to save us money but they are spending more as a premium. The argument is that they are doing more. The Democrats, especially Pete Stark who is the chair of the health subcommittee, is a real non-fan of managed care and he wants to find out why we are paying more money to them, what are they doing extra and where is it documented. There will be a whole set of hearings dragging managed care people in front of the Congress. There is no question that the managed care initiatives, even in Medicare, cut through a lot of that. For example, the Medicare advance plans have to provide the services that are covered by Medicare A and B but they can provide more and a lot of them do it without a lot of crazy paperwork.

Dr. Labadarios: This is perhaps a less naive question, and before I make it I will declare that I have no political inclinations. Are we not doing a disservice to our profession by allowing these things? When are we actually going to learn? The UK is a good example if you believe the conservative leader, the NHS is in the mess that it is because of the so-called administrators who come in, cut the best salaries for themselves, and then there is no money elsewhere. I am sure that Dr. Elia will second that. The question is, at what level do we professionals come in and try to do something about this? Surely we must have a say in the matter.

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Enteral Nutrition Reimbursement – The Rationale for the Policy: The German Perspective

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Abstract

Both the German statutory and private health insurances cover enteral nutrition (EN) products. Approximately 100,000 patients receive reimbursed EN; 70% are tube fed for an average 9 months. 70% of the tube-fed patients are cared for in institutions (i.e. for the elderly) and 30% at home. The prescription and reimbursement of EN is covered by Volume Five of the Social Legislation Code (Social Code Book No. 5). Reimbursement for EN depends on medical prescription and is in principle guaranteed whenever normal food intake is impaired and modification of normal nutrition and other measurements do not improve nutritional status. It is unclear what effect the reform laws will have on EN but they may impact the prices for medical devices and negotiations between health insurance funds and product manufacturers.

Introduction: The German Healthcare System

Roughly 10% of the German gross domestic product is spent per year on health services in the broadest sense (approximately EUR 200 billion or USD 290 billion). Approximately EUR 125 billion (USD 175 billion) are accounted for by the statutory healthcare system, which links 82 million insured, more than 100,000 office-based physicians, 22,000 pharmacies, 2,200 hospitals and roughly 300 private and statutory health insurers. The funding of statutory healthcare and access to it is based on the concept of solidarity: wage-indexed contributions are made according to the financial abilities of the insured who receive benefits that correspond to their needs. At present, employees pay an average 7.5% of their salary for health insurance coverage, with their

employers contributing 6.6%. The choice of not remaining in the social system has been made on a voluntary basis by 10% of the population who wish to be privately insured due to their income (>USD 4,700/month) or because they are self-employed.

The German statutory and private health insurances offer a comprehensive package of services, including outpatient treatment and hospital treatment, all necessary medication, dental treatment, dental prostheses, rehabilitation as well as enteral nutrition/food for special medical purpose (FSMP) products. In principle they even reimburse every newly licensed drug and medical device without limitations which, on a global comparison, is unusual. All other insurance schemes and healthcare systems throughout the world limit the range of benefits and reimbursement by means of positive lists and/or by means of admission hurdles. The pharmaceutical industry sets their prices freely without control by authorities: neither prices nor profits are officially controlled under the precondition that the products show evidence of a therapeutic improvement for patients compared with already existing products. In these cases the statutory health insurance funds in Germany fully reimburse the price set by the manufacturer for every product for the duration of patent protection. For all other products, the health insurance funds are allowed to fix maximum reimbursement rates based on the price of comparable products. The prices for medical devices are generally negotiated between the health insurance funds and the product manufacturers. If they form part of a comprehensive hospital treatment, they are factored in the hospital rates.

The statutory health insurance and packages of service is governed by special legislation which is laid down in Volume Five of the Social Legislation Code (Social Code Book No. 5).

Medicament Provisions, Diagnostic and Therapeutic Measures Are Defined through Directives: Responsibility of the Federal Joint Committee

A special feature in the regulation of medical services of the German healthcare system is the important role, alongside that of the legislature, played by the self-governing body of doctors and health insurance funds. The legislature creates the legal framework; the medical self-governing body, formed from the national associations of doctors and dentists, the German Hospital Federation and the health insurance funds, gives concrete definition to the legal requirements and implements them. The paramount decision-making body of the joint self-governing body is the Federal Joint Committee (G-BA). The G-BA was institutionalized by legislature as a legal entity under public law. It has wide-ranging regulatory powers. The various duties and wide-ranging powers of this committee are also laid down in Social Code Book No. 5, which governs statutory health insurance.

One important area of responsibility of the G-BA concerns the assessment of new methods of medical examination and treatment. In the sphere of ambulatory (outpatient) care in particular, the G-BA represents the 'eye of the needle', through which a new method must gain positive evaluation in terms of benefit and efficiency before it can qualify for reimbursement from the statutory health insurance funds. The Federal Committee's assessment of medical treatments and procedures follows a standardized procedure which rests on evidence-based medicine. The generally accepted current state of medical knowledge is ascertained for the purpose of assessing the effectiveness, quality and economic efficiency of the methods examined. The Federal Committee, however, is not responsible for licensing medicaments for the German market; this is the task of the Federal Institute for Drugs and Medical Products. In other words: in Germany, a Joint Committee of Physicians and Health Insurance Funds – and not the State – decides which treatment procedures are reimbursed by health insurance and which are not. The representatives of the health insurance funds, doctors, dentists and hospitals used to make important decisions on their own.

The regulatory powers of the G-BA include:

- To encompass recommendations on requirements regarding the content of disease management programs
- To issue directives defining diagnostic and therapeutic measures and governing quality assurance in the ambulatory, inpatient and cross-sector spheres
- To issue the directives that are necessary for safeguarding medical provision. These aim to ensure that services for those with statutory health insurance in Germany is adequate, appropriate and efficient. The directives cover, for example, early diagnosis of diseases, dental treatment, psychotherapy and rehabilitation
- To regulate through the directives remuneration exclusions and restrictions in medicament provision based on the efficiency requirement

All directives issued by the G-BA are based on nationally and internationally recognized (evidence-based) guidelines and are submitted for approval to the Federal Ministry of Health. The Ministry responds within 2 months if it has any objections. Otherwise the directives are published in an official journal and come into force.

Enteral Nutrition Reimbursement

In the sphere of ambulatory (outpatient) care approximately 100,000 patients receive reimbursed enteral nutrition, 70% of them are tube fed for 9 months on average. 70% of the patients are institutionalized, i.e. homes for the elderly, and 30% are taken care of at home. The average costs per patient and month are accounted for by EUR 580–650. EUR 600 million are spent for

FSMPs in Germany per year: EUR 200 million for technical devices like tubes and pumps, and EUR 400 million for tube and sip feed.

Traditionally the prescription and reimbursement of enteral nutrition is also covered by Social Code Book No. 5, though FSMP products are neither drugs nor medical products. Consequently it fell under the responsibility of G-BA to issue a directive for prescription provisions. Since 2002 the Federal Committee has drafted such a directive three times and submitted it for approval to the Federal Ministry of Health. Applying the standardized procedure which rests on evidence-based medicine even for the dietary management of patients by means of enteral nutrition, the draft directive defined numerous exclusions and restrictions and thereby caused severe dispute with patient organizations, scientific societies and industry. Three times the Ministry responded as it had severe objections itself. As the committee refused to take the objections into account, the Ministry decided on its own to publish a directive with the necessary amendments; this came into force on October 1, 2005. A court case which aims to clarify whether the Ministry is empowered to act in such a way is still pending. A decision is not expected before the end of 2007.

According to the directive, reimbursement for FSMPs depends on medical prescription and is in principle guaranteed whenever normal food intake is impaired, and modification of normal nutrition and also other measurements do not adequately improve the nutritional status. Limitations for reimbursement exist for the type of enteral formula and the price level, but no submission is needed for a single product as long as the general legal regulation for reimbursement applies. No diseases/clinical conditions/indications are defined for reimbursement and no lists of recommended products exist. Enteral nutrition may be prescribed when adequate normal nutrition is impaired or not possible at all. Besides the medical prescription, no documentation is required.

The directive requires some compositional criteria for reimbursement as follows:

- Standard sip and tube feeds must contain ≥1 kcal/ml for complete nutrition and must be consistent with the directive of the European Commission on foods for special medical purposes 1999/21/EC
- Fiber- or medium-chain triglyceride (MCT)-enriched formulae must not cause more costs than fiber- or MCT-free formulas
- Specifically composed age-adapted feeds for infants and children
- Disease-specific feeds for renal insufficiency
- Nutritionally complete sip feeds with highly hydrolyzed protein or amino acid mixtures for infants or children with cow's milk allergy or patients with multiple food allergies
- Low molecular or MCT-enriched products for patients with malassimilation (e.g. short bowel syndrome, HIV-associated diarrhea, cystic fibrosis)

- Special amino acid mixtures (also products containing fats and carbohydrates) for patients with phenylketonuria or further inborn errors of enzymatic functions which are treated with special amino acid mixtures
- Special products for patients with rare inborn errors of carbohydrate and fat metabolism (depending on the disease also carbohydrate- or fat-free nutritional supplements) and for further diseases in need of specific dietary treatments
- Ketogenic diets for patients with epilepsy

All other disease-specific feeds are not reimbursed.

The directives do not lay down a specific pricing mechanism; the prices are set by the manufacturing company. The reimbursement of enteral feeds is 100% (health insurance) based on the purchasing price of pharmacies (AEP) minus EUR 5--10 per line of prescription, which is regarded as the patient contribution. Depending on the health insurance, there may be different rates in addition (e.g. AEP + 10%).

Reform

As early as 2003, Germany's two largest parties negotiated a comprehensive healthcare reform. This reform was also necessary because between 2002 and 2003, the statutory health insurance funds had run up deficits to the tune of EUR 3 billion (USD 3.6 billion) each year with a total expenditure of some EUR 140 billion (USD 170 billion). As a matter of fact, the reform significantly improved the funds' financial situation. The deficits turned into surpluses. In 2004, the funds chalked up a surplus of EUR 4 billion and a surplus of EUR 2 billion is expected for 2005. As a result, the unlawful indebtedness of the health insurance funds, which had risen to a total of EUR 6 billion (USD 7.3 billion), no longer exists.

Developments in medicine, pharmacology and medical technology along with demographic social and economic changes will put further pressure for rationalization measures on our healthcare system. Recently the reform law passed the governmental institutions and it should come into force on April 1, 2007.

It aims to stabilize the financing of the healthcare system and to reduce labor costs and thus help to boost the competitiveness of the national economy. To date it is unclear how the reform law will affect enteral nutrition. It is expected that the law will at least have an impact on prices for medical devices and the negotiations between the health insurance funds and product manufacturers.

Discussion

Mr. Jedwab: My job at Nestlé is product development and as I listen to this and some of the other presentations, the impression I have is that all these rules and restrictions are there for the obvious reason of cost containment which, in the end, will lead to a stifling of innovation. In other words, if we take the German case, when I see the list of things that is not covered today or will not be covered in the future, I wonder what the point is of a company like Nestlé even bothering to start costly innovation programs if there is no chance that we will ever be reimbursed or that it could work economically. Nestlé and the other companies are not charities, we have to answer to shareholders, like everybody. At the end of the day, I think the whole system coming into place is lose-lose situation for everybody. Cost cutting now won't solve the issues for which there are needs for innovative products. By not treating the growing elderly population now and cutting out anything to do with malnutrition, it is just saving up the bill for the next generation. All of that is fairly negative, but on a more positive note, given the current climate in Germany, what is your opinion on how we can go about getting product XYZ covered? Assuming a great level of clinical proof, effectiveness and all the rest of it, what is the mechanism today by which we could go about influencing the various laws and regulations in countries like Germany?

Mr. Pahne: It is quite a difficult question. You are right that the evidence approach, if it is misunderstood, as is the case of the Federal Joint Committee, is innovation-blocking. What can we do, what can a company do to reach the goals? The very first thing to do is to try to make people understand the medical nutrition paradigm that we discussed yesterday. If you have a disease-specific product, it is not necessary to show evidence that it can cure the disease it is designed for, but to show that it helps the patient in a different way. In that way it is possible to save spending and costs. The cost argument is the most important one, but there is urgent need that the relationship between the product enteral nutrition on the one hand and the disease on the other hand is understood in the right way. This is not the case in Germany right now.

Mr. Jedwab: So, it's back to health economics again?

Mr. Pahne: Yes, absolutely.

Mr. Tatakis: In 1991, there were 1,200 health funds while now there are only 250. What happened to the rest of them and their members? Second, do you see any shift from public to private spending? Third, looking at it more positively, since in the German system the incurables are excluded, are we then moving to a healthier society? Do you see a shift to private spending?

Mr. Pahne: Yes, there is a shift to private spending, but the problem is you have to distinguish between private spending of patients, if they pay for enteral nutrition on their own, and the private insurance system on the other hand. There is a shift towards the private insurance scheme but there are limitations because not everyone is allowed to become a member of the private insurance system. As far as the situation of privately bought products is concerned, there is a shift and companies in Germany would like to help this shift to private spending to increase. The patient is informed that there it is possible and necessary to get a private prescription from the doctor. In most cases, patients don't know that it is possible to get a private prescription, but they have to pay for the product for themselves. In this case, the patients have to be convinced of the need for the products. Until now enteral nutrition products have not been well known in Germany, which is completely different to the situation in the US. Companies are switching to a different approach to make enteral nutrition and its advantages more public so that private people buy those products on a private basis. It is a different approach but it is a needed.

Mrs. Howard: Picking up a point that was made yesterday about the clinical remit being handed over to people who are telling us what to do, what is the composition of this Federal Joint Committee in terms of balance? How many clinicians are on it, how many bureaucrats, and how many lawyers? Is there any way to change that in the future? What is their term of office?

Mr. Pahne: The people on the Federal Joint Committee are, in most cases, physicians but are employed by either the health funds or physicians associations. So, they are more or less administrative people, and my experience is that most of them have never heard anything about nutrition. There is a lack of information and they do not know these products and they do not even understand the discussion if there is a hearing with people from the Medical Nutrition Society. They do not understand and still rely on the conventional medical paradigm. There is urgent need that these people somehow get an approach to medical nutrition, but I am not sure how this can be done. Due to the long process and long discussion procedure, it is a highly emotional issue in Germany now. Whenever we approach somebody from the Federal Joint Committee, just dropping the words 'enteral nutrition' upsets everyone. They do not listen to arguments anymore, so that is the situation and the reason why we have a court case now because discussion is over.

Mrs. Howard: So, I gather that no approach was made to the Enteral Nutrition Society in Germany which, I gather, is pretty active. What a shame!

Mr. de Man: I am just wondering whether another argument is being taken into account. There is a European Court decision that benefits European citizens who are not reimbursed in their own country but are reimbursed in others. Whether this is reimbursed or not by local insurance companies needs to be assessed in the context of the evidence within the international medical community, not just the German medical or healthcare community as such. The evidence that certain benefits will be paid should be assessed within the entire European medical community rather than the national medical communities. It will be interesting to see if this decision holds up in the European Court, and if there is enough evidence that enteral nutrition works for certain kinds of diseases. Of course, it also depends on how curative and expressions like that are defined. It may well be that this court decision can be some kind of benchmark or at least may play a role in how this case will be defined in the near future.

Dr. Kondrup: I think this is limited to ambulant patients. A roundtable is being prepared by the European Commission to start discussions, but I don't know if this will be discussed at this level.

Mr. Pahne: Perhaps we will end up at the European High Court, and without a doubt that would be quite amazing. You cannot imagine the amount of publications, documentation, position papers and whatever was available throughout the world that has been presented to the Federal Joint Committee. The documentation was not measured in pages but in kilos. All this information was not sufficient because the evidence-based medicine approach that they made use of is not available in the publications. There is no proof that food can cure disease. It is as simple as that.

Dr. Van Emelen: Are there similar decisions in other fields besides nutrition? I can imagine that in chronic disease management, or decisions related to it, there are similar decisions if evidence-based medicine is not followed. There are probably other decisions that are quite illogical. Among the 253 health insurance funds, do any of them represent the interests of their members? I can imagine that a lot of initiatives have been introduced to change the discussion.

Mr. Pahne: You are right, the Federal Joint Committee does not only decide on the reimbursement of enteral nutrition but they decide on medical devices, on innovations, on drugs, and there are even more cases comparable to ours. The approach of the Federal Joint Committee is to bring down costs, to look at the benefits and the efficacy

of a measure. There are quite a lot of similar cases where the Federal Joint Committee decided that some drugs or measures are not reimbursed anymore. So, we are not alone in the world and this is due to costs. Like everywhere, we have emerging costs and spending trends in the German healthcare system. The percentage growth rate in our system has gone down from 25 to about 3% over the past few years. Although every year there was reform of the healthcare system or a new law, the names of the laws have become even more complicated. In the 1990s, it was Gesundheitsreformgesetz, and in 2006 it was Arzneimittelversorgungs-Wirtschaftlichkeitsgesetz.

From one reform to the next one, even more stakeholders are involved. The measures in the beginning of this century were budgets, contracts, regulations, prize moratoriums, and exclusions from prescriptions to local contracts. The responsibility during the first steps was shared by physicians, the health funds became involved, the pharmacists, the manufacturers, and now the patients. Because of the lack of financial resources, there is a cut of reimbursement everywhere, so we are not alone in the world and I think everyone has the same problem. There is a need to show that, from the economic approach, prevention at a very early stage may save quite a lot of money at later stages. Until now, there is a lack of delivery and understanding of these facts.

Dr. Elia: I have a question on the consistency of thought across medicine and medical practice. Although medicine might aim to cure disease, often it does not and it does not aim to do so. It may aim to alleviate pain, suffering, discomfort, and to make people feel better. So, if the principle is not to fund nutrition because it doesn't cure diseases, theoretically that line of argument should apply to other fields of medicine. If it doesn't, why has nutrition been targeted?

Mr. Pahne: This issue has been addressed to the decision-makers, it has been addressed even by members of this small circle, and by Dr. Lochs, the president of the German Association of Medical Nutrition Physicians. But either the members of the Joint Committee were not interested in listening and understanding or the message was too complicated. In the end it was not accepted at all. Perhaps the main reason was that there is the task or duty to save money and to save it wherever possible, despite the nice or good arguments. I think the main approach is cost and the decision was made on the basis of costs. The simple costs of enteral nutrition products are EUR 600 million/year in Germany. It's not too much compared to total expenses, EUR 250 billion, but even this sum is so high that the Joint Committee decided to cut it down considerably. You are right, it is not saving, it is out of balance.

Dr. Elia: Exactly the same argument could be used to save costs in other fields of medicine because they don't cure conditions. I presume here it is because nutrition is a soft option. This is a case where we have to stand strong and send a message back that this should not happen for nutrition.

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Food Modification versus Oral Liquid Nutrition Supplementation

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Abstract

Oral liquid nutrition supplements (ONS) are widely used in community, residential and healthcare settings. ONS are intended for individuals whose nutrient requirements cannot be achieved by conventional diet or food modification, or for the management of distinctive nutrient needs resulting from specific diseases and/or conditions. ONS appear to be most effective in patients with a body mass index of ≤20. Studies are needed to evaluate the clinical and functional efficacy of food-based versus ONS nutrition interventions.

The conditions of energy undernutrition and protein-energy undernutrition remain devastating global problems, and are especially prevalent in older adults who are hospitalized or residing in long-term care (LTC) facilities. Many older adults are admitted undernourished or become undernourished during institutionalization. Lack of attention to nutrient intakes contributes to deterioration of nutritional status. Although a number of trials have been published over the past 3½ decades, there remains no consensus on the best method to enhance oral dietary intakes of older adults to help them achieve meeting their energy, protein and other nutrient requirements, and thereby improve body weight and body composition, physical and cognitive function, and clinical outcomes. Strategies to complement habitual dietary intakes include interventions using foods, such as manipulating the energy density of recipes, enhancing the flavor of food items served, adding snacks between meals or providing meals in community settings, and interventions using oral liquid nutrition supplements (ONS) before, during or after meals.

Enhancing Foods and Meals

Modification of foods and beverages to increase the energy or nutrient density (kcal or nutrient per gram weight of food) occurs by adding, substituting or enhancing energy- and/or protein-rich ingredients of food items served in the menu. Very few randomized controlled trials have been conducted to investigate the effects of increasing energy and protein density by recipe enhancement on clinical or functional outcomes in adults at nutrition risk. Manipulating recipes by adding fats such as cream or butter and carbohydrates such as glucose polymers have been used to enhance the energy density of meals served in a few care settings. In a case-control design, LTC residents who received energy-dense meals consumed about 30% more kilocalories per kilogram and were able to maintain their activities of daily living (ADL) after 15 weeks of meal enhancement [1]. In 35 older patients in a hospital rehabilitation ward, increasing the energy density of the meals served for 14 days increased caloric intakes by 25% [2]. In a randomized cross-over trial utilizing enhancement of the energy and nutrient density of the regularly served home-delivered lunch meal, both the lunch meal and 24-hour intakes improved for calories and key micronutrients in 45 older adult clients of a home health agency [3].

As reduced sensitivity to the taste and smell of foods with aging may impair the ability to appreciate the palatability of foods, flavor enhancement of foods has also been used to promote greater dietary intakes. Flavor enhancement of the protein-rich food items in a LTC menu was achieved by adding more chicken, beef, turkey or lemon butter flavor. Enhancement increased caloric intakes and resulted in a weight gain of 1.1 kg after 17 weeks [4]. In a residential home setting, flavor enhancement of energy-dense food items for 3 weeks improved immune function and grip strength in 39 older adults [5].

Providing Between-Meal Snacks

Adding between-meal snacks such as milk shakes, puddings, snack bars and cookies increased the energy intakes of LTC residents by 30% of total calories [6]. Notably, providing fruit and dairy-based snacks two times daily for 17 weeks to community-residing older adults improved serum levels for 25-hydroxyvitamin D, pyridoxal-5-phosphate, cobalamin and ascorbic acid [7].

In another study, investigators used the SNAQ screening tool to identify undernourished patients and trigger provision of between-meal snacks that provided an additional 600 kcal and 12 g protein/day to those patients who were classified as moderately or severely undernourished. Screening triggered significantly more referrals to a registered dietitian (76% of undernour-

ished patients vs. 46%) and shortened the interval to dietetic consultation from an average 5.8 to 2.6 days ($p < 0.001$). Between-meal snacks reduced length of stay in those patients with low handgrip strength (11.5 vs. 14 days) [8].

A pilot study of the Seniors Farmers' Market Nutrition Program, funded by the US Department of Agriculture, was conducted in which a basket of locally grown fresh fruits and vegetables was provided every 2 weeks to homebound older adult participants of home-delivered meal programs in Seattle, Wash. After 5 months of deliveries, the intervention group ($n = 100$) were consuming 1.3 more servings of fruits and vegetables per day compared to the control group ($n = 52$, $p < 0.001$) [9].

Providing Meals

In the US, about 3 million older adults receive congregate and home-delivered meals under Title IIIC of the Older Americans Act (OAA), which is administered by the US Department of Health and Human Services under the Administration on Aging. An evaluation of the OAA Nutrition Programs conducted in 1993–1995, using a nationally representative sample of meals participants, showed that the home-delivered meal comprises 30–50% of participants' total daily food and nutrient intakes. Use of the OAA meal programs resulted in dietary intakes that exceeded one third of the 1989 recommended daily allowances; congregate meals participants had significantly increased intakes for 16 nutrients and home-delivered meal participants had significantly increased intakes for 12 nutrients compared to age- and gender-matched non-participants [10]. In southwestern Ontario, Canada, nutrition risk was reassessed after 18 months of meal participation. A telephone administered follow-up of 263 meals participants, who had been categorized as high risk at baseline using the SCREEN questionnaire (SCREEN score ≤45), showed a significant decrease in nutrition risk [11].

To investigate the impact of adding a home-delivered breakfast meal to the home-delivered lunch meals, breakfast meals were provided in a case ($n = 167$) control ($n = 214$) intervention 5 days/week to OAA Nutrition Programs in 5 states in the US. The breakfast group consumed an average of 300 kcal and 14 g protein more per day ($p < 0.001$) and had significantly greater intakes of folate, calcium, magnesium, potassium, iron and zinc [12].

Despite the successes of food-based interventions (table 1) in a variety of community, residential and healthcare settings, inadequate funding for food-based interventions, inadequacies in the utilization and availability of registered dietitians, and lack of continuity of care at discharge limiting enrollment of at-risk individuals into food-based programs (such as congregate or home-delivered meals), contribute to the widespread use of ONS in all settings.

