Home Enteral Nutrition
Epidemiology and Legislation in Europe

A. Van Gossum

Department of Gastroenterology and Hepatopancreatology, Hôpital Erasme, Université Libre de Bruxelles, Bruxelles, Belgique

Introduction

Enteral nutrition is the preferred way of feeding patients who cannot maintain sufficient oral intake but have a functioning gastrointestinal tract. Enteral feeding has been used for several decades for hospitalized patients, but for the last 20 years home enteral nutrition (HEN) has been expanding in home care in many industrialized countries throughout the world. Despite the fact that the number of patients on HEN is now much higher than patients on home parenteral nutrition (HPN), scientific interest and medical concern were initially much higher for HPN [1–3].

The number of scientific publications on the use of HEN is quite weak. In many European countries, legislation on HEN has only quite recently come into effect or is lacking. There are no real guidelines on the correct use of HEN while guidelines for enteral nutrition in hospitalized patients have recently been published [4].

In this chapter, we have tried to collect data on epidemiology, legislation and the current use of HEN throughout Europe.

Definition

In 1999 a survey was performed by the ESPEN-HAN working group on legislation of home artificial nutrition in different European countries [5]. It appeared that there was little agreement about what constitutes HEN. Indeed, while in Italy, France and the UK only tube feedings covering >75% of requirements are considered as enteral nutrition, in 6 other countries (Belgium, Czech Republic, Denmark, Israel, Poland and Spain) both tube and
Home Enteral Nutrition

oral feeding covering >75% requirements apply for this consideration, and in two countries (Austria and Croatia) any kind of enteral diet or supplement is considered as enteral nutrition.

In the European epidemiological survey that was also done in 1999 by the ESPEN-HAN working group, HEN was defined as the provision of enteral diets as the main source of daily intake at home [6].

In an article entitled ‘Standards for home nutrition support’, the ASPEN defined enteral nutrition as ‘nutrition provided via the gastrointestinal tract’ either ‘orally’, meaning enteral nutrition taken by mouth, or ‘by tube’, meaning enteral nutrition provided through a tube or catheter or stoma, delivering nutrients to the oral cavity [7].

The BANS report on home artificial nutrition provided data on parenteral nutrition and enteral tube feeding [8].

In a recent report done by the NADYA-SENPE working group (Spain), Planas et al. [9] described 2,986 patients who were enrolled in HEN during the year 2000. Data were collected from 22 hospitals. Among these patients who were considered to be on HEN, oral nutrition was the preferential route in 50.8%, followed by nasoenteral tube (30%), and in 17.4% ostomy tubes were placed. A prospective observational study was also performed in the Valladolid area in Spain between January 1999 and December 2001 showing that HEN was administered orally to 79% of the patients [10].

The lack of agreement on the definition of HEN between the different European countries obviously hampers interpretation of the epidemiological data.

Incidence – Prevalence

The real incidence and/or prevalence of HEN in Europe are not really known. The main reasons are the large number of HEN centers in many countries and the lack of a registry including all newly enrolled patients.

Obviously, the incidence may differ regarding the definition of HEN per se as well as the consideration of adult patients only or children (as is the case in the BAPEN report). So, estimation of the incidence is generally based on clinical practice in some areas. In the European epidemiological survey, the incidence was considered to be reliable in 8 limited areas in which HEN was covered by a specific center [6]. The median yearly incidence of adult patients receiving HEN was 163 patients/million population/year but the range was between 62/million/year in Turin and 457/million/year in Ivrea (Italy). In the Valladolid area in Spain, the incidence was 150/million/year in 1999, 213/million/year in 2000 and 95/million/year in 2001 [10].

The BAPEN report showed that the point prevalence of registered adult patients receiving home enteral tube feeding (HETF) between the end of
1996 and the end of 2002 increased from 4,236 to 15,148 patients [8]. In the same report, they showed that, at the end of 2002, there were 4,219 children (<16 years) registered as receiving HETF from 170 reporting pediatric centers (~11% growth in point prevalence compared with 2001). Although the number of reporting pediatric centers submitting to BANS has remained similar over the past 7 years (1996–2001), the number of new registrations increased by 50% during this time.

In the Spanish annual report, data were based on 22 reporting hospitals which included 2,986 patients during the year 2000 [9]. So in the UK the number of registered patients (according to the period prevalence) was 50 per center, while in Spain this number reached 130/center. The difference is probably due to selection of the Spanish centers that were more interested in participating in the survey.

