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Report on Health and Social Subjects

31



The Use of Very Low Calorie Diets in Obesity

Report of the Working Group on
Very Low Calorie Diets

Committee on Medical Aspects
of Food Policy

Her Majesty's Stationery Office

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Committee on Medical Aspects of Food Policy

Working Group on Very Low Calorie Diets

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Preface

In December 1985 The Committee on Medical Aspects of Food Policy formed an *Ad Hoc* Working Group to enquire into and report upon the growing use of commercially produced very low calorie diet preparations (VLCD) in the treatment of obesity and their marketing to the general public.

The Working Group met on five occasions and reviewed the available published information. It also received written and oral submissions from interested parties, including the companies currently marketing VLCD in the United Kingdom.

This report summarises the findings of the Working Group and gives their conclusions and recommendations to the public, to the medical and allied professions, to the manufacturers of VLCD preparations and to Government Departments.

The Chairman and the Members of the Working Group have given generously of their time and knowledge and I am very grateful to them.

Donald Acheson

Chief Medical Officer

Chairman, Committee on Medical Aspects of Food Policy

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1. Introduction

1.1 Background to the Working Group

1.1.1 Overweight and obesity are increasingly prevalent in the United Kingdom, and there are many people who are not overweight but who nevertheless wish to lose weight for a variety of reasons. Dieting in order to slim is therefore very popular and there is an enormous variety of 'reducing diets' to choose from. Medically prescribed reducing diets are usually composed of normal foods taken in reduced quantities to reduce daily food energy (calories*) intakes below daily energy expenditure. Extreme restriction of food energy intake, even total starvation, is possible but is rarely recommended medically as a means of weight loss, and then usually under close medical supervision. Ideally, weight reducing diets should restrict only food energy intake, maintaining the consumption of all other nutrients (eg protein, vitamins and minerals) at an adequate level. One of the dangers of dietary restriction is the inadvertent, perhaps unsuspected reduction of these micro-nutrients; the more restricted the diet, the greater this risk becomes, unless deliberate measures are taken to avoid it. The question of undue losses of body protein also arises. Over the past few years a number of nutrient preparations of low energy content have been manufactured and marketed which are intended to replace ordinary foods completely for a number of days or weeks. These commercial low calorie food substitutes have been increasingly vigorously promoted for weight loss in the United Kingdom by the manufacturers. Queries about the safety and efficacy of these products have been directed to both the Ministry of Agriculture, Fisheries and Food (MAFF) and the Department of Health and Social Security (DHSS). The question of need for controls over their labelling and composition led MAFF to seek advice from the Committee on Medical Aspects of Food Policy (COMA), who set up this *ad hoc* Working Group on Very Low Calorie Diets as a consequence.

1.2 Terms of reference of the Working Group

To advise the Committee on Medical Aspects of Food Policy on the use of Very Low Calorie Diets and to make recommendations.

1.3 Interpretation of terms of reference

The Working Group discussed the treatment of obesity generally with particular reference to any form of stringent restriction of energy intake, including

*Although the unit of energy used for food is now the kilojoule (kJ) the earlier term kilocalorie (kcal) has been used in *this Report* because of the familiarity of the public who use Very Low Calorie Diets with this concept. For conversion 1000 calories = 1 kcal; 1 kcal = 4.184 kJ; 1000 kJ = 1 megajoule (MJ).

self-selected, low energy diets, but has restricted its recommendations to products defined as commercially produced nutrient preparations providing less than about 600 kcal (2.5 MJ) per day, marketed for use as a total food substitute.

1.4 Meetings of the Working Group

1.4.1 The Working Group was appointed at the beginning of 1986 following an earlier recommendation of the Committee on Medical Aspects of Food Policy. It has met five times.

1.4.2 We wish to express our appreciation and thanks for expert assistance to the Secretariat. We are grateful to those who have prepared working papers and have made documents available, and to those who have attended our meetings to contribute information. Their names are recorded in Appendix B.

1.5 Perspectives

1.5.1 The deposition of fat under the skin and around internal organs is a normal storage function for humans and animals. Its purpose is to provide a store of energy for use when food is unavailable. Fat stores are laid down when food intake exceeds energy needs and are used up when food intake is inadequate to meet these needs. In many societies today food intakes rarely fall short of requirements and fat stores are laid down but never used up. Some people accumulate excessively large fat stores and they are liable to discomfort, distress and disease as a result¹. However, the lesser degrees of overweight or 'plumpness', recognised as a Body Mass Index (BMI)* of 25 to 30, are associated with little or no increase in risk to health and life.

1.5.2 Fat stores can be reduced by calling on them to give up their energy. This will happen whenever more energy is expended than is consumed in food and drink. Therefore, excessive fat storage is reduced by consuming less food energy than the body needs; the energy deficit is met by drawing on the fat stores. Increasing the body's energy expenditure will accelerate the loss of stored fat. However, whenever the body is in a state of energy deficit, weight will also be lost because of the reduction of some non-fat tissues, ie a reduction in the fat-free mass (FFM). The FFM is made up of tissues such as muscle, body organs and bone. The degree of this loss of FFM may increase disproportionately with the degree of energy deficit.

1.5.3 Restricting the intake of food energy can range from complete starvation at one extreme to a reduction which just causes steady weight loss at the other. When food intake is lowered, the body adapts by reducing its energy expenditure to some extent. In an average sedentary person three-quarters of total energy expenditure is accounted for by the energy costs of

*The Body Mass Index (also known as Quetelets Index) is widely used as an indicator of weight for height and is defined as the weight in kg divided by the height in metres squared ($BMI = W/H^2$). Recommended 'normal' ranges of BMI are 20 to 25 for men and women².

resting metabolism, that is the energy cost of the body's activities in the resting state (eg breathing, heart action, chemical transformations, maintaining body temperature). A further 10 per cent or so is expended as heat produced in response to the intake of food (thermogenesis). The remaining 15 per cent accounts approximately for all other activities, including physical activity. When food energy intake is decreased the diet-induced thermogenesis also decreases. After some time on a reducing diet, the resting rate of energy expenditure (resting metabolic rate) will also decrease, roughly in proportion to the amount of non-fat tissue which has been lost. Weight loss will continue if food energy intake is kept below the level of energy expenditure which prevails after these adaptive changes have occurred.

1.5.4 Weight-reducing diets differ from each other in two ways. First, they vary in the *degree of restriction* of food energy (calorie) intake. Second, they vary in the *composition and types of food* which go to make up the energy-restricted diet. The first determines the speed of weight loss; the greater the degree of restriction of food energy intake the faster weight is lost. Both factors determine the acceptability and perhaps the safety of the weight reducing process.

1.5.5 The term Very Low Calorie Diet (VLCD) has come to be applied, as the name suggests, to food energy intakes restricted usually to below one third, and sometimes to as little as one sixth, of daily energy expenditure. A very low energy intake may result from a major reduction in the intake of normal foods, either self imposed or following a prescribed regimen. This may include the use of products formulated as meal replacements for one or more meals each day, and may bring energy intakes into the very low calorie range of below about 600 kcal per day. An alternative approach is to replace normal food entirely with a manufactured VLCD preparation which supplies the restricted energy intake desired. With greatly restricted food intakes there is concern that the body should not at the same time be deprived of essential nutrients such as protein, vitamins, salts, minerals, iron and 'trace elements'. It is also important to know that there will be no adverse effects from excessive reduction in the quantity, or from distortions in the balance, of protein, carbohydrate and fat in the diet. Concern has also been expressed that the rapid weight loss with very low calorie intakes involves disproportionately great loss of non fat tissues.

1.5.6 There is some evidence that the more rigorous the dietary restriction, the greater is the proportion of the weight loss from non fat tissues. The balance of 'costs' and 'benefits' may vary with the severity of the energy restriction.

1.5.7 The Working Group considered VLCD preparations as a method for obtaining rapid weight loss, the information presently available on the efficacy of such preparations in the short and the longer term, their advantages, disadvantages and possible hazards and the question of supervision during their use. The Report concludes with a series of recommendations.

1.6 Form of the Report

1.6.1 We have attempted in this Report to interpret complex evidence in such a way that our conclusions are clear to the general public; to medical practitioners and those responsible for offering advice and guidance to the general public on the use of VLCD; to manufacturers; and to those in the Government of the United Kingdom responsible for preparing legislation on food and drink. The Working Group also perceived a need for further research into aspects of the use of VLCD preparations, particularly their long term effects. It agreed that, with the relatively scanty scientific knowledge, the matter should be kept under review. The recommendations given in Section 9 are accompanied, where necessary, by a brief explanatory statement. The lines of evidence upon which the principal recommendations are based are summarised in Section 2-7. References are given in Section 10 and are confined to essential sources of facts and figures.

1.6.2 The recommendations put forward were agreed by all members of the Working Group.

2. History of VLCD

2.1 Currently available Very Low Calorie Diet preparations originated from two main sources. The first was from the use of 'synthetic diets' in investigations which required that the composition of dietary intake was constant and exactly known. The second was from the attempt to obtain the greatest possible energy deficit short of the disadvantages and risks of total fasting. The residual energy levels and compositions varied widely. Those now classed as VLCD (ie below 600 kcal) have usually been based on nutrient mixtures originally formulated for specific research purposes and composed of commercially available dietetic preparations such as powdered milk, protein and starch hydrolysates. Such VLCD preparations have been manufactured since the 1970s, used in research trials and marketed for the treatment of obesity.