Table 1. Strategies to improve the adequacy of dietary intakes using food

- Nutrition education and counseling
- Feeding assistance
- Improving dining environment atmosphere
- Flavor enhancement of menu items
- Enhancing the energy and/or nutrient density of food items
- Congregate meals
- Home-delivered meals
- Snacks between meals

Availability of Oral Nutrition Supplements

The number and variety of products marketed as ONS, the number and types of claims for these products, and the types of ingredients used has increased significantly since the 1970s when the first ONS became commercially available [13]. Most ONS are intended for those individuals who have altered dietary requirements that cannot be achieved by conventional diet or food modification, or for management of distinctive nutrient needs resulting from a specific disease or condition that impairs ability to ingest, digest, absorb or metabolize nutrients. It is most notable that there appear to be no published randomized trials comparing food modification to oral nutrition supplementation that is isocaloric or of equal nutrient composition, and thus, no systematic reviews with meta-analysis are available comparing these two oral nutrition intervention entities equally.

Oral Nutrition Supplements versus Dietary Intervention

A meta-analysis using the Cochrane method was conducted investigating the efficacy of dietary advice (i.e., nutrition counseling) compared to either: no advice, provision of ONS, or advice plus ONS [14]. Twenty-four randomized trials were reviewed that included dietary advice provided by a dietitian or other healthcare professional to adults who had chronic disease or were categorized as being at nutrition risk. The number of usable studies was small for all outcomes. No significant difference in mortality was observed comparing dietary advice to no advice. In comparing advice with provision of an ONS, greater energy intakes were observed and greater weight gain after 3 months of ONS. No differences were observed in length of hospital stay or mortality. In comparing dietary advice to advice plus ONS, no differences in energy intakes (1 study), weight change (3 studies) or mortality (5 studies) were observed, but a small favorable difference in hand grip strength was found with advice plus ONS. Although the authors concluded that there is a lack of evidence supporting providing dietary advice, these data are confounded

in that not all dietary advice was provided by a registered dietitian and there is a bias in comparing a cognitive intervention (dietary advice) to a physical intervention (ONS).

A randomized trial was conducted in 4 LTC facilities to compare provision of 3 between-meal snacks per day to an 225-gram 300-kcal ONS provided 3 times daily for 6 weeks [6]. Residents who were at nutrition risk based on a 2.5- to 3-kg weight loss over the prior 6 months were enrolled. No compensation in habitual caloric intakes was observed with snacks or ONS. Average energy intakes increased by 26–30% in the snack group and 46–50% in the ONS group. It is not clear from the data whether the kilocalorie and nutrient contents of the snacks provided were comparable to the nutrient contents of the ONS.

Oral Nutrition Supplements in Chronic Health Conditions

Hip Fracture

In a systematic review and meta-analysis of randomized controlled trials of nutrition support after hip fracture, 8 of 21 trials used ONS in 448 participants [15]. No significant effects on length of hospital stay or mortality were observed. When the data were pooled to combine the outcomes of complications and mortality into one outcome variable, ONS appeared to reduce the number of patients with the combined clinical outcome by 48% (RR 0.52, 95% CI 0.32–0.84). In an update of this review, 4 newer randomized trials showed a 52% reduced risk of complications of hip fracture with ONS (OR 0.48, 95% CI 0.24–0.96).

Pressure Ulcer

A pilot study was conducted with 9 adults (55–84 years old; BMI 17.9–27.2) who were admitted for surgical treatment of chronic skin ulcers. ONS were provided 1–4 times daily to meet a caloric intake goal of 25 kcal/kg. ONS provided 35% of total energy intakes and appeared to help with wound healing with a 90% rate of skin graft acceptance at 10 days postoperatively. Subjects also received a daily multivitamin and 500-mg vitamin C supplement [16]. A larger study of ONS with 672 older adults who were at increased risk of developing pressure ulcers showed ONS reduced risk by 43% (95% CI 1.03–2.38) [17]. However, a comprehensive search on clinical outcomes from ONS in adults with pressure ulcers resulted in only 5 of 15 studies that were useable for meta-analysis [18]. Of the 5, four (n = 1,224) compared ONS to routine care in adults at risk of pressure ulcers. Only intervention with a high-protein ONS showed a significant reduction in the incidence of pressure ulcers (OR 0.75, 95% CI 0.62–0.89). The authors estimated that 19.25 patients would have to receive ONS to prevent one pressure ulcer.

Oral Nutrition Supplements in Chronic Disease States

Diabetes Mellitus

A systematic review in which ONS were used with adult patients with type I or II diabetes mellitus resulted in 16 of 23 studies for meta-analysis [19]. In one short-term randomized controlled trial, ONS resulted in lower postprandial glucose and insulin levels and glucose area under the curve compared to routine care. In addition, using a diabetic-specific formula (i.e., higher in fat, fructose and fiber) versus isocaloric food-based afternoon snacks lowered postprandial glucose. Using a diabetes-specific formula compared to a standard formula also improved glycemic control as 6 randomized controlled trials showed significantly less rise in postprandial glucose level by 1.03 mmol/l, 2 trials showed significantly lower peak blood glucose concentration by 1.59 mmol/l, and 4 trials showed significantly lower glucose area under the curve.

Chronic Renal Disease

A systematic review of ONS in chronic renal disease resulted in 18 studies (n = 541), but insufficient comparable data to perform meta-analysis on clinical or functional outcomes [20]. In assessing the 14 studies that compared renal disease-specific ONS to routine care, it appeared that disease-specific ONS increased energy and protein intakes as well as the serum albumin concentration.

Stroke

In a 15-country randomized trial of acute stroke patients who were not dysphasic, usual hospital diet (n = 2,007) versus usual diet plus ONS (n = 2,016) showed no difference in the frequency of in-hospital complications (defined as pneumonia and urinary tract infections), length of hospital stay or mortality [21]. However, only 8% of patients in both groups were categorized as undernourished (by observation) and dietary data were not collected to evaluate actual consumption.

Cancer

In a meta-analysis of 3 randomized controlled trials of ONS provided to patients with cancer who were undergoing radiation therapy [22], the findings showed an average increase in energy intakes of 381 kcal/day as compared to caloric intakes from standard hospital meal services.

Oral Nutrition Supplements in General Hospitalized Patients

Several comprehensive meta-analyses have been conducted to summarize and evaluate the published evidence on outcomes of ONS in hospitalized patients with various conditions and disease states. In a review of the

literature published from 1970 through 1996, 20 clinical trials were evaluated in which ONS was used in 1,495 hospitalized patients [23]. Although less than one third of the authors reported reliable methodology, supplementation appeared to increase body weight with a pooled weighted mean difference of 2.06% (95% CI 1.63–2.49%) and reduce mortality by 37% (OR 0.61, 95% CI 0.45–0.82). These findings were supported by a prospective randomized trial in which the oral intakes of 381 patients (aged 61–79 years) were supplemented daily with a 180-kcal ONS that was distributed during daily medication rounds. Treatment group subjects consumed significantly more calories (1,409 ± 448 vs. 1,090 ± 417 kcal), had a 1% weight gain compared to a 1% weight loss in the control group, and had a significantly lower mortality rate (14.7 vs. 35%).

Another systematic review of 55 randomized or quasi-randomized trials using ONS in adults aged ≥65 years old (n = 9,187) showed significantly greater energy and protein intakes with ONS [24]. Nineteen of the 55 trials showed decreased in-hospital complications (i.e., infections, incomplete wound healing, pressure sores or exacerbation of disease) with an OR of 0.72 (95% CI 0.53–0.97). Reduced mortality was observed in 25 trials (OR 0.86, 95% CI 0.74–1.00), which was most pronounced in adults who were aged ≥75 years.

A review of 49 randomized or quasi-randomized trials included a total of 4,790 adults aged ≥ 65 years old, with 40% residing in the community and 60% in acute or chronic care settings [25]. The minimum ONS intervention was 10 days. Twenty-nine studies reported increased total daily energy and protein intakes with ONS; however the variety of dietary assessment methods used did not allow meta-analysis of dietary data. Data from 34 trials showed a benefit from supplementation for percentage weight change with a pooled mean difference in weight change of 2.3% (95% CI 1.9–2.7) and data from 14 trials showed a benefit for mid-upper arm circumference with a pooled weighted mean difference of 1.2% (95% CI 0.4–2.0). Data from 10 studies showed no benefit from supplementation for length of hospital stay with a pooled weighted mean difference of –1.98 days (95% CI 5.20–1.24). Thirty-two trials showed that the relative risk for mortality was significantly reduced by 60% in supplemented subjects (RR 0.40, 95% CI 0.59–0.92). However, reduced risk may have been specific to subjects who were categorized as undernourished (n = 1,825), with a relative risk of 0.72 (96% CI 0.55–0.94).

Oral Nutrition Supplements in Assisted Living and Long-Term Care

A randomized double-blind placebo-controlled trial was conducted with 68 adults (≥65 years old, BMI ≤25) living in homes for the elderly or sheltered

housing [26]. They consumed ONS twice a day between meals for 6 months. The supplement group had a significantly greater total energy intake and a 2.5% greater weight gain ($p = 0.031$), but no difference in body composition and physical function. Importantly, no compensation was observed in the amount of caloric intakes from regular meals.

Oral nutrition supplementation is the most often prescribed approach to prevent or attenuate unintentional weight loss in LTC. Studies show that consumption of ONS is high when residents are offered choices that meet taste preferences and when they receive adequate assistance to promote consumption [27, 28]. However, LTC residents receive ONS less than one third of the time that they are prescribed and nursing home staff spends only 5% of the time that is needed for adequate encouragement of oral supplement intakes. Hence, LTC residents consume more calories when provided with snack foods and beverages between meals [29] and family members rate providing multiple between-meal snacks throughout the day as a more preferable nutrition intervention [30]. Nevertheless, ONS do not appear to interfere with food and beverage intakes in LTC and energy intakes have been increased as much as 50% [6].

Conclusion

The conditions of adult marasmus (energy undernutrition) and adult kwashiorkor (protein-energy undernutrition) often remain unrecognized and untreated. Yet, undernutrition contributes to a poor prognosis for many acute and chronic conditions and disease states. The most common cause of undernutrition, inadequate dietary intake, is preventable. Despite the successes of food-based strategies, inadequate funding for food-based interventions and food-based research promotes the widespread use of oral nutrition supplements – even in conditions such as hip fracture, pressure ulcers and stroke where the scientific and clinical efficacy is weak. As oral nutrition supplements are considerably more expensive than foods, national and global efforts should be made to fund, design, implement and evaluate the clinical and functional efficacy of food-based nutrition interventions. To make an equitable assessment of the overall efficacy of food-based strategies versus oral nutrition supplementation, adequately powered randomized controlled trials must be conducted where the dietary treatments being contrasted are homogeneous with regard to nutrient contents and the administration regimen. Further, registered dietitians – as the best trained healthcare professionals for nutrition intervention – should be more rapidly and wholly utilized in all care settings for identification and treatment of inadequate dietary intakes [31].

References

1 Odlund Olin A, Armyr I, Soop M, et al: Energy dense meals improve energy intake in elderly residents in a nursing home. Clin Nutr 2003;22:125–131.
2 Barton AD, Beigg CL, MacDonald IA, et al: A recipe for improving food intakes in elderly hospitalized patients. Clin Nutr 2000;19:451–454.
3 Silver HJ, Dietrich MS, Castellanos VH: Increased energy density of the home-delivered lunch meal improves 24-hour nutrient intakes in older adults. Am Diet Assoc 2008;108:2084–2089.
4 Mathey MFAM, Siebelink E, de Graaf C, et al: Flavor enhancement of food improves dietary intake and nutritional status of elderly nursing home residents. J Gerontol 2001;56A:M200–M205.
5 Schiffman SS, Warwick ZS: Effect of flavor enhancement of foods for the elderly on nutritional status: food intake, biochemical indices, and anthropometric measures. Physiol Behav 1993;53:395–402.
6 Turic A, Gordon KL, Craig LD, et al: Nutrition supplementation enables elderly residents of long term care facilities to meet or exceed RDAs without displacing energy or nutrient intakes from meals. J Am Diet Assoc 1998;98:1457–1459.
7 de Jong N, Chin A Paw MJ, de Groot LC, et al: Functional biochemical and nutrient indices in frail elderly people are partly affected by dietary supplements but not by exercise. J Nutr 1999;129:2028–2036.
8 Kruizenga HM, Van Tulder Mw, Seidell JC, et al: Effectiveness and cost effectiveness of early screening and treatment of malnourished patients. Am J Clin Nutr 2005;82:1082–1089.
9 Johnson DB, Beaudoin S, Smith LT, et al: Increasing fruit and vegetable intake in homebound elders: the Seattle Senior Farmers' Market Nutrition Pilot Program. 2007 Feb 23. http://www.cdc.gov/pcd/issues/2004/jan03_00010a.htm
10 Administration on Aging: Nutrition Program Evaluations. 2007 Jan 18. http://www.aoa.gov/prof/aoaprog/nutrition/program_eval/eval_report.asp
11 Keller HH: Meal programs improve nutritional risk: A longitudinal analysis of community living seniors. J Am Diet Assoc 2006:106:1042–1048.
12 Gollub EA, Weddle DO: Improvements in nutritional intake and quality of life among frail homebound older adults receiving home delivered breakfast and lunch. J Am Diet Assoc 2004;104:1227–1235.
13 Food and Drug Administration: US Department of Health and Human Services. Federal Register: November 29, 1996. Volume 61, Number 231. http://www.cfsan.fda.gov/~lrd/fr961129.html
14 Baldwin C, Parsons T, Logan S.:Dietary advice for illness-related malnutrition in adults. Cochrane Database Syst Rev 2001;2:CD002008.
15 Avenell A, Handoll HHG: Nutritional supplementation for hip fracture aftercare in older people. Cochrane Database Syst Rev 2006;4:CD001880.
16 Raffoul W, Far MS, Cayeux MC, et al: Nutritional status and food intake in nine patients with chronic low limb ulcers and pressure ulcers: importance of oral supplements. Nutrition 2006;22:82–88.
17 Bourdel-Marchasson I: Nutritional supplementation in elderly people during the course of catabolic illnesses. J Nutr Health Aging 2000;4:28–30.
18 Stratton RJ, Ek AC, Engfer M, et al: Enteral nutritional support in prevention and treatment of pressure ulcers: a systematic review and meta-analysis. Ageing Res Rev 2005;4:422–450.
19 Elia M, Ceriello A, Laube H, et al: Enteral nutritional support and use of diabetes-specific formulas for patients with diabetes. A systematic review and meta-analysis. Diabetes Care: 2005;28:2267–2279.
20 Stratton RJ, Bircher G, Fouque D, et al: Multinutrient oral supplements and tube feeding in maintenance dialysis: a systematic review and meta-analysis. Am J Kidney Dis 2005;46:387–405.
21 Dennis MS, Lewis SC, Warlow C; FOOD Trial Collaboration: Routine oral nutritional supplementation for stroke patients in hospital (FOOD): a multicenter randomized controlled trial. Lancet 2005;365:755–763.
22 Elia M, Van Bokhorst-de van der Schueren MA, Garvey J, et al: Enteral nutritional support and eicosapentaenoic acid in patients with cancer: a systematic review. Int J Oncol 2006;28:5–23.

23 Potter JM: Oral supplements in the elderly. Curr Opin Clin Nutr Metab Care 2001;4:21–28.
24 Milne AC, Avenell A, Potter J: Meta-analysis: protein and energy supplementation in older people. Ann Intern Med 2006;144:37–48.
25 Milne AC, Potter J, Avenell A: Protein and energy supplementation in elderly people at risk from malnutrition. Cochrane Database Syst Rev 2005;1:CD003288.
26 Wouters-Wesseling W, Van Hooijdonk C, Wagenaar L, et al: The effect of a liquid supplement on body composition and physical functioning in elderly people. Clin Nutr 2003;22:371–377.
27 Lauque S, Arnaud-Battandier F, Mansourian R, et al: Protein-energy oral supplementation in malnourished nursing-home residents: a controlled trial. Age Ageing 2000;29:51–56.
28 Young KW, Greenwood CE, van Reekum R, et al: Providing nutrition supplements to institutionalized seniors with probable Alzheimer's disease is least beneficial to those with low body weight status. J Am Geriatr Soc 2004;52:1305–1312.
29 Simmons SF, Patel AV: Nursing home staff delivery of oral liquid nutritional supplements to residents at risk for unintentional weight loss. J Am Geriatr Soc 2006;54:1372–1376.
30 Simmons SF, Lam HY, Rao G, et al: Family members' preferences for nutrition interventions to improve nursing home residents' oral food and fluid intake. J Am Geriatr Soc 2003;51:69–74.
31 Institute of Medicine, Committee on Nutrition Services for Medicare Beneficiaries: The Role of Nutrition in Maintaining the Health of the Nation's Elderly: Evaluating Coverage of Nutrition Services for the Medicare Population. Washington, National Academy Press, 2000.

Discussion

Dr. Hoffer: I want to make some remarks and get your reactions to them. First, the use of meta-analysis in general, I understand the need for some way of summarizing or gaining an understanding from large numbers of studies. Meta-analysis, of course, has many potential difficulties because it condenses and its principle is that there should be no heterogeneity between the different experiments and it was designed for testing drugs. The two issues I see as potential problems, but I don't know the resolutions, because we do need something in the nature of meta-analysis, are that the types of therapy used vary tremendously and, returning to some comments about the grey zone, one needs to distinguish between providing nutrition to people who are malnourished and providing nutrition to people who don't need the nutrition. This is comparable to carrying out a large, controlled trial of blood pressure-lowering therapy for people whose blood pressure is normal.

Following from that, my suggestion, in terms of science and promoting the concept of the so-called nutritional paradigm, is that in future controlled trials we should only treat those people who have the disease, knowing full well that others would benefit through prevention of the development of malnutrition. People who are not in on this or don't comprehend it, like certain individuals in committees in Germany, they just won't get it unless there are dramatic examples. Big pharma knows this full well. Look at those pivotal trials for lowering blood pressure and lipids, they are the great exemplars of the pharmaceutical model of medicine. They were for people who had cholesterol levels of >6 and diastolic blood pressure of >105 mm Hg. I think that one has to be sophisticated or canny about it, and do studies that even you don't think need to be done because you are convinced. I think they must be done and must give dramatic results, because then the physicians and opinion leaders will click in, see it and shift to incorporate new ones. That is a suggestion, and I wonder what you and others think.

Dr. Silver: We all agree on the limits of meta-analyses. There are differences in the timeliness of the interventions included in meta-analyses, the duration of interventions, the delivery regimens, the targeted populations, measuring whether there was compliance or adherence, and differences in study design. So, there is a lot of opportunity for heterogeneity in meta-analyses and by no means do I suggest that is not true.

I also think that one of the key problems in clinical nutrition research is inadequate funding. Without adequate funding, it is very difficult to design randomized controlled trials, which are really very costly, and that is one of the things that I alluded to in my study which was randomized, controlled and cross-over designed. But, it was limited to 4 weeks and to looking at intakes in a 24-hour period because, even in a fairly well-funded study, we are still, at least in the US, very limited in terms of applied nutrition research and what we can do with the funding that we have.

I think that meta-analyses are a tool, and Dr. Elia is far more an expert than myself, but I think that they are meant to try to pull together a number of studies that may seem somewhat disparate but are in some ways trying to measure similar outcomes. So, we try to draw some inferences from that kind of data. I do think that there are some really good hints from the meta-analyses which have shown that these kind of outcomes, increased energy intake, increased weight gain, increased strength and decreased mortality, have been more significantly observed in older people who, because of age, may be more frail, and people of a low BMI. These are the older adults who are most likely to be at nutrition risk. We don't have agreed definitions, measurement instruments or outcomes. As I tried to point out in the oral nutrition supplementation literature, the outcome of complications; frankly, the word 'complications' doesn't really mean a whole lot to me, it is a very vague, loose term. I could pretty much decide which complication I think it should be and that is the one I will speak in favor of. There are some lessons to be learned and, because of our funding limitations, we don't have the kind of pharmaceutical money to do phase-one trials. I do think that we have to look at what evidence we have if we are trying to make an argument for types of interventions or reimbursement.

Dr. León Sanz: I fundamentally agree with you but I think that we need to include not just malnourished patients in those studies. I think that we could establish a comparison with metabolic syndrome, for instance, and we could use drugs to treat these patients before they actually fulfill the criteria for diabetes. Even in the drug area, we also treat patients at risk, not only patients with a formal diagnosis.

Dr. Elia: I agree with what Dr. Silver and Dr. Hoffer have said. I would like to reinforce some of the points. Meta-analysis can be used and abused. There is particular concern when meta-analysis is being done by technicians who know how the process of meta-analysis is done but have no clinical knowledge. Problems have arisen again and again. One of them is this categorization of heterogeneity and how that is mixed with other studies. Some meta-analyses have attempted to separate the so-called normally nourished from non-normally nourished people with completely different conclusions. This kind of problem may even arise within the study. In the Food trial, which is the largest trial ever in nutritional support, involving about 4,000 subjects, 92% of the patients were normally nourished. One has to take that into consideration. I would like to make one final point about heterogeneity, which is sort of said to be bad. In some situations, I would argue that it can be very useful. There is heterogeneity between studies and it is said that there should not be meta-analysis because you are looking at different populations, but sometimes you can find a covariate that beautifully explains that heterogeneity. This is the power of meta-regression which, I think, is not used sufficiently and can actually throw up new insights and new hypotheses as a result of looking into the causes of heterogeneity in a quantitative way, using meta-analytic techniques that are available on some software products.

Dr. Silver: Going back to the food-based intervention issue, I would like to raise a challenge to Nestlé because there is a big opportunity here in terms of food-based intervention and the concept of food modifications and enhancing energy and nutrient density. In our study the population was older Jewish adults and even though we were limited to using Kosher foods, which are much more expensive than regular foods

from a grocery store, the actual cost of the meal was only increased by USD 0.81. That is very low, considering the types of food we had to use. With the number of food products that Nestlé has available, Stouffer's packaged foods, the soups, the Lean Cuisines, the chef-made entrees, the Hot Pockets, Croissant Pockets, even the candy bars and cookies, and the Lean Pockets for obese older adults with malnutrition, there is a great opportunity there to be involved in food modification and food-based intervention. If you can look at it in terms of what Wyeth did when they created Centrum Silver, the concept that older adults have different nutrient needs, those needs could also be met by foods. But there might be a need for a line of food products that is specific to the nutrient needs of older adults.

Dr. Kondrup: I agree totally with you that this is an area that will see a lot of development in the future. About 97% of the money spent in hospitals on patient nutrition is actually on food. Artificial nutrition is really a small thing and I think that we could gain a lot of political influence and sympathy for our cause by working more seriously with the food part of it. I agree totally with you and would like to point out that this food thing is not just the technology offered. In our experience, when we label a patient as being at risk, he is eating too little and therefore should eat more. In about 50% of these cases, patients eat adequately because we tell them they are at risk. They have lost their incentive to eat, have lost appetite, but once prompted, a large number of them can eat adequately when they are given this label. For those who are not capable of eating adequately, we have the problem of early satiety, which is also a big challenge. Above all of this deductive natural side, we also have the narrative side of it, and we must remember that we are serving a meal to the patients, not just technology and energy. I think that there is a whole area of social sciences, sociology or whatever that we have to learn about to make this work with the food component.

Dr. Bistrian: I have comments for Dr. Hoffer and Dr. Elia, agreeing with some and disagreeing with others. For Dr. Hoffer, to disagree, some of the most convincing evidence for the role of nutritional support in the critically ill has occurred in non-malnourished patients, whether they be head trauma, burns or multiple trauma, that is the most convincing evidence we have. Those are people who are not malnourished and the earlier it is started, the more effective it is. Just doing it in malnourished patients is going to lose some of our most effective therapy. For oral nutritional supplements, probably the strongest evidence was in hip fracture, and mostly in very thin patients. To show that, without obvious malnutrition diagnoses, it was a tremendous benefit. In fact, in hip fractures, the number in several studies was so large that it was not necessary to combine them in a meta-analysis. They were three randomized trials all of sufficient size to justify the adoption, so to put them into a meta-analysis puts them in the problems that meta-analyses have.

There was a very important study on meta-analyses. They studied seven different conditions for which there had been meta-analyses conducted, in which large randomized trials were conducted subsequently that had para-analyses to show they could be definitive. The agreement between the meta-analyses done prior and the randomized trial, one third of the time you would have rejected a therapy that would have been effective, one third of the time you would have accepted a therapy that was not effective, and only one third of the time would the meta-analyses have predicted the right answer. So, these argue that even very well-conducted meta-analyses are better than experts saying what their expert opinion is, but it is a great distance from a randomized clinical trial.

