

**Vitamin and micronutrient
supplement advice given to post-
bariatric surgery patients by UK
dietitians**

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Abstract

This study was to determine the vitamin and micro-nutrient supplementation recommendations made by UK registered dietitians to patients following bariatric surgery. There is a well recognised risk of nutritional deficit following bariatric surgery. Twenty one members (10.5%) of “Dietitians in Obesity Management UK” responded to an anonymous on-line survey about their bariatric activity and nutritional recommendations to patients following “food limiting” and “nutrient absorption limiting” surgery. Nine respondents had each consulted with over 100 patients last year, with 85% of dietitians’ caseloads being within the NHS. Compared against the 2007 Inter-disciplinary European Guidelines on Surgery of Severe Obesity, 90% of dietitians were meeting the recommended nutritional supplement guidelines for food limiting procedures. Only one respondent (5%) was meeting the supplementation guidelines for nutrient absorption limiting procedures. Two dietitians were recommending additional vitamin or micro-nutrients to their patients’ general vitamin and micro-nutrient supplement following food limiting procedures. Four out of twenty dietitians, with smaller caseloads, were only recommending a general vitamin and micro-nutrient supplement to patients following nutrient absorption limiting procedures. The range of nutritional composition of products named by the dietitians was substantial, with iron, vitamin B₁₂, calcium and vitamin D levels below those known to prevent common nutritional deficiencies following bariatric surgery. Only five respondents (25%) stated that the results of laboratory tests influenced their recommendations. Increasing the awareness of the nutritional needs to this group of patients to all healthcare practitioners and exploration of the use of bariatric surgery specific nutritional supplements may reduce to risk of patients’ nutritional deficit.

Key words: vitamins, micro-nutrients, supplementation, nutritional deficiency, bariatric

Chapter 1

Introduction

The United Kingdom has witnessed a dramatic rise in the prevalence of obesity over the last third of a century (Knight, 1984; Bromley, Sprogston & Shelton, 2005; Northern Ireland Statistic and Research Agency, 2007; The Information Centre, 2008; Welsh Assembly Government, 2008).

What is Obesity?

Obesity can be defined as an excess accumulation of body fat and it is the amount of this excess fat that correlates to ill-health. The World Health Organisation [WHO] (2007) defines obesity, with its genetic-lifestyle aetiology and catalogue of pathological consequences, as a disease, with code number IDC-10 E.66. WHO (2000) define obesity as having a Body Mass Index (BMI) equal to or greater than 30 kg/m². As a subset of this category, the WHO (2000) define class III obesity as having a BMI equal to or greater than 40 kg/m². This is also known as morbid obesity (Thomas & Bishop, 2007).

Prevalence of Obesity in the United Kingdom

Using measured weights and heights, in 2006, 24% of adults in England were classified as obese (The Information Centre, 2008); in Northern Ireland, in 2005/2006, 24% of adults were classified as obese (Northern Ireland Statistic & Research Agency, 2007); in 2003, 23% of adults in Scotland were classified as obese (Bromley, Sprogston & Shelton, 2005) and in Wales in 2007, 21% adults were classified as obese (Welsh Assembly Government, 2008). There has been more than a three fold increase in obesity rates in the United Kingdom (UK) since 1980, when only 7% of adults were classified as obese (Knight, 1984). Unfortunately, the prevalence of obesity in England has been predicted to rise to 31.5% of adults in England, by 2010 (Zaninotto, Wardle, Stamatakis, Mindell & Head, 2006).

The morbid obesity prevalence for adults in England in 2006 was 1.0% men and 2.2% women (The Information Centre, 2008). In Northern Ireland, in 2006, 1.6% men and 3.5% women were classified as morbidly obese from information received from S. Bennett (personal communication, May 15, 2009). In Scotland, 1.6% men and 3.4% women were morbidly obese (Bromley, Sprogston & Shelton, 2005). In Wales the prevalence of morbid obesity in adults was 1.0% men and 2.0% women (Welsh Assembly Government, 2008).

What are the Causes of Obesity?

Obesity is the result of energy imbalance. The Government Office for Science, in 2007, used a systems mapping approach to gain insight into the biological and social complexity of obesity. The systems map, together with scientific and other evidence, confirmed that energy balance (or imbalance) was determined by a complex multifaceted system of determinants, where no single influence dominates (Vandenbroeck, Goossens & Clemens, 2007).