2.2 Maximum energy deficit is attained during complete starvation. Obese patients have been, from time to time, subjected to total fasting for prolonged periods under close supervision³. Total fasting has been virtually abandoned as a therapy because of a small number of unexpected deaths, attributed to loss of essential protein from certain tissues⁴. As early as 1924 Mason⁵ employed diets of 500 kcal in "a rather radical method for weight loss". These diets were used for as long as 100 consecutive days with weight losses of 31–43 kg, but no specific metabolic measurements were made. From these early observations came the suggestion that maintaining a high proportion of protein in the restricted diet would protect the fat-free mass from undue depletion while still permitting a large energy deficit and consequent loss of fat tissues. This gave rise to what was termed protein-supplemented modified fasting which employed different amounts and types of protein, with and without added carbohydrate.

2.3 An attempt at a more precise energy accountancy of the response to low food energy intakes was reported by Strong, Passmore and Ritchie⁶ who also enquired into the composition of the weight lost. They used diets containing 400 kcal and encouraged physical exercise. Some of their diets were based on restricted conventional foods and some were formulated from commercially available milk protein preparations. They termed this a 'strict reducing regimen' since the daily negative energy balance was as much as 3000 kcal, and they achieved losses of 2.1–2.7 kg per week.

2.4 Passmore *et al.*⁷ also concluded that there were significant differences between obese and normal weight people in their metabolic response to a hypocaloric diet. Those of normal weight appeared to lose more protein as a proportion of the weight loss than did the obese, a finding confirmed by Forbes and Drenick.⁸ This point has arisen in discussions about possible

differences in response to, and disadvantages from, the use of VLCD in massively, as compared with moderately, obese people. However, in this small study no relationship was found between the amount of weight lost and the size of the negative nitrogen balance. In the 1960s and the 1970s several research groups used similar diets in the treatment of grossly obese patients under their supervision.^{9, 10}

2.5 The first large scale commercial promotion of total food replacement for weight loss with a very low calorie protein supplemented diet took place in North America in the 1970s with a so-called "liquid protein diet". This was prepared from hydrolysed cattle hide and was originally marketed through the medical profession, though later also directly to the public. Other similar products soon appeared on the market varying in composition with respect to protein source and the quantities of added vitamin and mineral supplements. Sales ceased in 1977 after a number of deaths were reported in people taking liquid protein diets. A subsequent study showed that cardiac arrhythmias may be detected within two weeks of taking these diets as the sole source of nourishment.¹² From this and other clinical evidence serious disturbance of cardiac rhythm was considered to be the cause of the reported deaths. Several factors were thought to be responsible, including the amino acid composition of the protein source employed (deficient in tryptophan and lysine) and the inadequate content of certain important minerals such as potassium and magnesium.

2.6 The United States Food and Drug Administration introduced regulations to control the marketing of such liquid protein diets.¹³ They required a clear statement of composition on the label of any food product that derives more than 50 per cent of its total caloric value from either whole protein, protein hydrolysates, amino acid mixtures, or a combination of these, and that is promoted to reduce weight should bear the following warning:

Warning – Very low calorie protein diets (below 400 kcal per day) may cause serious illness or death. DO NOT USE FOR WEIGHT REDUCTION WITHOUT MEDICAL SUPERVISION. Not for use by infants, children, or pregnant or nursing women.

2.7 The subsequent development of VLCD has sought to meet these depletion-induced dangers by providing high quality protein, by formulating preparations which optimise the ratio of protein to carbohydrate and by including the complete range of minerals and vitamins. The further commercial development of the new generation of VLCD preparations took place in the United States in 1980, stemming from a UK patent by A N Howard in March 1972. This claimed novelty for a diet formulated from mixtures of at least 15 g of amino acids or high quality protein with 15–17 g of carbohydrate providing a total of 160–600 kcal. In the last few years several such preparations have been marketed and growing numbers of reports of their closely supervised use in treating obese people have been published.¹⁴ They are being increasingly vigorously promoted by manufacturers who have adopted a variety of strategies to advertise and distribute them.

2.8 Very Low Calorie Diets are now being marketed directly to consumers throughout the world, sometimes 'over the counter'. Manufacturers claim that more than 7 million people have used VLCD as a method of reducing weight. About half a million of these have been in the United Kingdom. There does not appear to have been any excess mortality associated with their use on the basis of broad estimates of usage and the numbers of reported deaths. However, little information collected systematically from long-term users of VLCD is available.

3. Definition of Very Low Calorie Diets (VLCD)

3.1 A Very Low Calorie Diet describes in general terms a level of food energy intake intermediate between total starvation and a modest reducing diet. By common usage, the term has been applied to diets which reduce the daily food energy consumption to levels below 600 kcal for several consecutive days or weeks. This definition lacks precision and reflects the variation in the available products. The Working Group concluded that little purpose would be served at this stage by imposing a tighter definition. It agreed to restrict the definition to dietary preparations which achieve these low calorie intakes by totally substituting for normal meals. The definition does not include preparations or regimens which seek to achieve similar low energy intakes by partial replacement only, (ie by replacing a meal with some very low calorie substitute while leaving the rest of the dietary pattern unchanged) or by overall reduction of normal food intake. The Working Group did not specifically formulate recommendations on such dietary regimens but the arguments and warnings given later in *this Report* about VLCD apply to these situations with at least as much force. The Working Group has given considerations to both the “very low calorie” aspect, and also to the “diet”, that is to say the composition of the VLCD preparation administered, the protein content and the relative proportions of the macronutrients and the quantities of micronutrients and non-nutrients included.

3.2 The quantity and type of food consumed by healthy individuals is, under ordinary circumstances, regarded as being a matter of personal choice and taste, after consideration of its possible bearing on health and such guidance as may be available. When an individual decides to reduce food intake below the level necessary for maintenance of body weight for the purpose of slimming, it is important that this is done in a way that minimises losses of body tissues which are not associated with adiposity and that does not deplete the body of components necessary for the proper functioning of tissues and organs.

3.3 Ideally, slimmers would wish to lose only fat from their bodies, but when food intake falls below energy expenditure other components are also consumed to compensate for the energy short-fall. There are, for example, unavoidable losses of protein, storage carbohydrate, and some minerals as well as of fat when weight is lost in this way. The more restricted the diet, the greater the further loss of these body components; a major concern in selecting a weight losing dietary regimen is to minimise or compensate for these losses, particularly of protein. In the scientific development of weight reducing diets for the obese much attention has been given to the *composition* of the diet in order to achieve maximum fat loss at lowest cost in terms of protein and other losses.

4. Composition of VLCD

4.1 Protein Balance

4.1.1 A composition for low calorie diets has been sought which minimises reduction in the body protein content which inevitably accompanies the fall in body mass. This depends partly upon the quantity of protein included in the diet, but also upon the total energy intake from all food sources. When this is very low, dietary protein will be utilised as an energy source and so will not be available to correct the protein loss. Precise measurement of intake of protein and output of its breakdown products (nitrogen balance) is difficult to perform. Accurate measurement of all intakes and the collection and estimation of all outputs make great demands both upon those who perform and those who submit to such studies. Under conditions of semi-starvation, some nitrogen may be lost from the body as the ammonium ion and this and other minor nitrogen losses may not be included in some of the methods used. Restricted intakes of food energy or of individual nutrients lead to adaptations in the body's use of foods as fuels. It may take weeks or months before these changes have been completed and a true balance between intake and loss can be assessed. Along with water and some fat loss there is an early phase or rapid protein loss during the first few weeks of total fasting when as much as 75 g of protein per day, or even more, may be lost.⁸ The subsequent rate of daily loss of protein in adults completely deprived of food, averaging about 40 g for women and 50 g for men, covers a wide individual variation of 20–60 g or more. The protein and energy content of VLCD preparations should aim at least to cover these potential losses.

4.1.2 Protein from several sources has been used in VLCD preparations. The deaths which occurred among users of the early liquid protein diets in the USA were ascribed to the use of proteins deficient in one or more essential amino acids (such as hydrolysed collagen which lacks tryptophan and lysine).⁴ Such preparations are now viewed with suspicion and should not be offered for use. (See Recommendations.)

4.1.3 It follows that minimum levels of intake of suitable protein must be set for VLCD preparations in order to minimise nitrogen deficits. In setting these account must be taken of both sex and body size, and of factors such as the energy level of the VLCD, duration of obesity, meal frequency, previous dietary intake and the range of individual variations in response.

4.1.4 There is also accumulating evidence that the relative concentrations of circulating amino acids affect the concentration in the brain of substances which may affect mood and drive. This may be a further reason for avoiding major distortions in the pattern of amino acid intake in very restricted diets.

