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THE ROLE OF ORAL NUTRITIONAL SUPPLEMENTS IN PRIMARY CARE

SUMMARY

-  The clinical use of oral nutritional supplements (ONS) has greatly increased in recent years in Ireland, especially in the elderly, but the evidence base for their usage is poor
-  Short-term use of ONS appears to produce a small weight gain in underweight patients and a shorter length of stay in underweight hospitalised patients, but the impact of long-term use is currently unknown
-  Audits suggest that up to 50% of prescribed ONS may not be consumed by patients
-  In the absence of evidence-based guidelines, the potential benefit of ONS in primary care should be critically assessed on an individual basis and closely monitored throughout use

INTRODUCTION

The clinical use of oral nutritional supplements (ONS) has increased greatly over the last decade. In 2002 they were the **second highest costing product in the General Medical Services (GMS)** accounting for €19 million (ingredient cost) and more than 260,000 prescriptions.⁽¹⁾ Over half of these prescriptions were for the over 70's age group. Similar trends have been reported from other countries.^(2,3) Although guidelines have been issued in respect of the use of ONS for specific disease states,^(4,5,6) there is conflicting guidance regarding the potential benefits of ONS in the prevention of disease, especially in the elderly living in the community. This bulletin will review the available evidence supporting the use of ONS, focussing in particular on usage in elderly patients in the primary care setting.

NUTRITION AND MALNUTRITION

Nutrients are substances that are essential for growth and good health - they promote energy, they help to form body structures and they are involved in regulating body functions.⁽⁷⁾ Protein, carbohydrate and fat are classified as **macronutrients** and primarily provide energy; protein also provides amino acids for synthesis. Minerals and vitamins are classified as **micronutrients** and play a key role in the body's structures and functions. Nutritional needs vary with age and activity - guidelines outlining recommended daily intakes of the various nutrients are available.^(8,9) **Malnutrition** is a broad term that can be used to describe any disorder of nutrition, including under-, over- and sub-optimal nutritional states. For the purposes of this bulletin malnutrition is defined as "a state of energy, protein or other specific nutrient deficiency which produces a measurable change in body function and is associated with a worse outcome from illness as well as being specifically reversible by nutritional support".⁽¹⁰⁾ Although nutritional status may be assessed in anthropometric terms, e.g. by changes in weight, by body mass index (BMI - weight in kg/height in m²) or triceps skin-fold thickness, it is important that measurement of function is also undertaken as thinness per se is not incompatible with normal health.⁽¹⁰⁾ However malnutrition caused by, or in the presence of, chronic illness may be associated with a worse prognosis for the patient.⁽¹¹⁾ Malnutrition may be divided into macronutrient and micronutrient deficiencies.⁽¹²⁾ Macronutrient malnutrition is referred to as protein-energy malnutrition and is usually associated with a reduction in body mass index (BMI <20 kg/m²). Micronutrient deficiencies may be more difficult to detect as they can occur in the presence of a normal body mass index (e.g. vitamin D deficiency).

Nutrition in the Elderly

A reduction in lean body mass and increase in body fat occurs in older age,⁽¹³⁾ with body fat also reducing from age 75 years onwards. This results in reduced mobility and subsequent risk of osteoporosis and falls. It also reduces basal metabolic rate (which depends on lean body mass), therefore energy requirements fall and appetite may lessen. The reduced intake of macronutrient foods may also decrease micronutrient intake (such as vitamins B, C and D). Physical activity helps to counteract / lessen the reduction in lean body mass. It also has the added advantage of improving balance (thus lessening falls) while helping to

maintain a healthy appetite and adequate nutrition.⁽¹³⁾

There are many problems which can interfere with proper nutrition in the elderly. Many of these relate to the physiological effects of increasing age.⁽¹⁴⁾ These include **dysgeusia** (a reduction in the number of taste and olfactory nerve endings which affects the desire for food); **dysphagia** (due to reduced salivary secretions) and **diarrhoea** (due to changes in motility and secretory activities of the GI tract). **Dental problems** may affect up to half of those aged >65 years - it has been shown that 20% of elderly people retaining their natural teeth and >50% of those with dentures had difficulty eating fresh fruit and vegetables, well-cooked meat and nuts.⁽¹⁵⁾

Other conditions that affect food intake include **depression, dementia or disability** (which can interfere with dietary intake either in terms of procuring or cooking food or in terms of being able to eat) and **the use of drugs** which may affect appetite or cause GI upset.⁽¹⁴⁾ Finally, **chronic disease states** such as arthritis, rheumatism, cardiovascular disease, hypertension, respiratory disease, stroke and diabetes may be present in up to 50% of elderly people and this proportion increases with age and is higher in women compared with men⁽¹⁶⁾; these disease states may also adversely affect nutrition.