Although there are no official data available for Germany, it seems that 140,000 percutaneous endoscopic gastrostomies (PEGs) are implanted every year, and 100,000 patients are on HEN including 40% with deep neurological alterations.

**Patient’s Characteristics**

In the European survey, the age distribution for adult patients was: 16–40 years (7.5%); 41–65 years (39%); 66–80 years (34%), and >80 years (21%) [6]. The male/female ratio was 1.62.

In the UK, the age distribution for adult was quite similar: 16–40 years (8.9%); 41–60 (20.6%); 61–70 (19.5%), and >71 years (51%). In this survey, compared to the patients already receiving HEN, the new registration consisted of a greater proportion of elderly patients (>70 years) and a smaller proportion of younger people (<50 years).

In the UK in 1999, the age distribution for children was: 0–1 years (37%); 1–2 years (13.4%); 3–5 years (16.8%); 6–12 years (19.4%), and 13–16 years (13%) [8]. The point prevalence remained stable between 1996 and 1999.

The age distribution may be related to the underlying disease of the patients requiring HEN. The Dutch national registry reported their experience over the period 1998–2000 for patients with head and neck cancer [11, 12]. The mean age was 60 ± 12 years for 1,094 patients.

In the Spanish national register, the mean age of 2,986 patients was 65 ± 19 years.

**Underlying Diseases and Indications**

In the European survey, underlying diseases for HEN in the 1,397 patients were: neurological diseases (n = 620); head and neck cancer (n = 423);
benign digestive disease (n = 148); geriatric disease (n = 101); AIDS (n = 10), and miscellaneous (n = 95) [6].

Dysphagia secondary to a swallowing disorder was the principal reason for HEN in 81% of the patients, oral failure (without dysphagia or a digestive disorder) in 14.4% and partial intestinal failure in 4.8%.

In the Spanish registry (2000), among 2,986 patients, 41.2% were diagnosed with neurological diseases and 33% with cancer [9].

In the BANS report (2002) [8], the underlying diseases were: cardiac disease (0.9%); central nervous system problems (60.5%); gastrointestinal diseases including esophageal cancer (24.2%); renal diseases (0.4%); respiratory diseases (1.7%), and other diseases (12.3%). Swallowing disorder was the main indication in 72.6% [8]. In the pediatric population, the distribution of underlying diseases was as follows: cardiac (9.2%); central nervous system (35.6%); renal diseases (2.1%); gastrointestinal diseases (16.6%); respiratory (6.2%) including 3.7% with cystic fibrosis, and other diseases (29.4%). The reasons for nutritional support were: failure to thrive (39.8%); swallowing disorder (21.1%); to improve nutritional status (24.3%), and malabsorption in 3.2%.

We obtained data from the Children’s Memorial Health Institute in Warsaw about 101 children with PEG suffering from primary neurological diseases (52%), metabolic diseases with secondary encephalopathy (20%), gastrointestinal diseases (22%), neoplastic diseases (3%), anorexic patients, and microsomic patients (3%).

**Technical Aspects (Route/Formula)**

In the 1,397 patients described in the European survey, HEN was administered through PEG in 813 patients (58.2%), a nasogastric tube in 410 patients (29.3%), surgical jejunostomy in 76 patients (5.4%) and by other access in 3.4% [6].

A pump was used in 43% whereas 57% received HEN by gravity without a pump. The proportion of patients fed via PEG and with a pump was different between countries. The mode of administration of HEN was cyclic nocturnal for 36.7%, cyclic diurnal for 24.8%, continuous for 4.4%, and by bolus in 34.1%. There were important variations between the centers concerning the mode of administration of nutrients. In some centers, most patients were on cyclic enteral nutrition whereas in others most were fed by bolus. Commercial rather than ‘home-brewed’ preparations were used in almost all patients; the feeds were standard or high energy (>1 kcal/ml) in 65.3%, enriched with fibers in 24.5%, elemental or semi-elemental in 5%, or modified in some other way in 5.2%.

In the Spanish registry, polymeric formula composition was used in 83% [9].
In Europe, the HEN technique was performed by the patients (17.1%), relative/caregivers (38.1%), nurse (35%), or others (9.8%), but important variations were observed throughout the centers. In the 2002 BANS report [8], 21% of the patients were independent and able to manage their nutritional support, 19.6% required some help, and 58.7% required total help. Patients were treated in a nursing home (38%), in their own home (54%), or other location (8%). On the contrary, for children, 97% were managed in their own home.

