The Association of UK Dietitians

Nutritional Borderline Substances – Case for Change

Contents

1 Executive Summary

Nutritional Borderline Substances (NBS) are an essential part of clinical care for patients with a diverse range of long term conditions and nutritional disorders. They are a vital part of a dietitian's toolkit. Effective use of NBS can impact critical outcomes such as admissions and readmissions to hospital, length of stay, complications and quality of life. The BAPEN/NIHR Report[1] estimates a net saving of £101.8 million per year due to reduced use of healthcare resources. The NICE Quality Standard (QS) 24[2] clearly states that people who are malnourished should have a management care plan that aims to meet their complete nutritional requirements.

The BDA wants to ensure patients have quick and appropriate access to the NBS they need, while improving the efficiency and effectiveness of the systems used to provide them. As experts in the nutrition care pathway, we believe that placing dietitians at the heart of this process is the best way to ensure that patients receive the appropriate products for the right duration and with maximum benefit. This document outlines the different mechanisms by which patients are currently able to access NBS across the UK. Dietitians, commissioners and others may wish to use aspects within the case studies and examples in order to redesign services locally. The document also highlights the challenges and inefficiencies for services and service users with accessibility of NBS.

Dietitians frequently recommend NBS products as adjuvant treatment for a range of different clinical conditions including inherited metabolic disorders in children, cows' milk protein allergy, coeliac disease, disease related malnutrition and gastrointestinal disorders.

These items are currently approved by the Advisory Committee on Borderline Substances (ACBS) as NBS, and can be prescribed on FP10, GP10 or WP10 in England and NI, Scotland, and Wales, respectively. These products are currently listed in the British National Formulary (BNF) in Appendix 2 Borderline Substances, and include Foods for Special Medical Purposes[3] designed for the dietary management of diseases or conditions (including enteral tube feeds, oral nutritional supplements (ONS), specialised feeds for infants to adults; gluten free foods and other nutritional products).

1.1 The Current Situation

NBS are typically prescribed in the same way as all other products within the Drug Tariff (i.e. prescribed by a healthcare professional who is registered as an independent or supplementary prescriber). Most doctors, when requested, will provide a prescription for NBS for a patient in the acute or community setting, whereas a dietitian can provide individual assessment, follow up, advice and guidance on the products and their use. In hospital, NBS are usually added to a patient's drug chart and then dispensed through the hospital pharmacy. In the community setting, dietitians will request a prescription from the patient's GP as appropriate. GPs may initiate and prescribe NBS themselves in the community or be requested to prescribe NBS by other healthcare professionals (e.g. nurses or health visitors).

With an ageing population and an increase in people living with long term conditions[4], demand for NBS could be anticipated to rise. Across the country, in an attempt to cut prescribing cost, some CCGs are choosing to restrict NBS. It is essential that prescribing policies secure the right balance between cost-efficient use of NBS and effective delivery of improved patient outcomes. This means ensuring patients who require them can access them at the right time for the right duration to drive the right outcomes, whilst minimising inappropriate use and wastage. The BDA believes that, as the experts in nutritional management of patients, dietitians play a critical role here to ensure nutritional assessment, review and follow up.

[1] http://www.bapen.org.uk/pdfs/economic-report-full.pdf
[2] https://www.nice.org.uk/Guidance/QS24
[3] https://ec.europa.eu/food/safety/labelling_nutrition/special_groups_food/medical_en
[4] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216528/dh_134486.pdf

The normal reimbursement mechanism, whereby a patient receives a prescription, is known as **ON SCRIPT.** This enables the safeguards in place for other products such as pharmaceuticals where there is an auditable trail of prescriptions to a named prescriber. However, whilst a dietitian may initiate the use of NBS, they are unable to write a prescription, and are reliant on the GP or other doctor to issue. It is possible for a dietitian to become a supplementary prescriber, but this is only available to more senior dietitians and is not intended for the prescribing of NBS. However, in some parts of the country, a dietetic service has been commissioned and NBS have been procured directly from the supplier without going through the reimbursement mechanism, known as **OFF** or **WITHOUT SCRIPT**. Typically these have been made available to patients through a homecare model, or in rarer examples, in the community using a form of voucher system with the pharmacist.

1.2 Recommendations

The BDA recommends a solution that maintains the safeguards of the prescribing and reimbursement mechanism, but which enables dietitians to access NBS for their patients without the need for a prescription. A sensible solution could be for NBS in Appendix A2 of the BNF (A2.1 – A2.7)[5] to become the ***"Dietitians formulary for the supply of Nutritional Borderline Substances"*** similar to the Nurse Prescribers Formulary. This would enable dietitians to lead nutritional care, which is uniquely their skill set, whilst leaving the procurement chain from manufacturer to wholesaler to pharmacy untouched. Dietitians would also be able to safely hold clinical responsibility for patient use of NBS, together with doctors.

A '**WITHOUT SCRIPT** model' is an alternative that we have evaluated in this document, both in terms of advantages and risks, and proposals on how to mitigate against those risks.

Whatever the route by which a patient accesses NBS, there are a number of critical success factors that the BDA is seeking to achieve:

- Improved compliance through dietetic lead nutrition care and service planning
- Patients who require NBS get the most appropriate product in the right dose at the right time
- Patients get the right nutritional advice, review and follow up from the right healthcare professional
- NBS supplies are ceased for patients who no longer require them, thereby minimising wastage
- Patient does not require multiple appointments with the GP to obtain the prescription for NBS
- Demand on GP appointments are reduced as nutritional care and prescribing of NBS are managed by the dietetic service.
- Hospital beds released more promptly as transition of patients on nutrition support from acute to community settings can be managed directly by dietetic lead service.

