Annex

Extract from the Codex Standard for Formula Foods for Use in Very Low Energy Diets for Weight Reduction (Codex Stan 203-1995) [3]

1 - Scope

This standard applies to formula foods for use in very low energy diets for weight reduction as defined in Section 2. These foods are defined as foods for special medical purposes and must be used under medical supervision by individuals with moderate or severe obesity. The matter of sale on prescription should be a decision made at national level. It does not apply to prepackaged meals presented in the form of conventional foods.

2 - Definition

A formula food for use in very low energy diets is a food specially prepared to supply a minimum amount of carbohydrates and the daily requirements of the essential nutrients in 450-800 kcal which represents the sole source of energy intake.

3 - Essential Composition and Quality Factors

The product as sold should comply with the following composition and quality factors:

3.1 Energy Content

A formula food for very low energy diets shall provide when prepared according to instructions a daily energy intake of 450-800 kcal as the only source of energy.

3.2 Nutrients Contents

3.2.1 Protein

- Not less than 50g protein with a nutritional quality1 equivalent to a protein-digestibility-corrected aminoacid score of 1 shall be present in the recommended daily intake of energy.[4]
- Essential amino acids may be added to improve protein quality only in amounts necessary for this purpose.

Only L-forms of amino acids shall be used, except that DL-methionine may be used.

3.2.2 Fats

Very low energy diets shall provide not less than 3g of linoleic acid and less than 0.5g of linolenic acid in the recommended daily intake with the linoleic acid/linolenic acid ratio between 5 and 15.

3.2.3 Carbohydrates

Very low energy diets shall provide not less than 50g of available carbohydrates in the recommended daily intake of energy.

3.2.4 Vitamins and Minerals

Very low energy diets shall provide 100% of the recommended daily intakes for vitamins and minerals. Other essential nutrients not specified below may also be included.

3" Available in full from: www.codexalimentarius.net/download/standards/296/CXS_203e.pdf

4" Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation, Bethesda, MD USA, 4-8 December 1989, FAO Food and Nutrition Paper No. 51, 1991, Rome, p. 23.

Vitamins

Vitamin A " 600 µg
Vitamin D " 2.5 µg
Vitamin E " 10 mg
Vitamin C " 30 mg
Thiamin 0.8 mg
Riboflavin 1.2 mg
Niacin " 11 mg
Vitamin B6 " 2 mg
Vitamin B12 " 1 µg
Folic Acid (as monoglutamate) 200 µg

Minerals

Calcium 500 mg
Phosphorus 500 mg
Iron 16 mg
Iodine 140 µg
Magnesium 350 mg
Copper 1.5 mg
Zinc 6 mg
Potassium 1.6 g
Sodium 1g

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National Obesity Forum

Targeting obesity and the metabolic syndrome

Position statement on Very Low Energy Diets for the weight loss phase of obesity management

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Introduction

Options to manage weight loss in the treatment of obesity are limited. Dietary restraint and increased physical activity form the basis of all conventional therapeutic approaches to achieve a sustained energy deficit that will ultimately reduce fat reserves and obesity.

At present pharmaceutical therapies remain confined in the UK and Europe to a single licensed drug, orlistat, for which preliminary weight loss should be sought through dietary control and enhanced physical activity prior to its being prescribed. However a reduced strength version is available over the counter. As a lipase inhibitor, its effect is to impede the absorption of fat during ordinary food intake.

Very low energy diets provide a therapeutic technique to assist an obese patient in losing weight more rapidly than would otherwise be possible, and may be undertaken voluntarily by patients wishing to lose weight in the short term, but are also indicated for medical reasons in certain circumstances, for example to achieve pre-operative weight loss or in managing obesity with co-morbidities such as type 2 diabetes.

Definition and terminology

Very low energy diets (VLEDs), alternatively referred to as very low calorie diets (VLCDs), consist of proprietary formula foods which provide the sole source of daily energy intake. They usually supply a minimum of 50g of carbohydrate and 50g of protein, but must provide all essential nutrient requirements daily, and may contain between 450 and 800 kcals overall. During VLED ketosis develops, as lipolysis converts fat stores into transformable energy.