4.2 Carbohydrate

4.2.1 Severe restriction of carbohydrate in a low calorie diet will augment the use of fat as a metabolic fuel, leading to increased production of ketoacids and acetonuria. There is some division of opinion about the consequence of this accumulation of the by-products of fat breakdown, such as beta hydroxybutyrate and acetoacetate. Raised levels of the ketoacids may reduce protein losses,¹⁵ but their subjective effects are controversial. In the obese individual, weight loss will increase insulin sensitivity and correct glucose intolerance.

4.2.2 Dietary carbohydrate appears to have a protein conserving effect; very restricted intakes of carbohydrate favour protein breakdown and hinder the achievement of nitrogen balance.¹⁶ Recent studies also suggest that calcium and zinc losses are diminished by increased proportions of carbohydrate,¹⁷ potentially of importance to women in whom preservation of bone calcium is a special consideration. Much of the advantage of maintaining relatively high proportions of dietary carbohydrate is ascribed to the "tonic" stimulatory effect this has on maintaining insulin secretion, the anticatabolic (or anabolic) hormone which may differentially regulate the selective breakdown of storage fat and structural protein and contribute to the conservation of calcium, zinc and other minerals.

4.3 Other nutrients

4.3.1 Some of the deaths of people taking the early so called liquid protein diets were attributed to deficiencies of potassium, calcium or other minerals.⁴ Individuals subsisting entirely on these products suffered significant depletion of body stores of potassium, calcium, magnesium and phosphorus¹⁸ and shortages of a number of vitamins would also have occurred unless supplements were taken. Although many of the B group of vitamins are utilised in the metabolism of fat, carbohydrate or protein, it is doubtful that the substantially reduced energy intakes offered by VLCD lead to proportionately similar reductions in micronutrient requirements. We do not know what the nutrient requirements of people on VLCD are, but until the necessary evidence is obtained, we believe that it is desirable for the daily intake of VLCD to provide the UK Recommended Daily Amount or, where no recommendation has been made, the US Recommended Daily Allowance of all the essential minerals and vitamins. (See Appendix C.)

5. VLCD – Risks and Safety

5.1 General considerations

5.1.1 A problem for reducing diets in general is maintenance of essential protein tissues in the face of an overall energy deficit, hence the concern about nitrogen balance during dietary restriction. Conventional reducing diets provide 800–1200 kcal, with protein and other nutrients to meet requirements.

5.1.2 Total starvation in the obese leads to the breakdown of protein to maintain the amino acid pool for the synthesis of essential tissue proteins. The degradative losses which accompany this recycling eventually lead to serious depletion of essential proteins which under conditions of prolonged or severe dietary deprivation is responsible for the progressive impairment of bodily function and ultimately for death. Compositions of VLCD are based on the assumption that this loss of essential protein will be countered by the protein and carbohydrate they supply. Although this seems a reasonable assumption, there is at present little evidence bearing directly upon it.

5.1.3 Although the consumption of liquid protein diets with an unsuitable amino acid composition was associated with increased mortality risk (see para 2.5), complete fasting for 3 or 4 weeks under close supervision carries no major risk to life in healthy overweight persons.² The ingestion of VLCD of *suitable* composition for a similar period may therefore be considered equally free of risk. However, for those who continue on such diets for considerably longer periods or repeat the course frequently at short intervals, additional risks may appear. In general manufacturers of VLCD preparations meet this possibility by recommending that the diet should not be continued for longer than 3–4 weeks at a time, warning against this in the package literature.

5.1.4 With the present generation of VLCD preparations there has in fact been no clear evidence of risk to health or life. What evidence there is available is largely indirect, ascertainment of adverse effects is less than complete, and there is inherent difficulty in demonstrating absence of risk. Nevertheless, the unhappy experience with liquid protein diets referred to earlier has ‘sensitised’ those who provide and those who consume VLCD to the potential dangers and some reassurance may be drawn from the fact that, despite this, there are no reports of major mishap. There is comparatively little information on the effects on health of prolonged use of VLCD.

5.1.5 Wechsler *et al*¹⁹ drew attention to other possible areas of concern when reviewing nitrogen balance studies on subjects reducing weight on VLCD:

'almost nothing is known about the mechanisms involved in regulation of protein metabolism . . . we do not know whether all body tissues are gaining or losing nitrogen to the same degree.'

The exact reason for the deaths of people using the earlier liquid protein diets remains uncertain.^{4,11} The balance of opinion ascribes the deaths to the unsuitable protein sources (deficient in the amino acids tryptophan and lysine) and inadequate mineral and vitamin supplements. However, this is not proven and other factors cannot be excluded.

5.1.6 Most of the assumptions about safety are based upon the response of otherwise healthy users of VLCD. Less is known about the outcome in those with other health problems such as coronary heart disease or other vascular disorders; and there are other groups in whom possible risks from VLCD may outweigh potential benefit, for example in the treatment of obesity in growing children and the pregnant. Although manufacturers of VLCD products recommend that medical sanction is sought before starting VLCD, the data of one manufacturer indicate that this was done by only 24 per cent of consumers in 1985 and by only 36 per cent in 1986. These conclusions are based on the follow up of only a small proportion of the original number of consumers surveyed.

5.1.7 A number of side effects is mentioned by the manufacturers, and they suggest that most of these will disappear on resuming a normal diet. However, systematically collected information is relatively scanty and this question cannot be considered to have been adequately answered. There is very little support in the literature for the suspicion that VLCD may be responsible for abnormalities of cardiac rhythm.^{14, 20-24}

5.1.8 According to data supplied by the manufacturers, and despite the recommendation that the diet should be taken for not more than 3-4 weeks at a time without medical advice, one quarter of consumers admit to using a VLCD for longer periods. Once a product is freely available on the market, there is no guarantee that the manufacturer's recommendations will be followed. Indeed in some of those who aspire to further weight loss, it is likely that the recommendations will be disregarded.

5.1.9 The use of VLCD has been questioned in persons who are only moderately overweight, ie, Body Mass Index (BMI) less than 30, partly on the ground that they may lose proportionately more nitrogen than more obese people.^{8, 25} Repeated use of VLCD may result in undesirably high, even permanent losses of body proteins.

5.2 Composition of tissue loss

5.2.1 The composition of the tissues representing the weight lost has long been the subject of research and of concerns mainly directed to the question of disproportionately high protein losses. Obese people have an associated increase in lean body mass; as the adipose tissue is reduced by dieting it would

be expected that this protein increment would be lost *pari passu*. The negative nitrogen balance observed during diet induced weight loss poses three questions:

- (a) Is the protein lost during weight reduction greater than that expected on the basis of the adipose associated excess?
- (b) From which body tissues is protein lost during weight reduction?
- (c) Is there evidence that such diet-induced losses of protein are associated with a threat to health and wellbeing?

5.3 Losses of fat and non-fat tissues

5.3.1 It is generally assumed that when energy consumption is less than expenditure, the deficit is met by the utilisation of stored fat and that this fat utilisation accounts for the loss of body weight. This is only partly true. Under conditions of restricted food energy intake, the body also loses some non-fat tissues which contribute to the total weight loss. It is probable that the greater the calorie deficit, the greater the proportionate contributions of the non-fat tissues to the body weight lost. In complete starvation it is estimated that non-fat tissues account for about half the weight lost. With a conventional (800–1000 kcal) reducing diet, non-fat tissues probably account for only about a quarter of the body weight lost. In a woman maintaining energy balance on 1800 kcal per day, an energy deficit (ie difference between intake and expenditure) of 800 kcal could be met by the utilisation of 89 grams of fat (providing 9 kcal per gram) or by the utilisation of 800 grams of non-fat tissue (providing about 1 kcal per gram, since non-fat tissue can be regarded as roughly a 25% solution of protein and carbohydrate in water, all of which are lost when the tissue is utilised). Thus although weight loss accelerates with the progressive restriction of energy intake, the acceleration is partly due to increasing proportionate losses of non-fat tissues. The greater weight losses achieved by VLCD compared with conventional reducing diets may therefore be largely by virtue, and at the expense, of increasing losses of non-fat tissues per unit of weight lost. The assumptions and calculations underlying the above statements are given in greater detail in Appendix D and the question is further considered in Appendix F relating to a recent submission of new material by a VLCD manufacturer.

5.3.2 It is apparent that satisfactorily formulated VLCD carry negligible immediate risks. However, at energy intakes approaching starvation levels a penalty is paid for the accelerated weight loss in increased losses of non-fat tissues (see Appendix D), reflected in increasingly negative nitrogen balance. Calloway and Spector¹⁶ concluded that, when energy intake was below 400 to 600 kcal per day, this negative nitrogen balance could not be ameliorated in non-obese people by increasing protein intake virtually all being used to provide energy. Although obese people conserve nitrogen more effectively under hypocaloric dietary conditions than the non-obese,⁸ many users of VLCD fall into the latter category.

5.3.3 While supplementary protein may partly compensate for the overall losses from non-fat tissues, it is not known from which organs and tissues protein losses occur, nor whether the protein consumed in VLCD preparations is directed to the organs and tissues which have been depleted.

5.3.4 There are therefore a number of questions and uncertainties, as yet unresolved by experimental observations in man, which explain the continuing reservations expressed by some nutritional scientists on the indiscriminate use of VLCD in the management of obesity.