1.3 Supplementary Prescribing

In 2016 dietitians were awarded supplementary prescribing status, which is a positive step forward. However, there is still a need to enable all dietitians (not just those registered as supplementary prescribers) to prescribe NBS as the key part of their toolkit. Supplementary prescribing status was not secured as a solution to this issue, but instead as an option for advanced dietitians to prescribe prescription only medicines. The BDA will be looking to work in partnership with the Government and experts to clarify the legislation and what is possible to enable all dietitians to be able to access NBS within their scope of practice, in a sustainable way.

[5] British National Formulary (BNF) March-September 2016

2 Introduction

This document considers the challenges facing dietitians with accessing NBS for their patients. It also investigates the issues around the prescribing and supply mechanisms of NBS, which dietitians frequently recommend as adjuvant treatment for a range of different clinical conditions.

2.1 Defining Nutritional Borderline Substances

NBS items are currently approved by the Advisory Committee on Borderline Substances as NBS and can be prescribed on FP10, GP10 or WP10 in England and NI, Scotland and Wales respectively. These products are currently listed in the BNF in Appendix 2 Borderline Substances, and include a diverse range of products such as gluten free, low protein or protein free foodstuffs, specialised infant formulae, ONS and enteral feeds.

Foods for Special Medical Purposes (FSMPs), which make up a significant part of NBS, are regulated by law under Delegated Regulation (EU) 2016/128 supplementing Regulation (EU) No 609/2013, which updates the specific compositional and information requirements for FSMPs and entered into force on 22 February 2016. These foods must be used under medical supervision.

Appendix 1 gives a synopsis of the range of the types of products included within NBS classification, examples of commonly used products and the clinical condition where they may be used.

2.2 Context

NBS, when used correctly and under appropriate supervision, are an essential part of clinical care providing patients with the nutrients necessary to prevent ill health from conditions such as:

- Disease related malnutrition
- Inherited metabolic disorders in children
- Cow's milk protein allergy in babies
- Coeliac Disease
- Gastrointestinal disorders

2.2.1 Malnutrition

The prevalence of malnutrition continues to increase and currently it is estimated that the cost of not treating malnutrition is in the region of £19.8bn in England alone[6]. As malnutrition can be both the cause of some illnesses, or a secondary consequence of disease and/or the consequence of some types of treatment, it is almost impossible to differentiate specific healthcare impacts and costs.

Treatment of malnutrition, irrespective of the many different clinical care pathways in existence, primarily involves:

- Nutrition screening to identify malnutrition risk,
- If identified, the development of an appropriate individualised care plan for diet and ONS, if necessary.
- Monitoring of this care plan to treat the malnutrition.

[6] Managing adult malnutrition in the community – A multi professional consensus panel 2014
http://malnutritionpathway.co.uk/downloads/Managing_Malnutrition.pdf

Treatment of malnutrition has significant consequences for the NHS. It has been shown in cost benefit analysis that investment to treat malnutrition results in a shorter length of stay in hospital, reduced admissions to hospital and reduced cost in clinical treatment through fewer infections.[7] The role of dietitians will therefore be at the forefront of any strategic plans to implement better nutritional care across all sectors of acute, community and residential or nursing home care settings. A recent document from NHS England on Commissioning Excellent Nutrition and Hydration Services[8] highlights the need for commissioners to work with dietitians and dietetic teams to ensure effective identification and treatment of malnutrition and the development of strategies that are relevant to the local population and work towards preventing a greater prevalence of malnutrition in the future. Dietitians are the experts who can support the local health and care services in delivering such strategies.

This is especially relevant with an ageing population and where cost savings in the NHS are needed. Dietitians have been shown to have a key role in helping to create a more streamlined person-centred service that is also cost effective in treating malnutrition.

Access to NBS are an essential tool for dietitians to effectively deliver the best possible nutritional care, in addition to individual advice on diet and dietary modification as standard.

Patients with the following conditions, amongst others, can benefit from nutritional supplements. For example, stroke, dementia, kidney failure, cystic fibrosis, diabetes, cerebral palsy, elderly malnutrition, paediatric malnutrition, difficulties with swallowing, loss of muscle mass, respiratory disease including chronic obstructive pulmonary disease (COPD) and pressure sores.

2.2.2 Inherited Metabolic Disorders (IMD)

There are over 500 known IMDs, and many are diagnosed in infancy or early childhood. A significant proportion of those that affect carbohydrate, lipid or protein metabolism, require specialist dietetic support as a major part of their ongoing management. Children with IMDs can become acutely unwell if they have an intercurrent infection. If not treated promptly, this can lead to metabolic decompensation, encephalopathy or possibly death. From the point of diagnosis paediatric dietitians will discuss information on the dietary management of the particular disorder and recommend the prescription of NBS such as specialist dietary supplements and low protein foods – all essential to maintain optimum function and growth in children.

2.2.3 Cows Milk Protein Allergy

Cows' milk is a leading cause of food allergy, especially in infants and children. Cows' milk protein allergy is characterized by acute and rapid onset symptoms, including urticaria, gastrointestinal upset, vomiting, respiratory distress or anaphylaxis. There are a number of available formulae for infants who cannot tolerate whole cow's milk protein or lactose (in the case of lactose intolerance) Following assessment, the dietitian will advise on the most suitable choice based on the infant's requirements, taste preference, degree of hydrolysis required, indications for amino acid formula, parental preference, and many other clinical and non-clinical factors.

2.2.4 Coeliac Disease

The prevalence of Coeliac Disease is estimated to be one in 100. It affects people of all ages, although the average age of diagnosis is between 40 and 60 years. It is a multisystem disease that effects many organs, not just the gastrointestinal tract. Treatment is a lifelong gluten free diet that avoids wheat, rye, and barley and their derivatives. Dietetic management aims to optimise absorption of nutrients and help prevent or treat complications (e.g. osteoporosis). Many staple foods in the diet will contain gluten (e.g. bread, pasta, and flour). As such, the dietitian will also recommend appropriate amounts of gluten free products listed in the BNF or that can be purchased commercially in order to maintain a balanced diet.