In a local series (Brussels) of 210 patients in whom a PEG was placed for enteral feeding, 30 (15%) were taught to manage their feeding independently (personal data).

In the Dutch registry, Van Reeuwyk-Werkhorst et al. [11] showed that feeding characteristics at baseline differ significantly between the hospitals. General hospitals (57%) used PEG at baseline more often than academic hospitals (32%) and oncology hospitals (41%). In all groups, HEN was administered mostly by bolus (36–64%) except for females in academic hospitals in whom HEN was mostly administered intermittently (49%). The most frequently used diameter of the feeding tube was 8 french (46%) in oncology hospitals and 14 french (33%) in academic hospitals. The medical devices most frequently prescribed were a syringe in oncologic hospitals (58%), a feeding pump (57%) in general hospitals and in academic hospitals a clamp for males (41%) and a feeding pump for females (39%) were used.

In the population aged <16 years, the use of nasogastric tube in patients was 92% and the use of PEG was 7%. HEN was delivered either by bolus in 73% or was intermittent in 17%. In infants, a syringe was mainly used (39%) and in children a pump with a rucksack (59%).

**Legislation**

According to the survey performed in 1999, five countries (Austria, Croatia, Germany, Poland and the UK) have no legislation regarding HEN [5]. Italy and France were the first countries to pass legislation on reimbursement policies in 1988 (table 1). This legislation is applied nation-wide in 6 countries and is regional in Italy. Except for Croatia and Belgium, it applies for both children and adults. In Belgium, children <2 years receive special reimbursement consideration. In Switzerland, there is also well-defined legislation.

In most of the countries (Austria, Belgium, Denmark, Germany, Israel, Italy, Poland, Spain and the UK) any hospital can take care of HEN patients. In France and the Czech Republic, HEN is restricted to a certain number of centers for geographical reasons, and in Croatia it is based on the hospital size or specialization. Nevertheless, almost any physician can prescribe HEN
Home Enteral Nutrition

Table 1. Date of approval of home enteral nutrition legislation

<table>
<thead>
<tr>
<th>Year</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>1988</td>
<td>Italy, France</td>
</tr>
<tr>
<td>1990</td>
<td>Czech Republic</td>
</tr>
<tr>
<td>1996</td>
<td>Belgium</td>
</tr>
<tr>
<td>1997</td>
<td>Israel</td>
</tr>
<tr>
<td>1998</td>
<td>Spain</td>
</tr>
<tr>
<td>1999</td>
<td>Denmark</td>
</tr>
</tbody>
</table>

From Moreno et al. [5].

except in the Czech Republic and Croatia, although preferably members of a nutritional support team (NST). In general, once the patient is sent home the general practitioner or the NST must take care of the medical follow-up. HEN is restricted to a limited number of diseases or conditions in 5 countries (Belgium, Croatia, France, Czech Republic and Spain) as well as in Switzerland. Any marketed enteral diet can be prescribed, except in Denmark, Croatia and Spain.

Funding

Regarding funding arrangements, the answers vary widely [5] (table 2). There are no clear indications about disposables and infusion pumps in most of the countries. Provision of an enteral diet and equipment does not follow a unique pattern, as shown in table 3.

We asked for the existence of written guidelines both for health care workers and for patients, and we did not receive a uniform answer. These data were confirmed in the survey performed by the ESPEN-HAN group in 1999 [6].

Daily costs of HEN were not available in centers from Denmark and the UK. In the other center the daily overall costs of HEN varied from EUR 7 to 25. The daily cost of HEN was EUR 12.4 in Belgium, EUR 10.0 in France, EUR 23.3 in Germany, EUR 24.2 in Italy, EUR 12.0 in Poland, and EUR 16.7 in Spain. These costs include the formula, the infusion pump, micronutrients, and all the necessary equipment: bags, tubing and dressings. They do not include the cost of the caregiver, cost of rehospitalizations, and medical monitoring.

In Poland, the situation is ambiguous. HEN is not considered to be an approved medical service although many patients are receiving HEN. Patients must pay for the feeds that they can buy open in a pharmacy, but they have difficulty with tube feeding.

