Foods for Special Medical Purposes available under the Irish Health System: An Evaluation of Current Evidence and Practices

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A Master's Paper submitted to the faculty of
the University of North Carolina at Chapel Hill
In partial fulfillment of the requirements for
the degree of Master of Public Health in
the Public Health Leadership Program.

Chapel Hill

2008

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Introduction

In 2006 the Irish government spent €35m on Foods for Special Medical Purposes (FSMP) under the states General Medical Scheme (GMS), accounting for 3.72% of GMS spending. There is increasing concern, both in Ireland and internationally, of widespread inappropriate over-prescribing of nutrition products resulting in unnecessary healthcare spending (NMIC, 2004; Loane et al, 2004, Okechukwu, 2008). Further to this, Ireland does not have a national Clinical Practice Guideline on the provision of nutrition support, and the process of product approval and listing for reimbursement under the GMS scheme has not been reviewed since the late 1990s. This paper takes a look at current Irish policy and practice relating to the provision of FSMP within primary care, reviews the evidence, compares the Irish situation to international guidelines and best practices, and suggests appropriate future steps for Irish policy makers,.

Approach and Methods

The paper is divided into four parts. **Part A** defines Foods for Special Medical Purposes (FSMP) and describes the most recent international guidelines for their use. Information was accessed from appropriate government and European websites. **Part B** looks at evidence for the effectiveness of Oral Nutrition Supplements (ONS), as a special sub-category of FSMP, it describes current prescribing practices in Ireland and elsewhere, and looks at available economic analysis supporting the use of FSMP. Recent systematic reviews, Pubmed and the Cochrane library were searched for relevant data. Given the quality of recent systematic reviews into the effectiveness of foods for particular nutritional purposes (PARNUTS), an additional systematic review of the literature was not considered necessary; rather, available literature since 2005 was reviewed and included as appropriate. **Part C** describes the current procedure for the approval

and listing of FSMP to be reimbursed under the Irish GMS and compares it to procedures under other national health schemes. **Part D** attempts to assess the importance of policy in relation to FSMP within the Irish context. provides suggestions for Irish policy makers as they begin to evaluate current Irish policies and guidelines for the use of FSMP in primary care and describes leadership action steps that might be considered in revising the policy.

To best determine which countries are most comparable to the Irish situation, relevant authorities, responsible for the governance of foodstuffs intended for particular nutritional uses, within each of the EU member states were contacted by email at:
(http://ec.europa.eu/food/food/labellingnutrition/nutritional/list_auth_art9_en.pdf).
Of twenty-five countries emailed, Germany, Sweden, Belgium, Cyprus, Iceland, Slovakia, Malta, and Latvia replied within the timeframe of the project. All the necessary information relating to policy and process in the UK was available on the World Wide Web and direct contact with authorities in Australia and Canada added to the available information on the process of product reimbursement in each of these countries. In addition to direct contact, government websites and peer reviewed journals were also accessed for relevant product reimbursement information. The relative low response to the request for information from EU countries was likely due in part to language differences, the short time-frame of the project and also inconsistencies, within each country, as to who has ownership of the issue of FSMP. This last issue will be discussed later in the document.

Part A

Terminology

The terminology, surrounding the area of food products for particular dietary purposes, is rather complex and has contributed, at least anecdotally, to much of the confusion among doctor's, nurses and policy makers as how best to provide nutrition support to sick and convalescing patients. The concept of "foods for special dietary purposes" was first defined, in the US, after WWII and later refined to include the following terms:

- *Foods for supplying particular dietary needs which exist by reason of a physical, physiological, pathological or other condition, including but not limited to the conditions of diseases, convalescence, pregnancy, lactation, allergic hypersensitivity to food, underweight, and overweight*
- *Foods for supplying particular dietary needs which exist by reason of age, including but not limited to the ages of infancy and childhood*
- *Foods for supplementing or fortifying the ordinary or usual diet with any vitamin, mineral, or other dietary property. Any such particular use of a food is a special dietary use, regardless of whether such food also purports to be or is represented for general use*
- *Products used as an artificial sweetener in a food, except when specifically and solely used for achieving a physical characteristic in the food that cannot be achieved with sugar or other nutritive sweetener, shall be considered a use for regulation of the intake of calories and available carbohydrate, or for use in the diets of diabetics and is therefore a special dietary use* (Talbot, 1991)