[7] Managing adult malnutrition in the community – A multi professional consensus panel 2014 http://malnutritionpathway.co.uk/downloads/Managing_Malnutrition.pdf

[8] Guidance – Commissioning Excellent Nutrition and Hydration 2015 – 2018 https://www.england.nhs.uk/wp-content/uploads/2015/10/nut-hyd-guid.pdf

2.2.5 Gastrointestinal Disorders

Patients with disorders of the digestive tract (e.g., Coeliac Disease, Inflammatory Bowel Disease (IBD) are nutritionally vulnerable and even minor disorders can have a major impact on nutritional status, particularly if they are persistent. Enteral tube feeding (i.e. nutrition support) has become a widely used method of ensuring adequate nutrition in patients who have a functioning gastrointestinal tract, but are unable to maintain an adequate or safe oral intake such as in pancreatitis, cancers of the stomach or duodenum and IBD.

Enteral feeding involves tube feeding directly into the stomach, duodenum or jejunum using enteral feeds listed as NBS. Dietitians uniquely provide assessment, guidance and recommendations regarding nutrition support dose, type and duration.

2.3 System of Provision

Approved formularies, as part of prescribing guidance, provide support to the GP in terms of when and what to prescribe. Prescribing support dietitians may be employed to assist implementation. In all of the examples in 3.1 where NBS are used, the dietitian is key to ensuring that they are used appropriately, safely and effectively. As part of multidisciplinary teams, this is widely accepted as a core role. That said, the system for obtaining NBS at NHS expense is via the prescription route, and this worked well for many years. However, the current system has come under increased scrutiny as NHS services are asked to deliver more for patients with limited resources.

Most doctors, when requested, will provide a prescription for NBS for a patient in the acute or community setting, whereas a dietitian can provide individual assessment, follow up, advice and guidance on the products and their use. In hospital, NBS are usually added to a patient's drug chart and then dispensed through the hospital pharmacy. In the community setting dietitians will request a prescription from the patient's GP as appropriate. GPs may initiate and prescribe NBS themselves in the community or be requested to prescribe NBS by other healthcare professionals (e.g. nurses or health visitors).

With an ageing population and increase in people living with long term conditions[9] demand for NBS could be anticipated to rise. Across the country, in an attempt to cut prescribing spending, there is an emergence of restrictive prescribing practices targeting NBS. It is essential that prescribing policies secure the right balance in driving effective and efficient use of NBS. This means ensuring patients who require them can access them at the right time for the right duration to drive the right outcomes, whilst minimising inappropriate use and wastage. The BDA believes that as the experts in nutritional management of patients, dietitians play a critical role here to ensure nutritional assessment, review and follow up. For example, the value of the efficient use of NBS in the treatment of malnutrition must be realised as identified in the BAPEN/NIHR report[10].

Pharmacists have a crucial role to play in the dispensing of NBS for patients both in the acute and community setting, providing the most convenient means by which patients can access the nutritional products they need.

As a profession, dietitians are best placed to ensure NBS are used safely, effectively and appropriately whatever the setting, ensuring that:

- Patients are assessed and monitored
- NBS are used only where clinically indicated
- Appropriate products are prescribed in the right quantity
- Products are ceased when no longer required

There are a few GP practices which have access to a dietitian to manage NBS prescribing for their patients. Prescribing support/medicines management dietitian roles are a relatively new one identified by trusts to help redesign NBS services so that:

- Patients can access appropriate nutrition services whilst providing assurance of value for money for the NHS

[9] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216528/dh_134486.pdf
[10] http://www.bapen.org.uk/pdfs/economic-report-short.pdf

- There is a reduction in the adverse consequences of poor nutritional status
- There is a reduction in inappropriate prescriptions
- Wastage is minimised through a review of procurement and supply mechanisms.
- Additional training is provided to healthcare staff on diet, nutrition and NBSs

The next section aims to illustrate the different models currently being used to access NBS on prescription across the UK. Each model has attempted to use the constraints of current legislation to provide the best and most cost-effective care possible for patients locally.

3 Different Models of Care

Previous work by the BDA working group investigated the many different supply mechanisms for NBS. It highlighted many different mechanisms whereby patients could access NBS products at NHS expense. In an acute hospital setting all dietitians work in a multi-disciplinary environment and as such a recommendation for patients to have any specific nutritional supplement is usually straightforward and the responsible clinician will endorse a hospital prescription request. The introduction of supplementary prescribing for advanced and or specialist dietitians is unlikely to significantly change this process. However, the most significant changes will be to prescribing of NBS in the community or general practice setting where a printed prescription on FP10, GP10 or WP10 is required.

There is a plethora of local papers and guidelines on appropriate prescribing of NBS that individual Trusts and Health Boards across the UK have produced. It is recognised that the initial impetus for many of these initiatives was primarily cost efficiency. In the last few years, and most recently a paper from British Association of Parenteral and Enteral Nutrition (BAPEN) shows the emphasis is now more on the benefits of *appropriate nutrition intervention* and health outcomes (especially in older age groups) to prevent emergency admission to hospital (often from falls in the elderly), reduce length of stay in hospital, and acknowledgment that well-nourished individuals tend to visit their GP less often and require less medications.[11]

Dietetic involvement in nutritional care will facilitate the measurement of clinical effectiveness and will also address the issue of ONS being appropriately discontinued when no longer necessary. The latter is most likely to happen if a dietitian is involved in prescribing and is responsible for follow up and regular review of the patient, as in the Malnutrition Pathway[12]. As noted previously, while this paper will address all NBS, most initiatives that have looked at more streamlined access to products and cost savings have focussed on ONS and home enteral feeding items, and most recently staple gluten free food items.[13]