In conclusion, the use of HEN is expanding in many European countries. It is surprising that the definition of HEN differs from one to another country (oral, tube or both). The real incidence and/or prevalence of HEN in Europe
### Table 2. Home enteral nutrition funding arrangements

<table>
<thead>
<tr>
<th>National health system</th>
<th>Formula</th>
<th>Disposable</th>
<th>Medical care</th>
<th>Nursing or dietician care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Totally</td>
<td>Croatia, Czech Republic, France, Germany, Italy, Spain and UK</td>
<td>Same</td>
<td>All except Belgium and Israel</td>
<td>All except Belgium, Israel and Poland</td>
</tr>
<tr>
<td>Partially</td>
<td>Austria, Belgium, Denmark</td>
<td>Same</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Private insurance</td>
<td>Germany</td>
<td>Germany</td>
<td>Germany</td>
<td>Germany</td>
</tr>
<tr>
<td>Totally</td>
<td>Israel and Poland</td>
<td>Israel and Poland</td>
<td>Belgium and Israel</td>
<td>Belgium, Israel and Poland</td>
</tr>
<tr>
<td>Partially</td>
<td>Austria, Belgium, Denmark</td>
<td>Austria, Belgium, Denmark</td>
<td>–</td>
<td>–</td>
</tr>
</tbody>
</table>

Belgium has specific regulation for children and varies according the type of formula. Germany has 100% national health system (NHS) or private insurance. Co-payments: Belgium NHS 30%, patient 70%; Denmark NHS 60%, patient 40%; Austria NHS 60–70%, patient 30–40% (for tube feedings 100% NHS).

From Moreno et al. [5].

### Table 3. Provision of enteral diet, disposables and pumps

<table>
<thead>
<tr>
<th>Enteral diets</th>
<th>Disposables</th>
<th>Pumps</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital</td>
<td>Croatia, Czech Republic, France and Spain</td>
<td>Croatia, Czech Republic, France and Spain</td>
</tr>
<tr>
<td>Private pharmacists</td>
<td>Austria, Belgium, Czech Republic, Germany, Israel, Poland, Spain and UK</td>
<td>Austria, Belgium, Czech Republic, Denmark, Germany, Israel and Poland</td>
</tr>
<tr>
<td>Home care firms</td>
<td>Austria, Belgium, Germany, Israel, UK and Italy</td>
<td>Belgium, Denmark, Germany and UK</td>
</tr>
<tr>
<td>Primary care</td>
<td>Italy and UK</td>
<td>Italy</td>
</tr>
</tbody>
</table>

Enteral diets: Croatia and France 100% hospital; Italy 100% primary care; data not available from Denmark. Disposables: Croatia, France and Spain 100% hospital; Italy 100% primary care. Pumps were not used. Poland and Israel used others.

From Moreno et al. [5].
are unknown; the incidence of HEN is estimated to be approximately 160/million inhabitants/year.

While the main indication is a swallowing disorder, the principal underlying diseases are neurological disorders and head and neck cancer. In an adult population, the percentage of patients older than 70 years is higher than 50%. Legislation and funding for HEN differs in several countries and are still lacking in some.

References


Discussion

Dr. Hébuterne: I have a question for both speakers about the incidence. The incidence in Europe is somewhere between 100 and 400 but probably closer to 100 than 400, and in the USA probably more than 400. Could you explain why there is this difference between Europe and the USA, and who is right?

Dr. Van Gossum: I know that the difference is the same for home parenteral feeding. We expect that there are 10 times more patients on home parenteral feeding in the USA than in Europe, and it is the same for enteral feeding. The distribution of the underlying disease is similar, so it is not a question of disease. The age of the patient is also similar, so it is probably a question of routine practice and, as you mentioned, probably that in the USA the patients are discharged home much faster than in Europe. For me this is the only reason.
Dr. Steinbagen-Thiessen: May I also ask you a question on the same topic? There were data about increasing enteral feeding and, if I remember correctly, in the adult it was an increase of 26% and in children of 14%. I can understand in the adults, but are there more children or, is this a growing population of the children?

Dr. Van Gossum: Those are data from the UK and perhaps we can ask our colleagues to give some more details about these data.