5.4 Protein losses from tissues

5.4.1 Estimates of nitrogen losses during weight reduction vary considerably, partly because of the difficulty of carrying out accurate long-term nitrogen balance studies in man. Allowing for the expected loss of excess adipose tissue associated protein, it seems likely that, at VLCD levels of energy intake, the obese person will remain in negative nitrogen balance regardless of the size of the protein component of the diet.¹⁶ There have been claims, however, that nitrogen equilibrium is attained after a few weeks²⁵ and even a report that the nitrogen deficit in the first 2 weeks was completely compensated by a gain during the next 6 weeks on a diet that supplied only 33 g of protein daily.¹⁹

5.4.2 Most of the investigative work has been carried out in the first few weeks of weight loss in the very obese. There is little or no information on nitrogen balance in those who were only moderately overweight or in obese subjects nearing target weight but nitrogen is lost more slowly during severely restricted energy intakes by the obese.⁸ Nor can the precise source and nature of the protein loss responsible for the negative nitrogen balance be demonstrated from the nitrogen balance measurements themselves.

5.5 Vitamin and mineral balance

5.5.1 Most of the VLCD preparations marketed in the UK contain at least 100 per cent of published Recommended Daily Amounts (RDA) of vitamins and minerals. These published RDA^{26, 27} are estimates of the amounts necessary for groups in a normal population to maintain health. They differ from group to group and with changing conditions (eg growth and pregnancy). They are added in the manufacture of VLCD preparations and cannot vary to meet special individual requirements. The absorption and utilisation of these quantities of micronutrients taken in a VLCD preparation over an extended period of time has not been investigated systematically. There is no clear assurance, for instance, that the daily quantities of micronutrients considered appropriate for healthy people on a normal mixed diet are necessarily appropriate for obese people consuming hypocaloric meal substitute preparations. Severe food energy restriction could increase the need for some and decrease the requirements for others.

5.5.2 In the absence of information relating to special micronutrient needs of people on VLCD, it seems reasonable to employ published RDA to set the

levels (see Appendix C). However, special requirements associated with unusual physiological or pathophysiological demands should be considered on an individual basis when undertaking weight loss with VLCD preparations or any other very restricted dietary regimen.

5.6 Long-term considerations

5.6.1 Claims for the safety of VLCD are based, *inter alia* and not unreasonably, on the absence of documented serious complaints from consumers. This does not exclude the possibility of unascertained adverse effects, nor does it bear upon the possibility of delayed adverse consequences which may become apparent only after continued use of VLCD or even long after a VLCD has been abandoned (eg acceleration of osteoporosis).

5.6.2 A major long-term consideration is the well documented liability to substantial weight regain after successful weight loss on any weight reducing regimen. There is no information as to whether such a relapse is more or less likely to occur after weight reduction by VLCD. It has been argued that if more lean body mass is lost with very restricted energy intake regimens, reduction of this more metabolically active tissue will make re-accumulation of fat more difficult to prevent.

5.7 Psychological implications

5.7.1 Obese people are generally no more likely to have primary emotional disturbances than their non-obese peers.²⁸ However, they do suffer the social effects of discrimination against the obese in present day society, a feature which may start at an early age and fuel the pressures which, in the most susceptible, lead to depressive states or eating behaviour disturbances such as anorexia nervosa or bulimia nervosa. Adverse psychological reactions attributed to the treatment of obesity may therefore, wholly or in part, be due to the effect of the obese state itself.

5.7.2 While there is some evidence that mild to moderate depressive symptoms may occur in a proportion of overweight people going onto weight reducing diets, successful dieting is normally accompanied by an elevation of mood.

5.7.3 There appears to be no reason to suppose that VLCD are more or less likely than other reducing regimens to provoke adverse psychological reactions. People of a particular frame of mind might be more likely to opt for the more rigorous and restricted nature of the VLCD, some perhaps out of desperation over past dietary failures. Others may be attracted by the apparent simplicity of total substitution of normal food by a preparation which relieves them of the need for 'calorie counting'.

5.7.4 Despite the potentially disturbed emotional setting in which VLCD preparations may be consumed, the relatively scanty evidence available does not indicate any particular liability of VLCD to worsen depression, and it has

been noted that substantial numbers of patients may experience a sense of improved psychosocial status.^{29, 30} Much may depend on the quality and quantity of support and advice received by the dieter as the psychosocial and psychological adaptations to VLCD are being made. Inadequate VLCD composition, deficient in vitamins and minerals, could lead to psychological symptoms of resulting deficiency states.

5.7.5 Expectations of VLCD preparations should not be extravagant. The early rapid weight loss and the shortening of a several months' long process of weight loss by just a few weeks must be set against possible costs and hazards. These include the possible social dislocation of complete withdrawal from normal foods.

5.7.6 In helping the patient to make a balanced decision about weight reduction, the doctor needs to bear in mind the psychological reinforcement arising from taking such a special slimming preparation or from the associated dramatic change of life style. For those who experience such gratifications it is important to emphasise the limited duration of all reducing diets and particularly those very low in calories; that the period on VLCD should not be unduly prolonged; that VLCD should be abandoned when the target weight is achieved; and that a life long change in eating habits will be necessary thereafter to prevent weight regain.

5.7.7 In addition to the clinical responsibility to warn against known contraindications to rigorous dieting, the doctor will need to decide on the scope of his or her responsibilities for supervising the diet and how that responsibility is to be discharged.

5.7.8 The promotion, distribution and consumption of some VLCD preparations are conducted with an almost evangelical zeal communicated to the dieter by way of the dietary counsellor system employed by some manufacturers. While this is doubtless of value in reinforcing the determination to succeed despite the discomforts of food deprivation, failure to live up to expectations may lead to loss of self esteem, guilt feelings and even resentment and hostility.

6. Therapeutic application of VLCD

6.1 Indications

6.1.1 Very Low Calorie Diets are normally taken to reduce excess weight. There is no mandatory clinical indication for the use of VLCD food substitutes and the preference of most physicians is to use more conventional diets consisting of normal foods but providing reduced energy intakes (800–1500 kcal) as the means of obtaining progressive and sustained loss. If, despite the provision of appropriate levels of supervision and support, the obese person is unable to lose weight, alternative approaches such as VLCD preparations may be considered. Acute caloric deprivation often results in an initial rapid decline in weight, much of it due to water loss. Occurring during the first few days on a VLCD, it may impress the user with the apparent efficacy of the regimen and reinforce the motivation to continue its use. This early response with VLCD may not have been noted with less rigorous reducing diets and may give rise to an erroneous belief that only VLCD are effective in obtaining weight loss in a particular individual.

6.1.2 Most of the Studies reported on the use of VLCD have been with individuals with a BMI above 30 in whom obesity carries clear health risks and where the reduction of obesity might be expected to reduce these risks. In such situations the hazards of obesity may be considered to justify the possible risks associated with the use of VLCD. This justification carries less force for the use of very restricted diets in the management of lesser degrees of obesity (so-called social obesity) in which the dieter's goals are largely aesthetic and where health risks are smaller.

6.2 Period on VLCD

6.2.1 Safety and efficacy of VLCD are judged on data derived from comparatively short-term studies, sometimes lasting only a week or two, usually carried out under close supervision within hospital wards, in special nutrition units or even among prisoners. There is little information on the effects of medium or long-term exposure to VLCD. It is reasonable to assume that the longer such restricted diets last, or the more frequently they are repeated, the greater the risk to the individual of suffering adverse effects of inadvertent deficiencies. As these dietary regimens are prolonged the more important it becomes to remain alert to possible development of significant deficiency states. Most firms marketing VLCD recommend their use for periods of no more than four weeks at a time. It is often less clearly recommended after what interval VLCD may be resumed, how often repeated and what nutritional habits should be adopted after VLCD is concluded.

6.3 Repetition

6.3.1 The relative efficacy and risks of single long term usage of VLCD versus repeated or intermittent use remain uncertain. Improved adaptive conservation of protein and reduced nitrogen losses are thought to favour the former approach; with the latter approach there may be better opportunity for nutrition education and behaviour modification with normal foods, in the hope of securing maintenance of the weight loss.

6.3.2 The nutritional arguments for comparatively long periods on normal foods between "courses" of VLCD preparations conflict with the major reason for the use of VLCD – a more rapid reduction to a target weight. In practice, many users of VLCD take the preparations virtually continuously until they obtain desired weight or become disheartened with their failure to do so.

6.4 Other observations

6.4.1 Attempts have been made to measure the composition of weight loss on VLCD but none has been entirely satisfactory. With the wide individual variation in protein (nitrogen) loss during severe energy restriction or starvation, nitrogen balance may not be achieved by some people. Studies of protein metabolism during VLCD use are based almost exclusively on nitrogen balance. This type of 'external accountancy' fails to indicate which tissues or organs are being depleted of protein.