The scientific community at large has, in recent years, settled on a number of terms and definitions. The overarching term, encompassing all food products manufactured for particular nutritional purposes, are **PARNUTS** (*Foodstuffs intended for particular nutritional uses*). This is the term most commonly used in the literature and the official term used in all EU regulations. The broad EU definition of PARNUTS is:

"Food which, owing to its special composition or process of manufacture, is clearly distinguishable from food intended for normal consumption, and is sold in such a way as to indicate its suitability for its claimed nutritional purpose."

S.I No. 579 of 2006

(http://www.fsai.ie/legislation/food/eu_docs/Parnuts/General_provisions/SI579_2006.pdf

PARNUTS are sub-divided into six categories according to EU regulation, the most important of which, in terms of eligibility for reimbursement, is **FSMP** (*Foods for Special Medical Purposes*), for which specific EU and national regulations exist. Foods for Special Medical Purposes (FSMP) are defined in EU regulation as:

"A category of foods for particular nutritional uses specifically processed or formulated and intended for the dietary management of patients and to be used under medical supervision. They are intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary foodstuffs or certain nutrients contained therein or metabolites, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet, by other foods for particular nutritional uses, or by a combination of the two."

Statutory Instrument No. 64 of 2001(http://www.irishstatutebook.ie/2001/en/si/0064.html)

In addition to dietary Foods for Special Medical Purposes (FSMP), other categories of PARNUTS as outlined in EU regulation include- follow-on formulae; processed cereal-based foods and baby foods for infants and young children; food intended for use in energy-restricted diets for weight reduction; foods intended to meet the expenditure of intense muscular effort, especially for sports-men and sports-women; and foods for persons suffering from carbohydrate-metabolism disorders (e.g. diabetes).

Enteral Nutrition is defined as the administration of a nutrient solution orally or by means of a feeding catheter with the purpose of contributing to the supply of all or part of the body's food requirements. Enteral Nutrition is really the clinical term to describe the administration of dietary Foods for Special Medical Purposes (FSMP). The term enteral nutrition is increasingly seen in relation to "organ specific nutrition" and "disease specific nutrition" (Hernández, 2006). Oral Nutritional Supplements (ONS) and tube feeding are routes to enteral feeding. There is much variability in the literature as to correct use of this term. Many investigators choose to include only tube feeding when referring to the term "enteral". However, the most recently developed European guidelines define "Enteral Nutrition" as including both oral supplementation and tube feeding. For the purpose of this document, ONS will be considered a type of enteral nutrition and come under the heading FSMP. **Parenteral Nutrition** refers to intravenous feeding, usually,

but not always, administered in the hospital setting. Parenteral nutrition is not the subject of this paper.

Recent guidelines on the provision of nutrition support in adults

Recent guidelines on the provision of nutrition support in adults were developed by the UK National Institute for Health and Clinical Excellence (NICE) and the European Society for Clinical Nutrition and Metabolism (ESPEN) respectively. Both of these groups conducted systematic reviews of the literature and produced comprehensive evidence-based guidelines including the use of FSMP as part of nutrition support. Both NICE and ESPEN are expert organizations respected in the scientific community and among governments worldwide.

In 2006, the UK National Institute for Health and Clinical Excellence (NICE) developed comprehensive guidelines on *Nutrition Support in Adults.* The full guidelines can be found at www.nice.org.uk/CG032 . The guidelines were developed by a multidisciplinary team of healthcare professionals and are internationally recognized. The group's recommendations are based on RCTs, meta-analysis, clinical experience, expertise and consensus. Databases searched included the Cochrane library, Medline, Embase, Cinahl, Allied and Complementary medicines, and the British Nursing Index. The guidelines describe general and specific indications for when and what kind of nutrition support should be provided to patients. It discusses the necessary training required for health care staff involved in nutrition support and explains the importance of a multidisciplinary approach to providing nutrition support. The guidelines emphasize the importance of screening as well as monitoring and evaluation and recommend that those receiving oral nutrition support and/or enteral tube feeding in the community should be

monitored and evaluated every 3–6 months or more frequently if there is any change in their clinical condition.