Dr. Elia: We have been amalgamating data in the British Artificial Nutrition Survey since 1996. In the UK the single commonest diagnosis for home enteral tube feeding in children is cerebral palsy, and there has been a tendency to have a lower threshold to start this. In the same way there has been a lower threshold for starting tube feeding in elderly, even when taking into account specific age categories. I would just like to raise one point about the amount of tube feeding taking place. When I look at different values from various parts of the world, I sometimes find it difficult to know exactly what they mean. It seems that they are sometimes referring to number of new cases over a period of time (period prevalence), at other times to the prevalence over a period of time (period prevalence) and yet at other times to the prevalence at a point in time (point prevalence). I feel that the distinction between these is sometimes confused, making it difficult to make direct comparisons.

Dr. Van Gossum: It is true that it is confusing and it is also true in other fields of medicine about epidemiology, the terms of incidence, prevalence, point prevalence, are probably not correctly understood. We are talking about the yearly incidence of new patients, and it is true that the number is probably different when we are talking about point prevalence. According to the data that I got from the UK for adults, there is a point prevalence of about 9,000, but the number, the approximation of the number of patients on home enteral nutrition was about 15,000 patients.

Dr. Elia: It has been growing since the 1999 or 2000 report that you refer to. Interestingly enough the growth has been increasing but beginning to slow down in percentage terms. We do not have the full picture although data from over 250 centers in the UK suggest that the point prevalence is now in excess of 25,000.

Dr. Thomas: Just a couple of comments regarding what we are seeing at least in the geriatric population because I think we have a slightly skewed view in most of the patients who we start feeding enterally very closed to the end of life. In all of the prevalence data, one of the things that we need to do is to throw out that population. For example in the United States over half of the patients are referred to hospice care in the last 2 weeks, so it is a very sort of failing end of life decision to put a tube in. It makes the family feel more comfortable, is often demanded, and so it is a term event. It is not really done for any sort of staying reason or rational therapeutic purpose. So I think if you remove those, which is a substantial percentage, then you are closer to the true number that are started. For that reason if you look at the data in long-term care, 40% of the patients who start enteral feeding in the geriatric population die within 6–12 months, and again it is because of this sort of false bias that occurs in this population. One of the reasons why we have more enteral tubes put in in the United States is simply because in nursing homes when people are restrained nasogastric tubes get pulled out very quickly, whereas the enteral tube tends to stay in longer. So it probably has more to do with that than it has to do with the 2 or 3 dollars difference in reimbursement.

Dr. Bowling: I would appreciate your views on providing the service. We have heard from the United States that patients are pretty much left on their own, plus or minus an enthusiastic physician, if they are lucky. In the UK it is certainly very patchy. If someone is very lucky there will be a full multidisciplinary nutrition team in the community, but they are the absolute exception rather than the rule. Sometimes it is just a dietician, sometimes it is just a nurse, sometimes it is a general practitioner and
very often it is nobody at all. So I was just wondering what your perception was around Europe as to providing home care?

**Dr. Van Gossum:** According to the survey that we performed it was also very variable from one center to another. There are some really well-organized centers, such as in Nice with Dr. Hébuterne, and they have the whole strategy to follow the patients. But we have to recognize that in many centers it is totally different. Sometimes there is a nutrition team who will join up with the home care but in many other centers there is no organization, and it is true that it depends on the general practitioner. Sometimes there is a dietician at home but it seems very infrequent to have a reevaluation of the nutritional needs of the patients once he is at home. The main problem is technical, but I am aware of at least one study showing that there is only a small percentage of patients on home enteral nutrition who will be reassessed for the need for the feeding [1]. So they are discharged with 1,500 kcal and then that is all, they will maintain that for 1 or 2 years, and nobody will take care about that, which is very common unfortunately.

**Dr. Bowling:** I think I have raised a very important issue as to removing a percutaneous endoscopic gastrostomy tube once the patients are out of the hospital setting. I am sure there are many patients who probably do recover their ability to swallow and can eat and drink but don’t get reassessed. There are a number of patients I have been contacted about, perhaps 3 or 4 years down the line, who are no longer using their tube and are eating quite normally, but no one has thought to take it out.

**Dr. Van Gossum:** That is the reality. I think that it is very important to provide the patients or their relatives with some information when they are discharged home. But it is not so common, in some hospitals it is not usual to have such a recommendation.