6.4.2 Other than in clinically supervised trials, the users of VLCD are self-selecting. A large proportion of them do not suffer the major degrees of obesity; indeed some are within healthy weight ranges with a Body Mass Index below 25. These observations are derived from usage surveys conducted by or on behalf of the manufacturers themselves. Lean tissue loss is proportionately greater when people with lesser degrees of obesity undertake VLCD regimens and there may thus be proportionately greater risk for these users from acute, repeated or prolonged episodes of negative nitrogen balance.

6.4.3 With current marketing practices, VLCD are easily available to the general public. Those groups for whom VLCD are not recommended or in whom there are contra-indications should be familiar to doctors, other health professionals and diet counsellors who may be called upon for advice (see para 7.1.2), but there is little information as to how often VLCD are used inappropriately.

6.4.4 A major criticism of the use of VLCD and indeed most weight reducing regimens is the high prevalence of relapse into obesity after the achievement of major weight losses. The risk of weight regain may be greater in those who have lost relatively more lean body mass by very vigorous food energy restriction (see above). The end result of repeated cycles of rapid loss and regain may be to create the self-defeating situation of progressive loss of metabolically active tissue and its replacement by energy-rich adipose tissue. Research is needed into this important sequel to weight loss.

6.5 Potential risk of VLCD

6.5.1 There is a temptation for the obese, attracted by the prospect of rapid weight loss, to employ VLCD regardless of possible contra-indications (see paras 6.4.3 and 7.1.2) and even against medical advice. Clear warnings and recommendations on the packaging and enclosed literature will reduce the chance of unsuitable use, but there is a need for greater public and professional awareness of possible risks.

6.5.2 Medical and para-medical persons directly involved in the management or support of patients on VLCD should also be alert to the possibilities of over-prolonged use of VLCD preparations in spite of verbal and printed recommendations.

6.5.3 Some users try to accelerate weight loss by taking less than the recommended quantity of the VLCD preparation. This clearly increases the hazard of deficiency states and should be warned against.

6.5.4 A few people of normal weight may be attracted to VLCD preparations to meet some emotional need or to achieve unrealistically low target weights. These include young women who have a history of, or are at risk of developing, anorexia nervosa. Ballet dancers, jockeys and sportsmen who use VLCD to maintain weight or reach a sporting or riding weight limit, should be aware of the risks of undernutrition. There is, however, some evidence that physical exercise during hypocaloric weight loss can lessen the losses of non-fat tissues and so, at any rate for a few weeks, reduce this potential risk from VLCD.

6.5.5 There is potential scope for abuse in a marketing system in which consumers depend for advice on counsellors or advisers who work directly, or on a commission basis, for the manufacturers. Where income is generated by selling the product direct to the consumer, there is the risk that formal recommendations may be ignored or the systematic enquiry for recognised contra-indications (para 7.1.2) may be inadequate. Although this could be countered by the system of referral to a doctor such professional support is not unlimited in availability and a responsibility generated by the patient's decision is not one that will necessarily be accepted by the doctor. At the very least, adequate training and systematic supervision of the counsellors and advisers should be undertaken by the parent company with prompt dismissal if ethical requirements are not met.

7. Role of the doctor, other health professionals and diet counsellors

7.1 Medical supervision

7.1.1 Manufacturers of VLCD preparations in Britain all suggest to prospective clients that they should present their doctor with a copy of a leaflet prepared by the firm's consultants. These leaflets summarise the advantages of VLCD and specify certain contra-indications to their use. However, the information at present available suggests that fewer than half of all prospective users do in fact consult their own doctor before commencing VLCD.

7.1.2 The suggested contra-indications include serious cardiac disorders, cerebro-vascular disease, severe hepatic or renal disease, gout and pregnancy, conditions usually listed by the manufacturers on packaging or accompanying literature. However, other conditions might be regarded as relative or absolute contra-indications to the unsupervised use of VLCD and merit clinical concern. These include the following:

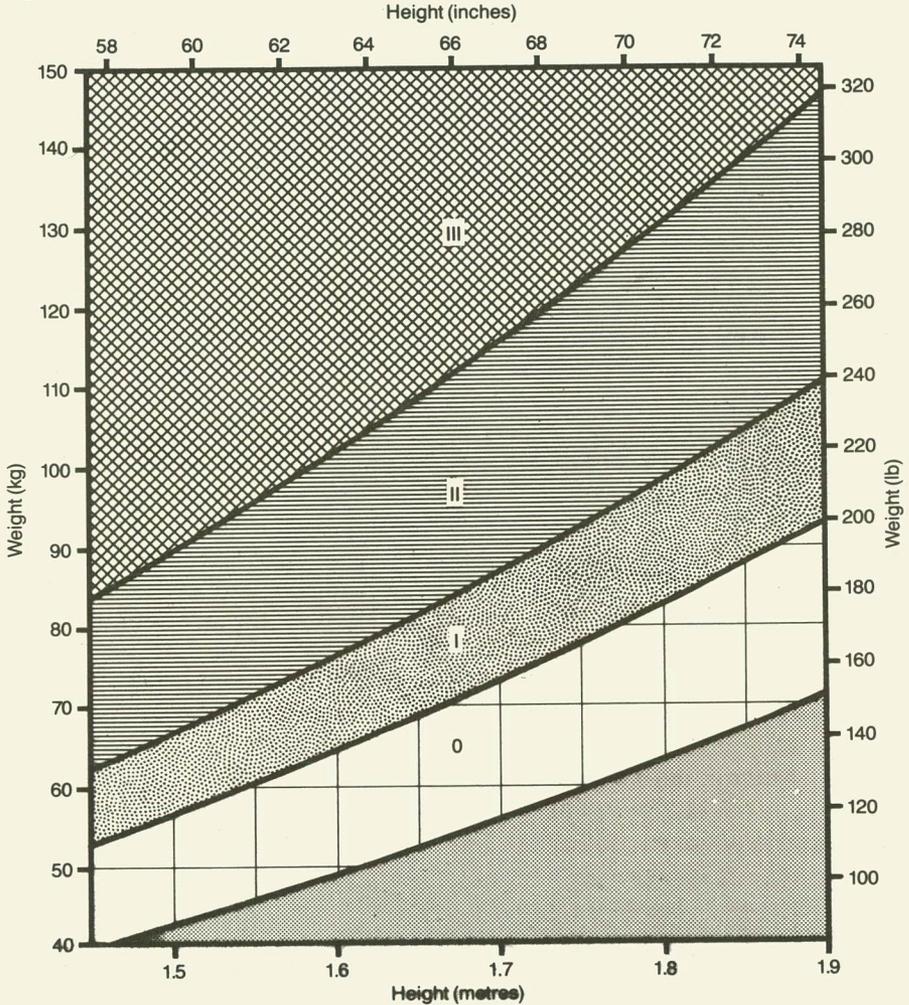
- (a) Individuals with abnormal psychological states including schizophrenia, depression of more than minor degree, those on lithium therapy, and those with severe behaviour disorders, especially if involving eating, alcoholism and drug abuse.
- (b) Persons with diabetes mellitus on insulin or oral hypoglycaemic drugs who, without appropriate adjustment of therapy, may be at risk from hypoglycaemia.
- (c) Patients with treated hypertension in whom the dosage of blood pressure lowering drugs may need to be reduced or stopped to avoid hypotensive episodes.
- (d) People with porphyria, active or latent, in whom acute attacks may be provoked by severe restriction of food energy intake.
- (e) Infants, children and adolescents, breastfeeding mothers and the elderly.

7.1.3 The role and responsibility of the personal doctor with a patient taking VLCD preparations will depend to some extent on whether the treatment was initiated by the patient or the doctor.

7.1.4 When the initiative comes from the patient and the doctor's opinion is sought, a professional view upon the suitability of VLCD in general should be

offered along with a warning of possible adverse effects. The decision to proceed lies with the patient and if so, the doctor's continued supervision may be requested. If this is agreed to, it might consist of setting a realistic weight target which often may be higher than the grade 0 shown in fig 7.1,* regular measurements of weight, enquiries for side effects, advice not to depart from manufacturers recommendations for use, and some preparation for continued control of normal food intake if the desired weight is achieved.

Figure 7.1: Degrees of obesity



Relation of weight to height defining the desirable range (0), and grades I, II and III obesity, marked by the boundaries of Body Mass Index (W/H^2) = 25–29.9, 30–40, and over 40 respectively (see para 7.1.4)

From Garrow (1981) with the kind permission of the publishers

- I = overweight
- II = moderately overweight
- III = severely overweight

*People may be designated by the band within which their weight and height intersect as “normal” weight (in band 0); overweight, plump or mildly obese (in band I); moderately obese (in band II) or severely obese (in band III).

7.1.5 Professional opinions differ on the place of VLCD in the treatment of obesity. Some doctors do not consider the use of VLCD preparations an appropriate or desirable approach to long-term control of obesity and will not initiate their use. Others may initiate the use of VLCD, sometimes as a last resort when a patient has failed to respond to conventional reducing diets or because it is thought that total diet replacement with VLCD is more likely to generate compliance.