The mechanisms of procurement of NBS in the community have tended to follow similar methods - '**ON SCRIPT'** where a GP prescription is still needed, '**WITHOUT SCRIPT'** where the local health service, medicines management and dietetic service have agreed to a dietetic led service and no formal prescription is required, or a combination of these. Although there are models which follow the 'without script' route and these have shown to be workable, they are not without their challenges. The Commercial Medicines Unit (CMU) do not provide any further guidance on the legal status of this. The current Best Practice Guidance states:

> *"The inclusion, within the tender documents, of requests to procure the feed in primary care via the non FP10 route has been challenged on occasions. If offers for this route are requested and a challenge is received, Trusts are advised to seek their own legal advice."*[14]

Figure 1 taken from the Procurement Guide illustrates the pathway taken in both scenarios where patients can obtain NBS via 'On script' or 'Without script' routes. Both of these pathways also involve close collaboration with a supplier of nutritional feeds Initial work in these areas concentrated on home enteral feeding products and the use of oral nutritional products when used as a feed to be administered via a feeding tube.

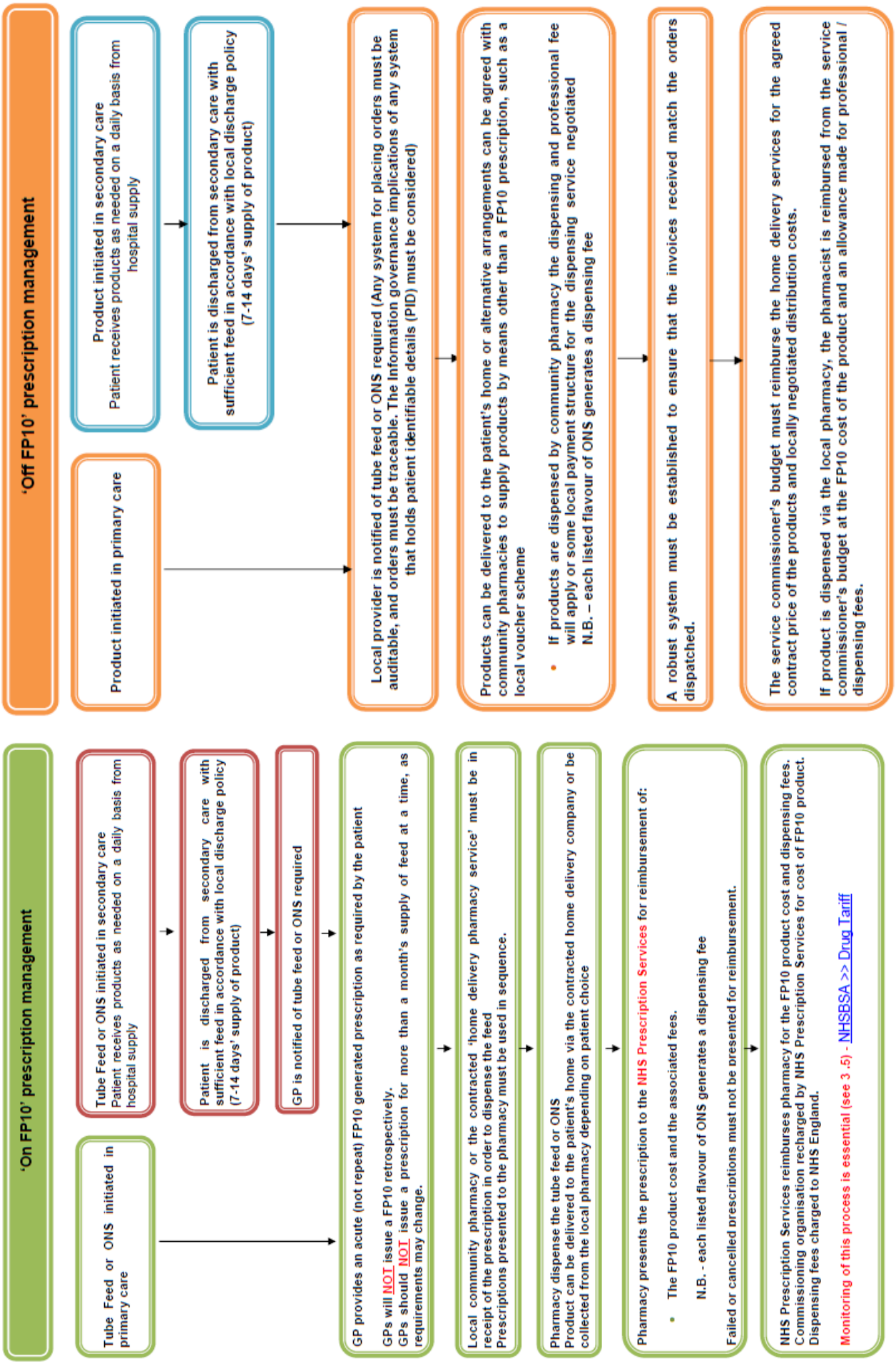
[11] The cost of malnutrition in England and potential cost savings from nutritional intervention BAPEN 2015
[12] http://www.malnutritionpathway.co.uk/
[13] Nutrition support for adults: oral nutrition support, enteral tube feeding and parenteral nutrition NICE 2006 https://www.nice.org.uk/guidance/cg32
[14] https://bsna.co.uk/uploads/banners/Best-practice-for-the-provision-of-nutrition-supply-services2.pdf

There follows two examples of where different models of care have been initiated which are predominantly dietetic led, which have shown to be more streamlined, improve patient care and provide a more cost-effective service. It must be acknowledged that it takes some time to embed a new way of working, and as more areas strive to provide a service that is cost effective, but also showing excellent clinical outcomes, we can learn from examples across the country.

Further case studies have been provided in **Appendix 2** which illustrate how dietetic departments have attempted to resolve prescribing, supply and administration mechanisms locally.

It is important to note that no one model can be identified as a “gold standard” in management of NBS, and as illustrated in Figure 1, each model has its challenges alongside the benefits.