Dr. Hoffer: I agree with what you have said, Dr. Bistrian, but I have a strong intuition that the critical care situation is different for the patient outside the ICU. I am talking about in-hospital because that is my experience. For that kind of patient, I

suspect, it will be necessary to just find the sickest and clear-cut cases and treat only those who should be treated.

Dr. Bistrian: Because they are so heterogeneous. The beauty of dealing with one disease in the critically ill is that it's one disease and we take away a huge amount of heterogeneity. If you look at the role of nutrition support outside the ICU, where patients have many diseases, there the homogenous nature is the malnutrition. So, if you are studying something homogenous in those, it is malnutrition. In the critical care unit, it's the disease process that is the homogeneity and enables you to find outcomes with relatively small numbers.

Dr. Silver: I think it is also important to remember that our meta-analysis process starts with a comprehensive review of the literature, with 2,000 or 3,000 studies being collected that are supposedly looking at similar interventions and outcomes. Then, through a very careful process, it really boils down to 15–30 studies that are actually used in that analysis. That was overwhelmingly the case in the studies that I reviewed in the meta-analyses that I included in the presentation. They went through very strict criteria to weed out the studies that really were addressing the outcomes as best as we have defined them.

Dr. Hoffer: There are two meta-analyses where the same literature was used on whether albumin works The first meta-analysis of a vast number of studies said that albumin increased mortality. The second meta-analysis done with the same data, showing why the first study was defective, the studies that were included and those that weren't, gave a better meta-analysis and gave exactly the opposite conclusions. We have a second group, with parenteral versus enteral nutrition; numerous studies have shown that total parenteral nutrition is worse than enteral nutrition. However, the most recent meta-analysis, done in intensive care medicine, where they used the best third of randomized trials, only the intention-to-treat trials show the opposite, that total parenteral nutrition reduces mortality by 50%. This is the problem, these analyses have to be viewed with a great deal of caution.

Mr. Jedwab: With regard to the food idea, I am not quite sure how to interpret what you have been saying in the sense that the difference between food and classical clinical nutrition is almost comparing apples with oranges in the sense that they are almost by definition covering different benefit territories to start with. While it is true that Nestlé and our competitors have a vast range of foods and clinical nutritions, the target populations for whom these products were designed are completely different. When you talk about making a clinical trial comparing the two, and I totally understand the logic, but you render the trials of the two different products isocaloric, I assume when you mention homogenous you also mean isonitrogenous when you talk about making the micronutrients the same. Somehow by changing the rules of the game you will be comparing apples with apples rather than apples with oranges that you wanted. So, I must admit that I am not quite clear on where we are going with this.

Dr. Silver: I really don't agree actually. I am not a food technologist or a food scientist, I am a nutrition scientist. I do think that it's entirely possible to take foods, whether it is an individual food item, like a broccoli dish, or an entire menu, or a 7-day cycle of menus in a long-term care facility, and clearly measure the same outcomes, we can increase caloric intakes, we can increase protein intakes, we can increase vitamin and mineral intakes. We could look at the same type of outcomes because we are increasing the same things. When you get down to it, oral nutrition supplements come from foods. They are nutrients and nutrients come from foods. Of course, there is a technology to formulate and produce the product but I think the issue is that we haven't invested the kind of funding, as limited as it is with oral nutrition supplements, we have invested even less in investigations of food-based interventions. Unless we are going to fund these types of interventions and really look at them in a scientific

and systematic way, we really can't make an argument, pro or con, if we haven't done the research.

Dr. Roessle: I am from the Nestlé Research Center and have often been involved in the design of clinical studies for nutritional outcomes. The difficulties that we have always faced, and are very different from mock trials, are that there is by definition no placebo treatment for any nutritional intervention. The benefits that we are talking about come from calories and protein in the first place. As soon as you render any intervention isocaloric or isonitrogenous with a different product you run into trouble. The second problem is that we are also looking at outcomes in nutrition where the patients are also getting drug treatments that cannot be suspend for ethical reasons during our nutritional intervention. This makes it so difficult to compare studies because a controlled treatment is not defined. So, the meta-analysis in our situation, if it shows a positive outcome, is the minimum consensus that you can get. But probably individual studies, if repeated, would get much more significant outcomes. But this is not possible for many reasons.

Dr. Kondrup: The question about who should have these specially developed foods: I think the supplements that we have now should be used in the hospital and perhaps until shortly after discharge from the hospital. Then, after that, there will be a period before the patient is capable of eating normally, and going shopping as usual. In that transition phase, it would be very useful to have some of these modified foods for the patient. So, we see the patient's journey and have to supply nutrients for the whole journey, from the ICU to full recovery.

Mrs. Anthony: Dr. Silver's challenge to Nestlé is very interesting, and this idea of the patient's journey makes great sense because, to me, enhanced foods and oral nutrition supplements don't necessarily compete. Oral nutrition supplements offer patients the option of meeting their needs and not having to worry about eating enough. It gives them one more option, but it is not their only option; they don't compete. Talking about reimbursement, what I find interesting about your proposal is that in many countries oral nutrition isn't reimbursed but patients don't want to pay for oral nutrition supplements because they see them as medicine. For example, patients may be willing to pay for an enhanced food that is more directed towards their age group. I am not sure that there will be foods for elderly diabetics, for instance, just because the economics of making these products have to hit a broad group to be economically reasonable. But it is a reasonable idea to ask if we can make a Lean Cuisine for the elderly; if we can make Hot Pockets for the elderly, etc. Yes we can; it might not be done, but it is an idea that we can't toss out and it is not necessarily for the sick elderly. When we talk about oral nutrition supplements, it is for people who are a little more ill. There are two things but they might help us a little in getting the public to think that they might have to pay a little more for a specifically designed food. It is an interesting thought and we just have to figure out how it can all be worked together.

Dr. Silver: We must remember what the patient's or client's preference is. In the study that Simmons and Schnelle [1] did on the long-term care facilities, the overwhelming preference was for food, not nutritional supplements, by both the residents and their families. I am not suggesting that there is no place for oral nutrition supplements, as you can see from the results of the meta-analyses, but I am saying that we must not forget about food.

Mrs. Anthony: I agree, but I also think that what we prefer and what actually happens are actually two different things. The challenge from dietitians is that food is better and we should work on food. I agree, but at one point we have to realize that if food isn't being accepted or isn't being taken, we need to look at other options. It also makes great sense to supplement foods and make them higher in energy and protein, but when we talk about cost, we always think food is cheaper. We never seem to take

into account the labor, extra people and the work it takes to get the food in. It doesn't always make it less cost-effective, but it is something that we need to think about because, in an institution where food is being individualized per patient, there will be extra labor costs which need to be taken into account. I am not against food; I fully support the use of food but, as dietitians, I think we are sometimes more idealistic than realistic.

Mrs. Skouroliakou: Are you talking about nutraceuticals because the young generation buys them everyday? Specifically people who are hard workers and don't like to cook. They think that, with nutraceuticals, they solve their problems. In my institution, I see these hard-working people and advise them to get nutraceuticals because it is good for them. Is that what you mean by enriched food?

Dr. Silver: That brings us into a whole different discussion. My study was a food-based intervention where we manipulated the energy and nutrient density of the meals themselves using actual food ingredients, and we showed a clear increase in caloric intakes without energy compensation. We did not look at longer term outcomes and we have not been funded to do that. Another thing that we have not been funded to do is look at the cost-effectiveness of food-based interventions. So, while we can make suggestions that it might be expensive, we actually have no data to support or not support food-based interventions.

Mrs. Le Tadic: I have a comment in reaction to the discussion on Nestlé's role with regard to providing food-based solutions. In the UK, we have put an approach together which is actually to go for food first. The solution that we give to healthcare professionals is to start by identifying those who need fortified meals to strive or to put on weight. We suggest food-based solutions first. One thing is that Nestlé doesn't have the same sort of portfolio of solutions in all the countries. In the UK, the main categories that we sell are confectionary and coffee. That put aside, we also have milk and concentrated milk which could be a basis for a solution. What we do face, and this is the reality check that Mrs. Anthony was talking about, although we go for this kind of solution, it is not necessary to say give this food systematically. The convenience of the solution competes with common sense most of the time. In a cost-driven economy, with reduced staff in nursing homes, reduced staff in hospitals, and less and less qualified staff as well, who can understand this counseling practice? It is much easier to drop something on the table. So, that is the reality check. At the end of the day, my question is not so much should there be competition between both forms but perhaps a different way of selling clinical nutrition to the patient in a more attractive fashion, instead of having to compete against solutions that, to be honest, are like banging our heads against the wall. There is no staff to take care of it. That is what I see everyday.

Dr. Silver: I don't think the purpose was to have a battle between food-based intervention and oral nutrition supplementation interventions. I think the question is where do we have evidence to show that either one works; where do we not have evidence; who should we really be providing, and what could we do more of?

Mrs. Le Tadic: But should it be a question of eating versus not eating?

Dr. Silver: I don't know if that's the question. The question is when to enhance food options and when to provide ONS.

Reference

1 Simmons SF, Schnelle JF: A continuous quality improvement pilot study: impact on nutritional care quality. J Am Med Dir Assoc 2006;7:480–485.

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Cost-Effectiveness Analysis and Health Policy

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Abstract

Economists have devised three main techniques to evaluate healthcare treatments: cost-benefit analysis, cost-effectiveness analysis and cost-utility analysis. Many countries have established regulatory authorities to examine the clinical safety, efficacy, and cost-effectiveness of a product. Currently, economic evaluations play a limited role in decision-making but may increase in importance as healthcare costs continue to rise.

The use of economic evaluations to inform decision-making has increased rapidly in the last two to three decades. There has always been a shortage of resources devoted to healthcare and there always will. With rising expectations and the explosion in the costs of new treatments, pressure on restricted healthcare budgets has become more acute. Consequently rationing decisions, which have always been present, appear to become more painful. There is a need, therefore, to ensure that the limited healthcare resources are used to their best effect. Economic evaluation aims to aid rational decision-making such that the best or most efficient use of available resources is made. Here the rationale for economic evaluations and their use by decision-makers will be discussed.

Resource Prioritization

Resource prioritization within the wider society is usually accomplished by the use of market mechanisms. Economic theory postulates the presence of perfect competition. For a market to work efficiently there are numerous sellers and buyers of goods and services. The consumer has perfect knowledge

of alternative goods and services and consequently sellers compete on quality and price. There are no barriers to entry into the market and consequently new sellers are attracted into the market when others exit. Inefficient sellers are driven out of the market as buyers or customers switch to alternative suppliers. If too many sellers are removed the price of a product rises, which encourages more producers into the market. Over the long run the price of a product reflects its worth or utility to the consumer. In the long run this should lead to the optimum allocation of resources in society: that is all the available resources are allocated in such a fashion that the most benefit or utility is gained for these resources.

Most markets do not behave in this fashion, however. Almost always there is some 'market failure' and delivery of the best goods and services are suboptimum or inefficient. For instance, through the judicious use of advertising some producers manage to convince customers that their product is of better quality than a rival, when in truth the converse is true. Customers are often ignorant about the true value of a good and sometimes pick a product on its higher price as they think that indicates higher quality. Furthermore, there are often high barriers to entry into a market. A new company wishing to make food products, for example, will face numerous regulatory and technical hurdles before it is in a position to compete with existing suppliers. As well as barriers to entry the natural tendency is for existing suppliers to become monopolies and discourage the formation of new firms and to drive out existing competitors. Once monopolies are established and competition is muted then there is less incentive to cut costs and prices and therefore the consumer pays more for a product than it produces in terms of its utility. However, whilst there are failures in the market place for most goods and services this failure does not lead to such inefficiency that market solutions are not the best for most things. There are exceptions, however, and healthcare may be one of these.

Healthcare Market

Healthcare is widely seen as a market failure. First, it suffers from the problem of monopoly. The medical profession has convinced governments around the world to confer monopoly privileges. The entrance to the medical profession is regulated, which allows salaries to be higher than they would if there was not a scarcity. Competition between different forms of medical practitioner is discouraged. As well as the problem of monopoly, patients are usually ignorant of the best treatments available for their condition. Consequently they will tend to judge quality on price and therefore clinicians that charge the most will tend to attract more patients even when they provide the same service as less expensive clinicians. This will have the effect of driving up prices leading to inefficient resource utilization. This problem of market failure leads

many governments around the world to intervene in the healthcare market. In the UK this intervention takes the form of the NHS. Nevertheless even with government intervention inefficiencies still exist as there is not a market to allow us to generate cost and utility estimates of the different healthcare services on offer. This leads to powerful medical interests obtaining more resources compared with those who have less power (e.g., cardiac surgeons versus geriatricians). One way to address the economic inefficiencies, and for that matter the inequities, within a healthcare system is to use economic evaluation methods to identify and make transparent the costs and likely benefits of different healthcare decisions.

Economic Evaluation Methods

There are three main techniques to evaluate different healthcare treatments: cost-benefit analysis; cost-effectiveness analysis, and cost-utility analysis. The oldest method is the cost-benefit analysis. This approach measures all the costs in money terms and the benefits as well. If the value of the benefits outweigh the costs then the program is efficient. The problem with this, however, is it is difficult to monetarize all of the healthcare benefits of a given treatment. Consequently health economists tend to use cost-effectiveness analysis and especially a form of this, which is cost-utility analysis.

In a cost-effectiveness analysis the thorny problem of valuing benefits in monetary terms is avoided. The output of a healthcare procedure is measured in its natural units, such as cost per cancer detected or avoided. Unfortunately, this approach is limited in that it is difficult to choose between health conditions: is it better to prevent breast cancer or treat prostate cancer? Therefore, a better alternative is the cost-utility approach. In a cost-utility analysis, benefit, or utility, is measured usually as some form of quality-adjusted life year (QALY). In a QALY, 1 represents perfect health and 0 represents death. An intervention that produces a gain of 1 year of life but 80% of full health is the equivalent to 0.80 of a QALY. By using this method it is possible to make purchasing decisions across a range of different health conditions.

Decision Making with QALYs

To make decisions for rationing scarce healthcare resources, decision makers should choose a bundle of treatments that maximize QALYs for the total budget available.

When a healthcare treatment is subjected to an economic evaluation there are four options: (1) the new treatment can be better and less expensive than the alternative; (2) the new treatment can be more costly and less beneficial

than usual care; (3) the new treatment can be better and more expensive than the alternative, and (4) the new treatment can be worse but less expensive. For the first two options we have a situation of dominance: if the decision is straightforward, we choose the least expensive option. For the latter two scenarios the decision of which treatment to adopt is less straightforward. The key is what are we willing to pay for 1 QALY? Is it 10,000 or 100,000? Generally, however, the choice of cost per QALY in the UK is around GBP 20,000–30,000 and in the USA around USD 40,000.

Use of Economic Evaluations to Prioritize Resource Use

Economic evaluations are seen, increasingly by policymakers, as an important aid for decision making. Whilst most countries have regulatory agencies to approve new products, particularly pharmaceuticals, in terms of their safety and efficacy there is a trend to add another hurdle for approval. This final approval is making economic considerations more explicit. The National Institute for Clinical Effectiveness (NICE) was established by the UK government in an attempt to prevent 'post code prescribing'. In other words to reduce geographical inequity. However, NICE has an important function beyond its role in ensuring improved equity of access: this role is one of cost-effectiveness. Because of the realization that the health system can no longer afford blanket approval of all new expensive interventions, economic analysis is playing a crucial role in its decisions.

Once NICE decides on an appraisal topic it undertakes an assessment by commissioning independent research groups to systematically review the effectiveness evidence and to assess the economic evidence. The latter usually requires a technology appraisal group to undertake economic modeling to ascertain whether or not the technology is likely to be cost-effective. This evidence along with submissions from both commercial companies and other interested parties (e.g., patient support groups) is presented to NICE for review. After taking all the evidence into account, NICE makes a recommendation. This recommendation can take a number of forms: full implementation, the technology is available for all suitable patients; limited with minor restrictions, usually available via clinical guidelines; limited with major restrictions, available to only a small subset of patients, those usually with the highest capacity to benefit or those for whom the evidence is strongest; or finally, no approval [1].

A review of NICE's decision-making by Raftery [2] found that the majority of negative recommendations were due to insufficient clinical evidence whilst the remainder was due to costs. NICE also tends to recommend approval for technologies that can produce a cost per QALY of lower than GBP 20,000. Other factors associated with a positive recommendation included: a lot of randomized trial evidence and lower cost-effectiveness ratio [1].

Sheldon et al. [3] in an analysis of a wide range of NICE recommendations found that the guidance was followed when there was a strong professional consensus behind the recommendations and these were underpinned by strong evidence. It seems that advice to disinvest from expensive treatments with limited effectiveness, e.g., laparoscopic hernia repair [4], is not taken up as much as advice to increase investment.

International Perspective

At present economic evaluation is relatively underused with a European survey suggesting that economic evaluations play a relatively limited role in decision-making [5]. It is likely, however, given increasing cost pressures on the healthcare systems across the world that economic evaluations will increase in importance. Even within the USA there are suggestions to establish a NICE-like organization: the Comparative Effectiveness Board. It is likely such an organization will include economic criteria to inform its decision-making.

Conclusions

Health economics is not about trying to reduce or save costs: it is a discipline that recognizes resource scarcity and attempts to make transparent rationing decisions. Rationing decisions have always been with us and always will. There are other methods of rationing treatment resources. A popular approach is for clinicians to embark on 'shroud waving', which results in extra resources being devoted to heroic possibly life-saving treatments among 'popular' patient groups (e.g., young women with breast cancer), which probably have limited success at the cost of moving resources from less medically popular (e.g., geriatric care) but efficient interventions. Although some of the complex economic modeling techniques may appear to be impenetrable, their conclusions are more transparent and open to challenge than other rationing techniques.

References

1 Walker S, Palmer S, Sculpher M: The role of NICE Technology Appraisal in NHS rationing. Br Med Bull 2007;81–82:51–64.
2 Raftery J: Review of NICE's recommendations, 1999–2005. BMJ 2005;332:1266–1268.
3 Sheldon TA, Cullum N, Dawson D, et al: What's the evidence that NICE guidance has been implemented? Results from a national evaluation using time series analysis, audit of patients' notes, and interviews. BMJ 2004;329:999.
4 Bloor K, Freemantle N, Khadjesari Z, Maynard A: Impact of NICE guidance on laparoscopic surgery for inguinal hernias: analysis of interrupted time series. BMJ 2003;326:578.

5 Hoffman C, von der Schulenburg JM: The influence of economic evaluation studies on decision making. A European survey. The EUROMET group. Health Policy 2000;52:179–192.

Discussion

Dr. McKinlay: Has anybody done a cost-effective analysis of health economics because what you have shown this morning is that this is a new treatment for looking at resource and you have not shown a single example where it has actually worked. So, it seems to be a use of resource with no benefit. Has that been analyzed and why? Because you said that it should be used, but things that are being used, new forms of treatment, new forms of analysis, should be analyzed before they are brought in. You have not analyzed this model for distributing healthcare at all but you are using resource. You have demonstrated that the National Institute for Clinical Excellence (NICE) hasn't really altered clinical practice. My argument about an increased use of drugs is that clinicians knew that they worked and got the green light from NICE. But you have not been able to change anything in the other direction. As a clinician, this looks like a treatment for distribution that doesn't work in its current form. What are the grounds for resourcing it? If resource is getting tighter, why put resource into something that doesn't work?

Dr. Torgerson: So, you want me to justify my job?

Dr. McKinlay: No, I don't, I just want more significance than that. Not your job, I want you to justify your profession.

Dr. Torgerson: I am trying to think of an evaluative technique that you would use. In theoretical terms, economic evaluation should make rational decision making.

Dr. McKinlay: You have demonstrated that it doesn't because even when you believe you have a rational decision, which, as you said yourself, economists make large assumptions, that it is not listened to by either government or the public. So, for example, Alzheimer's drugs, as a way of deciding where resource goes, this doesn't look like a model that works. I would suggest that it isn't very difficult for an economist to add up how much is being spent on this and to see how many outcomes have been changed. If, as a model, it is not changing outcomes usefully, should it take part in the evaluation of health techniques?

Dr. Torgerson: It should because, for a start, health economists are relatively inexpensive. The salary of a professor of health economics is about half that of a clinician's salary.

Dr. McKinlay: Is that effectiveness-based?

Dr. Torgerson: We don't have a strong monopoly as clinicians in terms of demanding higher salaries. Economic criteria will be used even if you don't have a health economist. It is just that they are not explicit. Governments can go against the financing of clinical trials when it suits them, but does that suggest that we should stop clinical trials? For example there have been randomized trials showing that educating children in schools about learning to drive actually increases car accidents. The government has gone against the findings of meta-analysis of clinical trials and are introducing education among children, thereby directly increasing the mortality rate of young people through car accidents when the evidence says that they are doing the wrong thing. That doesn't mean that we should abandon clinical trials just because government won't listen to good evidence.

Dr. McKinlay: That argument is superficial because there are a large number of clinical trials in medicine where, on trial grounds, the treatment has been found to be ineffective, and has been abandoned immediately. One cannot use that argument, it is superficial. What you are talking about here is distribution of resources. You are doing

it in a pseudo-science way, where a more honest way is to use a democratic process. So, perhaps the government should respond to public pressure, and just be honest and say that this treatment cannot be afforded in the UK at the moment, sorry, full stop.

Dr. Torgerson: They have tried that. You are probably familiar with the Oregon experiment, where people were to vote in a democratic process on privatizing healthcare resources for Medicare patients, and breast implants got a higher vote than repair of a fractured neck or femur. The democratic process produces some bizarre results, that being one of them. If we had a democratic process, we would have capital punishment. There are lots of democratic processes that give decisions that people don't like and I don't think that cosmetic breast implants should come before treatment of a fractured neck or femur. If we want to go on justifying professions, we could turn on the medical profession, given that there is an iatrogenic cost of medicine, what is the value of medicine? There have been some studies showing that, when doctors go on strike, the mortality rate actually falls during the strike.

Dr. Labadarios: I was very interested in the equation of your quality-adjusted life years (QALYs), particularly in relation to laparoscopic as opposed to vaginal or abdominal surgery. The conclusion that you drew was that it was not cost-effective. I didn't see anything in that equation about advances in medicine and the likelihood of better treatment in the future as a principle rather than for that specific example. Everyone knows that laparoscopic surgery is much more comfortable for the patient, is much shorter, etc. So, where in the QALY equation do you take into account the need to develop a profession, both academically and in terms of skills, in relation to benefiting the greater public? If that isn't taken into account, how valued is the equation, what are you measuring? You can't just measure whether I am depressed today and happy tomorrow and say that it works or doesn't work, there are other issues. what is the talk among economists regarding the validity of the QALY equation? Because there are only two parameters: one is good and the other is dead.

Dr. Torgerson: The QALY is based on health utility and doesn't just take values of one and zero, there are values in between. There is work looking at the cost of research in the future. Obviously, any research for developing a new surgical technique looks into whether it is worthwhile, and there is work to improve the cost-effectiveness of horizon scanning, to see which are the best ways to direct research budgets. For example, I was involved in a model looking at cost factors of vitamin D and calcium. We did a trial of calcium and vitamin D in the prevention of fractures. The economists were trying to push vitamin D as the way forward because it is so much cheaper compared to calcium. We eventually made a compromise where we had a factorial trial to evaluate them both and one fell through. With a new technology, we always run a sensitivity analysis. Obviously, the price of drugs always falls when they come off patent or when a competitor enters the market, so you won't base costs entirely on the current price of the drug. We would look at what we think the price of this drug will be in 5 years time, given the history of similar advances in pharmaceutical medicine. In 5 years, the price tends to halve because someone else comes in. In 10 years, it goes off patent so it becomes a tenth of what it was. Then, you can look at the cost utility or what it is likely to be given treatment. For laparoscopic treatment, the costs of the surgical instruments are usually based on the long-term. So, if you are doing a trial on a new laparoscopic technique, instruments will have been developed just for a small number of patients in that trial, so the costs are really high. If costs are based on that it is misleading, because if the technique were deemed acceptable the costs would fall as production costs fell. So, we would then try and base costs on the longer term.