Background

VLEDs are subject to regulation and recommendations embodied in the Codex Alimentarius Standard.[2] (See Annex for detailed specification). The Codex standard defines VLEDs as foods for special medical purposes, which must be used under medical supervision by individuals with moderate or severe obesity. The question of whether these must be controlled by medical prescription remains a matter for national authorities. In the UK, the NICE guidelines permit the use of VLEDs for a maximum of 12 weeks continuously, or intermittently with a low-calorie diet (for example for 2–4 days a week), by people who are obese and have reached a plateau in weight loss. NICE guidelines state that any diet of less than 600 kcal/day should be used only under clinical supervision.

"What has happened is that people have used VLCD or liquid or formula diet for a period of time and then have gone back to 'normality' with very little in the way of follow up or maintenance, and without maintenance they go back to doing what they did before."

Understanding VLEDs

Very Low Energy Diets provide an option for managing weight loss for obese patients. They provide controlled energy intake lower than the level than can be achieved with a reduced intake of normal foods, whilst ensuring essential micronutrient requirements are met. To undertake a micronutrient-replete energy restricted diet below 800 kcals per day cannot reliably be achieved using foods, so requires a VLED formula supplemented diet.

The panel considers that a greater understanding of the role, relevance and application of VLEDs, along with their associated benefits and their risks, is required among the medical and health professions now dealing with obesity. The provision of appropriate follow up at a requisite standard demands improved training for all involved. It is therefore important to ensure that both medical and health professional staff are fully conversant with VLEDs and with subsequent weight management and maintenance requirements.

The panel believes that some confusion exists in both lay and professional understanding of VLEDs with lack of distinction between weight loss products marketed with dubious claims and without adequate scientific attribution, and the prepared VLED formula foods that comply with specified standards and meet essential nutrient requirements.

Indications and Supervision of VLEDs

It is important that VLEDs are not misused. They are intended for those with high body mass index (BMI) requiring significant weight loss, but they should not be used as a first line treatment for general weight loss. VLED is not a "quick fix". VLED programmes represent an aggressive dietary change - a 'shock to the system. Following weight loss, there may be a benefit in using a stepped approach to increase food energy intake aimed at establishing a weight maintenance diet with extended follow up.

VLED is likely to bring benefit to all severely obese people, but caution is needed with some medical conditions. The present requirement for GP's approval for all patients to undertake a VLED programme is not considered essential, provided that staff involved have had externally validated training and also assuming the patient does not have one of the small number of medical conditions requiring medical supervision.

The main medical concern is with patients on drug treatments which may require dosage adjustments during rapid weight loss, e.g. insulin and hypoglycaemic drugs, antihypertensive drugs and warfarin. The VLED should be viewed in the context of an overall weight management programme, with regard to contact, support and supervision throughout, continuing into the weight maintenance phase.

The panel considers there is no scientific evidence or compelling rationale to restrict the maximum duration of a VLED programme to the present recommended term of 12-weeks if there is a need for continued weight loss and there is adequate support and supervision.

It is vital to determine at what stage in the programme to re-introduce for sustainable weight maintenance. There may be advantages in not attempting to reach the maximum potential weight loss in a single course, but first to ensure that the patient has training to prevent regain. Targets should be agreed between the patient and the healthcare professional providing the support and monitoring.

Fully compliant patients will lose a similar amount of weight through a VLED programme as with bariatric surgery. Both should receive a high standard of follow up and an evidence-based plan for long-term weight maintenance. The VLED programme should be considered an integral part of an overall weight management and weight maintenance programme, which may also provide a valuable approach to diabetes prevention within Primary Care.

VLEDs are normally contraindicated in children and adolescents. However, older adolescents with an extremely high body mass index are increasingly being considered for bariatric surgery. The consequences of bariatric surgery effectively involve a VLED diet that should result in long term monitoring. Therefore VLED diets may be considered as a medical option under specialized supervision in older adolescents, particularly in cases where there is a co-morbidity such as type 2 diabetes.