Figure 1:On Script and Off (Without) Script Models - Best practice for the provision of nutrition supply services, Commercial Medicines Unit, DoH.



3.1 MODEL One - Off Script (Somerset)

Home Enteral Feeding (HEF) products and ancillary items:

An Off-script contract agreed with the local CCG (included 2 counties). This has been in place for over 10 years due to geographically similar rural settings and each county having a comparable number of patients, which has economies of scale.

Originally HEF products were taken off-script in 2009. Only the community went off-script; hospitals and tertiary centres remained on prescription. ONS products are not included in the off-script model. The move to an off-script model went well initially, though the savings this model made when it was introduced were not recognised as dietetic savings. However, this has since changed and the entire budget for all HEF now sits within the dietetic department.

The acute services have contracts with the same nutrition company that the community have their off-script model with. The acute sector has a reduced price compared to the list price in the BNF. This community off-script contract has just been renewed and the budget, administration and management of the off script account sits within the community dietetic team.

There are no funded dietetic posts with this model, though it is recognised that a number of similar 'off –script' contracts do have attached dietetic posts. It is essential that clear direction is given from the National Procurement for Enteral Feeding as to the legal situation, or otherwise, of funded posts.

The nutrition company supplies five nurses across the two counties who provide a full nursing service to HEF patients. These nursing posts have honorary contracts with acute and community Trusts to provide care and treatment to patients but are not in any way linked to any hospital Trust.

There are no prescribing posts within this CCG, and as such dietetic services works closely with medicines management teams to ensure appropriate and cost effective prescribing to treat malnutrition effectively with ONS.

The off-script HEF model serves 650 patients across 2 counties. Each county employs at least 1x full time administrative assistant (Band 3) to manage the day to day running of an off-script service

Oral Nutritional Supplements (ONS), Specialist Infant Formula and Metabolic products:

These are not included in the contract and remain on FP10 where patients obtain them via their GP. The dietitian would write to the GP, and usually fax over requests for these products. This is time consuming and could be streamlined.

STRENGTHS	**WEAKNESS**
For home enteral tube feeding when off script has: • Good audit and budget trail • Good control of feed and ancillaries • Good nursing service 365 days/year from nutrition feed company • Agreed list of alternative products if chosen company's not suitable/ unavailable	Confusion over what ONS products are available – new companies on the market and rapidly changing formularies. Negative impact on local pharmacies (and a significant number of dispensing practices), as they miss out on dispensing fees for HEF items and ONS if used for enteral feeding via a tube. If the patient is not referred to a dietitian there can be the risk of wastage of ONS. Try to ensure all patients requiring nutritional support are referred to dietetic care even if ONS are instigated by medical staff. Gluten Free prescribing practices vary between different surgeries. Patients may not be aware of what products, and what quantities, they are entitled to each month. FSMP not available off script The sustainability of the model is dependent on increased dietetic resources but funding is not always available.
OPPORTUNITIES	**THREATS**
ONS, GF and other NBS could be brought into similar model of HEF and management could sit within the Dietetics team.	Strong administration processes and management is required

3.2 MODEL 2 Combination of OFF SCRIPT and FP10 (London)

ONS and Adult HEF products

Products are supplied in an off-script dietetic led-model by an urban community trust serving four hospitals and several tertiary centres. The budget for this service sits with community dietetic service for ONS, HEFT and plastics. There are no funded dietetic posts within the department. There are no prescribing posts and no additional funding for dietitians to work directly with the GPs or the CCG.

GF/ Infant Formula if not provided enterally / Metabolic Products

These remain on FP10 and are issued via the GP on the request of Community Dietitian or Tertiary Care Specialist Dietitian (e.g. Renal and Paediatrics for Metabolic Conditions).

'Off script' Service for adults

ONS and HEF products are delivered monthly or bi-monthly from the contracted nutrition company. If a product is required that is not within the scope of the contract, the patient gets an agreed voucher from the dietitian and can source the product from a local pharmacy. This voucher is used as if it is a prescription. All referrals received for Nutrition Support are contacted over the telephone within 10 working days of receipt of referral. This is managed within the team on a daily basis. A dietitian is allocated to contact 7-8 patients over the telephone and assess if ONS or food first information is required and if home visit or clinic appointment is required. GP can still issue a 14-day FP10 for ONS and HEF products whilst waiting for the initial contact to be made. For patients managed by dietitians within acute or tertiary settings, the patient is added to a shared care caseload and ONS/Enteral Nutrition is provided via this model under the direction of the Managing Dietitian. A competing nutrition company has a high percentage share of GP prescribed ONS despite GPs being encouraged to use the company contracted in the off-script model. GPs are confused about what to prescribe in their 14-day supply due to requests from external organisations who are on different contracts. As a result, ONS have been issued in an expensive format (and at full drug tariff cost) by GPs where a cost and clinically effective alternative could have been issued.

Dietitians write to the GP to request prescriptions for paediatric specialist ONS (if the patient is not enterally fed), gluten free foods, specialist infant formula and metabolic products. The plan for the future, is to work on the area of provision of ONS within paediatrics to fit into the off FP10 model.