Dr. Hoffer: It was very worthwhile and your lecture was very clear. You are absolutely convincing that economic methods will increasingly be used to identify the best use of healthcare resources, it is inevitable. At the same time, I was amazed at

how crude and error-prone the techniques being used are. Yet, these would be the engines of potentially extremely important decisions being made. Also, the mathematical language in which it is couched tends to lead an unsophisticated person, me, to assume that what you do must be valid because it is so complex and sophisticated in its language. In fact, its assumptions and likelihood for error can be enormous. I then thought about our group here, which consists largely of researchers and people interested in human nutrition, and I would agree with the previous comment that the implementation of this type of analysis is very likely innovation-stifling. In the surgical field, techniques improve over time. In fact, there is an upfront high cost, but as techniques improve, the benefits become apparent. It would be alarming to me if, among your group of health economists, you don't include people with experience in the clinical practice of medicine and the realities of looking after patients. That analysis, even though it is softer and not prone to fitting it into equations and algorithms, could be crucial. The major concern I have for our group here at this meeting is that the methods used to evaluate the treatment and prevention of malnutrition are not amenable to the kinds of techniques, particularly pharmaceutical randomized clinical trials. But that kind of analysis gets currency among healthcare economists who don't have that sophisticated view, suggesting that treatments or health policies that could be of enormous benefit to the population will actually be short-changed through the type of analytical approach you have described.

Dr. Torgerson: All the economic evaluations that I have worked on have always had at least one clinical co-author. The only economic papers that I have ever published without a clinical co-author tended to be theoretical pieces that don't have a direct effect on practice. We do work widely with clinicians to get clinical input into the various aspects of the decision analysis. I agree with you that a lot of the techniques are crude, it is difficult to measure QALYs. Unfortunately, as yet, there have been no advances to make things more sensitive. I don't know whether I agree that it is innovation-stifling. The main role of health economics is to make decisions explicit. As I showed, decisions are ignored and there are sometimes good reasons for ignoring them. People who sit on NICE appraisal committees are not all economists and even economists are not that stupid; they would like to encourage innovation. I don't sit on NICE but I talk to people who do, and they argue about giving a treatment the green light where the evidence suggests that it is cost-effective. Someone told me of an example where they knew there was a large clinical trial going on to evaluate a technology and existing evidence suggested that it did work, but if NICE gave it a green light, recruitment to that clinical trial would stop because nobody can recruit patients for it. So, letting clinicians decide to give the green light to treatment X just because a couple of their patients got better also stifles innovation because a clinical trial is immediately precluded. I hardly work as a health economist anymore because I am now the director of a clinical trials unit and the problem of getting clinical trials to recruit patients is phenomenal. Regardless of economics stifling it, clinical decision making stifles research itself because we have all heard clinicians say that they have always done this treatment and they know that it works, and another clinician says exactly the opposite. We are trying to get a clinical trial going for fractured humerus and we have two powerful clinicians saying exactly the opposite: one saying that this trial can't be done because all his patients will want surgery and the other clinician saying the opposite that they want conservative treatment. Both can't be right. So the variation in decision making with clinicians stifles research for a start. Clinicians refuse to recruit patients, so I suspect that clinicians stifle research more than we do.

Dr. Elia: In terms of trying to sort out these discrepancies, you are trying to use cost-effectiveness analysis to inform practices and trying to establish a measure of

social justice. The difficulty is, and perhaps you can clarify for the audience that has been variously exposed to cost-effectiveness analysis, is that there are two components to incremental cost-effectiveness ratios and that is that there is a cost component and a QALY component. The issue that I would like you to clarify is whose costs and whose QALY? For example, let's take the QALY aspect, many of the healthcare resources in developed countries go to elderly people and many elderly people have carers. In the UK, there are about 6 or 7 million carers, about 1 in 8 people are carers. They spend a long time looking after patients, usually their husbands, and the carers themselves are often elderly. If one looks at the surveys that have been done of carers, some of whom put in over 50 h/week, they suffer, they have health detriments. Should that go into the equation or should it just be the patient? On the economic side, whose money should it be? Is it just health service money, other governmental money, other public funds, and to what extent should the individual's money go into it? Is this consistent across all QALYs, cost-effectiveness analyses, because you are trying to distribute one resource against another?

Dr. Torgerson: In theory, all economists measure the costs wherever they lie. So, it is irrelevant whether they are health service costs or the costs of a carer. A cost is a cost and it doesn't matter who it accrues to. You measure the QALY of the patient and their carer as well and pull all that in an equation.

Dr. Elia: That's not really true, is it Dr. Torgeson? It's not always the patient's cost going into cost-effectiveness analysis surely?

Dr. Torgerson: It does sometimes; it depends. As one of my previous antagonists said, there is an opportunity cost through an economic evaluation and sometimes it is clear. If you are evaluating two laparoscopic treatments, where the treatment all occurs in hospital and there is little patient cost, it may not make sense collecting those costs in detail because it takes a lot of effort. As a colleague of mine said, it's horse and rabbit stew. If you make horse and rabbit stew, it doesn't matter how much rabbit goes in the stew, it's the amount of horse that goes in that is important. So patient costs often have little impact. Now, they do have a big impact on some diseases, for example community care for patients with schizophrenia; the non-healthcare costs are enormous. A colleague of mine did an economic evaluation where he showed that care in the community was cost-effective if you only looked at healthcare costs. But if you looked at wider costs to the carers looking after severely ill people in the community, the results change completely. NICE is not an economic evaluation, it is a form of economic evaluation and it only includes NHS costs. Lots of people quite rightly criticize NICE for that because it is a bias. The field that I work in is osteoporosis, so that decision will often bias decisions against treatment of osteoporosis because a lot of costs of caring for people who have had a hip fracture fall on the community and not on the NHS. So, osteoporosis will have a higher cost per QALY than something like hernia repair for surgery, where most costs fall on the health service. It is not a perfect system and NICE does have vocal critics from the economics community for the way they apply various methods.

Dr. Elia: Of course, NICE is part of the NHS, a special health authority, and it's a question whether other components in our society, apart from the health service, should come into those decision-making processes.

Dr. Kondrup: You showed the graph about the QALY after hysterectomy, laparoscopy or traditional surgery. I am curious to know how quality of life is measured in this kind of analysis. It is probably different kinds of quality of life measurements in different investigations and things. How, in this particular study with a hysterectomy was quality of life measured and how often was it measured to determine the shape of the curve? Could you give a very concrete answer to this; how was that particular graph made up?

Dr. Torgerson: It would have been measured before surgery with something called the EUROQOL. It would have been measured a short time after surgery to capture the immediate benefits of surgery, probably a week or so. The surgeons would have been asked about the most optimum time interval to show benefit of this surgery, and the patients in both groups would have been measured at the same time, probably at 12 months, 3 months and a week or 2 after the surgery.

Dr. Kondrup: In this particular study they used EUROQOL and that is one of many ways of measuring quality of life. It has not been said which one is the best or most sensitive to medical intervention or most irrelevant from the consumer's perspective.

Dr. Torgerson: I completely agree with you. In Europe, we tend to use the EUROQOL and in North America McMaster's utility measure is used. There is a North American utility measure and a European utility measure and both groups don't seem to talk. The EUROQOL originated from York; I was not involved in its development. we tend to use it because it is quite simple to put into questionnaires. It has a lot of problems and any I would probably agree with any criticisms you make of it. It is relatively insensitive; it has a terrible ceiling effect, and there are bold spots across the utility. For example, you can't score between, e.g. 0.86 and 1. It does have huge problems, and people are still working on trying to improve it.

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Implementing Nutritional Standards: The Scottish Experience

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Abstract

In the United Kingdom, 5% of the population are underweight or have features of malnutrition. The prevalence of malnutrition rises with age and is more common in the north of England than in the south, but comparable data are not available for Scotland. In 2003, the National Health Service Quality Improvement Scotland (NHS QIS) developed a standard for food, fluid and nutritional care in hospitals (FFNCH). In 2006, a peer review of Scottish health boards was published. The reviewers reported that all Scottish health boards had started to implement the standards, but not across all clinical areas. Every health board had set up a nutritional care group to oversee and advise on the implementation of the standards, but none had produced a financial framework to support the work of the groups. Most health boards had not fully developed a policy or strategic plan to improve nutritional care as required, and there was a shortage of specialist nutrition nurses and clinical and nutrition support teams to supervise the treatment of patients with complex nutritional needs. The Scottish experience emphasizes the size of the task that health services face to bring about change.

Introduction

In developed countries approximately 5% of the population are thought to be underweight, based on a BMI of <20 [1, 2]. A secondary analysis of data collected prospectively by the National Diet and Nutrition Survey, using the Malnutrition Universal Screening Tool (MUST) [3] criteria for people at medium to high risk of malnutrition, suggests a strong correlation between malnutrition and age. The prevalence of malnutrition in the community increases linearly from 10.7% in people aged 65–75 years, to 17.7% in those aged 85 years or more [4]. Elia and Stratton [4] have also shown a strong geographical trend in the UK, with malnutrition being higher in the north of

England than in central or southern England. Comparable data are not available for Scotland, but it would seem likely that the trend will continue north of the border, as deprivation scores tend to be higher in Scotland.

The prevalence of malnutrition in hospitals is known to be higher than in the community. A prospective study from a large teaching hospital in Scotland found that of acute admissions in five specialties 40% of the patients were undernourished and 75% of the patients actually lost weight during their hospital admission. The nutritional status of 78% of the patients who were nutritionally depleted at the time of their admission grew worse during their in-patient stay [5]. Other studies have found similar results. Data from another Scottish hospital, using different parameters to define malnutrition, identified 13% of the patients as being undernourished, but staff failed to identify this as a problem in 75% of the cases whose nutritional condition therefore deteriorated during their stay [6].

An audit conducted by the Clinical Resource and Audit Group (CRAG), now part of NHS Quality Improvement Scotland (NHS QIS), examined the nutritional condition of elderly people in long-stay settings. Whilst the energy content of meals usually met the dietary recommended value (DRV) in theory, the actual calorie intake of elderly people in care was below the DRV in the majority of subjects. This was more apparent in older age groups, particularly those aged 80 years or more. Other nutrients where intake was below the DRV included potassium, non-starch carbohydrate (fiber), vitamin D, folate and zinc [7]. These data were sufficiently worrying to prompt the Scottish Executive Health Department (SEHD) to explore immediate steps to improve the provision of food in NHS institutions.

The CRAG report caused particular concern because the problem of malnutrition has been known for many years and there has been no shortage of reports or expert guidelines trying to address the problem. For example the King's Fund Centre, an independent UK health think-tank, first drew attention to the high prevalence of malnutrition in UK hospitals in 1992, in the report of a working party chaired by Prof. John Lennard-Jones. It was estimated that 50% of surgical and 44% of medical patients were malnourished and that 10% of in-patients could have had their hospital stay reduced by 5 days with the proper use of nutritional support. The report concluded that the responsibility for nutrition was fragmented amongst different professions, that education in nutrition was poor particularly amongst doctors, and that the organization of complex nutritional support was inadequate, mainly due to a lack of clinical nutrition support teams (CNST) [8]. The conclusions are still apposite today.

The continuing problem with institutional malnutrition has never been due to a shortage of advice, but rather in devising effective strategies to bring about change. A report to the SEHD summarized the problem as follows:

'Changing attitudes and behaviour towards nutritional care is a major challenge for the NHS. Because lack of awareness and understanding of the key importance of

nutritional care is widespread, this will take time. Change has to be tackled at a number of levels' [9].

In other words the problem of malnutrition requires a fundamental 'hearts and minds' change at all levels of the organization, and this requires a sustained, focused effort.

The NHS QIS Food Fluid and Nutritional Care Standard

Following the publication of the CRAG report in 2000, the SEHD instructed the Clinical Standards Board for Scotland (CSBS) to produce a clinical standard for hospital food. When the working party convened, however, it was clear that a standard that simply addressed hospital catering would not correct the problems that the CRAG report had uncovered. In particular, it was doubtful whether any change in the provision of food would be effective, unless there was an improvement in the recognition of malnutrition by health professionals. Furthermore, the responsibility for nutrition was shared by a number of different professions and departments. A strategic plan and a coordinated approach would, therefore, be required at health board level. A broader remit encompassing 'nutritional care' was required and fundamental to this process was the need for a working definition:

'Nutritional care … represents a co-ordinated approach to the delivery of food and fluid by different health professionals, and views the patient as an individual with needs and preferences. It is the process that determines a person's preferences and cultural needs, defines his or her physical requirements, and then provides the person with what is needed. It follows a person's progress through an illness, by responding to changing nutritional requirements. It involves the monitoring and reassessment of nutritional status at regular intervals, referral for specialist care when appropriate, and good communication with services in the community. Good nutritional care will involve training for staff, carers and patients, and access to information' [10].

It was also appreciated that many patients in hospital do not receive adequate amounts of fluid and this was also incorporated into the remit. The working party was chosen to include not only representatives from the main professional groups, but also a significant number of lay people drawn from the voluntary sector. This proved particularly important as it served to prevent inter-professional squabbling and also helped to focus the working party on the bigger picture. The draft Food Fluid and Nutritional Care in Hospitals (FFNCH) standard was subject to extensive public and professional consultation and the revised document was published in 2003. Since then it has been reprinted five times, which is an unusually high figure and reflects the continuing public concern about nutrition in hospitals. CSBS was subsequently incorporated into NHS QIS, which is a special health authority charged with the maintenance of clinical standards within the Scottish Health Service. Scottish health boards are required to implement NHS QIS standards.

Each clinical standard consists of a series of 'standard statements' beside which is placed the evidence, or rationale, for the statement and the specific criteria against which the compliance will be assessed. In an individual standard some criteria may be designated as 'desirable' rather than mandatory, particularly if the evidence base is incomplete or the resource issues are felt to be too challenging. The FFNCH standard is unusual in that all criteria bar one are mandatory. Health boards are given time, usually a period of 12–18 months, to implement the standard before NHS QIS carries out a series of peer review visits. In the case of the FFNCH it was decided that only 3 of the 6 standard statements would be assessed on the first visit, specifically those relating to the organization and planning of nutritional care, the assessment of patients and screening for undernutrition, and the staff training, as these represent the bedrock on which the others rest. The peer review process commenced in May 2005 and all 17 health boards had been visited by February 2006. Health boards submitted a detailed self-assessment of their performance against the standards, which was then collated by NHS QIS. A review team consisting of the relevant health professionals and lay members then visited each health board. The visits took 2 days and the findings were published in a local report for each board and a national overview for Scotland, available to the press and public. The NHS QIS review process is, therefore, thorough, demanding for health boards and transparent, but labor intensive.

Findings of the National Overview

The national overview report was launched in August 2006 [11]. All Scottish health boards had started the process of implementing the standards but none had achieved full implementation across all their hospitals. Every health board had set up a nutritional care group to oversee and advise on the implementation of the standards, but none had produced a financial framework to support the work of the groups. Most health boards had not fully developed a policy or strategic plan to improve nutritional care as required, and there was a shortage of specialist nutrition nurses and clinical and nutrition support teams to supervise the treatment of patients with complex nutritional needs. The standard does not require every hospital to have a CNST as this would be quite impractical and unnecessary for small community hospitals, but it does require the health boards to ensure that all patients have access to one.

The standard requires health boards to introduce screening for undernutrition using a validated screening tool, such as MUST. NHS QIS found that most health boards had started to implement screening but none had introduced it across all clinical areas. Similarly care plans and, in particular, the requirement for discharge documents to contain relevant nutritional information, were still at an early stage of development. These findings emphasize the scale of the problem facing health providers. Aberdeen Royal Infirmary,

for example, is a large teaching hospital with over 5,000 nurses who have to be trained in the use of the MUST screening tool. It is not practical to withdraw large numbers of nurses from ward duties, so training has had to be carried out on a unit-by-unit basis requiring over 40 separate sessions. Moreover training has to be an ongoing process because of the natural turnover of staff, some of whom will come from outside areas or agencies. In Aberdeen the best solution has been to institute a process of continuous audit of wards by a dietetic assistant who monitors compliance and then offers retraining if the use of the screening tool is unsatisfactory. The maintenance of nutritional screening is particularly important as it emphasizes the importance of nutritional care at ward level and acts as a focal point for change.

NHS QIS also looked at staff training and education. The standard requires that all staff who are part of the food chain, receive training in nutrition commensurate with their duties. It was found that the development of training programs was still at an early stage, but the importance of conducting a training-needs assessment was clearly important. Training programs take time to develop, but the use of distance learning techniques and of placing information, such as nutritional screening tools, on the hospital intranet are likely to be increasingly important in the future.

NHS QIS did not assess the two standards that relate to the provision of food and fluid at ward level. Amongst the requirements are that all menus are analyzed for their nutritional content and that sufficient staff are present on wards to assist all patients who need help with eating, the latter being a particularly challenging requirement.

In one respect it seems disappointing that progress has been slow. On the other hand, there is no doubt that nutritional care has developed in Scotland and that this has been achieved with minimal additional resources mainly through the work of the many dedicated professionals who form the nutritional care groups. The FFNCH standard relates only to hospital patients and not to community services. Producing a relatively modest change in culture within hospitals has been a major undertaking. The resource implications of extending the work to the community would be significant.

Guidance versus Standards

In England the approach has been different. In March 2006 the National Institute for Health and Clinical Excellence (NICE) produced guidance on nutritional support [12]. Many of the recommendations are very similar to those contained in the FFNCH standard. NICE recommend the formation of strategic nutritional steering committees, support the introduction of screening for undernutrition, and recommend the adoption of CNST and specialist nutritional nurses for complex nutritional support. The NICE guidance was produced after an exhaustive review of the evidence base, which in itself

was not always easy to assess. Trials of nutritional therapies have tended to be small and many do not stand up to rigorous examination. On the other hand there are fundamental differences between nutritional trials and drug trials. Nutrition is not an optional requirement for human beings, nor does an adequate placebo exist for food. In contrast the FFNCH standard arose as a pragmatic response to findings of the CRAG report that patients in long-stay care were not being fed adequately, rather than as a rigorous scientific of review of the literature. This emphasizes some of the fundamental differences between standards and guidance. Guidance should be evidence-based, is often formulated without reference to resource implications, is often voluntary, and may not result in a process of inspection to determine compliance. NICE for example does not have plans to carry out a formal review similar to that performed by NHS QIS. It is not difficult to understand why. The population of England is nearly ten times that of Scotland. It took over 12 months to visit all of Scotland's health boards to review 3 of the 6 clinical standards. The resource implications for England would be formidable, particularly as NICE guidance also applies to community services. Instead, the English health service has brought in simpler requirements through the Commission for Health Improvement, where core standard C15 requires patients' nutritional needs to be met and assistance given to those who need help with eating [13]. These are the equivalent of two criteria statements in the FFNCH standard. The English health authority is expected to comply with NICE guidance, but is this sufficiently specific to improve nutritional care? Hospitals have been encouraged to undertake voluntary benchmarking as part of the 'Essence of Care' [14]. Will this be a sufficient catalyst for change?

Conclusions

Improving the quality of nutritional care is an important challenge facing most Western health services. It is enshrined in the Council of Europe, Committee of Ministers resolution on food and nutritional care in hospitals, to which most European governments are signatories [15]. The Scottish experience emphasizes the size of the task that health services face to bring about change. Even the introduction of screening for undernutrition in hospitals is a major undertaking. The advantage of setting standards is that they represent a clearly defined target against which health boards can measure their progress, whilst compulsory inspections also provide an incentive to initiate change. Scotland has started to make improvements and has done so with virtually no new financial resource. There is no doubt, however, that progress might have been faster if health boards had been compelled to provide some project management and administrative resource.

The detailed scrutiny inherent in the peer review visits forces health providers to examine their practice in detail, but is expensive in time and

resources. NHS QIS has indicated that it will inspect the full FFNCH standard but has not set a date for this. Is a more general approach, as adopted by the Commission for Health Improvement, likely to be more successful? My personal view is that good nutritional care depends on the standard of practice at the ward level, and that the inspection process has to be capable of identifying this. As the proverb observes, 'the devil is in the detail'.

References

1 Information Centre for Health and Social Care: Health Survey for England 2004. Updating of trend tables to include 2004 data. 2006. http://www.ic.nhs.uk/statistics-and-data-collections/health-and-lifestyles-related-surveys/health-survey-for-england/health-survey-for-england-2004-updating-of-trend-tables-to-include-2004-data (accessed 25th Feb, 2009)
2 Stratton RJ, Green CJ, Elia M: Disease-Related Malnutrition: An Evidence-Based Approach to Treatment. Wallingford, CABI, 2003.
3 British Association for Parenteral and Enteral Nutrition: MUST Complete. http://www.bapen.org.uk/pdfs/must/must_full.pdf (accessed April 3, 2007)
4 Elia M, Stratton RJ: Geographical inequalities in nutrient status and risk of malnutrition among English people aged 65 y and older. Nutrition 2005;21:1100–1106.
5 McWhirter JP, Pennington CR: Incidence and recognition of malnutrition in hospital. BMJ 1994;308:945–948.
6 Kelly IE, Tessier S, Cahill A, et al: Still hungry in hospital: identifying malnutrition in acute hospital admissions.[see comment]. QJM 2000;93:93–98.
7 Nutrition of Elderly People and Nutritional Aspects of Their Care in Long-Term Care Settings. Final Audit Report 1997–2000. Edinburgh, Clinical Resource and Audit Group (CRAG), 2000. www.show.scot.nhs.uk/crag/topics/nutrition/nut-main.htm.
8 Kings Fund Centre: A Positive Approach to Nutrition as Treatment. London, King's Fund Centre, 1992, p 48.
9 Scottish Executive Health Department: Report to Scottish Executive Health Department on the Implementation of the Clinical Standards for Food, Fluid and Nutritional Care in Hospitals. 2003. http://www.scotland.gov.uk/Resource/Doc/47171/0013511.pdf (accessed March 2007; Crown Copyright)
10 Food, Fluid and Nutritional Care in Hospitals. Edinburgh, NHS Quality Improvement Scotland, 2003. http://www.nhshealthquality.org/nhsqis/files/Food,%20Fluid%20Nutrition.pdf
11 National Overview ~ August 2006, Food, Fluid and Nutritional Care in Hospitals. Edinburgh, NHS Quality Improvement Scotland, 2006. http://www.nhshealthquality.org/nhsqis/files/FFNCH_NOV_AUG06.pdf
12 National Institute for Health and Clinical Excellence: Nutrition support in adults: oral nutrition support, enteral tube feeding and parenteral nutrition. Clin Guideline 2006;32:54.
13 Department of Health: Standards for Better Health. 2006. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4086665?IdcService=GET_FILE&dID=19479&Rendition=Web (accessed 25th Feb, 2009)
14 Department of Health, NHS Modernisation Agency: Essence of care, patient-focused benchmarks for clinical governance. 2003. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4005475?IdcService=GET_FILE&dID=29341&Rendition=Web (accessed 25th Feb, 2009)
15 Council of Europe, Committee of Ministers: Resolution ResAP(2003)3 on Food and Nutritional Care in Hospitals. 2003;2006(7/14).

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Innovative Models for Clinical Nutrition and Financing

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Abstract

By translating the principles of 'disease management' in an insurance environment, health insurance funds play an important role in the management of chronic diseases of their members. The independent health insurance funds in Belgium have developed an obesity disease management approach based on the integration of collective and individual prevention, early detection and immediate action. Incentive monetary prizes are provided if body mass index (BMI) is reduced by at least 5% following participation in the prescribed treatment plan. The independent health insurance funds plan to launch multimedia projects about the program to educate the target audience of lower income, less educated, obese patients.

By translating the principles of 'disease management' in an insurance environment, health insurance funds play an important role in the management of chronic diseases of its members. Here the experiences of the Mutualités Libres – Onafhankelijke Ziekenfondsen (MLOZ; Independent Health Insurance Funds) in the obesity field are presented. The same approach is possible in the global field of nutrition disorders. MLOZ is the association of 7 independent health insurance funds in Belgium with 1,850,000 members in total, 18.4% of the Belgian population. Over the last years the MLOZ has been growing fast (3.4%), making it the third largest health insurance fund after the Christian and the Socialist funds. The marked difference between the MLOZ and the other funds is the free and independent thinking and working principles. The mission of Belgian health insurance funds is double: to insure the health expenditures of its members, and the good governance of the national health insurance system within social security system.