The panel considers the present contraindication for use by the elderly to be unnecessary. There is no scientific support for an upper age limit for use of VLEDs and many obese patients may benefit in later life from weight reduction to relieve osteoarthritis and other co-morbidities. However the panel considered that anyone contemplating such a diet over the age of 70 should be medically assessed and remain under medical supervision.

The panel considers that VLED programmes:

- may be suitable for weight loss for anyone with a BMI above 30 kg/m^2, and for some overweight patients with a BMI below 30 kg/m^2 with type 2 diabetes or other co-morbidities;
- may be continued for as long as is necessary to provide ongoing therapeutic weight loss subject to monitoring and consultation, and the appropriate/agreed weight management/maintenance stage being reached;
- may be considered as an option for adolescents with morbid obesity under strict medical supervision and as an alternative to bariatric surgery;
- may be considered suitable for some elderly patients in appropriate circumstances, with medical supervision for those aged over 70;
- should be seen within the framework of Primary Care and an overall package which supports long term weight maintenance;
- could be provided without GP approval if those involved in VLED provision have externally validated training and qualifications.

Expected weight loss

Full compliance with a diet of 800 kcal/d may induce an "energy deficit" of around 2000 kcal/d for all obese patients – much more than this in the very obese, and more if the patient is physically active. This energy deficit means that fully compliant patients could be expected will lose at least 2 kg/week. There is often greater loss in the first week through loss of body water, but thereafter weight loss >3 kg/week may indicate exclusive dieting, and possible failure to take the VLED and its micronutrients.

Weight losses below 2 kg/week in the first few weeks of the diet may imply non-compliance and continued consumption of additional foods. The decline in metabolic rate on adaptation to semi-starvation, combined with that associated with the fall in weight using a VLED, may lead to slightly lower rates of weight reduction over time. Clinical trials show that around half of the people starting VLCD are able to adhere to them sufficiently to lose 15-20 kg. This seems a reasonable individual target before focusing on long-term maintenance.

Side Effects

Reported side effects of some VLEDs include those related to limiting water consumption and fibre intake, e.g. dry mouth, dizziness, headache, constipation or diarrhoea. More general symptoms include nausea, cramps, fatigue, hunger, feeling cold, menstrual changes and hair thinning. Serious adverse events from rapid weight loss may include acute gout, and cholelithiasis.

Contraindications

Infants and children; pregnancy; lactating women; unstable cardiac or cerebrovascular disease; acute and chronic renal failure; severe or end stage liver failure; acute psychiatric disorder; gout; porphyria.

Participation

The National Obesity Forum gratefully acknowledges the contribution of members of an ad hoc advisory panel who met in June 2010 to discuss the content of this statement. Those who took part in the meeting were:

- Professor Andrew Hill (University of Leeds)
- Professor Michael Lean (University of Glasgow)
- Professor Stephan Rössner (Emeritus Professor, Karolinska Institute, Sweden)
- Professor David Haslam (Chair, National Obesity Forum)

The following panel members took part in consultative discussions or provided written evidence to the panel in reviewing the final statement:

- Dr Michelle Hession (London School of Hygiene and Tropical Medicine)
- Professor Iain Broom (Robert Gordon University, Aberdeen)
- Dr Matt Capehorn (Hon. Clinical Director, National Obesity Forum)

The meeting was moderated by Neville Rigby, strategic adviser to the NOF, who also acted as rapporteur.

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Disclosures:

Prof Iain Broom is medical director of LighterLife

Prof David Haslam is an adviser to LighterLife

Dr Michelle Hession completed a PhD funded by LighterLife in 2009.

Prof Andrew Hill is an adviser to Slimming World

Prof Stephan Rössner has received research support and lecturing honoraria from Cambridge Diet (UK) and Cederroths (Sweden).

Prof Mike Lean has received research support and lecturing honoraria from Cambridge Diet (UK) and Novo Nordisk.

Neville Rigby provides consultancy services to the Obesity Forum.

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