7.1.6 If the doctor initiates the treatment with VLCD, then it should be in the full knowledge of the patient's health status and conducted under supervision, the intensity of which will be governed by the doctor's assessment of the patient's needs. The precise nature of the supervision may vary from patient to patient but could include periodic follow-up attendances with regular weight checks, systematic enquiry for symptoms, reinforcement and encouragement to maintain resolve and a decision whether or when to abandon VLCD and revert to a controlled normal diet. The doctor should institute measures to assist in the maintenance of lower weight when the VLCD is discontinued.

7.2 Non-medical supervision

7.2.1 Several of the firms marketing VLCD preparations offer the user an advisory and support service based upon the advice of their own dietary counsellors. The qualifications for such a role are variable and may, in some cases, consist of little more than having used the diet (successfully or not). The quality of counselling that an unqualified person can offer may be very limited, even if some brief and rudimentary 'training' has been offered by the manufacturers. There are only scanty mechanisms for monitoring the adequacy and validity of the advice given, so it is very difficult to evaluate its effects. Supervision of the client is often linked with the continued supply of the VLCD preparation on a commission basis. The most that such counsellors can be expected to do is to press the intending VLCD user to seek adequately qualified medical advice, to consider and advise appropriately if there are known contra-indications, to motivate the new recruit to maintain the regimen, and to advise prompt recourse to qualified assistance should worrying reactions develop.

8. Conclusions

8.1 Safety

8.1.1 The best way to reduce obesity is to follow a diet properly designed to reduce food energy to the point where it falls short of bodily energy expenditure. This may be assisted by increasing physical activity.

8.1.2 Very Low Calorie Diets are not generally regarded as a first choice means of achieving weight loss in obese people. Some people who have failed using conventional reducing diets will be attracted to VLCD preparations and use them with or without supervision, because of the high rate of weight loss that can be attained, and the apparent simplicity of taking a complete dietary replacement rather than following a plan for restricting normal foods.

8.1.3 The use of VLCD should be considered only after the failure of determined attempts to lose weight with conventional restriction of normal diets and this has included the advice and support of a person properly trained in the dietary management of obesity.

8.1.4 There are no hard and fast data on the most desirable rate of weight loss. It has been argued that, after the initial period of rapid weight loss, rates of 0.5–1 kg per week are optimal. Losses of up to 2 kg per week may be sought but even if it were possible for this to be entirely from adipose tissue, it could only be achieved by virtually complete starvation. In fact these high rapid rates of weight loss can only be achieved at the expense of non-fat tissues and the more rapid the rate of weight loss the greater will be the proportion of it derived from losses of lean tissue, generally considered to be undesirable in health terms.

8.1.5 The use of VLCD preparations is inappropriate for infants, growing children, women who are pregnant or breastfeeding.

8.1.6 People with porphyria and gout should not use a VLCD.

8.1.7 The use of VLCD for weight loss is unsuitable for the elderly.

8.1.8 People suffering from abnormal psychological states including schizophrenia, depression of a more than minor degree, people on lithium therapy, those with severe behaviour disorders involving eating, alcoholism or drug abuse, those suffering from heart disease, kidney disease, hypertension, cancer or diabetes treated with insulin or sulphonylureas should consider using a VLCD only with the advice and supervision of a doctor.

8.1.9 Prolonged use of VLCD carries potential hazards.

8.1.10 Little is known of the adverse effects of VLCD. Patients should be encouraged to report untoward or unexpected symptoms to the doctor and to the manufacturer concerned.

8.1.11 More information is needed on the long-term effects of both repeated short-term and of prolonged use of VLCD. Research into these should be encouraged. Further research is also required into the nature and composition of the non-fat tissues lost during VLCD.

8.1.12 The use of VLCD should be further reviewed in the light of new evidence from such research.

8.2 Composition and standards

8.2.1 Very low calorie diets should conform to compositional standards formulated either by a Manufacturer's Voluntary Code of Practice or by Government Regulations.

8.2.2 At daily food energy intakes below about 800 kcal the proportion of lean to fat tissue loss rises progressively. To reduce potential risks from undue loss of lean body tissue, VLCD preparations should provide a *minimum* of 400 kcal per day for women and 500 kcal per day for men and tall women (taller than 173 cm or 5ft 8in.), accompanied by 40 g and 50 g respectively of suitable protein per day.

8.2.3 Although preparations containing a high proportion of low quality protein with little or no added vitamins and minerals fall within our definition of Very Low Calorie Diet preparations, we recommend that in view of earlier experience with them, they should not be made commercially available.

8.2.4 All VLCD preparations should specify, for a day's supply, the total energy content, the quantity and source of protein, the composition with respect to fat and available carbohydrate and the content of vitamins and minerals. The UK Recommended Daily Amounts (RDA) of vitamins and minerals or the USA Recommended Daily Allowance should be stated. (See Appendix C.)

8.3 Efficacy

8.3.1 Weight loss with VLCD can be spectacular but such major reductions in body weight can only be achieved with loss of non-fat, as well as fatty, tissues. A return to nitrogen equilibrium after several weeks on the VLCD is possible in some individuals but negative nitrogen balance may persist for as long as the VLCD is taken.

8.3.2 Very Low Calorie Diets induce a high initial weight loss which can reach over 3 kg per week, but this loss includes considerable amounts of fluid

and non-fat tissue and is not sustained. Subsequent long-term high rates of weight loss may be at the expense of disproportionate depletion of non-fat tissues. The effects of weight loss constituted in this way are unknown.

8.3.3 Little is known of the restoration or permanence of losses of lean body mass, of the reconstitution of individual tissues or of the variation between different people in these respects which occurs after VLCD and a return to conventional dietary practice. There is no *prima facie* evidence of lasting impairment, but scientific data relating to this question are scanty.

8.3.4 There is little evidence on which to judge whether weight regain to previous levels of obesity is more or less likely after VLCD than after weight loss achieved by less rigorous regimens. Subsequent attempts at weight loss may be affected by a higher fat content of the reconstituted body mass. Nor is it known whether the ultimate establishment of new eating patterns to maintain lower weight is assisted or impeded by prior VLCD induced weight reduction.

8.4 Marketing

8.4.1 There are at present no special controls on the manufacture and marketing of VLCD (see Appendix E). To reduce the possible hazards of unsatisfactory preparations and to maintain ethical standards manufacturers should urgently consider the development of a Voluntary Code of Practice covering the composition, labelling, marketing and monitoring of VLCD. Failing this, Government action to amend Regulations to control the marketing of VLCD should be considered.

9. Recommendations

9.1 Recommendations to the general public

9.1.1 Members of the general public can estimate their degree of overweight or obesity by consulting Fig 7.1. If they wish to reduce weight they should always first try to do so by moderate restriction of their food energy intake along conventional lines, as advised by a qualified person. To prevent the re-accumulation of fat after successful weight reduction, it is important to maintain life-long restraint in eating behaviour.

9.1.2 With a properly designed conventional reducing diet, a weight loss of about 0.5–1 kg per week can be achieved by overweight but otherwise healthy people. Losses in excess of this may be undesirable because of the increased loss of protein from the lean body mass. The use of VLCD is not recommended as a method of weight reduction in the mildly obese, plump individual or in people with known contra-indications to its use.

9.1.3 People considering the use of VLCD are strongly recommended to check with their doctor that there are no major contra-indications. Medical supervision is required if the use of VLCD is to be prolonged beyond a few weeks or if courses are to be repeated frequently at short intervals.

9.1.4 Very Low Calorie Diets are totally inappropriate for use in infants who should not be put on any reduced calorie diet without professional advice and supervision. This recommendation is endorsed by the COMA Panel on Child Nutrition.

9.1.5 VLCD are not suitable for children because they are still growing and developing. Adolescents should not start such a diet without some medical supervision and monitoring for disturbances of eating behaviour. This recommendation is endorsed by the COMA Panel on Child Nutrition.

9.1.6 It is considered undesirable that adults with a BMI of 25 or less should start, or that those achieving this BMI should continue with, VLCD to achieve rapid weight loss.

9.1.7 Pregnant and breastfeeding women and the elderly should not consider using a VLCD as a way of losing weight unless advised to do so by a physician who will undertake to monitor the response.

9.1.8 People who know they are suffering from heart disease, kidney disease, hypertension, cancer, diabetes or other major medical or psychological

disorders should consider using VLCD as a way of losing weight only if advised to do so by their doctor.

9.1.9 As the sole source of nourishment, the use of VLCD should not exceed the period recommended by the manufacturers (up to 3 to 4 weeks at a time) without reverting to a normal mixture of foods.

9.2 Recommendations to the medical profession

9.2.1 Very Low Calorie Diets should be considered to achieve weight loss only if less rigorous reducing regimens (eg 800–1000 kcal) have been given adequate trial with suitable dietetic supervision and have failed because of the patient's inability to maintain the food restriction.

9.2.2 In general, VLCD are not suitable for infants, children and adolescents, women who are pregnant or breastfeeding or for the elderly.

9.2.3 There are certain clinical conditions which may be provoked or exacerbated by severe calorie restriction for example porphyria and gout. People with such conditions should not be treated with VLCD.

9.2.4 In certain other clinical conditions such as heart disease, kidney disease, hypertension, cancer and diabetes treated with insulin or sulphonylurea drugs, weight loss for obesity is more safely achievable by conventional methods of restricted food intake. Medical supervision, perhaps under hospital conditions, may be necessary if the use of VLCD is considered.