The most comprehensive evidence and consensus based Clinical Practice Guidelines (CPG) on enteral nutrition (including ONS and Tube feeds) for specific groups/diseases were developed by experts at the ESPEN between 2004 and 2005. The guidelines provide comprehensive data on a range of diseases /groups and include indications, contraindications, screening tools, application and type of formula to be provided based on the evidence and clinical expertise of professionals in each area. Diseases/groups covered by the ESPEN CPG include cardiology and pulmonology, gastroenterology, geriatrics, hepatology, wasting in HIV, intensive care, non-surgical oncology, pancreas and renal failure. The guidelines make no specific distinction between primary secondary and tertiary nutrition support and are available at http://www.espen.org/npages/nespenguidelines.html (individual papers provided in reference section).

Other guidelines in the area of nutrition support are generally adapted from the two guidelines described above. Guidelines that are not evidence-based and peer-reviewed were not considered for inclusion in this report because their credibility could not be established.

Part B

The Evidence for Oral Nutrition Supplements (ONS)

Oral Nutrition Supplements (ONS) are a sub-category of FSMP. They account for up to 60% of Irish health care spending on FSMP (PCRS, 2006) and therefore warrant particular attention.

Some suggest that dietary counseling should precede the use of ONS due to the fact that advice can be individually tailored and may be associated with lower economic costs to the health service (Thomas, 2001). Others contend that ONS is simple and more convenient. A number of studies have highlighted compliance as a significant problem with the use of ONS (Keale et al 1997; Munro 1998; Pearl et al 2002). Despite persisting uncertainties on some issues, evidence is growing demonstrating that nutritional supplements can confer improved clinical outcomes, increased function and decreased weight loss (Stratton et al, 2003). Stratton, Elia and colleagues at the University of Southampton in the UK have conducted a number of reviews and meta-analyses on the impact that ONS has on outcomes in specific client groups across different care settings (Stratton and Elia, 2007, 2000 & 1999; Stratton, 2005 & 2000). Meta-analysis indicate significant reductions in mortality (odds ratio 0.59 (9% CI 0.48, 0.72), n 3258) and complication rates (odds ratio 0.41 (95% CI 0.31, 0.53, n 1710) with ONS versus routine care (Stratton 2005). Most recently Stratton and Elia (2007) consolidated thirteen systematic reviews in a "review of reviews" on the use of ONS in clinical practice concluding increasing evidence to support the use of ONS in clinical practice, particularly in individuals with a BMI <20 kg/m^2, acutely ill and older patients.

With regards to ONS, the previously described NICE guidelines concluded that *"although the studies identified were small with marked heterogeneity in study populations and outcomes, they do show improved outcomes for malnourished patients given oral nutritional supplements. These benefits were somewhat inconsistent but our meta-analysis shows that the use of oral nutritional supplements in such patients leads to*

statistically significant improvements in body weight along with reductions in complications and mortality."

In contrast to the more cautious endorsement, for the use of ONS, given by the NICE guidelines, the European Society for Clinical Nutrition and Metabolism (ESPEN) guidelines provide the following more compelling endorsement for ONS and tube feeds- *"The general indication and effectiveness of ONS and enteral tube feeding in patients who cannot fulfill their substrate needs adequately is well established and the whole consensus group strongly agreed on this. Although, as the authors of the various sections conclude, results may vary according to diagnosis, prior nutritional status, age, the technical adequacy of treatment, and patient selection. In some areas, evidence for specific questions like timing and composition of enteral nutrition is still lacking upon which to make level A recommendations and much practice, as in other areas of medicine, is guided by level C evidence. Further studies are clearly required in these areas".*