In summary the proven causative factors of obesity include biology and the impact of early life and growth patterns. Other contributory factors are food intake and activity behaviours and the living environment (technological advances, opportunities for physical activity and food and drink access). Economic drivers of food and drink consumption (the price of food and drink, food marketing, purchasing capacity and its impact on eating patterns), along with the impact of working practices, are also proven causative factors of obesity (Government Office for Science, 2007).

Why be Concerned about Obesity?

Obesity is known to lead to both chronic and severe medical problems. These have been long documented, but only formally classified by the WHO in 1997. Not only do these medical conditions adversely affect people's quality of life, but they create serious, rising financial and social burdens (Government Office for Science, 2007). Several conditions are associated with overweight and obesity, including type 2 diabetes, hypertension, coronary heart disease and stroke, metabolic syndrome, osteoarthritis and cancer (Kopelman, 2007).

Micro-nutritional Implications of Obesity

There is growing evidence about the generally poor micro-nutrient status in obese individuals. In a study of 232 morbidly obese individuals by Ernst, Thurnheer, Schmid and Schultes (2009) micro-nutrient deficiencies were found. Four point seven percent were deficient in magnesium; 24.6% for zinc and 3.4% for folate. In the higher BMI sub-sample, 32.6% showed selenium, 2.2% vitamin B₆ and 2.2% vitamin E deficiency. Ernst et al. (2009) demonstrated that 29.0% of 379 morbidly obese patients were thiamine deficient, whilst Farhanghi, Mahboob and Ostadrahimi (2009) established that 27.0% obese women in their study were deficient in serum magnesium.

Considering iron, Skroubis, Sakellaropoulos, Pougouras, Mead, Nikiforidis and Kalfarentzos (2002) suggested that 26.0% - 32.2% incidence of iron deficiency anaemia in patients seeking weight loss surgery, whilst Flancbaum, Belsley, Drake, Colarusso and Tayler (2006) noted 43.9% iron deficiency, prior to surgery.

Madan, Orth, Ticnansky and Ternovits (2006) found that of their 100 morbidly obese patients pre-operatively, 13% had abnormal levels and 5% were deficient in vitamin B₁₂, whilst Ernst et al. (2009) established 18.1% morbidly obese were deficient in vitamin B₁₂.

In the study by Goldner et al. (2009), vitamin D deficiency has been demonstrated to be more common in the obese. In their study of 41 patients undergoing surgery to assist with weight loss and 41 non-obese controls, 61% obese subjects and 12% controls ($p < 0.0001$) were vitamin D deficiency, with 90% compared with 32% controls ($p < 0.0001$) found to have vitamin D deficiency and insufficiency pre-operatively. Hamoui, Kim, Anthone and Crookes (2003) using the same definition of vitamin D deficiency, demonstrated 22% deficiency in 165 morbidly obese

patients. The possible mechanisms responsible for this deficiency are inadequate dietary intake, sequestration of vitamin D in adipose tissue (Holicks, 2005) and the inefficiency of obese subjects to increase their serum vitamin D levels when exposed to UVB radiation (Wortsman, Matsuoka, Chen, Lu, & Holick, 2000). With Vitamin D, Ernst et al. (2009) found 25.4% of their morbidly obese subjects with a severe 25-OH vitamin D₃ deficiency, which was accompanied by secondary hyperparathyroidism in 36.6% cases and Flancbaum et al. (2006) found 68.1% were 25-OH vitamin D deficient. Vitamin D deficiency treatment guidelines have been published (Holick, 2007).

Abnormality of calcium metabolism has been described in the morbidly obese (Hamoui, Anthone & Crookes, 2004). The prevalence of hyperparathyroidism is high in the morbidly obese, but serum calcium tends to be preserved within the normal range, although 25% of patients prior to weight loss surgery have sub-clinical calcium deficiency (Hamoui et al., 2004). A possible explanation for this is inadequate calcium intake. A small study of 30 women awaiting weight loss surgery, by de Campos, Dalcanale, Pajecki, Garrido & Halpen (2008) established that just over half the recommended calcium intake was being ingested.

Treatment of Obesity

Treatments are of limited effectiveness, but there have been some successes (Wilding, 2007). Being obese is often seen as being the patient's own 'fault' and medical and other healthcare practitioners are rarely trained in obesity and its management.

Treatment is often started in the absence of an appropriate support programme and is frequently unsuccessful. Effective programmes offer ongoing support, with realistic weight loss goals and monitoring of the effects of treatment. Long term follow-up is essential if weight regain is to be avoided (Avenell et al., 2004).