The Belgian social security system is based on a strong compulsory health insurance that covers 75% of the individual healthcare costs. The other 25%

is partially covered out of pocket, and partially by complementary insurances. Reimbursement by compulsory insurance is discussed and decided within the insurance committee, gathering medical suppliers and health insurance funds in a perfect balance. The main problem here is the vertical or silo approach that inhibits the development of logical and integrated care-by-care paths. The fastest growing expenditures are in the field of the chronic diseases and their complications, and in the field of the elderly dependence and care. The actual growth rate of the budget is fixed by government at 4.5%, e.g. EUR 19.6 billion or EUR 1,830/person in 2007. The expenditures for healthcare are growing much faster than the gross domestic product. Can the Belgian system afford this growth in the future?

The MLOZ developed a health disease management approach for the obesity issue which was launched on April 27, 2006. This strategy, including the disease management concept, can be applied to all forms of malnutrition. The approach is based on the integration of collective and individual prevention, early detection, and immediate action at the beginning of overweight.

An important hurdle in any chronic disease setting is the participation of the insured client and medical suppliers in the care path. In this matter the MLOZ proposes the introduction of an individual contract between the insured client, the suppliers and the insurer. This contract has positive financial consequences for each stakeholder. The accountability of the contract encourages the insured client to follow the care path, the supplier also profits by following the path, and the insurer wins by having fewer hospitalizations and less pathological complications, conditions for which it is financially responsible.

From pure risk insurance, the health insurance funds strategy changes towards risk management.

The 'Globesity' Challenge

The situation in Belgium is identical to that globally (table 1). The rapid increase in overweight and obesity challenges the healthcare system. Intervention by compulsory health insurance is limited to bariatric surgery for patients with a BMI of >40 or >35 with comorbidity.

A recent survey (2005) by Flemish universities (source SBG – www.steunpuntsbg.be) shows amazing figures of overweight and real obesity in both adult sexes (fig. 1).

A national nutrition plan was the political answer in 2005, creating a framework in which a lot of initiative could be undertaken. The Belgian Association for the Study of Obesity and its obesity forum are specific examples of these initiatives.

The MLOZ developed a disease management platform, where the basic principles of disease management are translated into an insurance context.

Table 1. Global estimates of the prevalence of obesity, overweight and mean BMI: 2005–2015

Global	Mean BMI	Population $\times 10^6$	Obesity prevalence		Overweight prevalence	
			BMI $\geq 30 \times 10^6$	BMI $\geq 30\%$	BMI $\geq 25 \times 10^6$	BMI $\geq 25\%$
2002	23.5	4,393.5	356.1	8.5	1,418.8	33.2
2005	23.7	4,626.6	415.3	9.3	1,593.2	35.2
2015	24.6	5,337.7	704.4	13.1	2,298.2	43.0

Source: WHO Global Infobase/IOTF 2006.

The basic activities of a health insurance fund are: (1) the management of the core business – compulsory health insurance; (2) the development of complementary health insurances, and (3) the development and spread of correct information for members. This is what MLOZ has been doing with regard to obesity and overweight. Within the package of complementary insurances, and based on the solidarity principles, we developed an obesity platform and specific information on non-surgical treatment, which has been published on the internet.

The basic approach is disease management, which means a system of coordinated healthcare interventions and communications for populations with conditions in which patient self-care efforts are significant.

Disease management means:

- Support for the physician or practitioner/patient relationship and plan of care
- Emphasis on prevention of exacerbations and complications using evidence-based practice guidelines and patient empowerment strategies
- Evaluation of clinical, humanistic, and economic outcomes on an ongoing basis with the goal of improving overall health
- Population identification processes
- Evidence-based practice guidelines
- Collaborative practice models to include physician and support-service providers
- Patient self-management education (may include primary prevention, behavior modification programs, and compliance/surveillance)
- Process and outcome measurement, evaluation, and management
- Routine reporting/feedback loop (may include communication with patient, physician, health plan and ancillary providers, and practice profiling)

The MLOZ obesity platform is a complementary insurance that all members can benefit from by simply contributing EUR 0.38/month. It offers two

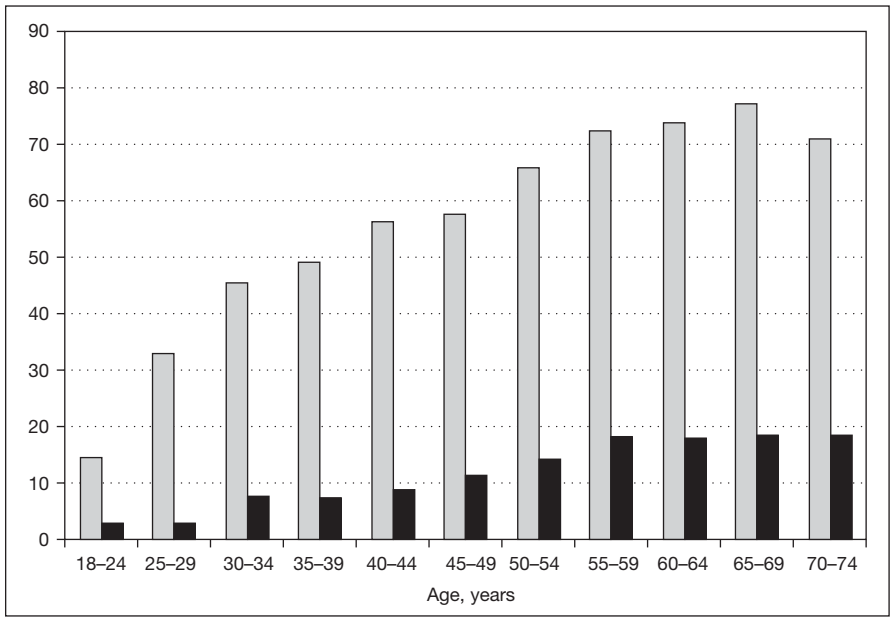

Fig. 1. Overweight and obesity in Flemish men.

professional care plans to the patient, a light one and a heavy one. Both of them start with a questionnaire for self-identification of overweight and obesity, with particular attention paid to children. The first care plan (individual approach) is a light version and is based on dieticians and financial incentives if a 5% BMI reduction is achieved. The second care plan (multidisciplinary approach) starts with a complete check-up: nutritional, medical and psychological, followed by an intensive coaching program based on interventions in these domains. This program can take several months, sometimes even more than a year. The anchor physician of the multidisciplinary center decides when the patient can successfully stop the program. If, after ending the program, no effective progress has been made, a limited financial intervention with pharmaceuticals is possible.

The conditions to benefit from reimbursement are very simple. Having a BMI of >24 is sufficient to enter the light version, a BMI of >24 and having an active General Practitioner File are the necessary conditions to open the multidisciplinary approach (fig. 2).

The financial interventions are substantial. For the individual care plan the dietician receives EUR 15 twice/year, and incentive cheques of EUR 40 (sports and wellness) are paid if BMI is reduced by a minimum of 5%.

In the multidisciplinary care plan the financial reimbursements are: EUR 50 for the check-up; EUR 175 is paid once at the end of a 3-year period for

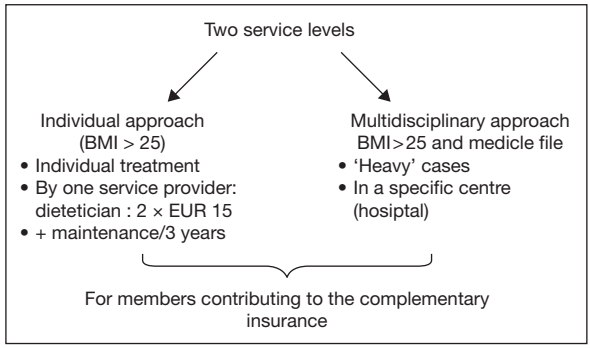

Fig. 2. Conditions to benefit from reimbursement.

care; the result is reimbursed by EUR 45 after 1 year of coaching or surgery and EUR 40 is paid after correction of BMI (–5%), and medication is reimbursed by EUR 100 once after 3 years only if former treatment fails.

Specific information concerning obesity, the insurance package, self-testing questionnaires, and information on the multidisciplinary centers in the hospital center are available on the MLOZ websites, brochures, newsletters and magazines.

The complementary insurance product was launched in April 2006. Five months later, the frequentation figures of the website were impressive: 3,087 for the questionnaire; 5,526 of the list of centers; 1,291 for the testing of children, and 4,686 for the testing of adults.

The figures for use after 5 months are somewhat lower but show a great interest in the individual care plan: 963 dietician consults; 1 incentive light; 22 bilans center; 2 multidisciplinary positive results, and 1 multidisciplinary negative result.

Discussion

Structural Changes in the Healthcare Funds

It is obvious that the structural change in healthcare funds from a pure insurance mission towards patient support for chronic disease management involves a lot of discussion and many practical problems.

The healthcare funds' front office workers at the counter and in their environment do not have sufficient insight, time or space to explain this 'medical' approach. They simply reimburse a healthcare cost note and know the codes and operational instructions exactly, enabling correct booking of reimbursement. The new product that was launched by the independent healthcare funds needs another type of front office worker who has to be acquainted

with the obesity problem and has sufficient insight into the treatment and the linked reimbursement. This office worker needs a specific environment with respect to privacy, and must have specific social skills allowing active coaching of the insured client. Within the independent healthcare funds, an internal investigation has started to answer these questions.

If other insurance products (chronic disease platforms) are launched in the same way, these changing conditions have to be fulfilled.

Information for the Member and the 'Mattheuseffect'

Deleeck [1] launched the term the 'Mattheuseffect' in social security discussions, referring to a passage in the gospel according to St. Matthew, 'he who has, will receive', meaning that richer people, well educated, from the better social classes, and with higher IQs have more chances than poor people with less skills to use the different opportunities in the social security system. The same is obvious for information about obesity and its treatment. On a regularly basis the MLOZ publishes beautiful dossiers and brochures on health issues. The most important group of people with obesity issues belong to the lower social classes who do not read classic magazines. Other multimedia instruments have to be developed and used to bring the correct message to the target group. The MLOZ hope to start with multimedia projects in autumn of 2007.

The Contract

Until now, classic health insurance funds offer exactly the same conditions of insurance and reimbursements to all candidates. A member who behaves negatively towards health by continuing to smoke, drinking too much, having overweight or obesity problems, and refusing to do any sports and physical activities is treated the same way as well-intentioned insured who take care of their physical condition.

For the insurers, little incentive exists to study and follow the evidence-based guidelines and the care paths. Can we continue to work like this in the future?

By launching the obesity and diabetes platform in 2005, the MLOZ introduced a breakthrough in this classical approach, making a distinction in reimbursement between insured with and those without behavioral change. Each insured person retains the right to choose his/her own lifestyle freely, but if that person changes his/her lifestyle in a positive way, this choice is rewarded by substantial incentives. The ambition is to develop this for other chronic diseases, a further contract between the different players: patients, suppliers and insurers. Each stakeholder has his/her own accountability in the contract. Different domains of this evolution must be explored: the ethic values; the legal framework, the economic and financial area; the operational feasibility, and the concrete acceptance and management. However, the idea creates the possibility of enhancing the empowerment of the patient and the supplier.

Reference

1 Deleeck H: Het Matteüseffect. De ongelijke verdeling van de sociale overheidsuitgaven in België. Antwerp, Kluwer, 1983.

Elia M, Bistrian B (eds): The Economic, Medical/Scientific and Regulatory Aspects of Clinical Nutrition Practice: What Impacts What?
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ENHA: What is It and What Does It Do? Strategies to Make Malnutrition a Key Priority in EU Health Policy

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Abstract

In 2005, the European Nutrition for Health Alliance (ENHA, the Alliance) was established to raise awareness of the relevance and urgency of malnutrition and ensure that this important issue is included in policy discussions and appropriate action is taken by policymakers and stakeholders at EU and member state levels. Malnutrition remains under-recognized, under-detected and under-managed across Europe, 4 years after the publication of the Call to Action resolution issued by the Council of Europe in 2003, on food and nutritional care in hospitals. The goal of the ENHA is to implement policy changes in nutrition and health at government and healthcare organizational levels. The value of specific evidence-based medical interventions must be demonstrated.

ENHA: What Is It and What Does It Do?

Introduction

In September 2004, the Netherlands EU Presidency organized an informal council of EU Ministers of Health to discuss the future of healthcare and healthcare financing in the European Union. Anticipating the policy discussion among 25 ministers, 450 representatives of the EU stakeholders in public health, the healthcare and healthcare financing arenas gathered at the conference 'Shaping the EU Health Community' to discuss six topics they selected to be the priorities in future EU health policies. One of these six is 'Ageing' with malnutrition as a priority in this arena. In 2005 the European Nutrition for Health Alliance (ENHA, the Alliance) was established to raise awareness of the relevance and urgency of malnutrition and ensure that this important issue is included in policy discussions about nutrition and appropriate action is being taken by policymakers and stakeholders at the EU and member state levels.

The Issue

The urgent need to raise awareness and implement change reflects the Call to Action issued in 2003 by the Council of Europe on food and nutritional care in hospitals [ResAP(2003)1]. The resolution reads:

- Considering that access to a safe and healthy variety of food is a fundamental human right
- Bearing in mind the beneficial effects of proper food service and nutritional care in hospitals on the recovery of patients and their quality of life
- Bearing in mind the unacceptable number of undernourished hospital patients in Europe

The Council of Europe then calls upon member states to draw up and implement national recommendations on food and nutritional care in hospitals and ensure that these plans be implemented with the participation of all relevant stakeholders at a policy, community and practice level.

Today, 4 years after publication of the resolution, the challenge issued by the council is still unmet in most European countries. Malnutrition remains under-recognized, under-detected and under-managed across Europe. Some countries have made progress in putting the systems and policies in place to help prevent malnutrition in hospitals and care homes, however much remains to be done. Moreover, initiatives aimed at ensuring appropriate management of malnutrition at the community level remain inadequate. Awareness and training of general practitioners and social care personnel on the realities of malnutrition are also largely insufficient.

Clear national and EU commitment to making the issue of malnutrition a priority on the political agenda is needed, and needed urgently. Malnutrition costs EUR 12 billion/year in the UK alone [2, 3]. In existing policy documents, 'poor nutrition' is too often understood to only cover obesity and overweight. The problems of underweight and malnutrition are poorly understood and considered of little relevance to our wealthy Western nations.

In addition to strong direction from policy, dedicated resources are needed to ensure that practical solutions to tackle malnutrition are implemented across all care and community settings. These solutions must take into consideration the inherent complexity of malnutrition. The causes of malnutrition are both social and clinical. Food poverty and poor socioeconomic conditions may exacerbate malnutrition in individuals of all ages. Malnutrition may also arise as a consequence of a particular illness, such as cancer.

It is particularly prevalent in older people, with up to 15% of older people living in the community and above 50% of care home residents being malnourished. Older people are also at greater risk of not recovering from malnutrition.

Rationale

In recent decades, medical societies, the European Society for Clinical Nutrition (ESPEN) and the European Union Geriatric Medicine Society and others, performed extensive research. Their data show that malnutrition is

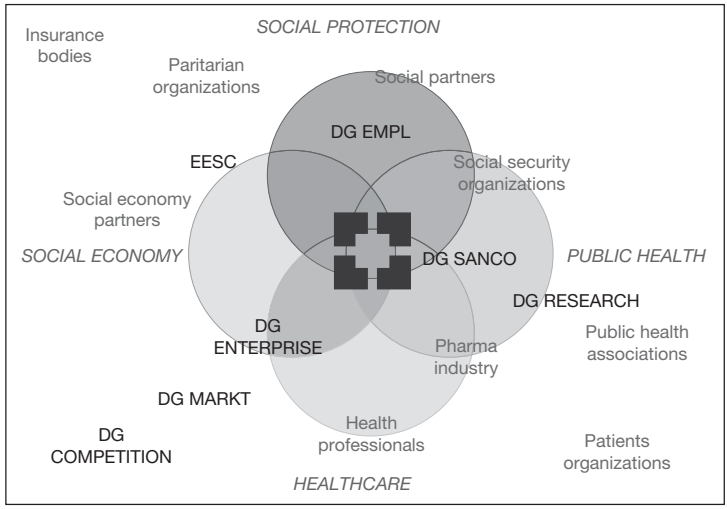

Fig. 1. Complexity of the EU healthcare policy arena.

a most relevant health issue, a crucial health indicator that directly contributes to health status and health outcomes. Despite the evidence and unlike obesity, beyond the medical societies, malnutrition has not been on the radar screen of EU, national policy makers or stakeholders in the healthcare arena. The rationale behind the establishment of the Alliance is the need to not just get the message across but implement change of policies in nutrition and health at government and healthcare organizational levels. Engagement of the relevant stakeholders is an important condition for change.

Multi-Arena, Multi-Stakeholder

In figure 1 by the Association Internationale de la Mutualité (AIM), the complexity of the EU healthcare policy arena is shown: by definition public-private and driven by at least 6 economic sectors.

In order to cover this complex arena and to be able to implement change effectively, key stakeholders decided to unite their efforts and establish the Alliance which per July 2007 consists of:

- The insurers: Association Internationale de la Mutualité (AIM)
- The hospitals: European Hospital and Healthcare Federation (HOPE)
- The physicians: European Society for Clinical Nutrition and Metabolism (ESPEN)
- The managers: European Nursing Directors Association (ENDA)
- Organizations for older people: International Longevity Centre-UK (ILC-UK)
- Mel Read, former Member of the European Parliament
- The industry: the Medical Nutrition Industry Group (MNI)

Objectives

Key objectives of the Alliance are:

- To raise awareness of the urgent need to prevent malnutrition and ensure that effective nutritional support is available to all those affected in the community and across all clinical settings
- Obtain recognition of malnutrition
  - As a disease in its own right in the EU
  - As a huge societal issue with significant economic consequences
  - As being preventable, treatable and curable
- Convince policymakers and stakeholders that solutions are available, successful and affordable and they must implement them
- Involve patients and consumers to raise awareness and political relevance

EU Platform

In November 2006 the members of the Alliance together with partner organizations like AGE, European Federation of Nurses Associations (EFN) and the European Federation of The Associations of Dieticians (EFAD) presented the issue of malnutrition at the EU platform in Brussels.

With the publication of the conference report in March 2007, which includes the summary of the evidence as well as calls for action of the conference partners, the Alliance has defined its agenda for bringing malnutrition to the table of EU and national decision-makers.

Action Plan 2007 – 2008

(1) Inclusion Malnutrition in National and EU Policy and Health Professional's Agendas

- National nutrition/public health plans
- EU policy in public health, health and nutrition, ageing
- Producing nutrition care plans for all clinical care settings
- Positioning alongside obesity as one of the main manifestations of poor nutrition
- March 2007: Policy briefs + specified calls for actions to 27 ministries of health of the EU member states, EU NGOs, EU Commission, EP, WHO-Euro Council of Europe

(2) Accountability of Professionals and Management

- To include screening, diagnosis and full management of malnutrition across hospital, community and residential care settings
- To examine appropriate care standards
- To promote accredited standards in nutrition training set by professional organizations
- To promote nutritional competence within all health care professionals and food service providers

(3) Innovative Delivery and Finance Models
- To conduct an EU-wide 'burden of illness' study on malnutrition based on the 2006 BAPEN study
- To define the added value of specific medical nutrition interventions in the healthcare delivery chain, including cost-effectiveness, quality of life and improved health
- To define models of best practice for effective nutritional care delivery

Strategies to Make Malnutrition a Key Priority in EU Health Policy

The Issue

In a number of European countries the debate among governments, healthcare stakeholders and the industry relative to nutrition and health is focused on reimbursement. Should clinical nutrition be reimbursed? And if so, unrestricted or only in selected disease areas? Policy debates in these countries show that the reimbursement debate is often about cost and price. Professionals or suppliers bring arguments to the table relative to the added value of clinical nutrition, but governments or payers play their cost and budget cards, and thus look at clinical nutrition in the healthcare setting as a bulk product.

Negotiating Table

In the aforementioned setting, the reimbursement debate is often one dimensional:
- Professionals versus government, insurer or management
- Provider or supplier versus government or insurer

This one versus others situation at the negotiating table does not reflect the relevance of the issue of clinical nutrition within the healthcare delivery chain and its positive effects on outcomes of care. It simplifies the debate, restricting it to a price/cost discussion. As Prof. Gordon Jensen reflects, 'we are not a source of revenue, we are an expense'.

Continuous Reform

In nearly all European countries, stakeholders in the healthcare arena aim to organize healthcare delivery more effectively. Reform has become the norm, a continuous process to optimize the quality/cost ratio of healthcare delivery. Continuous optimization also implies competition among interventions, as mentioned by a number of speakers during this workshop: 'we are not the only ones' (fig. 2).

The Solution, Not the Product

As long as partners in the healthcare arena consider clinical nutrition a cost, a bulk product that can be squeezed, we are playing the wrong game on

Fig. 2. We are all part of the solution: Patient, professional, provider, insurer and society.

the wrong field. We can only help patients who need appropriate nutritional care if we are able to show and convince policymakers and the healthcare community that nutrition and clinical nutrition are part of the solution. Some of the steps we have to take are:

- Strengthen multi-stakeholder interest; learn to look through the eyes of our partners and get them on board; activate the medical nutrition community
- Demonstrate the benefit; improved health, quality of life (effectiveness of interventions) and cost effectiveness
- Translate evidence into added value of specific medical nutrition interventions in the healthcare delivery chain; deliver disease/patient group-specific solutions including professionals, providers, insurers and/or government (patient, disease management)
- Reimburse the solution (not the product).

References

1 Council of Europe: Resolution AP(2003) 3.
2 Elia M, Stratton R, Russell C, Green C, Pang F: The cost of diseaserelated malnutrition in the UK and economic considerations for the use of oral nutritional supplements (ONS) in adults. A report by The Health economic Group of The British Association for Parental and Enternal Nutrition (BAPEN). Redditch, UK: BAPEN; 2005.
3 Elia M, Stratton RJ: Geographical inequalities in nutrient status and risk of malnutrition among English people aged 65 years and over. Nutrition 2005;21:1100–1106.

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Brief History of Parenteral and Enteral Nutrition in the Hospital in the USA

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Abstract

The meteoric rise in parenteral and enteral nutrition was largely a consequence of the development of total parenteral nutrition and chemically defined diets in the late 1960s and early 1970s and the recognition of the extensive prevalence of protein calorie malnutrition associated with disease in this same period. The establishment of Nutrition Support Services (NSS) using the novel, multidisciplinary model of physician, clinical nurse specialist, pharmacist, and dietitian, which, at its peak in the 1990s, approached 550 well-established services in about 10% of the US acute care hospitals, also fostered growth. The American Society of Parenteral and Enteral Nutrition, a multidisciplinary society reflecting the interaction of these specialties, was established in 1976 and grew from less than 1,000 members to nearly 8,000 by 1990. Several developments in the 1990s initially slowed and then stopped this growth. A system of payments, called diagnosis-related groups, put extreme cost constraints on hospital finances which often limited financial support for NSS teams, particularly the physician and nurse specialist members. Furthermore, as the concern for the nutritional status of patients spread to other specialties, critical care physicians, trauma surgeons, gastroenterologists, endocrinologists, and nephrologists often took responsibility for nutrition support in their area of expertise with a dwindling of the model of an internist or general surgeon with special skills in nutrition support playing the key MD role across the specialties. Nutrition support of the hospitalized patient has dramatically improved in the US over the past 35 years, but the loss of major benefits possible and unacceptable risks of invasive nutritional support if not delivered when appropriate, delivered without monitoring by nutrition experts, or employed where inappropriate or ineffective will require continued attention by medical authorities, hospitals, funding agencies, and industry in the future.

The rapid ascension of parenteral and enteral nutrition into an important component of clinical care in the hospital setting can be traced to three developments that occurred over an about 5-year period in the late 1960s and early 1970s. First and foremost was the first successful use of total parenteral nutrition (TPN), initially in beagle dogs to show the feasibility, and then its successful extension to 30 patients with chronic, complicated gastrointestinal disease by Dudrick et al. [1] at the University of Pennsylvania. At about the same time chemically defined or elemental diets were developed in normal volunteers to be employed in the US Mercury Space Program [2] where storage space and a low residue made these diets very desirable. These novel formulas were subsequently used in clinical conditions in which digestion and/or absorption was impaired and were provided usually through nasoenteric feeding tubes [3]. Both parenteral and enteral nutrition were initially studied in surgical patients in whom protein calorie malnutrition through gut malfunction had long been an often insurmountable problem. The third and final development was the identification of the extraordinary prevalence of malnutrition in hospitalized patients occurring in up to half of those on both surgical [4] and medical [5] services described in 1974 and 1976 respectively, when defined by simple anthropometric tools of weight, height, and upper arm anthropometry and serum albumin levels.