Despite these physiological changes, studies undertaken in the UK⁽¹⁷⁾ have shown that most of the elderly patients living in the community are adequately nourished; problems only arise where lack of adequate intake of macro- and/or micronutrients in the presence of concomitant disease may further worsen the underlying disease, leading to a worsening of the patient's general condition and a potential further reduction in nutrient intake.

TYPES OF ORAL NUTRITIONAL SUPPLEMENTS

The type of ONS most commonly prescribed in the community are the "sip feeds", which include ready-made milk-, juice- and yoghurt-based or savoury drinks. Other formulations available include dessert type products and powder supplements that are made up into a drink/added to drinks or food. These products contain different amounts and types of vitamins, minerals and/or macronutrients (see individual products for composition). Some products are "nutritionally complete", i.e. they contain all essential nutrients which enable them to be used as the sole source of nutrition **providing that a certain amount is consumed**; others are used as a supplement to normal dietary intake (see individual products for specific recommendations). Formulations are available which also contain dietary fibre.

Table 1 provides information on the most commonly used ONS in Ireland.

Table 1: Average cost of the most commonly prescribed ONS on GMS (Jan 2004) * contain micronutrients

Type of ONS	Content			Calorie content (KCal/100ml)	monthly cost/prescription (€)
	CHO	PROT	FAT		
High calorie sip feed (200ml)*	++	+	+	150	78.60
Standard sip feed (250ml)*	+	+	+	125	87.75
High fat sip feed (1 litre)	-	-	++	450	44.57
High protein sip feed (200ml)*	+	++	+	125	79.42

CHO = Carbohydrate; PROT = Protein

ROLE OF ONS IN CLINICAL PRACTICE

Introduction: The American Society for Parenteral and Enteral Nutrition (ASPEN) has recently issued guidelines on the use of nutritional supplementation.^(4,5,6) These give detailed guidance for use of oral and parenteral supplementation in specific disease categories (e.g. liver disease, HIV) where there is a known risk of malnutrition. However, the use of ONS in other disease situations or in those judged to be at risk of malnutrition is less clear. The ASPEN guidelines recommend that evaluation for normal nutrient requirements should be individualised, based on assessment of body composition and function and should take existing physiologic and pathophysiologic conditions into account. Several nutritional screening tools have been developed^(18,19) which estimate risk on the basis of parameters such as BMI, recent unintentional weight loss, concurrent disease etc., but they are not widely used in practice at present. Moreover, recent studies have suggested that such tools may lack reliability and may fail to recognise many cases of under-nutrition.^(19,20)

ROLE OF ONS IN THE HOSPITAL SETTING

Background: It has been reported that patients, especially elderly patients admitted to hospital are likely to be malnourished.⁽²¹⁾ Furthermore while in hospital, underweight patients have been shown to experience greater weight loss and to suffer from increased mortality and morbidity compared with normal weight patients. Since much of the ONS usage in primary care originates in the hospital setting it is important to review the evidence base.

Evidence: A review of the usefulness of ONS during hospitalisation has been undertaken.⁽²²⁾ Overall results suggested that use of ONS in hospital may improve nutrient intake and prevent/attenuate weight loss. Results also suggest a reduction in mortality rates, in the rate of complications and in the length of hospital stay with ONS use, particularly for underweight patients (BMI <20kg/m²). However, the robustness of the review is limited due to the poor quality of the studies. [The importance of clinical design has been covered in a recent NMIC bulletin.]⁽²³⁾ Moreover, there was uncertainty about the optimal composition and timing of administration of the ONS regimen. The author recommended that large well-designed randomised controlled trials (RCTs) in specific patient groups should be undertaken to fully characterise the clinical benefit and cost-effectiveness of ONS in hospitalised patients.