Dietary modification (Avenell et al., 2004a), increased physical activity (Bensimhon, Kraus & Donahue, 2006), behaviour approaches (Avenell et al, 2004b), combined approaches (Avenell et al., 2004b) and pharmacotherapy (Sjostrom et al., 1998; James et al., 2000; McNulty, Ur & Williams, 2005; Wilding, 2007) have been shown to be effective in short term weight loss and are recommended by the National Institute for Health and Clinical Excellence [NICE] (2006).

However, bariatric ('baros' meaning 'heavy' in both ancient and modern Greek) surgery, having evolved over the last fifty years, is now recommended as a treatment option for people with class III obesity or for those with a BMI greater than 35 kg/m² with other significant disease (NICE, 2006). Bariatric surgery is recommended as a first line treatment for people with a BMI greater than 50 kg/m² (NICE, 2006).

Overview of the Main Types of Bariatric Surgical Procedures

The three main types of surgical procedures performed in the UK are:

- Restrictive such as laparoscopic adjustable gastric band (LAGB)
- Restrictive / malabsorptive such as Roux-en-Y gastric bypass (RYGB)
- Malabsorptive / restrictive such as biliopancreatic diversion (BPD) with duodenal switch (BPD DS).

Since NICE (2006) recommended bariatric surgery as a treatment option for morbid obesity there has been a rise in the number of procedures performed by the NHS, but only 1,890 procedures were performed in England in 2006/2007 (The Information Centre, 2008). In Scotland, the number in 2007 was 185 (Information Services Division, 2009). In Wales, the number of bariatric procedures performed, according to information received from M. Y. Wong (personal communication, June 11, 2009) 12 procedures were performed in 2007/2008 and in Northern Ireland with information received from C. Kennedy (personal communication, May 19, 2009) less than five procedures have been performed since 2002/2003. The number of procedures performed in the private sector on British people (both here and abroad) is unknown.

Laparoscopic Adjustable Gastric Band (LAGB)

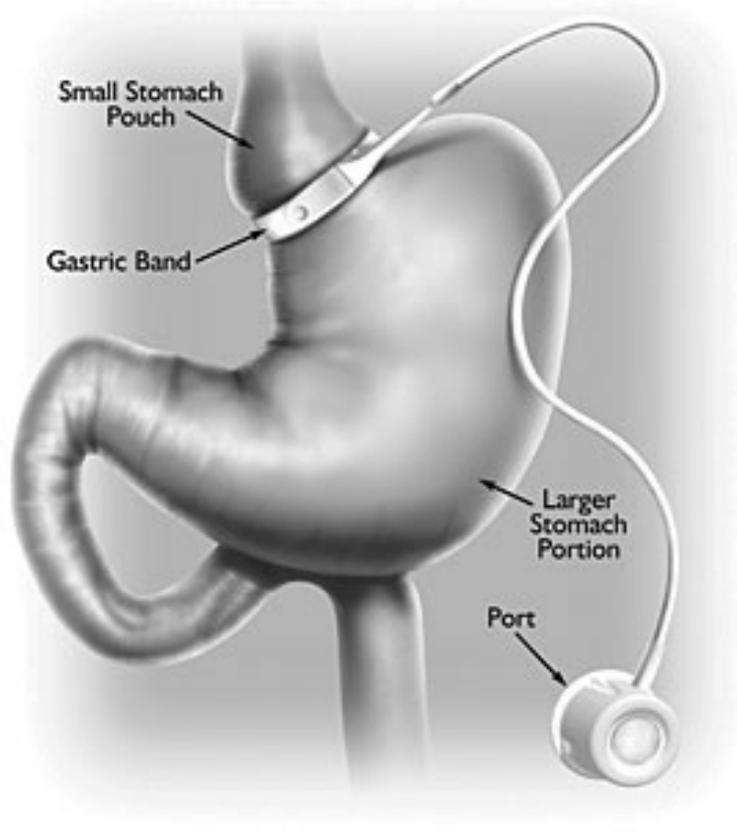


Figure 1 Diagrammatic Representation of an Adjustable Gastric Band

This is a purely restrictive procedure and the nutrient absorbing capacity of the gastrointestinal tract remains intact. The adjustable gastric band is a hollow band made of silyastic. Under general anaesthesia and usually laparoscopically the band is placed around the upper third portion of the stomach. This creates a small stomach pouch causing early and lasting satiety. Attached to the band is a tube that ends with a port attached to abdominal muscles just below the ribs. The purpose of the port is to provide access to the band to add sterile saline which fills the band, causing increased restriction of the stomach. The band is empty on surgical placement. Once the swelling around the stomach has settle, usually six weeks after surgery or whenever a

plateau in weight loss is reached, a radiologist injects a small volume of sterile saline in the band via the port. This is repeated incrementally until weight loss of the desired velocity is achieved or weight lost is maintained.