Current use of ONS and prescribing practices in Ireland

Within Ireland, the National Medicines Information Centre (NMIC) (Bulletin 2004) looked at the role of Oral Nutritional Supplements (ONS) in primary care, with a particular focus on the elderly in the community, and found a marked increase in the prescribing of ONS in recent years. The report questioned the suitability of ONS for widespread use in Ireland given that most of the evidence, at that time, was limited to specific indications and sub-groups. The report also highlighted probable extensive misuse of ONS in the management of the elderly in the

community. There is no published evidence to support the routine use of ONS in the "healthy elderly" and as described in the NMIC article there is mounting evidence in Ireland, and elsewhere, of the inappropriate prescribing of ONS.

Community dietitians in what was the Irish Midlands Health Board (MHB) carried out a number of exploratory studies on the prescribing and use of Oral Nutritional Supplements (ONS) in the community including an ongoing pilot project to improve GP and PHN knowledge and use of ONS. Loane et al (2004) published a study which assessed trends, decision-making processes and the monitoring of the use of ONS for older patients in a community within the midlands. The investigators also looked at whether standard practices, including nutritional assessment and appropriate indicators, exist in prescribing ONS within the community in question. The study involved a telephone questionnaire administered to 99 GP's and 120 PHNs. The results suggest an increasing trend in the prescribing of ONS to older patients within the community, inadequate screening and assessment of patients, poor knowledge of the composition of ONS, inadequate counseling to patients, and poor monitoring of the need for continued use of ONS once prescribed or recommended. The study raises concerns regarding the current practice of ONS prescribing and monitoring in the community and suggests the need for guidelines for health professionals. The usual limitations of telephone interviews as well as generalizability apply to this work but it provides an important insight into current practices in Ireland. Kennelly et al investigated the demographics of those prescribed ONS in a community setting (Kennelly et al, 2006). Ten GPs involving 78 patients, prescribed ONS, were involved in the study. Older female patients suffering multiple chronic diseases were most likely to be prescribed ONS and some patients not at risk of malnutrition were found to be prescribed ONS. The investigators

concluded that nutritional assessment before prescribing ONS is necessary in the community setting. In another study of 78 adult patients prescribed ONS by ten GPs in Co. Westmeath, Ireland, Kennelly et al describe a range of social factors which compromise the nutritional status of the elderly. The social factors cited include social isolation, difficulty accessing and preparing food, and support financial difficulties. The authors suggest establishing multidisciplinary community support teams as well as increased training and education for primary health care professionals to address social issues which may compromise nutritional status (Kennelly, Unpublished). In an ongoing pilot project, Kennelly and colleagues provide evidence that once-off educational interventions may improve the knowledge and practice of the use of ONS in a community setting (Kennelly et al 2008). The investigators implemented an educational intervention that incorporated the nutrition screening tool 'MUST", to assess the knowledge and practice of GPs and nurses in the community. A total of 14 GPs and 82 nurses participated in the intervention which involved twenty-two educational sessions over a three-month period. Six months post-intervention, 80% of participants reported that 'MUST' was an acceptable tool for their work setting; sixty-nine percent reported weighing their patients more frequently as a result of the intervention; and 46% reported providing appropriate advice on ONS to patients at risk of malnutrition. Despite the small size of these studies, taken together, they represent the best picture of current use of ONS in Irish community settings and offer a model to improve the knowledge and skills of primary health care professionals in the area of ONS.

A recent doctoral thesis, from Trinity College Dublin (Okechukwu, 2008), looked at the patterns of prescribing of ONS in Ireland, and how they vary according to the profiles of patients who receive them. The study examined the Primary Care Reimbursement Service (PCRS)

prescription database for the Eastern Region Health Authority (ERHA), from January 2004 to December 2004 and found that prescribing of ONS was strongly associated with increasing age, residence in nursing home facilities and decreasing socioeconomic status. The investigators also suggested that prescribing of ONS may have been more associated with the presence of chronic diseases than with diagnosed undernutrition. The results of this study add weight to the work from the midlands and to our knowledge of prescribing practices within primary care in this country but are limited by the fact that neither the nutritional status nor the clinical diagnosis of each patient were recorded on the GMS database.