STRENGTHS	WEAKNESSES
• Empowering for dietitians to provide clinically appropriate prescriptions for ONS in accordance with evidence based and best practice • Cost savings- this has allowed for investment in new posts to make dietetic team more robust • Friends and Family Test has been positive and Quality of Life scores have increased for patients • Patients experience feedback is positive for delivery of ONS to home on a monthly schedule • Clinically the service has shown an average of 11% weight gain for patients and patients are discharged from dietetic care according to their BMI/% weight gain, if they are eating well and stable or if they have achieved maximum improvement. • No other AHPs can prescribe nutritional supplements GP feedback – feel the budget and provision of these products is appropriately managed by the correct Clinical Team • Dietitians work in close proximity with community nursing and acute dietitians	• Patients becoming more complex and dietitians require appropriate skill mix to manage this (counselling, motivational interviewing and dietetic knowledge). • Dietitians can feel uncomfortable triaging patients over the telephone and prefer only to provide direct face to face intervention. • The contracted nutrition company has limited flavours of first line products, and this may affect compliance. Also not all products are vegetarian which a significant issue in the populations locally • Difficulties engaging with CCGs and Medicine Management Team in regard to management of initial FP10 prescriptions generated by GPs • Voucher system can be difficult for housebound patients and so may need to rely on a designated supplier rather than having the choice • Staff and manpower intensive to run the service especially the KPI of contact within 10 working days of receipt of referral • Management time intensive. Particular care is required for dealing with invoices and receipts, a strong finance and administrative department is required

3.3 Further Considerations

Whichever model is used, in whole or part, there are four distinct aspects to consider:

1. *Autonomy for all qualified dietitians to be able to access NBS for their patients (within their scope of practice) which is separate to dietitians having supplementary prescribing rights.*
2. *A supply mechanism for NBS ensuring cost effective access to, and appropriate use of, NBS to support the correct nutritional care plan for patients.*
3. *That dietitians continue to practice within a legal framework if the statements above are in place.*
4. *Sufficient dietetic staff to manage the model.*

A process for establishing local arrangements is given below:

Process to Establish Local Arrangements for NBS

- Identify all stakeholders in your area
- Establish a working group of key individuals eg: dietitian/s, medicines management, pharmacy supply in hospital, GP, hospital clinician/s, nutrition company representatives
- Meet to discuss and prepare case to investigate different methods of supply of specific NBS nutrition products
- Who will run and manage the service? - Medicines management/Dietetics
- What are clinical governance arrangements/PGD or similar? Systems may need to be changed.
- Tender for nutrition company service if 'off script' and /or using voucher system instead of prescription or
- Agreement for dietetic autonomy while still on FP10/WP10/GP10

Clinical Governance Arrangement for Dietetic Use of NBS

- NHS Trust or Health Board
- Clinical Governance Arrangements
- Identify who has clinical accountability
- Dietetics
- Develop training and competency in use of all Nutrition related NBS products
- Regular review of individuals' competency as part of annual appraisal process
- Local annual audit of NBS usage and costings- any cost savings reinvested to further improve dietetic service. It may be that *more* needs to be spent on ONS.
- Reporting to Patient Safety and Quality Committee on treatment of disease related malnutrition

4 Other Options

4.1 Supplementary Prescribing

In February 2016, Minister George Freeman announced that legislation will be expanded to enable dietitians to prescribe medicines for their patients under supplementary prescribing responsibilities. This means that experienced dietitians who have successfully completed an approved postgraduate course will be able to prescribe medicines listed on a clinical management plan and agreed with a doctor.

Supplementary prescribing responsibilities can only be undertaken by advanced level dietitians and will be used to prescribe prescription only medicines (POMs). For example, an advanced level dietitian could prescribe insulin for a diabetic patient in their care without the need for the patient to make another appointment with their GP simply to obtain their prescription. Supplementary prescribing has great potential for shortening the care pathway helping patients to remain fitter for longer in their own homes. It will also enable timely access to medicines, saving GP appointments and most importantly improving clinical outcomes for patients where the interaction between diet and medicines are key to management of certain long term conditions such as diabetes, chronic kidney disease and cystic fibrosis.

Whilst supplementary prescribing will be used by advanced level dietitians primarily to prescribe prescription only medicines listed in the BNF, they can also use them to prescribe NBS for the nutritional management of their patients if required.

The vast majority of NBS, however, are managed by entry level dietitians. All dietitians, at the point of registration, are able to manage NBS within their scope of practice. Managing NBS is not an advanced level skill for the dietetic profession, and therefore supplementary prescribing is not appropriate for the majority of dietitians who are currently managing NBS in the hospital and community setting.

The knowledge and skills required to manage NBS on an individual patient basis is taught at undergraduate level and as such all qualified dietitians have these skills when they enter the profession at Level 5.

4.2 Exemptions

Exemptions within the Human Medicines Regulations 2012 are defined in law allowing specific listed medicines to be sold, supplied and/or administered to patients by a specific health professional group without the need for another appropriate prescribing or supply/administration mechanism. It is important to recognise that exemptions are a supply and administration mechanism and are not a prescribing mechanism.

If dietitians were granted exemptions status, then upon successful completion of an approved training programme, they would gain annotation on the Health and Care Professions Council (HCPC) register as being qualified to use exemptions within the Human Medicines Regulations 2012.

Dietitians would be able to sell (when they are providing care in the private sector), supply or administer any NBS for any condition within their scope of practice and competence.

Although like supplementary prescribing, this may be an option it is not without its limitations. Exemptions are intended for prescription only medicines where a single dose or single course is required for a patient. There is no indication for NBS products to be used in the longer-term management of conditions such as malnutrition, coeliac disease or metabolic disorders in children.

5 Recommendations

No one model currently provides an ideal solution to this highly complex and multi factorial situation. However, dietitians are experts in the field of nutrition and in the case of NBS products it would be reasonable to propose that the clinical responsibility for these items should sit with dietitians.

One possible solution that maintains the safeguards of the prescribing and reimbursement mechanism, but which enables dietitians to prescribe NBS. A sensible solution could be for NBS in Appendix A2 of the BNF (A2.1 – A2.7)[15] to become the **"Dietitians formulary for the supply of Nutritional Borderline Substances"** similar to the Nurse Prescribers Formulary. This would enable dietitians to lead nutritional care, which is uniquely their skill set, whilst leaving the procurement chain from manufacturer to wholesaler to pharmacy untouched. This would enable dietitians to hold clinical responsibility for patient use of NBS, together with doctors.