Boudreau and Hodgson (2007) concluded following their systematic review that LAGB has been shown to produce a significant loss of excess weight while maintaining low rates of short term complications and reducing obesity related comorbidities. The mean age for this procedure was 40.7 years (Cunneen, 2008). The systematic review by Tice, Karliner, Walsh, Peterson and Feldman (2008) clarified that after one year, patients with LAGB lost 48% of their excess body weight, with 50% having resolution of their diabetes. Peri-operative mortality was less than 0.5% with peri-operative complications at five percent. However, 24% require long term reoperation.

Roux-en-Y Gastric Bypass (RYGB)

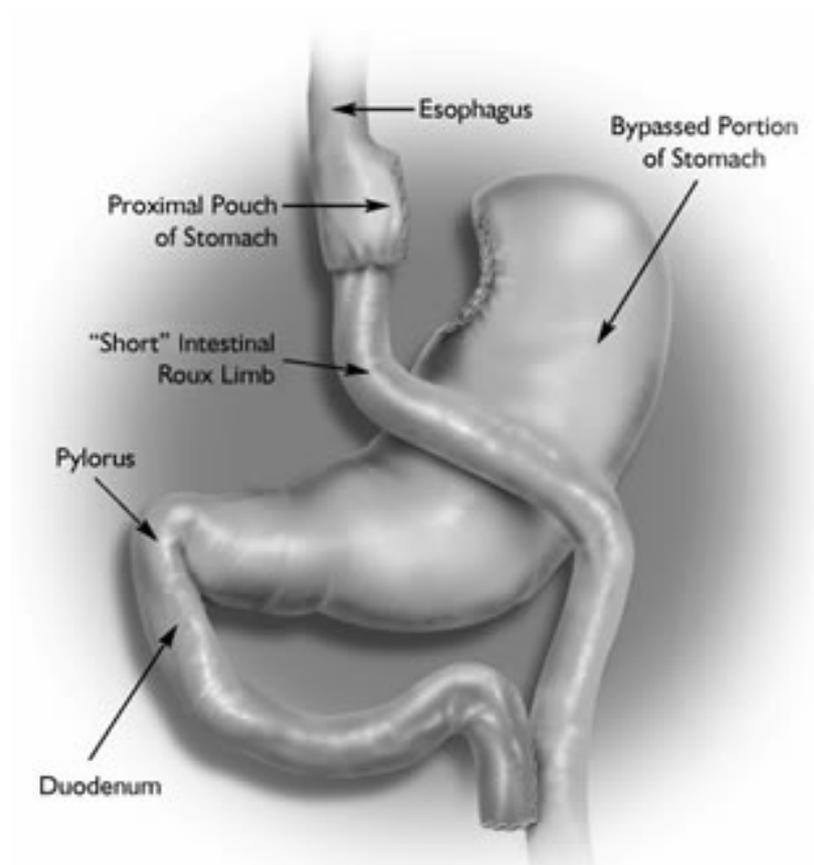


Figure 2 Diagrammatic Representation of a Roux-en-Y Gastric Bypass

This is a mixed restrictive / malabsorptive procedure. The RYGB limits the amount of food consumed and causes a degree of malabsorption. This procedure is performed laparoscopically under general anaesthesia. The normal small bowel is 600 to 1000 centimeters (cm) in length. The small bowel is divided about 45 cm below the lower stomach outlet, and is re-arranged into a Y-configuration, to enable outflow of food from the proximal pouch of the stomach, via a "short" intestinal Roux limb. In the proximal version, the Roux limb is constructed with a length of 80 to 150 cm. This causes some malabsorption of the foods ingested. If the Y-connection is moved

farther down the gastrointestinal tract, the amount of bowel capable of fully absorbing nutrients is progressively reduced, and in the 'distal' version this is usually 100 to 150 cm from the lower end of the small bowel. This causes greater malabsorption of food. Difficulty in accurately measuring the Roux limb in laparoscopically performed procedures has been recognized and has implications on the nutritional deficiencies experienced by patients (Hamoui et al., 2003). Research papers often neglect to identify the limb length of the RYGB, making interpretation of results difficult (de Campos, Dalcanale, Pajecki, Garrido & Halpern, 2008; Vargas-Ruiz, Hernández-Rivera & Herrera2008).