Barr and Kane (2002) reviewed the use of nutritional products in nursing and residential homes in the Northern Health and Social Services Board (NHSSB) area of Northern Ireland. ONS were the most commonly used means of nutrition support among the 122 nursing and residential homes involved in the study. There was wide variability in the monitoring of patients on ONS and the authors called for the development of guidelines to standardize the practice of prescribing ONS to frail patients in nursing and residential homes. Although not conducted in the Republic, this study provides a look at a comparative population within a residential setting and provides further evidence for the need for guidelines and education.

Prescribing of FSMP: An international perspective

Despite convincing evidence-based research suggesting a beneficial role for the use of FSMP, including ONS, for the prevention and treatment of malnutrition, there is much concern over perceived wide spread inappropriate prescribing of Foods for Special Medical Purposes (FSMP) within primary care (NMIC, 2004; Loane et al, 2004, Okechukwu, 2008). There is, however,

little published data nationally and internationally to definitively support this. A likely reason for the lack of evidence is difficulty in accessing data from patient records. Electronic databases are still developing and mandatory recording of vital patient data (such as height and weight) is not standard practice.

For a number of reasons, prescribing of FSMP by general practitioners (GPs) has greatly increased over the years in Ireland (NMIC, 2004; Loane et al, 2004) the UK (Gale, 2001) and elsewhere (Ravasco, 2004). Targeted marketing by pharmaceutical companies directly to GPs, an explosion of new products, and increased patients knowledge on the availability of products have likely contributed to the increase. However, as has been shown above, there is little monitoring of the prescribing practices of GP's in relation to FSMP and training and education on the benefits and appropriate use of FSMP is unavailable. Furthermore, as already described, in Ireland, there may be inadequate screening and assessment of patients, poor knowledge of the composition of ONS, inadequate counselling to patients, and poor monitoring of the need for continued use of ONS once prescribed or recommended, within the primary care setting (Loane et al, 2004) . Additionally, GPs report being inadequately trained in the area of ONS and often feel pressured into prescribing products (primarily from patients, families) that they have little knowledge of (Madigan et al, 2007, Loane et al, 2004)

A study by Gale et al (2001) looked at the prescribing practices of GPs in the UK during 1996 and 1997. At that time, a large proportion of patients prescribed FSMP were babies and young children, many of whom had been diagnosed as suffering from milk intolerance or failure to thrive. Enteral feeds were most commonly prescribed to the elderly with over half prescribed to

elderly patients diagnosed with cardiovascular disease or cancer. The investigators were unable to draw any conclusions about the appropriateness of prescribing because of insufficient weight and height data to calculate BMI (only 4% of patients had body weight or height recorded prior to prescription). Since 2001, other than the recent Irish doctoral thesis described above, there have been few studies looking at prescribing practices in the area of nutritional foods. A recent UK study found height and weight are still not routinely monitored in patients prescribed FSMP; patients are often prescribed ONS before other dietary measures are employed, and patients are often discharged from secondary care on prescribed ONS which continues for years without reassessment (Fitzgibbon, 2006). Furthermore, compliance with prescribed ONS products in the community is low (Lad, 2005). Gall et al (2001) evaluated the effect of introducing guidelines supported by education on the prescribing of ONS in primary care. This was a small study of only 50 GP practices in the UK but it did show that education on guidelines incorporating a Nutritional Screening Tool resulted in more appropriate prescribing of ONS. Similarily, In a 2004 Portuguese study (Ravasco, 2004), the rates for prescribing were higher than monitoring rates and there appeared to be a general lack of involvement of dieticians in the provision of nutrition support to patients.