At this point one can view the glass as half full or half empty. From the optimistic or glass half full standpoint the period from 1975 to 1985 after the above advances could be described as a logarithmic phase of growth in clinical nutrition. Nutrition Support Services (NSS) using the novel, multidisciplinary model of physician, nurse specialist, pharmacist, and dietitian initially began in the early 1970s [6, 7] and at their high point probably approached 550 well-established services [8] in about 10% of America's acute care hospitals by 1990. A number of studies during this early period demonstrated the ability of such groups to dramatically reduce the risk of catheter-related sepsis and to limit the development of electrolyte and metabolic abnormalities with TPN and to reduce complications and increase the adequacy of enteral nutrition [9]. Financial benefits were less certain in part due to difficulties to fully estimate costs and benefits [9], but at the very least were cost neutral in most circumstances [10].

The American Society of Parenteral and Enteral Nutrition which reflected this unique multidisciplinary membership of the NSS was established and had its first meeting in Chicago in 1976. Membership, initially less than 1,000 grew to nearly 8,000 by 1990 and was composed of approximately 20% physicians, 15% nurses, 15% pharmacists, and 50% dietitians in 1990. The annual ASPEN Clinical Congress, which continues to date, became an important venue to educate and train and provide a forum for the presentation of new research findings.

Fellowships in parenteral and enteral nutrition, clinical nutrition, or metabolic support became widely available during this period as well, with annual

growth throughout the 1970s and 1980s. For instance in our training program at the New England Deaconess Hospital, which averaged from 3 to 6 fellows/year from 1975–2000, there were 3 training paths. The most common, 1 year of clinical training in parenteral and enteral nutrition including primary responsibility for central catheter placement and care, hyperalimentation and enteral nutrition order writing, and conduct of a clinical research project, was primarily taken by mid-level surgical residents, board-eligible internists interested in clinical nutrition as a field or in preparation for a gastroenterology fellowship, and gastroenterologists and endocrinologists at the completion of their fellowship training. Longer fellowships with 6 months to 1 year of clinical training as above as a component of a usual 3- to 4-year PhD program and shorter clinical rotations of 1–3 months for medical and surgical residents in training as an elective were the other options. All these individuals, which in total exceeded 100 fellows, generally met their goals of either being able to join or direct a NSS at a new institution or to practice clinical nutrition as a component of their practice. Even at the discontinuation of our fellowship program in 2002, with the semi-retirement of the two co-directors, there were many more applicants than positions available each year.

Finally from a personal perspective when I first became involved with nutrition support during my PhD training in Nutritional Biochemistry and Metabolism at MIT from 1972 to 1975, a period in which we were conducting the early surveys of nutritional status [4, 5], there was a general lack of appreciation for the nutritional status of patients. Protein calorie malnutrition was so widespread and undertreated that we developed a system of measurement of delayed cutaneous hypersensitivity to document cutaneous anergy [11] in order to convince clinicians that their patients required invasive nutritional support to reverse anergy. By 1990 there was a general appreciation that hospital protein calorie malnutrition was common, that invasive feeding could improve outcome, and that lack of feeding for periods of longer than 7–10 days in critically ill patients was an unacceptable practice. During this period from 1975 to 1990 there was a steady increase in the number of converts to better nutritional practices, particularly in surgical patients and in the critically ill in intensive care units, both medical and surgical. Testing for cutaneous anergy was abandoned at our medical center in the mid 1980s [12], principally because prolonged inadequate feeding became so uncommon, and there was little difficulty in convincing the primary physician of the need for invasive feeding when appropriate.

What happened subsequent to 1990? Now we can discuss the glass that is half empty, and this largely relates to medical funding. In the early 1980s the Medicare system in the US began a system of hospital payments based on diagnosis-related groups, where a fixed amount of money was paid according to diagnosis rather than actual costs. Medicare is the government system of reimbursement for patients 65 years or older, the disabled, or those receiving dialysis therapy. But the other source of hospital payments from medical

care for the indigent through the government program Medicaid is the joint responsibility of the individual state and the federal government, and private insurance links their payments to government policy. The severe cost-containment pressures brought on by these changes in medical insurance have adversely affected nutrition support team staffing which began to have its greatest impact in the 1990s and was particularly harsh on hyperalimentation nurses and physicians involved in nutrition support. Although there are medical and financial costs associated with the termination of a nutrition support nurse [13], this cost must often be forcefully documented with hospital authorities, and generally can be in terms of unacceptable rates of catheter infection without their presence. With physicians there is no acknowledged medical specialty for clinical nutrition, although there was a split vote of 2–1 against by the American Board of Medical Specialties in the 1990s which would have accomplished this had it passed. Therefore, if the local hospital administrator or chairmen of medicine or surgery cannot be convinced of the value of providing partial financial support to nutrition support physicians for their clinical participation, then either it is done as a free service as an avocation by these individuals or done as a component of their underlying specialty. Thus most intensivists will provide parenteral and enteral nutrition as part of their care, as will many surgical specialists, particularly trauma surgeons, burn surgeons, and general surgeons. Oversight for home parenteral and enteral nutrition is often provided by gastroenterologists. However it is likely in many instances that nutritional care by these specialists is at an acceptable if perhaps not ideal level. For medical patients parenteral and enteral nutritional support is now often delivered under the care of dietitians which is reasonably good vis-à-vis enteral nutrition, but with parenteral nutrition may sometimes be outside their level of clinical competence, particularly for the management of fluid and electrolyte disorders and insulin management in diabetic patients. Dietitians have been less severely impacted by cost considerations, because there is a Joint Commission on Accreditation of Hospital Organizations (JCAHO) requirement that hospitals nutritionally monitor their patients. Pharmacists are also very important in the provision of parenteral nutrition, particularly by determining compatibilities of parenteral nutrition admixtures, checking the stability of orders from day-to-day, and by making certain of the completeness of parenteral regimens. Their continued availability to provide this level of expertise is also mandated by JCAHO as well as by their own professional standards.

With these cost constraints there have been a number of changes in the provision of nutritional support over the past decade. In 1992 we conducted a survey of NSS. Of a total of 425 surveys, 144 responses (34%) were analyzed. The average size hospital was 387 beds with a range of 28–1120 beds. As a percentage of hospital beds (3.5%) received TPN ranging from 3.2 to 3.7% in hospitals with <200, between 200 and 499, and >499 beds. 35% of the hospitals surveyed used 3-in-1 admixtures, accounting for 60% of parenteral

formulas prescribed. 75% of hospitals used the parenteral admixture as a drug vehicle including H_2-receptor antagonists, heparin, albumin, insulin, and metoclopramide. The vast majority of TPN orders were written by internists or surgeons. Thus the conclusion at that time was that TPN was widely but not excessively employed in US hospitals and that innovations like 3-in-1 formulas begin in larger hospitals [14]. The number of NSS has almost certainly declined in the ensuing decade. This development has occurred despite continued evidence as to the medical benefits of nutrition support teams [15–17] that are at the very least cost neutral [10, 13].

There has also been a change in the membership of ASPEN that reflects this trend. After an initial fall of total members through the 1990s, the number has more recently stabilized, but there has been a dramatic decrease in nurses from nearly 1,000 to about 300 in 1999 and less than 200 at present (2006) with a concomitant increase in dietitians to about 60% of a total of 5,000 members, which has been relatively stable for the past 7 years, and a slowly diminishing number of physicians from 1,000 (20%) in 1999 to 735 (15%) in 2006. However both physician and pharmacist numbers have stabilized from 2001 to 2006, at approximately 750 and 620 members. Fellowship opportunities for physicians have also diminished, and there is some concern about what the future holds for physicians principally interested in parenteral and enteral nutrition. The second major American society for clinical nutrition after ASPEN was an independent group of academic physicians and PhD nutritionists interested in this field, the American Society for Clinical Nutrition. Last year by vote of its members it chose to disband and become a component of the American Society of Nutrition. Hopefully this group of individuals will maintain their interest in this field and continue to promote the improvement of parenteral and enteral nutrition for the hospitalized patient. However the likelihood of getting specialty recognition from the American Board of Medical Specialties is dim under the present conditions.

How does this bode for the future? Presumably there will always be some physicians trained in clinical nutrition, but some programs, like the exemplary program at MIT which trained many of the academic clinical nutritionists, have been discontinued and not been replaced. Certainly there is ample evidence for the need for such individuals. For instance one of the most important recent developments in clinical medicine has been the demonstration that tight blood glucose control in the critically ill can dramatically improve the morbidity and mortality of patients [18]. However this was primarily a study in cardiac surgical patients, and a similar study in medical patients by the same group demonstrated that tight blood glucose control improved morbidity but did not affect mortality [19]. In fact in those medical patients who received therapy for less than 3 days, mortality was actually increased. These superb innovative studies were primarily conducted by an endocrinologist who is a specialist in critical care. However an important variable in these two landmark studies, not previously commented on, is that in the surgical study

the patients also received hypertonic dextrose initially for the first 24 h and TPN subsequently [18]. The medical patients in the second study received the initial hypertonic dextrose followed by inadequate nasogastric tube feeding for the first 3 days providing substantially less calories and grossly inadequate protein [19]. It may well be that it is the combination with tight glucose control in the setting of adequate feeding that is essential to achieve all the benefits rather than the control of hyperglycemia alone. Similarly a recent study in cardiac surgical patients receiving tight glucose control during their surgery and tight regulation of both treatment and control postoperatively showed no benefit and, in fact, a suggestion of harm in the treatment group [20]. Perhaps lowering blood glucose in cardiac patients not receiving hypertonic dextrose before revascularization may deprive the heart of an essential fuel. Having some physicians thoroughly trained in clinical nutrition to discern these possibilities may be important in the future to design and interpret the results of clinical trials.

However it would appear that the delivery of nutritional support will need to be adjusted for the clinical realities in the US. Intensivists from both medical and surgical services will be largely responsible in many settings for the initiation and monitoring of parenteral nutrition. Dietitians can be of assistance to advise on parenteral nutrition in terms of the standard provision of adequate nutrients but are more limited in their ability to advise on the combination of nutritional and metabolic support together in one formula. Dietitions have more direct responsibility for enteral nutrition in terms of the amount and choice of product, since enteral support is generally not employed to meet fluid, electrolyte, and metabolic needs. Surgical specialists, such as trauma surgeons and general surgeons, will perform the same functions with or without the assistance of dietitians. Backing them both will be pharmacists who will have the ultimate word in the composition of parenteral admixtures. In certain venues, particularly in very large academic institutions, physicians specifically trained in nutrition from either surgery, endocrinology, gastroenterology, or internal medicine will be able to convince their respective chairmen that the very highest level of parenteral and enteral nutrition support can be provided by a physician-directed team. From such teams we can expect most of the new developments to occur in nutritional therapy. As a corollary to this, it is essential that, nurse specialists care for central and peripherally inserted central catheters used in parenteral nutrition to reduce the unacceptably high level of infectious complications in virtually any circumstance without their involvement. Furthermore it will demand the continued demonstration in future randomized clinical trials of the value of nutritional support, the added benefits of nutrition specialists in many settings, and the value of new support techniques and novel compounds such as glutamine, n-3 fatty acids, or hormone, vitamin or mineral supplementation.

In conclusion nutritional support of the hospitalized patient has dramatically improved in the US over the past 35 years. The recent development of

severe cost constraints has made it imperative to convince as many hospital administrators and clinical chiefs as possible of the major benefits and unacceptable risks of invasive nutritional support if not delivered when appropriate, delivered without monitoring by nutrition experts, or employed where inappropriate or ineffective. The subject of the level of expertise necessary to meet these needs and how this is to be achieved in the future will require continued attention.

References

1 Dudrick SJ, Wilmore DW, Vars HM, et al: Long term parenteral nutrition with growth, development, and positive nitrogen balance. Surgery 1968;64:134–142.
2 Winitz M, Graff J, Gallagher N, et al: Evaluation of chemical diets as nutrition for man-in-space. Nature 1965;205:741–793.
3 Stephens RV, Randall HT: Use of a concentrated, balanced, liquid elemental diet for nutritional management of catabolic states. Ann Surg 1969;170:642–667.
4 Bistrian BR, Blackburn GL, Hallowell E, et al: Protein nutritional status of general surgical patients. JAMA 1974;230:838–860.
5 Bistrian BR, Blackburn GL, Vitale J, et al: Prevalence of malnutrition in general medical patients. JAMA 1976;235:1567–1570.
6 Wade JE: Role of a clinical dietitian specialist on a nutrition support service. J Am Diet Assoc 1977;70:185–189.
7 Blackburn GL, Bothe A Jr, Lahey MA: Organization and administration of a nutrition support service. Surg Clin North Am 1981;61:709–719.
8 McShane CM, Fox HM: Nutrition support teams-a 1983 survey. JPEN J Parenter Enteral Nutr 1985;9:263–268.
9 Gales BJ, Gales MJ: Nutritional support teams: a review of comparative trials. Ann Pharmacother 1994;28:227–235
10 Trujillo EB, Young LS, Chertow GM, et al: Metabolic and monetary costs of avoidable parenteral nutrition use. JPEN J Parenter Enteral Nutr 1999;23:109–113.
11 Griffin RE, Champagne CD, Bistrian BR, et al: Delayed cutaneous hypersensitivity response in patients receiving nutritional support. Clin Pharm 1983;2:432–435.
12 Carle G, Duncan JL, Thomson S, et al: A new device for delayed hypersensitivity skin testing. J Am Coll Nutr 1985;4:515–520.
13 Goldstein M, Braitman LE, Levine GM: The medical and financial costs associated with termination of a nutrition support nurse. JPEN J Parenter Enteral Nutr 2000;24:323–327.
14 Schifferdecker C, Driscoll DF, Blackburn GL, Bistrian BR: A national survey of nutrition support teams and TPN therapy (abstract 155). ASPEN 16th Clinical Congress, 1992, p 458.
15 Gurgueira GL, Leite HP, Taddei JA, de Carvalho WB: Outcomes in a pediatric intensive care unit before and after the implementation of a nutrition support team. JPEN J Parenter Enteral Nutr 2005;29:176–185.
16 Sutton CD, Garcea G, Pollard C, et al: The introduction of a nutrition clinical nurse specialist results in a reduction in the rate of catheter sepsis. Clin Nutr 2005;24:220–223.
17 Saalwachter AR, Evans HL, Willcutts KF, et al: A nutrition support team led by general surgeons decreases inappropriate use of total parenteral nutrition on a surgical service. Am Surg 2004;70:1107–1111.
18 Van den Berghe G, Wouters P, Weekers F, et al: Intensive insulin therapy in the critically ill patients. N Engl J Med 2001;345:1359–1367.
19 Van den Berghe G, Wilmer A, Hermans G, et al: Intensive insulin therapy in the medical ICU. N Engl J Med 2006;354:449–461.
20 Gandhi GY, Nuttall GA, Abel MD, et al: Intensive intraoperative insulin therapy versus conventional glucose management during cardiac surgery. Ann Intern Med 2007;146:233–243.

Discussion

Dr. Labadarios: Regarding a comment that was made earlier, if you are now proposing that in the future there should be randomized control trials, should reinvestment go the drug way? You said that we will have randomized control trials, and earlier we were discussing the pharma or nutrition route, and the point was made that if we do randomized control trials, one of the ways of proceeding might be the pharma route. Does that have implications? Is that why you mentioned it?

Dr. Bistrian: I mentioned it because the data are already available for the general value of nutritional support, either as enteral or parenteral nutrition. I think that you ought to popularize that a little more and industry ought to have white papers written or do whatever they can to make sure that this kind of information becomes more broadly available. For the randomized trials to come, I believe that you will need to identify – we had a discussion with Dr. Hoffer on this earlier – homogenous sets of patients to do new trials for certain disease states. As I said to Dr. Hoffer earlier, the reason why getting rid of the grey zone is important is that on the medical service, malnutrition is a reasonable indication if the patients are severely malnourished because that is homogeneity and not the disease state. However, I think that the future lies in finding the value among different disease states and having large enough trials with your products.

I believe that the future is great for new therapies. People have been doing work with antioxidants that appear to make a difference and there are some new anti-inflammatories that also appear to make a difference. There are a lot of things that industry will need to do in the future and, for me, the pharma model is not bad because the Food and Drug Administration (FDA) and the other regulatory agencies, at least in the US, will not hold you to such a high standard of how many patients you need to have as for a usual drug trial. When statins were studied, many 1,000's of 1,000 patients were needed – we are talking about a reasonable number of patients. The last trial I worked on in pharma was an MCT/LCT trial in 100 patients, and they allowed us to be a phase-3 trial for drug approval.

Mr. Parver: I would like to bring up something that we might just want to be mindful of if we pursue drug benefits that include parenteral nutrition, for example. As I mentioned yesterday, the TPN that is covered under Medicare at the moment is for long-term parenteral nutrition of at least 90 days. Congress recently enacted a prescription drug benefit which covers those things that are not covered under Part B. That therefore means that short-term TPN would be covered under this drug benefit, except that the agency – Centers for Medicare and Medicaid Services (CMS) – has determined that the only things that they will cover under the benefit are those components of TPN that are regulated as drugs. Therefore, the vitamins, minerals and other non-drug components would not be covered.

Dr. Bistrian: When the vitamins go into the TPN, there is FDA approval on that formula, and vitamins, amino acids and glucoses are included in this. It is interesting that you should mention this because the home TPN patients are fed 365 days/year while the average duration of TPN in the hospital is only 10 days/person. About half of the TPN formulations given in the country are therefore given to home TPN patients and half are given in the hospital.

Another issue here is that we always thought of TPN as being extremely expensive therapy. That is old information. The lipids that are used are now a commodity item and, for usual use, cost USD 2/day. The amino acids cost USD 0.10//g, and therefore cost about USD 7–8/day, and glucose is really cheap. Most patients in a critical care unit have a central line placed in any case, and TPN in many instances is therefore much cheaper than most of the special enteral formulas. Things have changed and the cost of the formulas will never be a big factor.

Mr. Parver: If there is something that indicates that the vitamins should be covered, I would like to see it, because they have been telling us that they are not covered and have denied us several claims for vitamins under the drug benefits. I would love to see that and use it.

Dr. Bistrian: We got an orphan drug acceptance from the FDA for the company that makes most of the vitamins to change the vitamin's formulation.

Mr. Parver: The other thing that I just wanted to mention was that unfortunately the drug benefit explicitly does not cover the parenteral pump services or even supplies. All that is covered is the drug – or, at least, component parts of the drug – which is no way to run a railroad. Additionally, it is probably not being very widely used under that benefit. With a pharmaceutical benefit approach, therefore, you have to be careful that it is not being taken as literally as the one in the US because it is not really working that way.

Dr. Hoffer: In terms of the home parenteral nutrition program, I need a little clarification. If there is no coverage for the pumps or to make it economically possible for people who require home parenteral nutrition, it seems to me that this will self-correct because the patients will die.

Dr. Bistrian: What is happening is that they are getting the service in another setting. They will therefore get it in a hospital or nursing home. We have no evidence that the lack of coverage is resulting in the lack of care in the home benefit; we are seeing rather that they are just getting it somewhere else, often in a more expensive setting than the homecare setting.

Dr. Hoffer: We provide home parenteral nutrition in the province of Quebec, but it is extremely limited and rationed. However, the argument that made the Ministry of Health act in that way was that if home parenteral nutrition was not provided, these patients would be treated in hospital for unlimited periods of time. It did not take long to make the cost calculation. Surely that cost calculation is so obvious, with the cost per day of hospitalization that, again, this has to self-correct as long as there is someone who has functioning neurons in the administration of the policies?

Dr. Bistrian: You are right. That should be the case and, in fact, it was that concern about hospital cost that led to the decision to cover home TPN and enteral nutrition in the first place. Having said that, the way the congressional budget office and CMS have looked at issues means that they have compartmentalized things to such a degree that covering home enteral or parenteral nutrition is simply a cost to Part B. The implications for Part A are not being fleshed out. How you keep score and ask the question determines the policy. Right now, they have urged us to go to Congress because they will not fix it on their own. If we want the TPN services to be covered under the drug benefit, we need to get Congress to do it, and if we want an extended coverage of infusion therapy or anything else under Part B, we have to go to Congress. They feel hamstrung in how they and their own Office of the Actuary have interpreted the budget rules and are therefore not doing the very commonsense thing that you have described, which is to look at the whole picture. They are simply not doing that. They understand that this makes them look very silly, but they just cannot get themselves out of Congress stepping in for them.

Dr. Hoffer: In the early days of home TPN – where Mr. Parver helped us – in fact it was not covered by many private insurers. We had no difficulty saying that we would just keep the patients in hospital to receive it there. We had no problem doing that. Medicare is actually a minor player in home TPN because people have to be over 65 or get disability. Private insurers are extremely large in the home TPN field and Medicaid.

Dr. Jensen: Our Institute of Medicine committee called for a change in this particular ruling back in 2000 and of course nothing has actually transpired. The reality is very simple in the United States in that many practitioners will simply document that the requirement for parenteral/enteral support will be 90 days or more, even though they know full well that that is not going to be what happens.

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What Went Right? The Story of US Medicare Medical Nutrition Therapy

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Abstract

When President Lyndon Johnson signed the Medicare and Medicaid bill into law in 1965, it ended the 46-year campaign to enact a healthcare program for senior citizens and started what is now a 42-year effort by the American Dietetic Association (ADA) and its members to expand its coverage to 'nutrition services' for all appropriate diseases, disorders and conditions. In December 2000, Congress passed a Medicare Part B Medical Nutrition Therapy (MNT) provision, limited to patients with diabetes and/or renal disease, effective January 2002. In December 2003, the Medicare Modernization Act expanded access to MNT benefit and ADA continues to focus on the role of the registered dietician in MNT. Successful expansion of MNT benefits will require that ADA continues to demonstrate the cost-effectiveness and efficacy of nutrition counseling, as performed by the registered dietitian.

The New York Times Business Section of March 11, 2007 included an article, 'Knowledge is power only if you know how to use it'. Denise Caruso, executive director of the Hybrid Vigor Institute, wrote:

'If we can land a man on the moon, why can't we …?'

This 'familiar, fill-in-your-pet-peeve lament about the state of the world since Neil Armstrong's historic giant leap in 1969' is a 'question that continues to engage innovators and scholars', she said.

This document draws significantly from Medical Nutrition Therapy: The Core of ADA's Advocacy Efforts (Part 1), published in the Journal of the American Medical Association, May 2005. The author thanks her colleagues and co-authors Ron Smith, Mary Hager and Pam Michael, professional staff of the American Dietetic Association, for their expert contributions.

For the purposes of this conference, let us begin by asking:

If we can land a man on the moon, why can't people receive life-saving medical nutrition therapy (MNT), as well as basic nutrition care, provided by the best trained professionals to provide such services?

In her article, Caruso answered the question by separating 'knowhow' from 'knowledge'. 'Knowhow', she said, 'puts knowledge to work in the real world'. My presentation examines knowhow and knowledge, the concept of good fortune, as well as extraordinary stamina. All are necessary to advance ideas in our complex world – and they are especially important when decisions are left to politicians.

This document also examines the background rationale behind the American Dietetic Association's (ADA's) efforts in support of MNT, both as part of Medicare Part B and, more generally, as part of various national health insurance proposals.

Integral to any discussion of MNT coverage history and ADA's advocacy effort is acknowledging the larger issue and context of this effort: the US government's struggle to pass a comprehensive national health insurance program (a part of which resulted in Medicare's passage). When President Lyndon Johnson signed the Medicare and Medicaid bill into law, it ended the 46-year campaign to enact a healthcare program for senior citizens and started what is now a 42-year effort by ADA and its members to expand its coverage to 'nutrition services' for all appropriate diseases, disorders and conditions.

After Medicare was enacted, ADA immediately recognized that not having nutrition and diet therapy services covered was a setback to the profession. As early as 1966 – one year after the enactment of the Medicare bill – the ADA House of Delegates voted to take the necessary action to include nutrition and diet therapy services in all medical care legislation.

Although ADA lobbied for inclusion of nutrition services in various national health insurance plans during the 1970s–1990s, no bills were enacted. In support of those efforts, work continued in many venues. It was not until 1999 that major breakthroughs occurred. One of the prerequisites to getting Medicare coverage was the development of specific nutrition service codes, or current procedural terminology (CPT) codes, which set up the structure to distinguish MNT from other services in medical billing systems. Another important factor was the findings by the preeminent National Academies of Science Institute of Medicine that MNT was effective, and that registered dietitians (RDs) are uniquely qualified in providing MNT.