**Dr. DeLegge:** There is an important fact I forgot to mention before in patients with dementia. In the United States upon entering a hospital, the patient signs a living will which outlines whether the patient wants aggressive interventional care such as respirators or tube feedings. Additionally there is a code status assigned to each patient detailing whether aggressive life support is desired or warranted for a particular patient. Recent trends have shown that if the physician or nurse took the time to make sure that the family sat down and addressed the patient’s living will and code status upon hospital admission, then there would be a significant drop in feeding tube placement as compared to statistics from 5 years previously when these items were not addressed. Family pressure to do something has a significant influence on whether physicians will or will not place feeding tubes.

**Dr. Buchman:** One of the comments though in terms of family pressure has again to do with how the physician explains the situation. In fact there is a study that was done with a group of patients, if they had a cardiac arrest would they want cardiopulmonary resuscitation, and I think something like 70% of the patients said yes. Then they re-asked the question after telling them that the outcome at 1 year is not very good and the majority of those 70% said actually we changed our mind, we don’t want to have cardiopulmonary resuscitation. A similar survey was also done in nursing home patients with tube feeding and of those patients who were not demented and could understand the question, something like 55 or 60% said yes, they would consent to tube feeding, but then when they were told that actually with tube feeding a lot of patients had to be restrained, only 25% now wanted tube feeding. So a part of the problem here in terms of the family issue is that the physician has not appropriately informed the family of the situation. The physician often biases the family, using what his beliefs are and what he wants to do. If I want to put a percutaneous endoscopic gastrostomy tube into a patient, almost 100% of the time I can convince the family by slanting the facts of how it is to their benefit and the patient’s benefit to put a tube in. If the family wants a tube and I don’t want to do it, 90% of the time I can convince
them why I don’t want to do it because I will emphasize the risks. Now I am rare in doing that because that means that I just make a few hundred dollars less with that patient and I get paid USD 30 for convincing him not to do it. Most gastroenterologists won’t do that; they would rather put the tube in and make a couple of hundred dollars. But the fact is that I keep hearing about the family, the family is important but it is rare in my experience. I work in a hospital where we have patients of a very high income level and very high education level, and it is very rare that the patients ask for a tube. It is the physician who suggests it, often the primary care physician, and then when the gastroenterologist gets there who is he to say that the primary care physician is wrong and the patient should not have a tube. So it is really the physician who shapes the family's wishes.

**Dr. Pierlich:** I have a question regarding the legal situation. In Germany economic pressure is increasing as in other European countries and so there is a new law in preparation which limits the funding for enteral feeding in certain situations. For instance the joint commission of physicians and insurance companies suggested to stop malnutrition and accept as an indication enteral feeding for funding. And now we are arguing against it and are showing data but they try to focus on certain diseases. So my question is how is it in other European countries?

**Dr. Van Gossum:** I tried to show you that in some countries, and I know the case much better in Belgium. There is a list of underlying diseases which has been accepted. Obviously this list of underlying diseases will include the majority of the patients. In some other countries there is no restriction, you may use enteral feeding for all the patients, but for example in Belgium for dementia it is not normally recognized, you may always try to use it. So it is true that there is some economic pressure and as doctors we have to be careful about such a list. I agree with you because for some patients there are some limitations that we could not accept but that is always the border between medicine, economics and ethics, and I think there will be a topic devoted to ethics in nutrition.

**Dr. Steinhagen-Thiessen:** Besides this problem that was just mentioned, we have another problem in our country: we have two different budgets. We have the hospital budget and we have the budget of all these things which are done by the family doctors on the ambulant track. These two budgets are very much in competition, and there we have huge problems. I also think that all these data you have shown us from the different European countries are very difficult to compare because we have such different systems in medicine, how we are organized, for example. In our country the work the family doctor is doing is far separated from the work we are doing in the hospitals.

**Dr. Van Gossum:** I agree, it is true that in the ESPEN-HAN group, which includes doctors, dieticians and nurses from at least 10 European countries, when we compare legislations it is totally different and also changing. From this time there is some new legislation in different countries. In Italy for example, Dr. Bozzetti perhaps you could give some details, I know that it is from one region to another, it is not at the national level in Italy. Is that true?

**Dr. Bozzetti:** Yes, you are right. There are regulations which are different from region to region, and I would say also from town to town in the same region. For instance in Prato, the town where I am working now, the company responsible for the hospital is also responsible for public health in the region, so the budget is unique. In this situation it is easier to have funding for home enteral nutrition because it is the same budget as the hospital. So there is no difference in spending this money for the hospital or for people outside the hospital. But it changes from region to region.