Economic Considerations for the use of FSMP

A recent review by Russell (2007), using data produced by the British Association for Parenteral and Enteral Nutrition (BAPEN), looked at evidence for the cost-effectiveness of nutritional support in the UK. Previous reviews had concluded that the evidence for the cost-effectiveness of nutritional support, particularly in the community setting, had yet to be established (Green,

2001; Pritchard et al, 2006). Russell estimated the total annual cost of managing patients with medium or high risk of disease-related malnutrition in the UK in 2003 to be at least £7.3 billion; £3.8 billion of this was due to the treatment of malnourished patients in hospital and £2.6 billion was due to the treatment of those in long term institutional care. Smaller contributions were due to visits to general practitioners, outpatient attendance and the provision of nutritional support, mainly in the community. Most of the total costs (almost £5 billion) were spent in the care of individuals over the age of 65 years.

When the costs of ONS were applied to clinical outcomes such as length of stay in hospital and the incidence of complications, it was demonstrated that cost savings can be achieved through the use of ONS in selected patient groups (specifically, the elderly, patients undergoing abdominal surgery, and orthopaedic surgery patients) (Russell, 2007). Russell found data from the community to be lacking and less amenable to economic evaluation but suggested that in a system of universal government healthcare, overall economic benefits can be achieved from the use of ONS in the community but that in these cases it is the community that bears the cost of the intervention and usually the hospital sector that derives the financial benefits as a result of reduced nutrition related hospital admissions.

Part C

Current procedures for the approval of FSMP in Ireland and other national health systems

The approval of dietary Foods for Special Medical Purposes (FSMP) for reimbursement under the Irish General Medical Scheme (GMS) are decided upon by a non-drug review group of the Primary Care Reimbursement Service (PCRS) of the Irish Health Services Executive (HSE) and

approved by the Minister for Health. Decisions are made once a year at an Autumn Review. Manufacturers/Agents are invited to submit applications to PCRS each autumn. Products must comply with criteria set out in Guidelines for Manufacturers/Distributors on Clinical Nutritional Products Reimbursable under the GMS Scheme which were developed in the 1990s. Products must comply with EU legislation, manufacturers must submit satisfactory results of relevant clinical trials, submit a final sample of the product and must comply with agreed pricing structures. Applications to PCRS must also include a product name, category type, pack size, a suggested Irish trade price, price in the UK and/or other member state(s) and relevant exchange rates. There is currently no procedure for having a product removed from the list of reimbursable products.

The most comparable health system, to Ireland's, in terms of the use and reimbursement of FSMP, is the UK's National Health Service (NHS). In fact, current guidelines for manufactures seeking to have non-drug items placed on the Irish health care reimbursement list were modeled on the UK guidelines at the time of development. In the UK, the Advisory Committee on Borderline Substances (ACBS) advises the minister on the addition of particular foods etc. to the National Health Service (NHS). ACBS have very recently (2008) updated their procedures for product approval and listing under the NHS and are currently receiving stakeholder feedback on the updated guidelines. Draft guidelines are available online at http://www.pasa.nhs.uk/PASAWeb/Productsandservices/Pharmaceuticals/ACBS.htm.
Submissions are made to ACBS six weeks prior to the ACBS meetings (The committee plans to meet twice annually). An application form along with a submissions guidance form is available

to help companies in the application process. ACBS proposes considering three types of submissions as follows:

- New formulations which the manufacturer perceives to have well characterized and substantiated advantages in terms of nutritional composition and patient tolerance / acceptability
- Formulations which are broadly similar in composition to existing products already on the market and which could be considered to be suitable alternatives
- Existing products to which minor changes are proposed

Manufacturers must submit product applications under one of six categories proposed by the ACBS; namely, nutritionally complete non-disease specific enteral tube feeds; sip feeds and nutritionally incomplete non-disease specific supplements and modules; disease specific formulations e.g. for pancreatic cancer; products designed for the specific management of inherited metabolic disorders; staple food products e.g. gluten free foods designed to optimize nutritional status as part of the clinical management of formally diagnosed chronic disease states; or products designed to enhance the safety and / or acceptability of foods or feeds which are prescribable in any of the above categories e.g. thickeners. A complete quantitative formulation as well as nutritional composition for the product must be provided. Details of the manufacturing process and quality control mechanisms, shelf life data and evidence of clinical efficacy must also be submitted.