Internally at ADA, other steps were occurring. Within months of these events, ADA adopted a new strategic plan defining the association's mission as 'leading the future of dietetics', with a vision that ADA members would be the preferred providers of food and nutrition services. ADA became one of the first health professional associations to embrace evidence-based practice and outcomes analysis.

In December 2000, Congress finally passed a Medicare Part B MNT provision as part of the Benefits Improvement and Protection Act, P.L. 106–554. The important features contained in the new MNT benefit are the following:

- The benefit was limited to patients with only diabetes and/or renal disease
- The decision to cover only diabetes and kidney diseases was based on cost projections by the Congressional Budget Office
- The benefit was contingent on referral from a physician, with only an RD or licensed nutrition professional approved as providers
- The Centers for Medicare and Medicaid Services (CMS) were directed to report to Congress on its recommendations on future expansion of the MNT benefit
- The reimbursement rate was set at less than 80% of the actual charge for the services or 85% of the amount determined under the physician fee schedule for the same services if such services had been furnished by a physician
- The benefit would become effective January 1, 2002

Other studies and events have incrementally advanced MNT in the United States. In March 2003, Medicare sent Congress recommendations on how to expand the MNT benefit. The key findings of that report were that dietary modification using MNT for patients with hyperlipidemia and hypertension also benefited patients, and MNT can help cancer patients eat and keep down foods as they endure chemotherapy.

The Medicare Modernization Act, which Congress passed in December 2003, expanded access to the MNT benefit. There is an MNT component to the 'Welcome to Medicare Physical' benefit that went into effect in January 2005, and there is another stipulation that MNT be a part of Medicare's disease management initiatives. Medicare Advantage, a managed care program, requires that participating private insurance companies include MNT for diabetes and renal diseases.

Outside Medicare, Congress in 2006 made MNT a core medical service under the Ryan White CARE Act, our national program that provides assistance to persons with HIV/AIDS. Private insurers tend to follow Medicare, so diabetes and kidney disease MNT coverage are common, and some private insurers have provided finite coverage for weight management and other conditions.

ADA continues to work for expanded Medicare MNT coverage so that any disease, disorder, or condition in which MNT is cost-effective will be offered. In 2007, we are particularly focused on diabetes screening and risk factors gaining coverage in Medicare and Medicaid, the health insurance program that covers a portion of the nation's poor.

In moving ahead, ADA is continuously asked if we can demonstrate the cost-effectiveness of MNT. The second question we face is: 'What unique benefits are acquired from the services of a RD that are not available from other nutrition or healthcare professionals?'

Both questions underscore the need to shift from traditional practice to evidence-based practice. Without adopting evidence-based practice, the dietetics profession will be unable to distinguish itself as the best provider of MNT, and RDs will not be able to successfully compete in a new healthcare environment where proven efficiency, cost-effectiveness, and sharing outcomes will be essential.

The ADA's official position is that 'MNT not only improves the quality of life, but it reduces healthcare costs and hospital admissions for seniors with a number of serious conditions'. For that position to be viable, the profession must be able to justify the following three assertions:

- RDs perform MNT better than anyone else
- MNT improves the quality of life
- MNT is cost-effective

These assertions can only be defensible when dietetics professionals adopt evidence-based practice and document their competencies through positive outcomes, patient and provider satisfaction, and cost-effectiveness. This implies that the dietetics profession will undergo a paradigm shift in the performance of services. Medicare MNT providers must understand this shift and begin using the Nutrition Care Model and Process, which provides a framework for describing the specific components involved in providing MNT, such as nutrition assessment, nutrition diagnosis, nutrition intervention, and nutrition monitoring and evaluations. Medicare MNT providers must use evidence-based protocols or guides for practice to illustrate that the MNT offered by RDs has a positive medical impact on patients and a positive impact on healthcare budgets.

Successful expansion of MNT benefits will require ADA not only to illustrate the cost-effectiveness and efficacy of nutrition counseling, but also to prove that such counseling performed by an RD is measurably different than counseling provided by other nutrition professionals. At that point, we may finally get past this long phase of working primarily with politicians.

A Long Road and Many Steps

The ADA established a government relations program in the 1960s. Over time, ADA expanded in the number of issues addressed, added staff and increased association resources. Throughout it all, a primary goal has been to obtain reimbursement for nutrition services. Since 1992, the program has focused toward the passage of legislation that provides for the reimbursement of nutrition services under the Medicare program. Attention to other nutrition issues often occurred in the background as ADA made MNT the core of its advocacy efforts [1].

Although the term MNT was not specifically cited in the profession's early years, in 1918 the term dieto-therapy was used and was a section within the

profession. In 1899 a group of dietists (the precursor of dietitians) met in Lake Placid. This group of cooks and dietists went on to later form the American Home Economic Association and defined dietitians as 'persons who specialize in the knowledge of food and can meet the demands of the medical profession for diet therapy' [2]. This phrase most likely provided the framework for the creation of the term MNT in the early 1990s.

Up to that point, the terms most often used in place of MNT were nutrition services, clinical nutrition, or nutritional counseling, for which there seems to be no specific definition. In 1995 Carey and Gillespie [3] defined MNT as follows:

'Medical nutrition therapy involves the assessment of the nutritional status of patients with a condition, illness, or injury that puts them at risk. This includes review and analysis of medical and diet history, laboratory values, and anthropometric measurements. Based on the assessment, nutrition modalities most appropriate to manage the condition or treat the injury are chosen and include the following:

- Diet modification and counseling leading to the development of a personal diet plan to achieve nutritional goals and desired health outcomes
- Specialized nutrition therapies including supplementation with medical foods for those unable to obtain adequate nutrients through food intake only, enteral nutrition delivered via tube feeding into the gastrointestinal tract for those unable to ingest or digest food, and parenteral nutrition delivered via intravenous infusion for those unable to absorb nutrients'

Congress passed legislation that for the first time provided for MNT services under Medicare Part B in December 2000. (Medicare has two parts: Medicare Part A helps cover hospital stays, skilled nursing facility care, some home healthcare, and hospice care. Part B helps cover doctors' services, outpatient hospital services, and other medical services that Part A does not cover, including some home healthcare.) In that law [4], MNT was defined statutorily as: nutritional diagnostic, therapy, and counseling services for the purpose of disease management, which are furnished by an RD or nutrition professional.

In a different section of the law, Congress limited MNT services (in a non-hospital setting) to only those beneficiaries with diabetes and renal disease. (After the bill was signed into law, Medicare interpreted renal disease to mean non-dialysis kidney disease and after kidney transplants) [5]. However, the above definition does not limit MNT per se to any particular disease.

MNT can further be defined as the service provided by an RD to address individual or group health requirements. Those services might be needed as a result of diagnosis of a chronic disease, disorder, or condition, or they might be intended to prevent the onset of future health problems. MNT can be viewed as the core of what RDs do in a clinical setting or in private counseling of patients. (RDs also perform nutrition education, complementary and alternative therapies, and preventive nutrition services, and they direct and manage food service operations, which are distinct from MNT.)

Justification for a Medical Nutrition Therapy Benefit

ADA's reasons for supporting MNT as a part of any healthcare insurance program are multifactorial. The effort to have nutrition services (including but not limited to MNT) covered by federal, state, and private health insurance programs has been justified using several different rationalizations. At various times this rationalization has been focused on helping RDs obtain additional work; that MNT is effective in fighting chronic diseases; that all Americans deserve access to the best quality care, which includes nutrition services; that MNT is an essential component to managed care organizations and integrated delivery systems, and that it is cost-effective. The following examples describe reasons used to argue in support of incorporating nutrition services into federal healthcare programs.

1992 – It is the position of the ADA that quality healthcare should be available, accessible, and affordable to all Americans. Quality healthcare is defined to include nutrition services that are integral to meeting the preventive and therapeutic healthcare needs of all segments of the population [6].

1993 – Cost-effectiveness has been a major part of the ADA's strategy for promoting MNT as one of the solutions to runaway healthcare expenditures [7].

1993 – It is the position of the ADA that health maintenance organizations and systems of managed care provide nutrition services as an essential component of preventive and therapeutic healthcare and that these services be provided by qualified nutrition professionals [8].

1995 – It is the position of the ADA that MNT is effective in treating disease and preventing disease complications, resulting in health benefits and cost savings for the public. Therefore, MNT provided by dietetics professionals is an essential reimbursable component of comprehensive healthcare services [9].

1996 – It is the position of the ADA that managed care organizations and integrated delivery systems provide MNT as an essential component of healthcare and that it be provided by qualified nutrition professionals [10].

1999 – It is the position of the ADA that MNT and lifestyle counseling are integral components of medical treatment for the management of selected conditions for which pharmacotherapy is indicated. The association promotes a team approach to care for clients receiving pharmacotherapy and encourages active collaboration among dietetic professionals and other members of the healthcare team [11].

1999 – After an initial period of implementation, coverage for MNT can result in a net reduction in health services use and costs for at least some populations. In the case of people aged 55 years and older, the savings in use of hospital and other services will actually exceed the cost of providing the MNT benefit. These results suggest that Medicare coverage of MNT has the potential to pay for itself with savings in use of other services [12].

2000 – The ADA supports both the provision of comprehensive food and nutrition services and the continuation and expansion of research to identify the most effective food and nutrition interventions for older adults over the continuum of care [13].

2002 – It is the position of the ADA that MNT is an essential component of disease management and healthcare provided by managed care organizations, and that such care 'must be provided by qualified nutrition professionals' [14].

2004 – It is the position of the ADA that nutrition services are essential components of comprehensive care for infants, children, and adults with developmental disabilities and special healthcare needs. Nutrition services should be provided throughout the life cycle in healthcare, educational, and vocational programs in a manner that is interdisciplinary, family-centered, community-based, and culturally competent [15].

Whatever the stated reason or argument used to support passage of an MNT provision, ADA's support has always been based on the desire to increase the demand for and use of RD services.

In 1992, ADA worked extensively on healthcare reform issues to 'promote the key role nutrition services and RDs play in the country's healthcare system' [16]. ADA's focus on healthcare reform was in response to the association's Strategic Thinking Initiative report, Achieving Competitive Advantage [17]. This document was viewed as 'a carefully crafted business plan ... but all the talk of "key linkages" and "strategic initiatives" boils down to a single objective: to ensure the success of the dietetics professional in an increasingly competitive marketplace' [18].

That objective continues to be a central focus of ADA today. One of ADA's current strategic goals is to 'increase demand for and utilization of services provided by members' [19]. Although there are many ways that this goal can be achieved, few are more important than expanding the MNT benefit. The underlying reason for ADA's support for nutrition services has long been that to increase the demand for RDs and their rates, nutrition services had to be a covered benefit under Medicare and/or any other national health insurance program administered by the federal government.

40-Year Effort to Pass and Expand Medical Nutrition Therapy

It is impossible to discuss the history of MNT and ADA's advocacy efforts without discussing the larger issue, which is the struggle to pass a comprehensive national health insurance program.

The issue of national health insurance has been debated during presidential campaigns and in Congress beginning as early as the 1912 election campaign of Theodore Roosevelt, who first introduced and supported national health insurance. In 1915 a model bill for health insurance was presented, but

defeated, in numerous state legislatures [20]. A national healthcare policy has been considered and/or proposed by Presidents Franklin Roosevelt, Truman, Kennedy, Nixon, Ford, Carter, and Clinton [21]. Some of the proposals included nutrition services, and others did not. In various manifestations, that struggle continues even today. Although there is currently no national debate about passing a universal healthcare program, efforts continue to expand coverage of Medicare, Medicaid, and other federal and state programs.

Enactment of Medicare was part of a long struggle to pass a national health insurance program that began immediately after the Social Security Act was passed in August 1935 [22]. President Roosevelt created the Interdepartmental Committee to Coordinate Health and Welfare Activities in October 1936. Based largely on the recommendations of that committee, Sen. Robert Wagner (D-NY) introduced S. 1620, the National Health Act of 1939 [23] – the first comprehensive national health insurance bill introduced in Congress. Although the Senate held several hearings on the Wagner bill, the bill never got out of committee.

In 1943, President Roosevelt's State of the Union Address called for 'assurance against the evils of all major economic hazards – assurance that will extend from the cradle to the grave' [24]. He further elaborated on this point in his State of the Union Address in 1944, when he called for a second Bill of Rights that included 'the right to adequate medical care and the opportunity to achieve and enjoy good health' [25]. In 1945, President Harry Truman sent a message to Congress asking for legislation establishing a national health insurance plan [26].

It was not until July 1965, when President Lyndon Johnson signed the Medicare and Medicaid bill into law (P.L. 88–97) that Social Security was amended to include healthcare by adding Titles XVII for Medicare and XIX for Medicaid [27]. This enactment ended the 46-year U.S. campaign for senior healthcare. It also started what is now a 40-year effort by ADA to attain coverage of nutrition services for all appropriate diseases, disorders and conditions.

ADA immediately recognized that not having nutrition and diet therapy services covered was a setback to the profession. As early as 1966, one year after the enactment of the Medicare bill, the ADA House of Delegates voted to take necessary action to include nutrition and diet therapy services in all medical care legislation [28]. As a result, ADA concentrated its efforts on incorporating a nutrition services provision in an assortment of healthcare and Medicare reform bills introduced throughout the 1970s and 1980s. These bills varied greatly in their approach, from installing a compulsory universal national health insurance program to simply expanding Medicare coverage. In their own way, each bill represents an opportunity for ADA to fulfill the House of Delegates' desire to expand nutrition and diet therapy services.

In 1971, President Richard Nixon proposed a national health insurance program consisting of:

- A program to ensure that no American family will be prevented from obtaining basic medical care by inability to pay
- A major increase in and redirection of aid to medical schools, to greatly increase the number of doctors and other health personnel
- Incentives to improve the delivery of health services, to get more medical care resources into those areas that have not been adequately served, to make greater use of medical assistants, and to slow the alarming increase in the costs of medical care
- New programs to encourage better preventive medicine by attacking the causes of disease and injury and by providing incentives to doctors to keep people well rather than just to treat them when they are sick

In 1972, Congress passed the Social Security Amendments Act (P.L. 92–603), which expanded Medicare coverage to people with end-stage renal disease, effective July 1, 1973.

On December 13, 1977, President Jimmy Carter signed into law H.R. 8422, a bill to provide payment for rural health clinic services [29]. The bill also established demonstration projects for services provided by physician extenders employed by such physician-directed clinics in urban, medically underserved areas. ADA lobbied Congress to ensure that the term physician extenders included RDs. As a result of that effort, Rep. Tim Lee Carter (R-KY) introduced H.R. 6259, which defined preventive health services (in part) as '... health education and counseling designed to prevent nutritional or other medical problems of the elderly, including counseling for terminal illness ...' [30]. But when signed into law, the bill did not include the provisions suggested in Rep. Carter's bill.

In the mid 1970s, dietetic professionals working in private practice were a relatively new development and insurance coverage for their services was virtually nonexistent. In 1978 Trithart and Noel [31] put it this way: 'While nutrition services are recognized as being desperately needed by the population at the grassroots level, dietitians are keenly aware that their knowledge and skills do not have government support in legislation or in the form of third-party payments for insurance purposes'.

By 1979, national health insurance once again had taken center stage as a national issue. Several bills were introduced in the Congress, including a comprehensive proposal by Rep. James Corman (D-CA), H.R. 21, the Health Security Act, which would have established a universal national health insurance program that included coverage for supporting services, including nutrition. The issue was raised to a higher level when, in response to extremely high inflation rates for medical care, President Carter asked Congress to enact a national health insurance program. He argued during his 1979 State of the Union Address that 'We must act now to protect all Americans from healthcare costs that are rising USD 1 million per hour, 24 hours a day, dou-

bling every 5 years. We must take control of the largest contributor to that inflation: skyrocketing hospital costs' [32].

As introduced, Carter's bill, H.R. 5400, contained no mention of nutrition services. Although Congress held hearings, the bill never made it out of committee [33]. During hearings before the Senate Finance Committee Subcommittee on Health, ADA testified that: '... nutrition services under the supervision of qualified nutritional personnel should be a component of all health and health-related programs and should be designed to reach the total population with priority to such nutritionally vulnerable groups as infants, children, and youth in growing years; women in the child-bearing years; and the elderly'.

The American Dietetic Association's position is that the inclusion of nutrition as a component of home healthcare will significantly reduce the number of people requiring sick care services and, therefore, contribute directly to:

- A relief in the strain on the nation's healthcare delivery system
- A decrease in the escalating healthcare costs
- An increase in physical, mental, and social wellbeing of people so that they may achieve and maintain productive and independent lives [34].

In his final State of the Union Address in 1981, President Carter again proposed to Congress a national health plan to 'enable the country to reach the goal of comprehensive, universal healthcare coverage' [35]. His plan received little attention in part because of the significant shift toward a more conservative Congress, high inflation, and economic anxieties caused by dramatic increases in healthcare costs [36]. His plan included the following features:

- Nearly 15 million additional poor people would receive fully subsidized comprehensive coverage
- Prenatal and delivery services would be provided for all pregnant women, and coverage would be provided for all acute care for infants in their first year of life
- The elderly and disabled would have a limit of USD 1,250 placed on annual out-of-pocket medical expenses and would no longer face limits on hospital coverage
- All full-time employees and their families would receive insurance against at least major medical expenses under mandated employer coverage
- Medicare and Medicaid would be combined and expanded into an umbrella federal program, Healthcare, for increased program efficiency, accountability, and uniformity
- Strong cost controls and health system reforms would be implemented, including greater incentives for health maintenance organizations

Ronald Reagan's election in 1980 ushered in a move to 'shrink' government. But as the national debate on a comprehensive national healthcare diminished, ADA decided to move ahead and increase its lobbying capabilities by opening a Washington office [37]. Before that, ADA's government relations

staff was located in Chicago, making it virtually impossible for the association to directly and effectively lobby the Congress.

In 1988, Congress passed the greatest expansion of the Medicare program since its enactment. The Medicare Catastrophic Coverage Act, P.L. 100–360 [38], however, was highly controversial. The opposition from many higher-income seniors protesting the higher taxes contained in the bill led to its repeal only a year later. Congress adopted a new fee schedule for physician services called the resource-based relative value scale [39]. This is the same fee structure used today by Medicare, and one that has caused numerous problems.

In 1991, the ADA House of Delegates adopted the position that 'quality healthcare should be available, accessible, and affordable to all Americans. Quality healthcare is defined to include nutrition services that are integral to meeting the preventive and therapeutic healthcare needs of all segments of the population' [40].

In 1992, Bill Clinton ran for President calling for passage of a national health insurance program that would cover most Americans. With the renewed interest in a national health insurance program, ADA increased its activity toward including nutrition in healthcare reform legislation. In a white paper on healthcare reform, published in June 1992, ADA adopted the position that '... nutrition services be included in any healthcare reform legislation. The dietetics professional (qualified dietitian) should be identified as a qualified provider of reimbursable nutrition services' [41]. ADA identified healthcare reform as its highest priority and developed a platform entitled 'The Economic Benefits of Nutrition Services' that provides a financial rationale for including nutrition services in a healthcare reform package [42].

Newly elected President Bill Clinton made passage of a national health insurance program one of his top legislative priorities on his arrival in Washington. ADA focused its efforts on making sure nutrition services were included in any healthcare reform bill that might pass [43]. In June of that year, ADA, along with a number of other nutrition organizations [44], took the position that:

> ... quality healthcare must be available, accessible, and affordable to all Americans. Quality healthcare is defined to include nutrition services that are integral to meeting the preventive, therapeutic, and rehabilitative healthcare needs of all segments of the population. Nutrition services of screening, assessment, education, counseling, and treatment must be included in healthcare reform proposals. Nutrition services must be covered as a benefit in the basic benefits package currently being considered by the Administration. Coverage for nutrition services must be provided under Medicare and Medicaid, other public programs, and private and corporate insurance programs. These services must be provided by an RD or other qualified professionals who meet licensing and/or other standards prescribed by the Secretary in regulations.
>
> Any healthcare reform proposal must include nutrition services. These cost-effective services must be a component of the basic benefits package currently being considered by the Administration for the Medicare and Medicaid programs, other public programs, and private and corporate insurance programs. Nutrition services must

be maintained in all comprehensive federal, state, and local programs designed to improve the public's health.

This basic benefits package is fundamental to meeting minimum healthcare needs of all Americans [45].

In November 1993, Clinton's healthcare reform legislation, the Health Security Act (H.R. 3600 and S. 1775) [46], was introduced and for the first time, several nutrition provisions were included:

- MNT would be covered as a basic benefit if it were medically appropriate
- Clinical preventive services would specifically include nutrition counseling
- Nutrition counseling was singled out as an example of health education and training that would be covered by health plans
- Home infusion therapy (i.e., tube or intravenous feedings) would be covered
- The Special Supplemental Food Program for Women, Infants, and Children (WIC) would be fully funded by 1996
- Public health nutrition was identified as a core public health function; therefore, state grant funding would be available to support public health nutrition projects
- School health education programs that included nutritional health among the subjects studied would be developed
- Funding would support research initiatives in health services that focus on promoting health and preventing diseases, such as breast cancer, heart disease, and stroke, that have a clear nutrition component [47]

After months of hearings and debate, the 103rd Congress adjourned without passing a healthcare reform bill, and ended Clinton's push for a federal universal healthcare program. Small businesses opposed the Clinton plan because it required them to pay 80% of their employees' insurance, and there was no limit on pain and suffering damages for malpractice suits. Health insurance companies vigorously opposed the plan because it put restrictions on premiums and forced them to accept high-risk patients [48]. Republicans in the 1994 November elections won a majority of both the House and Senate, dooming any possibility that Clinton's healthcare reform would pass in the foreseeable future.

New Strategy Takes Shape

Out of many failures came the seeds for success.

Recognizing that universal national health insurance was not going to pass any time soon, if ever, ADA adopted a strategy to get MNT incorporated into Medicare [49]. In the 104th Congress (1995–1996), just 7 months after the Clinton healthcare reform plan died, Sen. Jeff Bingaman (D-NM) introduced

S. 1964, the Medical Nutrition Therapy Act of 1995. In August 1995, Rep. Jose Serrano (D-NY) introduced an identical bill in the House, H.R. 2247. Eventually, H.R. 2247 was cosponsored by 91 members of Congress, signaling strong bipartisan support for the bill.

How did MNT attract the interest of 91 lawmakers? ADA began training its members on the importance of self representation, and taught them how to ask for support from lawmakers. A national 'grassroots' campaign followed. And that campaign continues even today as ADA has made knowing how to work in political circles a goal in and of itself. Knowing that has made it possible for ADA to be more effective in areas such as aging and child nutrition, health literacy and nutrition advancement, food and food safety, nutrition research, and in discussing the many issues related to overweight and obesity.

In the 105th Congress (1997–1998), Rep. John Ensign (R-NV) reintroduced the Medical Nutrition Therapy Act, which received 225 cosponsors; for the first time, Medicare MNT was supported by at least half of the House of Representatives. Support for the Ensign bill was viewed as 'a major milestone' in seeking passage of MNT legislation [50]. Also in 1997, Sen. Larry Craig (R-ID) offered an amendment to the budget reconciliation bill to provide for a study and report by the Institute of Medicine analyzing the short-term and long-term benefits and costs to Medicare of coverage of MNT services by RDs. The amendment was adopted by voice vote. The bill was passed and became P.L. 105–33.

In an effort to build support for coverage of MNT within Medicare Part B, ADA contracted with a Washington-based firm to 'gather additional data to strengthen ADA's position that providing coverage for MNT in the Medicare program would help contain costs by reducing and preventing expensive medical complications' [51]. In April 1999, the Lewin Group reported that, based on their analysis, 'After an initial period of implementation, coverage for MNT can result in a net reduction in health services utilization and costs for at least some populations. In the case of persons aged 55 years and older, the savings in utilization of hospital and other services will actually exceed the cost of providing the MNT benefit. These results suggest that Medicare coverage of MNT has the potential to pay for itself with savings in utilization for other services' [12].