**Dr. Labadarios:** In relation to the comment made regarding variability between countries: how do you plan to actually use all these data? Do you see the European
Union or the European Council approach as a way of standardization? Are there any moves towards that, or would you rather not go that route?

*Dr. Van Gossum:* We didn’t plan that but it seems to be useful at least to provide such data and such legislation in Europe to some countries, previous eastern European countries where there is no legislation and where home enteral feeding is totally unknown and unrecognized. I talked with Dr. Pertkiewich from Poland who was involved in home enteral and parenteral feeding, and he explained to me recently that he is still fighting to have such reimbursement. So we hope that such a survey could be helpful for these countries, especially now because they have very recently joined the European Community. When I was asked to prepare this talk I sent an e-mail to different colleagues in former eastern European countries and in most of them there is no reimbursement and no practice of home enteral feeding. So throughout Europe we have to improve a lot in the use of such therapy.

*Dr. Labadarios:* I don’t want to preempt Dr. Buchman’s forthcoming talk but there is the question of human right of access to food. So one wonders how can one reconcile that with what is happening in different countries?

*Dr. Van Gossum:* I have no answer but maybe some reaction?

*Dr. DeLegge:* It is a double-edged sword. I will give you a classic example in the US with home parenteral nutrition. Back in the 1980s there was a great deal of time spent collecting data on home parenteral nutrition utilization in the US, and the outcome was that the average number of days patients were on parenteral nutrition, whether they died or came off therapy, was 60 days. Subsequently Medicare, the federal insurance system for seniors and disabled patients, came out with their new criteria for patients to receive parenteral nutrition in the US. One of the criteria was that the physician had to attest to the fact that all patients would require parenteral nutrition for 90 days or greater. They decided to elevate the bar in the US for approval of parenteral nutrition therapy at home.

*Dr. Elia:* Is there a risk under those circumstances that people may be kept on parenteral nutrition for longer to fulfill the 30-day requirement?

*Dr. DeLegge:* Yes, absolutely. If the patient comes off home parenteral nutrition before 90 days, the home parenteral nutrition therapy payment is subject to disqualification.

*Dr. Morley:* It seems to me that we have an absolute posit of data saying who benefits or doesn’t benefit from home enteral feeding. Therefore what is happening is if there is money available to pay for it people get it, and if there is no money they don’t get it. We clearly have made decisions for unconscious people who get fed enterally forever. They are enterally fed forever which certainly doesn’t suggest any quality of life issue there. It would seem that you are in the position to go to the EU now with your data and to at least collect basic quality of life data from around the EU, looking at people going on it and saying does it at all improve the outcome and is it different in various countries. If there was no improvement in the outcome even without a control, which would be ideal but let’s accept that you could not do the control yet, that would make us feel that perhaps we are over-feeding people with enteral feeding. On the other hand if quality of life truly goes up then maybe we should be pushing to give more people enteral feeding, but it is seems from where you are coming from that you are in the ideal position to go to Brussels now and say let’s really find out how much we should be spending.

*Dr. Van Gossum:* Yes it is true, but it is a difficult topic because it is really the border between caring for the patients and ethics. And when we are talking about orally feeding patients, it is true that for many patients when we start either parenteral or enteral feeding, we don’t know exactly the life expectancy of these patients, and most of the time we over estimate the life duration. But it is very difficult to make
the decision not to feed the patient because of the question of duration of life, because there are some cultural, some religious, some traditions of feeding patients, but there will be a topic about ethics and nutrition.

Dr. Ockenga: We recognize that there are several differences in funding as well as in clinical practice in all of our countries, in the US or in Europe. So one step may be just to improve the quality of clinical care for all patients and we could do this by introducing standards, and that is what we would like to do on the European level. We finished the Germany standards on enteral nutrition and now we will introduce these German standards or clinical practice guidelines into the European area, and we will hopefully finish that this year. So that will be a first step to improve the quality, and then we can check if really by doing medicine on equal standards everywhere we can improve the outcome of our patients.

Dr. Steinhagen-Thiessen: Do you have any knowledge about the comorbidity of all these patients, and especially do you have any knowledge about those patients who get tube feeding and also had pressure?

Dr. Van Gossum: This is quite common but we don’t have data about that. When the patients are discharged home it is quite difficult to have a good follow-up, so I have no answer.

Reference