ACBS also provide specific guidelines for each of the three types of product submissions allowed. Submissions must also include proposed price to the NHS, product administration to

the patient data, contraindications and precautions, proposed presentation of the product, packaging and product samples as well as promotional policies. Approval for any product to be reimbursed at NHS expense will be valid for 5 years. The ACBS will review the product at the end of this period and may request resubmission. The ACBS also propose a mechanism for removing items from the reimbursement list.

The process for selecting and approving products for reimbursement under other national health systems appears to vary widely. Information is very limited and where available often only appears in the local language. A further limitation to comparing the Irish process to procedures elsewhere is a lack of clarity (or at the least available information) on whether FSMP undergo separate or similar procedures as do the listing and approval of drugs for reimbursement. There exists an abundance of information on the application processes for drug approval, and guidelines for conducting drug trials is available in almost every country. However, with regard to FSMP, based on correspondence with relevant authorities and on the available literature, it appears as though many countries either make no distinction between the application process for FSMP versus drugs, or reimburse only a very limited number of FSMP, involving mainly enteral tube and parenteral feeds for nutrition specific diseases.

Germany, Belgium, Cyprus, Sweden and Slovakia all report reimbursing FSMP under their national health systems but the application and approval procedures are not available (at this time) in English. The Canadian authorities provide an abundance of information but categorize FSMP as either ”Natural Health Products” or drugs, depending on the particular ingredient formulation. Detailed information on the regulatory process for therapeutic products as well as

guidelines on clinical trials for the approval of natural health products in Canada are available at http://www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/access-therapeutic_acces-therapeutique-eng.php. Due to the fact that it was not possible to make a clear comparison between the Irish and Canadian processes, details of the Canadian procedure are not provided here.

Part D

The importance of developing a policy on FSMP within the Irish context

Based on the current evidence, it is clear that Foods for Special Medical Purposes (FSMP) have an important role to play in the provision of nutrition support. Despite the evidence as well as relevant guidelines from NICE in the U.K and the European society for clinical nutrition and metabolism, Ireland does not have a clear policy to help guide practitioners and other health professionals in providing appropriate nutrition support through the use of FSMP. As a result, practices are inconsistent and vary widely across the system. In addition, there is evidence of inappropriate prescribing of products, usually in the form of over-prescribing which is costing the Irish health service and resulting in sub-standard care for patients. This is perhaps a good example of where scientific consensus and available evidence are not enough to ensure good clinical practices. In a small country, such as Ireland, with government run universal health care, a national policy is essential for a consistent, appropriate approach to healthcare practices.

Policy Recommendations

Irish policy makers should give serious consideration to developing a national Irish guideline on the clinical- and cost-effective use of FSMP to guide GPs, PHNs, dieticians and everyone involved in providing nutrition support in the primary care setting. The UK National Institute for

Health and Clinical Excellence (NICE) and the European Society for Clinical Nutrition and Metabolism (ESPEN) both recently published comprehensive guidelines on nutrition support for adults; these guidelines are evidence-based and could be used as a framework for an Irish guideline.

Revised guidelines for manufacturers, applying to have FSMP products placed on the Irish General Medical Scheme (GMS) list of reimbursable non-drug items, should also be considered. The UK's Advisory Committee on Borderline Substances (ACBS) recently revised their guidelines for manufacturers; given that many of the products reimbursable under the Irish GMS scheme are also listed for reimbursement by the NHS, the ACBS guidelines are an obvious first step in revising current Irish guidelines. In revising guidelines for manufacturers, current GMS categories for FSMP should be clarified, perhaps by adopting the newly proposed UK categories; this would help clarify the ever-expanding list of items currently reimbursed under the Irish system and allow for possible future category additions (for example, products designed for the specific management of weight loss).

Rather than a narrow national guideline, dealing only with enteral nutrition, Irish policy makers should consider developing a broader guideline to include areas of Nutrition Support such as nutrition counseling and parenteral nutrition. Other countries have chosen to develop generic guidelines covering primary-, secondary- and tertiary-nutrition support under one guideline. This would help to facilitate a seamless transition in patient care from hospital back into the community setting.