Advice: Use of ONS, especially in underweight hospitalised patients may be associated with improvement in clinical outcome. From the studies currently available it is not possible to identify the optimum dosing regimen of ONS either in terms of amount to be administered or duration of use. From a **primary care perspective** there are no data to identify the optimum duration of continued usage of ONS after discharge from hospital.

ROLE OF ONS IN THE PRIMARY CARE SETTING

Background: Several studies^(24,25) have noted malnutrition in approximately 8-9% of patients in general practice, primarily in patients with cancer or chronic disorders (of CNS, lung, GI tract). The prevalence of malnutrition has been shown to increase with increasing severity of illness and is also influenced by social inequality.⁽²⁵⁾ It has been difficult to define exact levels of malnutrition in the "healthy" elderly living in the community, because of the high level of concomitant chronic illness in this age group,⁽¹⁴⁾ but it is estimated that 5-10% of this population may suffer either macro- or micronutrient deficiencies.⁽²⁶⁾ As the elderly constitute an increasing number of potential patients it would be important to know whether ONS can improve mortality and morbidity outcomes.

Evidence: There is a lack of good quality clinical data, evaluating the use of ONS in the community setting. One review (n=108 trials; n=3747 subjects) evaluated the **overall usefulness of ONS** in the community setting.⁽²²⁾ This review was based on a heterogeneous group of people, (children and adults including elderly) suffering from a wide variety of diseases such as HIV/AIDS, malignancy, COPD, Crohn's disease, cystic fibrosis and renal disease. The use of ONS in the elderly living in the community was reviewed in 767 subjects. Overall results suggested that use of ONS caused an increase in energy intake and body weight. Greater improvements were recorded in subjects with a BMI <20 kg/m² (% weight change of +3-4%) compared with those with a BMI >20 kg/m² (% weight change of +1-2%) and in certain underlying conditions such as COPD (% weight change of up to +5%). However, it was not possible to correlate level of ONS use with weight gain, and data were insufficient to determine the effect of ONS on body muscle/fat composition. It was not possible to assess the effects of ONS on appetite or spontaneous food intake but it was suggested that long-term usage might result in reduced food intake. Data on the **effect of ONS on clinical outcomes** was available from only 17/108 studies, which contained heterogeneous data. Overall no association between ONS and improvements in either mortality or functional outcomes was seen. Moreover, many of the benefits seen with ONS were not sustained with discontinuation of use. The author⁽²²⁾ recommended that adequate prospective RCTs should be undertaken, to ascertain the true role of ONS.

Evidence in at-risk groups: The potential value of ONS in **elderly people at risk from malnutrition** was assessed in a Cochrane review.⁽²⁶⁾ The review included 2464 subjects aged > 65 years, from 31 trials who received ONS for a minimum of 1 week. The majority of subjects were either in long-stay nursing homes with no specified illness or disease (56%) or were community based, with / without underlying disease (22%). Results showed a small but consistent weight gain and a shorter length of hospital stay (for in-patients). There was a statistically significant beneficial effect on mortality but this was felt to be potentially due to study bias. The available data showed no improvement in either functional status (such as improvements in mobility or grip strength, or reduction in number of falls) or quality of life indices. Most studies were too short to be able to detect such benefits. A second Cochrane review⁽²⁷⁾ compared the effectiveness of dietary advice versus ONS or no advice in the **management of illness-related malnutrition in adults**. Both in-patients and community-based adults (n=2135) with a wide variety of conditions (including HIV, cancer, COPD, recent unintentional weight loss) were included. The review noted that the group receiving ONS gained more/lost less weight (weighted mean difference of 1.09kg) compared with the other groups. However, there was a lack of evidence to show whether this additional benefit could be sustained or whether it might lead to improved survival and/or morbidity. The authors of both reviews stated that additional data from large RCTs are required to provide clear evidence of benefit from ONS.

Patients who are debilitated or immobile are at risk of **pressure ulcers/sores**.⁽²⁸⁾ Although malnutrition is recognised as a risk factor for the development of pressure sores, causality has not been established; it is suggested that the most important risk factor is a reduction in local tissue perfusion, commonly seen in immobility.⁽²⁹⁾ There is conflicting evidence regarding the benefit of ONS in the prevention or treatment of

pressure sores, ^(30,31) but it is suggested that ONS in debilitated patients may only work by increasing mobility and thereby reducing risk. ⁽²⁹⁾

Advice: Although use of ONS in the community setting may be associated with an increase in body weight (especially in underweight patients and those with concomitant disease), there are insufficient data to determine what **improvements in clinical outcome** may be achieved with their use.