Later that year, the congressionally requested Institute of Medicine study was published. It found:

- Nutrition therapy is 'effective as part of a comprehensive approach to the management and treatment of many conditions affecting the Medicare population'
- RDs are 'currently the single identifiable group of healthcare professionals with standardized education, clinical training, continuing education, and national credentialing requirements necessary to be directly reimbursed as a provider of nutrition therapy'

- Two tiers of nutrition services exist. Basic nutrition education and advice 'can generally be provided by most healthcare professionals', but the second tier of nutrition services, nutrition therapy, is 'an intensive approach to the management of chronic diseases and requires significantly more training in food and nutrition science than is commonly provided in the curriculum of other health professionals. It requires a broad knowledge base to translate complex diet prescriptions into meaningful individualized dietary modifications for the lay person'
- Medicare coverage of enteral and parenteral nutrition-related services in the acute care setting should continue at current levels. A multidisciplinary approach to providing this care is endorsed
- The Health Care Financing Administration (now called the Centers for Medicare and Medicaid Services, CMS), as well as accreditation and licensing groups, should reevaluate existing reimbursement systems and regulations for nutrition services along the continuum of care (acute care, ambulatory care, home care, skilled nursing care, and long-term care) to determine the adequacy of care delineated by such standards [52]

The report from the prestigious Institute of Medicine significantly reframed the concept of MNT and nutrition services in general. It was represented a breakthrough in knowledge about MNT. Combined with the knowhow of working effectively on Capitol Hill and a separate campaign to create a political action committee of dietitians for dietitians, ADA was well positioned to reach its goal of Medicare MNT.

A Complementary Focus

ADA's efforts in the late 1990s were not only focused on enactment of a Medicare MNT benefit. In both the legislative and regulatory arenas, ADA was working to promote the 'importance of nutrition therapy and seeking opportunities to change and expand state and federal laws and administrative guidelines in a coordinated push to elevate the role of dietetics professionals' [53]. A critical element of this effort was the development and approval of specific nutrition service codes, or CPT codes [54]. Establishing codes was an essential step for the dietetics profession because the codes uniquely define MNT services and provide a means for submitting claims for MNT services to the government and to private health insurance companies.

In 1987, the ADA Board of Directors appointed a Reimbursement Team, formerly known as the Nutrition Services Payment Systems Committee, to develop recommendations and an implementation plan for nutrition services payment systems, and for 13 years it too was stymied as the American Medical Association (AMA) repeatedly declined ADA's request for the inclusion of specified nutrition services in CPT codes [55].

In 1999, however, the AMA finally signaled that it was willing to hear an ADA proposal. With the likely passage of Medicare MNT legislation, and after considerable facilitation with AMA medical groups, the AMA's Editorial Panel notified ADA that its request for specific nutrition services codes had been accepted and three codes were settled on [54]. In August 2000, AMA recommended temporary values (Relative Value Units, RVUs, used to establish code payment amounts) for the three MNT CPT codes. These were lower than ADA recommendations and survey data.

Another landmark decision was made in 1999, as ADA upgraded from protocols to evidence-based guides for practice. The first guides would focus on diabetes and kidney disease – the two conditions covered under Medicare MNT. ADA sought publication of the guides on the government's website.

By 2000, ADA was investing resources to develop evidence grading processes and shortly after that, to train members how to use evidence in nutrition care. Members led in identifying topics for grading and analysis, and for application in new guides for practice. The ADA model of evidence grading was taken as a model for the US Food and Drug Administration's evidence grading system for regulatory purposes. Evidence has become the basis for the 2005 and future 'Dietary Guidelines for Americans'.

More than 250 members have been trained in evidence grading. More than 20 ADA practice guides are either in development by members or they have been completed and are now in circulation. ADA established its Evidence Analysis Library, a global resource which posts summaries of the best available research on dietetics and nutrition, current evidence-based guidelines and resources related to the Nutrition Care Process and Model.

The requirements for attaining public support for MNT were clearly beginning to change the way we think about nutrition issues in the United States. Whether evidence-based practice changed dietetics practice or if practice changes cemented evidence-based care and services is debatable – although probably immaterial. ADA's Board of Directors knew it was necessary to reconsider the touchstones of professional healthcare in the United States. They directed a new framework be created for dietetics practice, stressing the practitioner's knowledge, skills and competencies, critical thinking, collaboration, communication and evidence-based practice in all settings. As that framework was developed, ADA's Code of Ethics, Standards of Professional Performance, Standards of Practice in Nutrition Care, as well as resources for practitioners were included. In about the same period, ADA commenced work to develop standardized language for nutrition care to further dietetics practice, knowledge, education, care, research and policy. ADA has initiated a multi-year process to consider the educational requirements that will best serve dietetics practitioners and the public.

All have become critical assets in ADA efforts to advance dietitians and MNT.

ADA's work on MNT has not stopped with passage of the MNT benefit in 2000. ADA's advocacy agenda moved in parallel paths during 2001 as it worked with the CMS to draft regulations implementing the benefit, continued work with Congress to determine how best to expand the benefit beyond diabetes and renal patients, and began an educational campaign for consumers and physicians about the importance and availability of the new benefit [56].

As part of the Association's communication plan, an educational campaign about the importance and availability of the new benefit was initiated for consumers and physicians regarding the new MNT CPT codes and the Medicare MNT benefit.

ADA also was active in the states, and many state legislatures passed laws that mandated coverage of diabetes self-management training, including MNT provided by RDs. ADA was also involved in training members to work with private insurance companies to obtain private-sector MNT coverage [54].

In the summer of 2001, it became apparent that CMS' interpretation of the statute that determined MNT provider reimbursement rates was flawed, if not inconsistent with the intent of Congress. As noted above, the statute set the reimbursement rate at the lesser of 80% of the actual charge for the services or 85% of the amount determined under the physician fee schedule for the same services if a physician had furnished such services. On August 2, 2001, CMS published proposed regulations that defined (inter alia) the Medicare MNT regulations, including reimbursement rates for RD Medicare MNT providers. According to the proposed regulations, CMS concluded that physicians would not be able to satisfy the qualification requirements and therefore could not provide MNT. As a result, CMS refused to establish physician work RVUs essential for establishing payment levels for Medicare MNT providers; instead, the agency used what is known as a zero work pool methodology [57]. In doing so, CMS determined RVUs for MNT CPT codes (in which each code is given a payment amount that is based on the relative value for physician's work, practice expense, and malpractice or liability expense). To determine the final reimbursement amount, CMS applied a formula and conversion factor to yield a dollar amount [57].

ADA was able to influence the CMS to adjust the reimbursement amount for follow-up MNT and group MNT to reflect an increase of 31 and 20%, respectively, from earlier proposed RVUs. The debate over physicians providing MNT continues to roil.

At the beginning of 2007, we achieved another – albeit, modest – adjustment in MNT payment rates.

ADA is still not satisfied with the current MNT payment amounts. And so we ask:

> If we can land a man on the moon, why can't we have people receive lifesaving MNT, as well as preventive and disease management nutrition care and services? Why can't they apply to all diseases and conditions where they will make a difference? And why can't our members be paid commensurately for their services?

When measured against those questions, we may have relatively minor degrees of progress. Still, ADA's successes seem to have come about by stressing the growing knowledge of dietitians and the organization's demonstrated commitment to put that knowledge to work in the real world. Knowhow has come over time – mainly from learning from what didn't go right and why. Add to those the concept of good fortune and enormous patience – more of which is needed – and ADA seems to have found a formula for success.

References

1 Discussion Paper on Food, Nutrition and Health Policy. Nutrition Policy Task Force. Washington, American Dietetic Association, 2002, p 3.
2 Petrillo T: Live the ADA legacy – annually. J Am Diet Assoc 2002;102:1046–1050.
3 Carey M, Gillespie S: Position of the American Dietetic Association: cost-effectiveness of medical nutrition therapy. J Am Diet Assoc 1995;95:88–91.
4 P.L. 106–554. The Benefits Improvement and Protection Act of 2000.
5 Federal Register; in: Proposed Rules. 2001, vol 66, no. 149, p 40388.
6 American Dietetic Association: Affordable and accessible health care services. J Am Diet Assoc 1992;92:476–478.
7 Who is paying for nutrition services? Billing, coding, and reimbursement trends. J Am Diet Assoc 1993;93:1255.
8 American Dietetic Association: Nutrition services in health maintenance organizations and other forms of managed care. J Am Diet Assoc 1993;93:1433–1438.
9 American Dietetic Association: Cost-effectiveness of medical nutrition therapy. J Am Diet Assoc 1995;95:88–91.
10 American Dietetic Association: Nutrition services in managed care. J Am Diet Assoc 1996;96:391.
11 American Dietetic Association: Medical nutrition therapy and pharmacotherapy. J Am Diet Assoc 1999;99:227.
12 Sheils JF, Rubin R, Stapleton DC: The estimated costs and savings of medical nutrition therapy. The Medicare population. J Am Diet Assoc 1999;99:428–435.
13 American Dietetic Association: Nutrition, aging and the continuum of care. J Am Diet Assoc 2000;100:580–595.
14 American Dietetic Association: Nutrition services in managed care. J Am Diet Assoc 2002;102:1471–1478.
15 American Dietetic Association: Position paper update for 2004. J Am Diet Assoc 2004;104:276–278.
16 Finn S, Gallagher A: Health care reform – where ADA stands). J Am Diet Assoc 1993;93:1043–1044.
17 Join ADA's lobbying efforts on health care reform. J Am Diet Assoc. 1992;92:932.
18 Dodd JL, Derelian D, Grant JM, Bajus B: How the new strategic plan works – for you. J Am Diet Assoc 1992;92:1069–1072.
19 ADA Strategic Plan. http://www.eatright.org/Member/Governance/85_9457.cfm
20 Terris M: National health insurance in the United States: a drama in too many acts. Journal of Public Health Policy. http://members.aol.com/jphpterris/ntlhealins.htm (Accessed December 2, 2004) Health insurance in the United States encyclopedia – health insurance. http://www.factmonster.com/ce6/sci/A0858569.html (Accessed March 3, 2007)
21 http://web.cwoc.ufl.edu/owl/archives/2002_05_23/messages/412.html
22 A brief history of social security. http://usinfo.state.gov/russki/infousa/society/ssbriefhistory.pdf
23 Centers for Medicare and Medicaid Services: History of Medicare and Medicaid. 2004. http://www.cms.hhs.gov/about/history/ssachr.asp (Accessed March 3, 2007)
24 Roosevelt FD: State of the Union Address, January 7, 1943. http://www.usa-presidents.infor/union/fdr-10html

25 Roosevelt FD: State of the Union Address, January 11, 1944. http://www.usa-presidents.infor/union/fdr-11htm
26 Brief History of the Medicare Program, 2004; http://www.seniorjournal.com
27 http://www.cms.hhs.gov/about/history/. Accessed March 3, 2007.
28 Discussion Paper on Food, Nutrition and Health Policy. Chicago, Nutrition Policy Task Force, American Dietetic Association; 2002, p 8.
29 http://thomas.loc.gov
30 Legislative highlights. J Am Diet Assoc 1977;71:55–56.
31 Trithart E, Noel MB: New dimensions: the dietitian in private practice. J Am Diet Assoc 1978;73:60–62.
32 Selected Speeches, Jimmy Carter Library. http://www.jimmycarterlibrary.org/documents/speeches/su79jec.phtml
33 http://thomas.loc.gov
34 ADA urges Congress to make nutritional care a reimbursable le benefit in Medicare's home health care. J Am Diet Assoc 1979;79:460.
35 http://www.thisnation.com/library/sotu/1981jc.html
36 Birn AE, Brown TM, Fee E, Lear WJ: Struggles for national health reform in the United States. Am J Public Health. 2003;93:86–91.
37 Discussion Paper on Food, Nutrition and Health Policy. Chicago, Nutrition Policy Task Force, American Dietetic Association; 2002, p 13.
38 http://thomas.loc.gov
39 DeLewN: Medicare: 35 years of service. 2004; http://www.cms.hhs.gov/review/00fall/00Fallpg75.pdf (Accessed November 27, 2004)
40 American Dietetic Association: Medical nutrition therapy and pharmacotherapy. J Am Diet Assoc 1992;92:227.
41 White paper on health care reform. J Am Diet Assoc 1992;92:749.
42 Finn SC: 1992–1993 annual report. J Am Diet Assoc 1993;93:1448–1455.
43 ADA's lobbying efforts focus on health care reform. J Am Diet Assoc 1993;93:754.
44 Association of the Faculties of Graduate Programs in Public Health Nutrition, Association of State and Territorial Public Health Nutrition Directors, and the Society for Nutrition Education.
45 American Dietetic Association: Affordable and accessible health care services. J Am Diet Assoc 1993;93:686–690.
46 http://thomas.loc.gov
47 Clinton's Health Security Act recognizes value of nutrition: An update on the legislative debate over health care reform. J Am Diet Assoc 1994;94:25–26.
48 http://www.studyworld.com/The_Clinton_health_plan.htm
49 Discussion Paper on Food, Nutrition and Health Policy. Chicago, Nutrition Policy Task Force, American Dietetic Association, 2002, p 32.
50 ADA's medical nutrition therapy campaign reaches milestone. J Am Diet Assoc 1997;97:1092.
51 Johnson R: The Lewin Group study – what does it tell us and why does it matter? J Am Diet Assoc. 1999;99:426–427.
52 The Role of Nutrition in Maintaining Health in the Nation's Elderly, Evaluating Coverage of Nutrition Services for the Medicare Population. Washington, Institute of Medicine, National Academy of Sciences, 2000.
53 The Campaign for Coverage of Medical Nutrition Therapy – ADA's public policy activities reach beyond Medicare. J Am Diet Assoc 1999;99:1208.
54 Michael P. The three Cs for MNT (Coverage, codes, and compensation). J Am Diet Assoc. 2000;100:1140–1141.
55 ADA joins national coding and provider classification projects. J Am Diet Assoc 1999;99:19–20.
56 Patrick S: MNT: success means ongoing effort. J Am Diet Assoc. 2001;101:408.
57 Federal Register: Thursday, August 2, 2001;42 CFR, Parts 405. http://frwebgate4.access.gpo.gov/cgi-bin/waisgate.cgi?WAISdocID = 1552191446 + 1+0 + 0&WAISaction = retrieve (Accessed March 3, 2007)

Discussion

Mr. Parver: During the time that the legislation was pending, especially the year in which it passed, what was the position of the Centers for Medicare and Medicaid Services (CMS) on the bill?

Mrs. Patrick: We never got a position from CMS on the bill. They were silent – they did not oppose us and they did not support us. At the point where 300 people had already signed on in the House and the Senate, we knew that we would move ahead.

Dr. Jensen: I would like to be a little provocative, although I do not want to single you out. However, a pet complaint of mine, and I am sure for many physicians, is the whole evidence-based practice concept and, I suppose, in particular how the evidence-based practice, American Dietetic Association (ADA) library is being used or is intended to be used. At our institution, just as a simple example, we have a clear movement for all of our dieticians to apply a very standardized approach to assessing a patient's calorie needs across the board, based on the ADA evidence-based guidelines. This has basically eliminated skilled clinical judgment, individual assessment, and awareness of the latest standards of care, such as in critical care energy assessment. Personally, I have trouble with that.

Mrs. Patrick: I think that you should have trouble with it, if you stop and think about the process. when did the nutrition care model and process come on board in your facility?

Dr. Jensen: Within the past 2 years.

Mrs. Patrick: People are therefore new to it and trying to grasp it. It will not withstand the withering kinds of criticisms that you make unless people are actually smart enough to come back to the patient's own value as opposed to just going through the motions of data outcome and collection.

Dr. Jensen: I see where evidence-based practice is a very appropriate response to the last decade of accountability and consolidation that we have and it can be very useful. However, it cannot be intended to eliminate individual clinical judgment. For dieticians in particular, I think that it is something in fact that we would like to strengthen.

Mrs. Patrick: You are absolutely right. The first person I ever heard talk about evidence-based practice was Newt Gingrich, who said that this was the only way that you can interject accountability into the US medical system. It is a bit of a legacy – we are with it. Whether it will work or not, I do not know.

Mr. de Man: I have an additional question that is relative to what Dr. Jensen has just said. What about the integration and cooperation between the approach from the ADA relative to other professional organizations such as ESPEN? Has there been any coordination in that respect?

Mrs. Patrick: Mr. Parver has been around longer than I have as far as the Washington and nutrition communities are concerned. I have only been there since 1999. We collaborate frequently in the nutrition community in Washington, although a little less so in the clinical area. I am hoping that when we go back we will have many more opportunities to approach things and find the ways to support one another in the process.

Mr. de Man: On the work floor itself, you work with each other and are confronted with these perhaps differences of interpretation?

Mrs. Patrick: It also depends on the venue. The benefit that Mr. Parver talked about yesterday was secured through a regulatory process and we had no choice but to go to Congress. When Mr. Parver talks about the next round, he has to go up to the Hill and seek benefit changes with legislators, as opposed to going through a regulatory process.

Dr. Labadarios: What a nice, positive way that was to finish this session, with all your achievements. Taking up Mr. de Man's point, the European Association of Nutrition has a lot to learn.

Mr. de Man: It is highly political and sensitive. While the dietitians were involved in the Brussels conference, they have chosen not to join the Alliance as such yet. Nevertheless, we keep on talking to them. That is what I discussed with Dr. Silver. The level of organization, for instance, between the various NGOs in Brussels differs a lot. However, even the European Hospital Association – if we may call it that – has about 3 or 4 people in its office and is far from being an influential organization yet.

Mrs. Anthony: Continuing from there, within the European Nutrition for Health Alliance, you said that the European Federation of Associations of Dietetics (EFAD) has decided not to join yet. Is it necessary for that organization to be a European-level group? I ask this because while EFAD plays its role, I think that it is weaker than some of the member state organizations, such as the British Dietetic Association or the Dutch Dietetic Association – the strong associations in Europe. I just wonder whether they would not be better players than EFAD?

Mr. de Man: You are absolutely right. We try to be as practical as possible. First of all, as a mechanism, you cannot have 15 organizations on the board of an alliance. That makes it difficult to work with. There are a number of organizations who want to be associated with us and with whom we work, such as patient organizations and European public health associations, but they do not want to be members for a number of reasons. We have therefore chosen to be practical and have a core group, with standing invitations to a number of other organizations, such as the dieticians, to join us. The European Nursing Director Association will join us within a couple of months and, as for the others, we just work together. That works perfectly and we also have good relations with, among others, the patient organizations.

Mrs. Howard: I totally second what Mrs. Anthony has just said. However, what I am concerned about is if EFAD decides not to join you, how will you get dietetic representation within your group?

Mr. de Man: In the way Mrs. Anthony just mentioned, I suppose. We then go to a national organization. However, I do not think that that will happen because, for instance, the Vice President of EFAD spoke at our Brussels meeting and I do not expect that to happen at this stage.

Mrs. Anthony: I also hope that you will let Mrs. Howard and me to help you. I think that one of Mrs. Patrick's key messages is that it takes grassroots. EFAD is saying that they are not so sure that it is worth their efforts, but if the member associations start to hear from members that it is worth their effort, eventually it will be so. I think that we can start some efforts that way.

Mr. de Man: The same issue relates to discussions we had with International Alliance of Patient Organizations, the kind of overall global patient organization. They have so many issues that it is impossible, and even ineffective, to add another. We therefore work with their individual members who are specifically important for these issues, such as Alzheimer's Europe.

Mrs. Anthony: I would like to ask Mrs. Patrick one more question, at the risk of getting myself into trouble as a dietician. The ADA talks about standardized language and we talk about the nutrition care process. However, I am a little more ignorant on those absolute processes that I should be. Nevertheless, in forming and formalizing them, how much work has been done with other organizations such as the Medical Association and the Nursing Association so that we are not creating a language that is unique to dieticians and further heightening the walls between professions, which is something that I think we have all been working to lower?

Mrs. Patrick: The nutrition care process and model are unique to dieticians and are intended to be directed towards the education of dieticians. We are not trying to change people who have been in the profession and develop judgments and expertise back to a process that is really not as good as where they were before. Instead we are trying to create new disciplines within the profession. We partner more with other dietetic associations; however, this year we launched an initiative, and have on several occasions met with representatives of the American Medical Association to work on everything starting from scope of practice. We hope that we can invite them and get their participation in issues such as the Farm Bill and nutrition research.

Dr. Hoffer: I simply want to emphasize the message that we heard from Dr. Bistrian. He illustrated with concrete examples how crucial it is for understanding and developing the field of nutrition and medicine that we have individuals who have some understanding of research or have participated in it and are sophisticated and understand metabolism and nutrition in a deep way. In a way, Dr. Jensen also spoke about that very point in his question. Nutrition, in fact, affects people in disease and health and will continue to do so, and we have to be able to interpret and understand what is happening. I myself have seen examples in recent years of many studies that have been carried out. Examples that come to mind are some of the huge randomized clinical trials of antioxidants and other nutrients in preventing disease outcomes, and descriptive studies where the results are simply misinterpreted. The studies were misdesigned and inappropriately analyzed because the individuals involved were either epidemiologists or clinical trial experts who did not really understand what they were dealing with. I do not have the solution as to how you continue to promote this cadre of wise, educated people with good judgment, but this should not be forgotten.

Mrs. Le Tadic: That is a very important point and I would just like to add some comments. It is also very important for the medical community to understand what is behind food and what food is. We have to win from our knowledge of both the food field and the medical field and cross-fertilize that. Sometimes, I feel that approaching food as a drug is simply impossible as there are so many factors in food which can intervene in the mechanisms, and it is not as clear as for a drug to demonstrate any effect. With regard to the whole safety issue, I think that the medical community needs to understand all the rules that are behind food safety because there is a huge amount of food and we definitely do not have less scientific substance behind food than behind drugs. While it is not the same, the level is probably very comparable.

Dr. León Sanz: Do you think that there is a link between the reimbursement of professional services and the reimbursement of products for enteral or nutritional purposes? We have had two different views this afternoon – the reimbursement of products and the reimbursement of professional services. Perhaps we can learn from the second, but the main issue here at this conference might be what right of reimbursement is there for products? What is your opinion on that?

Mrs. Patrick: I have learned a great deal in the last couple of days. Over the last 7 years I have focused my career on the reimbursement of services. It is a completely different approach, and for a professional association, what we do makes sense – we have to represent our members. On the other hand, you have to go about it in a responsible way. You have to stay within the law and respect the other professions, and you always have to stay focused on the patient because if you do not, it becomes a turf issue.

With regard to products, I am so unfamiliar with the European system that it is quite difficult for me, and listening to the description today I realize that I do not understand it. You were talking about distrust, and from my perspective and background the average European has a completely different attitude and trust factor about science and food than we have in the United States. We are willing to go with the science and are not very distrustful of it, for example genetically modified organisms

or animal agriculture. For any number of things, you could conclude that the systems and people within them are very different.

However, this is a marketplace that is becoming more global. What you described in the European Union as far as products are concerned is not that dissimilar to what professionals have to endure moving back and forth between states. We have an interstate commerce clause on products that prevents the Balkanization of trade of products among states that it appears you can do here. On the other hand, professionals, including healthcare professionals, are regulated at the state level and those scopes of practice can vary significantly in the way the laws play out. We also have a similar situation in other regards. These are political issues and need to be addressed at a political level. It requires time, patience and facts.

Note Added in Proof

In the 2 years since we met in Scotland, the campaign to advance medical nutrition therapy has continued. In the summer of 2007, MNT was added as a core medical service within the US health program for persons with HIV-AIDs. MNT was also approved as a service in the US Older Americans Act.

In 2008, Congress overrode President Bush's veto of the Medicare Improvements for Patients and Providers Act. A new preventive services title is of enormous significance to registered dietitians. Title I, which goes into effect in 2009, establishes a procedure by which Medicare may expand coverage of preventive services, including Medical Nutrition Therapy.

To gain approval, a preventive service has to meet three requirements: (1) Medicare must determine that the service is reasonable and necessary for the prevention or early detection of an illness or disability; (2) it has to be recommended with a grade of A or B by the United States Preventive Services Task Force, and (3) it has to be appropriate for individuals entitled to benefits under part A or enrolled under part B.

The United States Preventive Services Task Force has given intensive behavioral dietary counseling for adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease a B rating. The USPSTF also recommended that intensive counseling can be delivered by primary care clinicians or by referral to other specialists, such as nutritionists or dietitians.

In order to determine if a service is necessary and reasonable, Medicare will use the National Determination Process. NCDs are made through an evidence-based process, with opportunities for public participation.

In 2009, the agency that administers Medicare continued to adjust the reimbursement level for MNT upward, responding to repeated requests by ADA to appropriately interpret the statute for MNT.

Finally in 2009, MNT was written into a pilot program for overweight and obese children covered by the State Children's Health Insurance Program.

As the US Congress prepares to debate health reform this year, ADA recommends that the primary goal of such legislation be to improve the health of Americans. ADA also recommends that all have access to healthy food and quality health care provided by professionals. Prevention should be a focal point for new US health policies, and nutrition is the cornerstone of prevention, says ADA. ADA will seek the inclusion of the RD in clinical and community health teams emanating from health reform.