A '**WITHOUT SCRIPT** model' is an alternative that we have evaluated in this document, both in terms of advantages and weaknesses, and proposals on how to mitigate against those weaknesses.

Whatever the route by which a patient accesses NBS, there are a number of critical success factors that the BDA is seeking to achieve:

- Patients who require NBS get the most appropriate product in the right dose at the right time
- Patients get the right nutritional advice, review and follow up from the right healthcare professional
- Improved compliance through dietetic lead nutrition care and service planning
- NBS supplies are ceased for patients who no longer require them, thereby minimising wastage
- Patient does not require multiple appointments with the GP to obtain the prescription for NBS
- Demand on GP appointments are reduced as nutritional care and prescribing of NBS are managed by the dietetic service.
- Hospital beds released more promptly as transition of patients on nutrition support from acute to community settings can be managed directly by dietetic lead service.

In March 2016 dietitians were awarded supplementary prescribing status, which is a positive step forward. However, there is still a need to enable all dietitians (not just those registered as supplementary prescribers) to prescribe NBS as the key part of their toolkit. The BDA will be looking to work in partnership with the Government and experts to clarify the legislation and what is possible to enable dietitians to be able to prescribe NBS in a sustainable way

6 Acknowledgements

The BDA would like to acknowledge all those who provided support, advice and guidance in the preparation of this document.