Furthermore, there is conflicting evidence regarding the durability of improvements with ONS. From the studies currently available it is not possible to identify the optimum dosing regimen of ONS either in terms of amount to be administered or duration of use.

1. Advice on portion sizes, nutrient variety, texture modification and food frequency
2. Advice on food choice and preparation techniques
3. Food and drink fortification using normal household ingredients
4. Supplementation with prescribed ONS under the supervision of a professional

Table 2
Hierarchy of nutrition support for the community
(adapted from ref. 32)

AUDIT OF ONS USAGE IN CLINICAL PRACTICE

Audit of Use in Elderly Units: The use of ONS was monitored in several Care of the Elderly units. ^(33,34,35) These studies showed an inconsistent relationship between prescription of ONS and patient need, resulting in potentially inappropriate use. Moreover, compliance (defined as failure to consume any / all of the supplement supplied) ranged from 37-76%, with resulting wastage of ONS. The most commonly reported cause of non-compliance was difficulty with palatability of the supplement(s). These audits highlight the need for guidelines in the use of ONS and training of staff in their usage.

Data from General Practice: A study evaluated the effect of introducing specific nutritional guidelines on the prescription of ONS by GPs and community nurses ⁽³⁶⁾ in 50 practices in the UK. Results showed that inappropriate prescribing (described as use in patients who were not either a) underweight, b) suffering from a specific disease requiring supplementation or c) socially deprived) fell by 15% with use of the guidelines. However, 59% of prescriptions were still judged to be inappropriate. The results suggested that there was a need to provide ongoing training of health professionals in primary care in relation to ONS prescribing. A recent Irish study ⁽³⁷⁾ assessed the decision-making and monitoring procedures of GPs (n=51) and public health nurses (PHN; n=49) in the use of ONS for the elderly living in the community. Results showed that incomplete nutritional assessment was carried out by both GPs and PHNs before the prescribing, and during use of ONS. Moreover, only 55% of GPs stated that they would specifically review a patient's ONS prescription. The majority of prescriptions were not influenced by taste or nutritional content and in fact most patients would not have been given the opportunity to taste the ONS beforehand. Only 5 GPs and 35 PHNs had received any form of nutritional training, the overwhelming majority of which came from sales representatives. These results highlighted the need for training to improve prescribing practices for community use of ONS.

SUMMARY

The American Dietetic Association has stated that the best nutritional strategy for promoting optimal health and reducing the risk of chronic disease is to have a varied diet. ⁽³⁸⁾ Examination of the dietary intake in elderly people living either in the community or nursing home setting has shown that a highly varied diet is associated with better nutritional status. ⁽³⁹⁾ **Therefore food is the best vehicle for appropriate nutrient consumption.** ⁽⁴⁰⁾ For patients judged to be at risk of malnutrition, advice on dietary management as outlined in Table 2 is recommended. ⁽³²⁾ In addition, studies have suggested that increased exercise / mobility will reverse reductions in appetite, often seen with increasing age and will also improve muscle strength. ⁽⁴⁰⁾ Although ONS are widely used, currently the evidence base for their usage is poor. In addition, audits have suggested lack of compliance in >50% of patients and the overall weight gain with use appears to be low (<2kg). Therefore, it is **not possible to determine optimum usage** in terms of the most appropriate patients, the optimum dose or duration of use.

REMEMBER!

Before ONS are prescribed, a full nutritional assessment should be carried out to determine the adequacy of the existing diet. ONS should not replace food and should not be the first line of nutritional treatment. Advice from community dietitians, where available, should be sought. It is important to monitor benefits of ONS on a regular basis, using basic tools such as weight, BMI, or functional measurements (muscle strength etc.) relevant for that patient. ONS should not be continued if there is no evidence of benefit. Compliance should be checked regularly and alternative types of ONS prescribed in the case of palatability problems.

References available on request. Date prepared: June 2004

Every effort has been made to ensure that this information is correct and is prepared from the best available resources at our disposal at the time of issue. Prescribers are recommended to refer to the drug data sheet or summary of product characteristics (SPC) for specific information on drug use.

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