9.2.5 VLCD should be used with caution, if at all, when obesity is associated with certain major abnormal psychological states. These include depression of a more than minor degree, lithium therapy, schizophrenia, severe behaviour disorders, especially those involving eating, alcoholism and drug abuse. VLCD should be used only under close medical supervision.

9.2.6 A doctor approached for advice by a person preparing to use a VLCD for weight loss should ensure that conventional methods have been given adequate trial, be prepared to offer general information on dietary approaches to weight reduction, and to review the individual's medical history for the presence of specific contra-indications.

9.2.7 Patients should be warned not to exceed the manufacturer's recommended duration (3–4 weeks) for using the product as the sole source of nourishment. Prolongation or repetition require further advice and supervision.

9.2.8 Doctors should emphasise the importance of making rational life-long changes in eating behaviour to minimise the risk of regaining weight and reaccumulating fat during the period after VLCD.

9.2.9 Doctors should be on the look out for adverse reactions to VLCD. Reports of side effects from patients should be communicated to the manufacturers concerned.

9.3 Recommendations to manufacturers of VLCD

9.3.1 VLCD preparations should provide a minimum of 400 kcal per day for women and 500 kcal per day for men and tall women (taller than 173 cm). They should also provide respectively 40 g and 50 g per day of suitable protein.

9.3.2 The vitamin and mineral content should meet at least the UK Recommended Daily Amounts or USA Recommended Daily Allowances (RDA) (Appendix C). Manufacturers should modify formulations in response to changes in RDA and other advances in knowledge.

9.3.3 Manufacturers should try to ensure that consumers take the whole of a total food substitute. The most effective way is to make all the components available in a single package to reduce the scope for omission of any part of the diet.

9.3.4 VLCD should carry a statement clearly printed on the outside of the packaging warning purchasers that "you should consult your doctor before starting to use this product". A similar statement should appear prominently on any accompanying information leaflet or advertising material enclosed in the package. The absolute and relative contra-indications to the use of VLCD should be specified. Certain of these are mentioned in this report. A fuller compilation should form part of any voluntary code of practice formulated by the manufacturers (recommendation 9.3.7) or statutory Regulation.

9.3.5 VLCD should carry a statement clearly printed on the outside of the packaging stating the maximum period of use recommended as sole source of nourishment. A similar statement should appear prominently on accompanying information leaflets or advertising material enclosed in the packaging. Clear instructions as to the need for close medical supervision during prolonged or repeated use of VLCD should be given.

9.3.6 Manufacturers of VLCD should continue to improve their methods of collecting and collating reports of side effects from users, dietetic advisers, doctors and other sources and should make these reports available to the Health Departments.

9.3.7 The manufacturers of VLCD should hold themselves responsible for ensuring that counsellors and advisers acting on their behalf receive proper training on the use and possible abuse of VLCD. This should include instruction on the recognition and recording of side effects and medical advice and supervision.

9.3.8 People with a BMI below 25 should not use VLCD as a sole source of food.

9.3.9 In consultation with the Health Departments, manufacturers of VLCD should formulate a Voluntary Code of Practice which embodies these recommendations.

9.4 Recommendations to Government

9.4.1 Serious risks to health are associated with the use of Very Low Calorie Diet preparations containing substantial proportions of low quality protein or inadequate quantities of minerals or micronutrients and the sale of these products should not be permitted.

9.4.2 We recommend that VLCD preparations offered for sale as a total food substitute should meet the requirements in respect of daily food energy, protein, mineral and micronutrient intakes, and those recommendations regarding their composition, presentation, monitoring and marketing outlined in this Report.

9.4.3 The Government should enter into discussions with the manufacturers of VLCD to formulate a Voluntary Code of Practice to establish standards implementing these requirements and recommendations.

9.4.4 If a Voluntary Code of Practice cannot be agreed, the Government should make appropriate Regulations.

9.4.5 The Government should encourage users of VLCD and those supervising their use to report side effects of VLCD to the manufacturers as part of an ascertainment system for any serious adverse responses to VLCD. (see recommendation 9.3.6). The issue of an adverse effect report card with the VLCD preparation pack might encourage users to report such events.

9.4.6 The DHSS should issue a circular to the Medical Profession incorporating these recommendations on VLCD.

9.4.7 The Government should consider initiating research and the collation of published data on the long-term effects on health of the use of VLCD, including particularly the repeated or prolonged use of such preparations.

9.5 Recommendations to the media concerning the advertising of VLCD

9.5.1 In media presentations about VLCD, their possible misuse and the importance of independent qualified advice and supervision should be stressed.

9.5.2 Advertisements of VLCD to the public should emphasise the temporary nature of their use, the need to use them in accordance with the manufacturer's advice and the fact that once weight loss has been achieved, quite different measures will be required to prevent weight regain.

9.5.3 There is no evidence that VLCD regimes are more likely to achieve enduring weight loss than conventional weight-reducing diets, nor that they are more or less likely to be followed by weight regain than conventional diets. Claims for superiority in these respects over other diets are at present unsupported by valid data and are not allowable unless supported by new and satisfactory evidence.

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Appendices

Appendix A: Affiliations of Members of the Working Group

Chairman

Professor H Keen Unit for Metabolic Medicine, Department of Medicine, United Medical and Dental Schools of Guy's and St. Thomas's Hospitals, Guy's Campus, University of London.

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Appendix B: Acknowledgements

We wish to express our thanks to the following for their helpfulness.

Dr I M Baird	Cambridge Nutrition Ltd
Sir John Butterfield	
Dr A Coxon	
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Dr A Howard	
Mr A P Howard	
Mr J Howard	
Dr R B Howard	
Dr D Jones	
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Dr C Weinkove	
Ms C Roberts	Univite Nutrition
Mr C Rose	
Dr J Stordy	
Professor V Wynn	
Dr Z Hurst	Wander Ltd
Mr S Sigley	
Mr M Hanssen	Dietary Specialities Ltd
Ms L Quinn	

Appendix C: Recommended Daily Amounts (RDA) of some micronutrients

Nutrient	RDA		Country
Vitamin A	750	µg	UK
Thiamin	1.2	mg	UK
Riboflavin	1.6	mg	UK
Niacin	18	mg	UK
Vitamin B ₆	2	mg	USA
Folic acid	300	µg	UK*
Vitamin B ₁₂	3	µg	USA
Pantothenic acid	4	mg	USA
Biotin	100	µg	USA
Vitamin C	30	mg	UK
Vitamin D	2.5	µg	UK
Vitamin E	10	mg	USA
Vitamin K	70	µg	USA
Calcium	500	mg	UK
Chlorine	1700	mg	USA
Copper	2	mg	USA
Iodine	140	µg	UK
Iron	12	mg	UK
Magnesium	350	mg	USA
Phosphorus	800	mg	USA
Potassium	1875	mg	USA
Selenium	0.05	mg	USA
Zinc	15	mg	USA

UK Department of Health and Social Security. *Recommended Daily Amounts of food energy and nutrients for groups of people in the United Kingdom*. 1979, London HMSO.

USA National Research Council *Recommended Dietary Allowances*. 1980 Washington DC, National Academy of Sciences.

* The RDA for folate was withdrawn by COMA in 1981, but is still used for labelling purposes.

Appendix D: Composition of weight loss

Possible patterns of daily weight loss in a woman who maintains energy balance on 1800 kcal/day

Assume weight lost is either

Fat (energy 9000 kcal/kg) or

Fat-free mass (FFM) (energy value approx 1000 kcal/kg)

In starvation weight loss is about 50:50 fat:FFM⁸

In obesity excess weight is 75:25 fat:FFM, so these are the proportions in which excess weight should be lost.

Energy Balance (kcal per day)

	Normal	Starvation	Conventional reducing diet (800 kcal)	VLCD (a)†	VLCD (b)††
Output	1800	1620*	1720*	1760*	1760*
Intake	1800	0	800	330	330
Deficit	0	1620	920	1430	1430

Weight Loss (per day)

Fat (kg)	0	0.162	0.098	0.153	0.143
(kcal)	0	1458	887	1379	1287
FFM (kg)	0	0.162	0.033	0.051	0.143
(kcal)	0	162	33	51	143
TOTAL (kg)	0	0.324	0.131	0.204	0.286
(kcal)	0	1620	920	1430	1430
kg/week	0	2.27	0.92	1.43	2.00

VLCD(a)† calculation based on the assumption that the proportion of fat to non-fat tissue lost is 3:1 and resembles the pattern seen with conventional (800 kcal) reducing diet.

VLCD(b)†† calculation based on the assumption that the proportion of fat to non-fat tissue lost, is 1:1 and resembles the pattern seen in starvation.

* under conditions of energy balance about 10 per cent of energy output is attributable to diet-induced thermogenesis. On a restricted diet this thermogenesis is reduced roughly in proportion to energy intake, so in starvation it is 0, on 800 kcal it is 80 kcal, and on 330 kcal it is 33 kcal.