[15] British National Formulary (BNF) March-September 2016

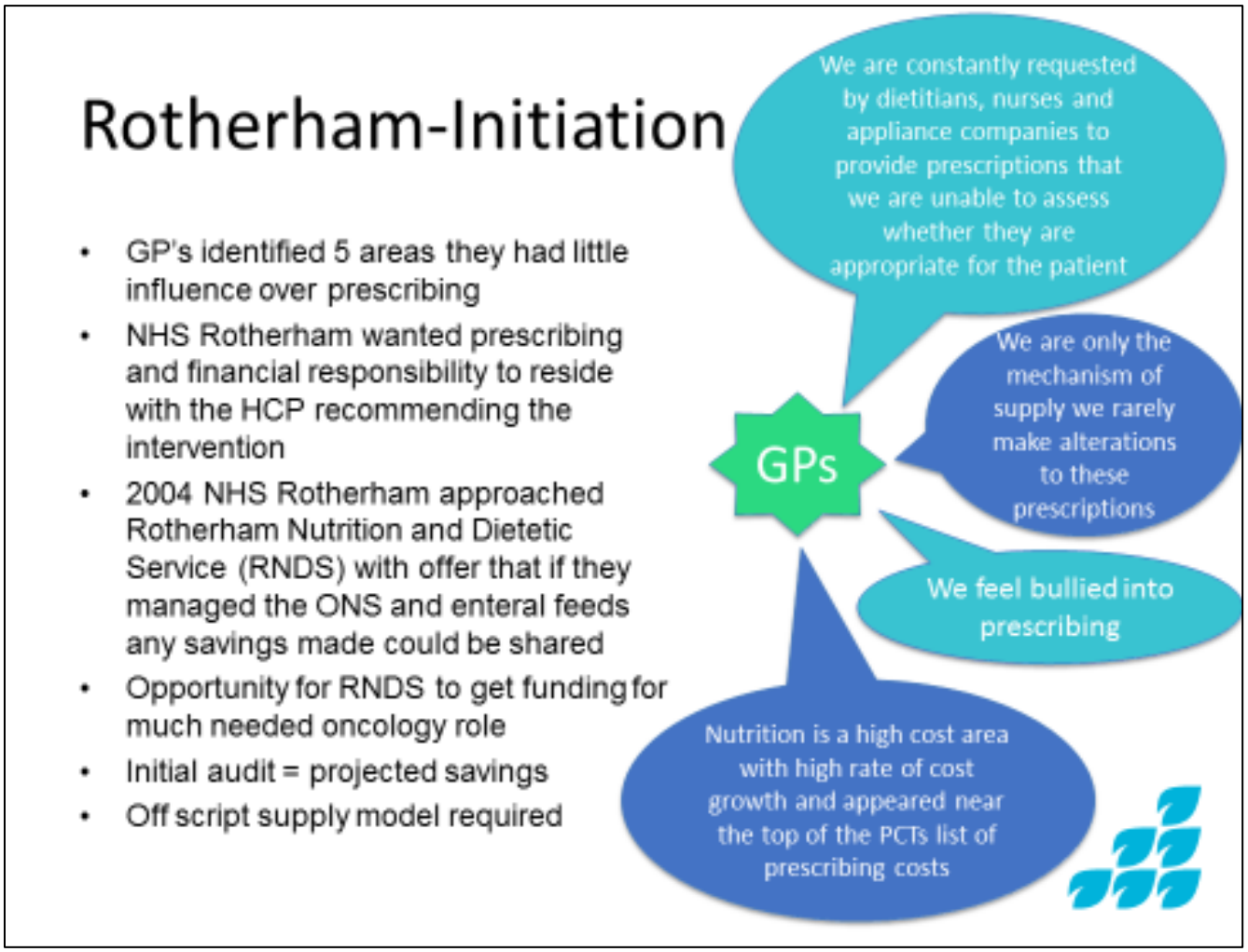
Appendix 1

NBS Section	Example Product	Clinical Indication of Need
Enteral Feeds Standard Feed (1kcal/ml) High Energy Feed (1.5kcal/ml) Elemental Feed	 Jevity Nutrison Protein Plus Peptamen HN	Used in enteral feeding in many conditions- following stroke, before and after surgery. Crohn's disease
Oral Nutritional Supplements (ONS) Ready to use: Standard Feed (1-2kcal/ml) Low volume Feed (2.4kcal/ml) Low volume with added fibre Semi Elemental Feed Juice type Feed ONS Powder feed to mix with milk: Standard Powder feed High Energy Powder feed	 Fresubin 2Kcal Drink Ensure Compact Fortisip Compact Protein Vital 1.5kcal Fortijuce Aymes Shake Scandishake Mix	Disease related malnutrition which is wide ranging. Especially useful in treating malnutrition associated with poor appetite and elderly patients unable to consume adequate quantities of energy dense nutritious foods. As above but need to consider the requirement to make the feed up which can impact on compliance in some patients
Modular feeds Fat Source- MCT Protein Source Carbohydrate Source	 Liquigen Prosource Liquid Maxijul Super Soluble	 steatorrhea due to malabsorption or in ketogenic diet for epilepsy Increase protein requirements in malnutrition or ITU/HDU e.g. burns patients Malnutrition form any cause to increase energy intake
Specialist Infant Formula Hydrolysed formula Extensively Hydrolysed formula Semi Elemental formula NBS Section High energy formula	 Aptamil Pepti 1, Similac Alimentum Neocate LCP Infantrini Peptisorb Example Product Similac High Energy	 Cow's milk protein intolerance Severe cow's milk protein intolerance Malabsorption often following gut surgery e.g. gastroschisis or NEC in infants Clinical Indication of Need Faltering growth

Gluten Free and Low Protein Foods: Flour- white and brown Bread and rolls Bread mix crackers crispbread pasta pizza base breakfast cereals	Most companies will all produce ranges of these products: Juvela Glutafin Genius Lifestyle Loprofin PK Foods Promin	Gluten free- Coeliac Disease Dermatitis herpetiformis low protein: Renal failure Liver failure Inherited metabolic problems affecting protein metabolism
Metabolic products Amino acid supplement	 PKU Anamix- Infant PKU Lophlex LQ10 PKU Aid 4 SOS Mix	Inborn Errors of Metabolism such as: Phenylketonuria (PKU) “ “ MCADD (Medium chain acyl- CoA dehydrogenase deficiency)
Thickening Agents for Dysphagia	Nutilis Clear Thick & Easy	All degenerative neuromuscular condition- NMD, MS, PD, HD and stroke

This table is for general information only to give examples of NBS products. It is NOT a formulary nor does it promote the products of any one manufacturer over another, and has included examples from different companies where possible.

Appendix 2



Case Study 1 – Rotheram, South Yorkshire

In 2006, an off script prescription supply model of NBS products was set up by NHS Rotherham whereby the Nutrition and Dietetic Service took over the management of the prescribing of ONS products from the 39 Rotherham GP practices. An NHS Rotherham dietetics voucher was produced which instructs local pharmacies to dispense the the ONS products and this is then returned to the Dietetics service for reimbursement at drug tariff prices, including a dispensing fee. Cost savings have continued year on year from a peak of £707,000 on 2006/07 to £513 000 on 2010 /11.

In 2008, the success of the project enabled NHS Rotherham to become partners in a joint nutrition contract alongside the acute service, which allowed further benefits to the quality of patient care.

In 2010/11, when compared to national trends, the cost savings were estimated to be £1,165,194. Advantages of the project included that GPs were no longer requested to prescribe products they are unable to review or monitor, there was improved supply of ONS to patients and improved compliance with NICE guidance on treating malnutrition.

In September 2010, in recognition of the continued success of the project,the commissioners requested that the Nutrition and Dietetic Service should manage and prescribe gluten free, low protein and specialised baby milks. This initiative was funded from the cost savings achieved by the initial dietetic led ONS supply model.

Case Study 2 - Scottish Gluten Free Food Service (GFFS)

The Scottish Gluten-Free Food Service (GFFS) is an NHS Scotland service delivered through community pharmacy. Under this service, patients with coeliac disease or *Dermatitis herptiformis* are registered with a community pharmacy of their choice that is responsible for dispensing gluten-free foods without a prescription and providing an annual pharmacy coeliac health check. The service was commissioned by the Scottish Government in autumn 2015 following an 18 month pilot and is now a permanent aspect of the community pharmacy contract..

How does it work?

Patients diagnosed as having coeliac disease (or *Dermatitis herpetitformis*) are given a referral form from their GP or dietitian, which confirms their eligibility to use the service.

The patient and pharmacist then sign the form and a patient care record (PCR) is created. The referral form is retained by the pharmacist for payment verification purposes. A new referral form is required where there is a change in units required, for example: age or pregnancy.

An annual health check should be completed by the pharmacists at registration and annually thereafter, using the PCR, which contains the patient assessment questions.

The person orders their GF products on the NHS Scotland GF food requirement order form, hands it in to the pharmacy and pharmacists use CPUS prescription forms to prescribe the GF products, ensuring that the CHI number is added. The GP cypher number is also added to the GP Reference Number box on the CPUS form.

Pharmacists can register the patient for the Chronic Medicines Service, but this is not a requirement of the service. However, each pharmacy designates a named pharmacist to be responsible for the on-going management and delivery of the scheme.

Pharmacists receive £125 per month for providing the service.

Formularies

The 14 NHS Boards in Scotland can choose to select a range of products from the national guidance to meet local needs of patients, and they publish a local formulary which should be adhered to.

Patients may order products from this local formulary up to the number of allocated units assigned to them.

Conclusion

The Scottish Government has welcomed the GFFS as the service makes optimum use of clinicians' skills and allow patients to actively manage their own condition, as well as offering a cost effective system for NHS Scotland. An evaluation of the GFFS 18-month pilot reported overwhelming support from both patients and GPs, and was able to carry a 31.6% increase in volume with just 4.6% increase in costs.

The service has also received widespread support from patients, pharmacists and GPs, with 85% of GPs saying the GFFS had reduced their workload, as well as the number of visits to GP surgeries. **The scheme has fostered an improved multidisciplinary working relationship between dietetics and pharmacy**, as well as initiating a strong clinician-patient relationship

The Review of the Gluten-free Food Additional Pharmaceutical Service can be found here: http://www.gov.scot/Publications/2015/09/4234

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