A comprehensive Irish guideline on the provision of nutrition support should describe the current evidence relating to the effectiveness of FSMP in nutrition support; clarify the terminology surrounding the area of PARNUTS, including a definitive definition for Oral Nutrition Supplements (ONS); clearly define the role of the community dietitian; recommend an appropriate malnutrition screening tool, adapted from the ESPEN guidelines; provide guidelines on monitoring and evaluating patients prescribed FSMP; and describe procedures for the removal of products from the GMS list.

Action Steps for Leaders within the Irish Health System

The first step should be the establishment, by the minister for health, of a multidisciplinary team of experts, healthcare professionals and patient representatives to develop a national policy on the use of FSMP in nutrition support. The inclusion of all stakeholders in the development stage is essential to the long term success of the policy.

The second step is for the Irish health minister to commit to changing the status-quo by enacting a policy through the publication of a national guideline on the use of FSMP in Ireland. The Health Services Executive (HSE) would be responsible for disseminating the guideline.

Thirdly, a national guideline should be accompanied by the provision of multidisciplinary primary care nutrition support teams as well as widespread education and training for doctors, nurses and others involved in the provision of nutrition support. Training should include information on the importance of screening; details on nutritional needs and indications for nutrition support; nutrition counseling education; information on options for nutrition support

(i.e. counseling, oral, enteral tube and parenteral); ethical and legal concepts surrounding nutrition support, potential risks and benefits; inappropriate prescribing of ONS; and the importance of monitoring and patient evaluation. This support is necessary to ensure that the guideline does not simply gather dust on the shelves of health professionals nationwide. The HSE would be responsible for delivering this support. It involves buy-in from HSE leadership in the form of a financial commitment to the support necessary to make the policy a success on the ground.

Finally, regulation of any policy is a necessary step to ensure its successful implementation. Regulatory responsibility falls once again on the government through the HSE. Both the "carrot and stick" approach are likely to be necessary, i.e. incentives and penalties. Monitoring and evaluation could be aided by the continued development of a primary care electronic patient record system including, as standard, height and weight measurements. Developing an electronic medical records system is costly but already underway in Ireland. The addition of height and weight measurements to medical records would add little additional cost but would require a fundamental change in thinking and practice, particularly in primary care. This is perhaps where health care professional, as public health leaders, need to step up to the plate by embracing the policy both in principle and practice.

Conclusion

Inappropriate health care provision and inefficient spending in relation to the use of FSMP is likely to continue in Ireland until a national policy is produced and implemented. Successful implementation is dependent on buy-in from healthcare leaders right across the health care

system. Government needs to commit to enacting a policy as well as providing funding and regulation. The Health Services Executive (HSE), on behalf of the government, must identify appropriate pathways to disseminate a national guideline and to provide ongoing support, monitoring and evaluation. Clinical nutritionists must be willing to take on the role of educators on the ground. Finally, practitioners must commit in principle and fundamentally change their current thinking and practices. Successful implementation of a national policy in relation to FSMP cannot therefore be achieved with the simple stroke of a pin; rather, successful implementation requires buy-in right across the health system and can only be achieved through the willingness of health care leaders to commit, actively participate and change.

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Abbreviations

ACBS	Advisory Committee on Borderline Substances
BAPEN	British Association for Parenteral and Enteral Nutrition
BMI	Body Mass Index
CPG	Clinical Practice Guideline
ERHA	Eastern Region Health Authority
ESPEN	European Society for Nutrition and Metabolism
FSMP	Foods for Special Medical Purposes
GMS	General Medical Scheme
GP	General Practitioner
HSE	Health Services Executive
MHB	Midlands Health Board
NHS	National Health Service
NHSSB	Northern Health and Social Services Board
NICE	National Institute for Health and Clinical Excellence
NMIC	National Medicine Information Centre
ONS	Oral Nutritional Supplements
PARNUTS	Foods Intended for Particular Nutritional Uses
PCRS	Primary Care Reimbursement Services
PHN	Public Health Nurse
RCT	Randomized Controlled Trial