Appendix E: Existing controls on reducing diet preparation

1. The Food Labelling Regulations, 1984 include controls on slimming claims and on claims that a food is suitable to replace part of a daily diet, but there are no specific controls over foods that may be used to replace the whole of the normal diet. Nor are there any official compositional standards for such foods in the United Kingdom.

2. Claims that a food is an aid to slimming or weight control cannot be made unless the food is capable of fulfilling that claim; furthermore, such foods must state that they can help slimming only as part of a calorie controlled diet and they must also declare the energy value in kilojoules and kilocalories per 100 grams and their carbohydrate, protein and fat contents per 100 grams. A claim that a food has a reduced energy value requires a reduction of at least one quarter from the energy value of a similar food for which no such claim is made. A claim that a food has a low energy value requires that it provides no more than 167 kJ (40 kcal) per 100 grams or per 100 millilitres, and that a normal serving should also provide no more than 40 kcal. Vitamin and mineral pills may not claim to be slimming foods.

3. A food claiming to be a complete meal replacement must in addition state that it should not be used to replace the whole diet and that it should be supplemented by at least one daily meal having a high nutritional quality. There are no further controls, even though the Food Standards Committee Second Report on Claims and Misleading Descriptions³¹ recommend that such meals should contain at least 24 g protein and one third of the recommended daily intake of the nutrients for which the DHSS had made recommendations²⁶, but no more than 1500 kJ (350 kcal).

Appendix F: Evidence submitted by Cambridge Nutrition

While this report was being prepared Cambridge Nutrition submitted evidence to “demonstrate that any apparent protein loss” (on VLCD) “can be accounted for by the protein released during weight reduction.” They also submitted evidence to show that due to the diuretic action of VLCD there was a greater initial water loss than with conventional reducing diets, and they “believe that the extra water loss on VLCD may be between 2 and 3 kg”.

The Working Group accept the data presented, and also the conclusion that there may be an initial loss of 2–3 kg water with VLCD treatment. However they cannot accept the calculation of the amount of protein “released during weight reduction”. To calculate this “allowable” protein loss, Cambridge Nutrition have made the following assumptions:

- (a) The excess weight in obese people consists of 68 per cent fat and 32 per cent Fat Free Mass (FFM).
- (b) The FFM contains 25 per cent protein.
- (c) Weight lost is either fat or FFM with 25 per cent protein.

On these assumptions a person losing 10 kg in weight would be assumed to have lost 3.2 kg FFM which contained 0.8 kg protein: in other words 8 per cent of weight loss is “allowably” protein, however that weight loss is achieved. On these assumptions Cambridge Nutrition set out calculations to show that on VLCD the actual protein loss was less than the “allowable” amount, implying that after some time on VLCD the patient would have a relatively increased body protein store.

The Working Group was unable to accept this calculation for the following reasons:

- (a) The estimate of 32 per cent FFM in the excess weight in obese people was based on a study by James *et al.* (1978) using body potassium and skinfold measurements to compare the body composition of obese and lean people. More recent measurements by more accurate methods indicate that the correct value is 25 ± 3 per cent (Garraw & Webster, 1985).
- (b) Although some tissues contain 25 per cent protein, this is a higher value than that found by chemical analysis of whole cadavers, which show an average 20.5 per cent protein in FFM (Garraw, 1978). Furthermore studies on energy balance and nitrogen balance show that on a conventional reducing diet about 19 per cent of the FFM lost is protein (Garraw *et al.* 1979). Adipose tissue obtained by biopsy contains about 2.5 per cent protein (Garraw, 1974).
- (c) In view of the demonstration by Cambridge Nutrition that 2–3 kg (say 2.5 kg) of the initial weight loss may be water, not FFM, it is not

permissible to use the first 2.5 kg of weight loss to calculate “allowable” protein loss.

Some of the sets of data submitted by Cambridge Nutrition do not correspond with the cited published sources, and some are unpublished or in draft form. However for as much of the data as possible the results are set out below as presented by Cambridge Nutrition (Column A), as recalculated on the basis that the “allowable” protein loss is 19 per cent of 25 per cent (ie 4.75 per cent) of the weight loss (Column B), or that the allowable protein loss was 4.75 per cent of total weight loss less 2.5 kg (Column C). Figures refer to g protein for the whole study period.

EXAMPLE 1. Data of Howard & Baird (1977) ^a

31 g protein intake for 6 weeks ^b

Weight loss 16.2 kg

	A	B	C
Lost in urine & faeces	1523	1523	1523
Miscellaneous losses	216	216	216
Total losses	1739	1739	1739
Total intake	1386 ^c	1302	1302
External balance	-353	-437	-437
“Allowable” loss	1296	769	643
“Corrected” balance	+943	+332	+206

^a in this study the VLCD were administered after a period of total starvation which would tend to enhance the apparent N retention

^b this protocol is not reported in the publication cited

^c the protein intake appears to have been miscalculated.

EXAMPLE 2. Data of Wilson & Lamberts (1979)

31 g protein intake for 4 weeks

Weight loss 9.97 kg

	A	B	C
Lost in urine & faeces	1356	1356	1356
Miscellaneous losses	114	114	114
Total losses	1470	1470	1470
Total intake	924 ^a	868	868
External balance	-546	-602	-602
“Allowable” loss	979	473	355
“Corrected” balance	+251	-129	-247

^a the protein intake appears to have been miscalculated.

EXAMPLE 3. Data of Hanefield (1987) unpublished

33 g protein for 28 days

Weight loss 10.0 kg

	A	B	C
Lost in urine & faeces	966 ^a	966	966
Miscellaneous losses	110	110	110
Total losses	1076	1076	1076
Total intake	924	924	924
External balance	-152	-152	-152
“Allowable” loss	800	475	333
“Corrected” balance	+648	+323	+181

^a N excretion was measured in urine only: the faecal contribution has been estimated. It is notable that the calculated N output in the Hanefield studies is less than that observed in studies in which both urine and faeces have been collected and analysed.

EXAMPLE 4. Data of Hanefield (1987) unpublished

34.5 g protein for 28 days

Weight loss 9.7 kg

	A	B	C
Lost in urine & faeces	1120 ^b	1120	1120
Miscellaneous losses	110	110	110
Total losses	1230	1230	1230
Total intake	924 ^a	966	966
External balance	-306	-264	-264
“Allowable” loss	776	461	342
“Corrected” balance	+470	+197	+ 78

^a protein intake appears to be miscalculated

^b the footnote to the previous example also applies here.

EXAMPLE 5. Data of Ditschuneit et al. (1985)

33 g protein for 4 weeks

Weight loss 11.6 kg

	A	B	C
Lost in urine & faeces	1366	1366	1366
Miscellaneous losses ^a	?	?	?
Total losses	1366	1366	1366
Total intake	924	924	924
External balance	-446 ^b	-442	-442
“Allowable” loss	926	551	432
“Corrected” balance	+486 ^c	+109	- 10

^a no information is given in the publication about how N balance was measured

^b there appears to be a miscalculation

^c there appears to be a miscalculation.

EXAMPLE 6. Data of Ditschuneit et al. (1985)

33 g protein for 4 weeks

Weight loss 11.0 kg

	A	B	C
Lost in urine & faeces	1247	1247	1247
Miscellaneous losses ^a	?	?	?
Total losses	1247	1247	1247
Total intake	924	924	924
External balance	-323	-323	-323
“Allowable” loss	880	523	403
“Corrected” balance	+557	+200	+ 70

^a see footnote ^a above

EXAMPLE 7. Data of Alban Davies & Baird (1987) unpublished

33 g protein for 8 weeks

Weight loss 16.0 kg

	A	B	C
Lost in urine & faeces	2222.5	2222.5	2222.5
Miscellaneous losses	115.5	115.5	115.5
Total losses	2338	2338	2338
Total intake	1848	1848	1848
External balance	-490	-490	-490
“Allowable” protein loss	1280	760	641
“Corrected” balance	+790	+270	+151

Summary

The protein balance in the above 7 examples is therefore as follows:

	Example	1	2	3	4	5	6	7
As calculated in								
Column A		+943	+251	+648	+470	+486	+557	+790
As calculated in								
Column C		+206	-247	+181	+ 78	- 10	+ 70	+151

Conclusion

The Working Group note that in several examples the estimated average protein loss is no greater than that “allowable” on the basis of reasonable assumptions about the fat-free tissue associated with obesity. However it is not convinced by the evidence submitted that there is really a strongly positive protein balance on VLCD, so the question of protein sparing does not arise. The data analysed above are derived from severely obese patients who are known to conserve protein more efficiently than normal-weight subjects.

Any tissue proteins may be subject to the catabolic processes associated with severely energy restricted diets. Protein mobilised during adipose tissue reduction will not necessarily be redistributed to the most vulnerable organs and tissues.

The submission from Cambridge Nutrition does not address the point that more favourable protein sparing is achieved on conventional reducing diets than on VLCD.

Having reviewed the evidence submitted, the Working Group remained of the opinion that conservation of lean tissue during weight loss was an important issue, and that they were justified in suggesting a minimum value for the energy content of VLCD, and setting a limit of obesity below which it was considered unsuitable.

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