Patients experience very rapid onset of a sense of stomach-fullness, followed by a feeling of growing satiety, or "indifference" to food, shortly after the start of a meal. The systematic review by Tice et al. (2008) confirmed that 76% of excess body weight was lost after one year following RYGB, with 78% resolution of diabetes. Peri-operative mortality was less than 0.5%, with a nine percent risk of peri-operative complications with RYGB. However, long term reoperation rates were low (16%).

Bilio-pancreatic Diversion (BPD)

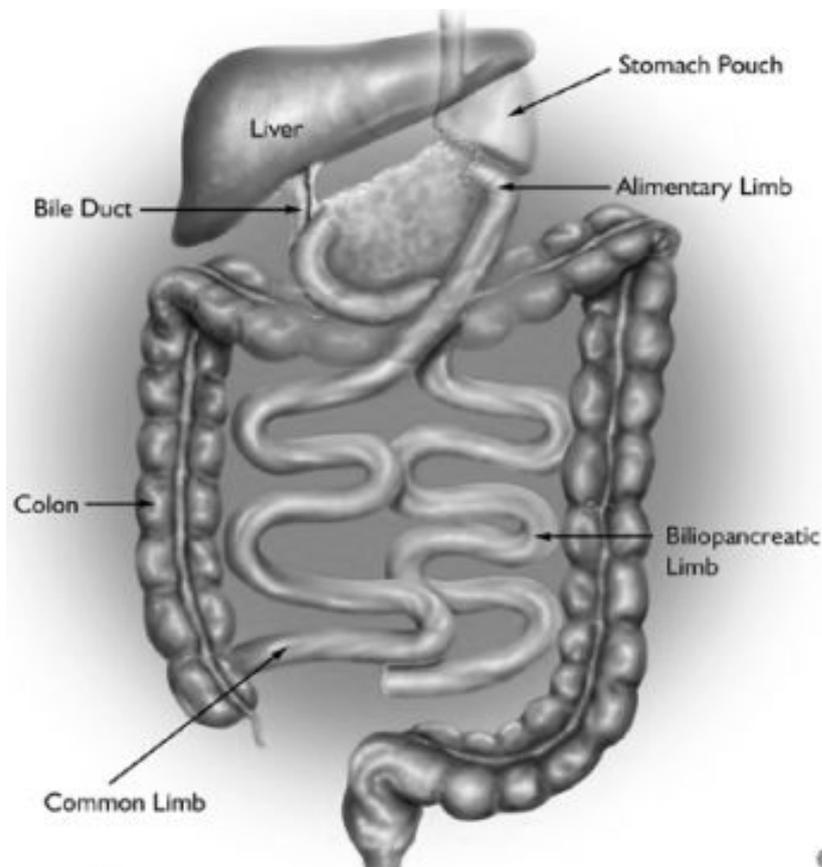


Figure 3 Diagrammatic Representation of a Bilio-pancreatic Diversion

The BPD has two components. Firstly, a limited stomach removal that results in reduction of oral intake, inducing short term weight loss. The second component of the weight loss operation is a construction of a long limb Roux-en-Y anastomosis with a short common intestine length of only 50 cm. This creates a significant malabsorptive component which acts to maintain weight loss long term. The advantages of this operation are the ability to eat large quantities of food and still achieve long term weight loss results (Scopinaro, Gianetta & Civalleri, 1996). Disadvantages of the procedure are the association with loose stools, intestinal ulcers, foul smelling stools and flatus. The most serious potential complication is protein

malnutrition, associated with hypoproteinaemia, anaemia, oedema and hair loss (Scopinaro et al., 1996).

Scopinaro et al., (1996) published the long term results of this operation, reporting 72% loss of excess body weight, maintained for 18 years. However, specific late complications included anaemia (less than 5%), stomal ulcer (2.8%) and protein malnutrition (7% with 1.7% requiring surgical revision by common limb elongation or by restoration). The conclusion was that BPD was a very effective procedure but potentially dangerous, if used incorrectly.

Bilio-pancreatic Diversion (BPD) with Duodenal Switch (DS)

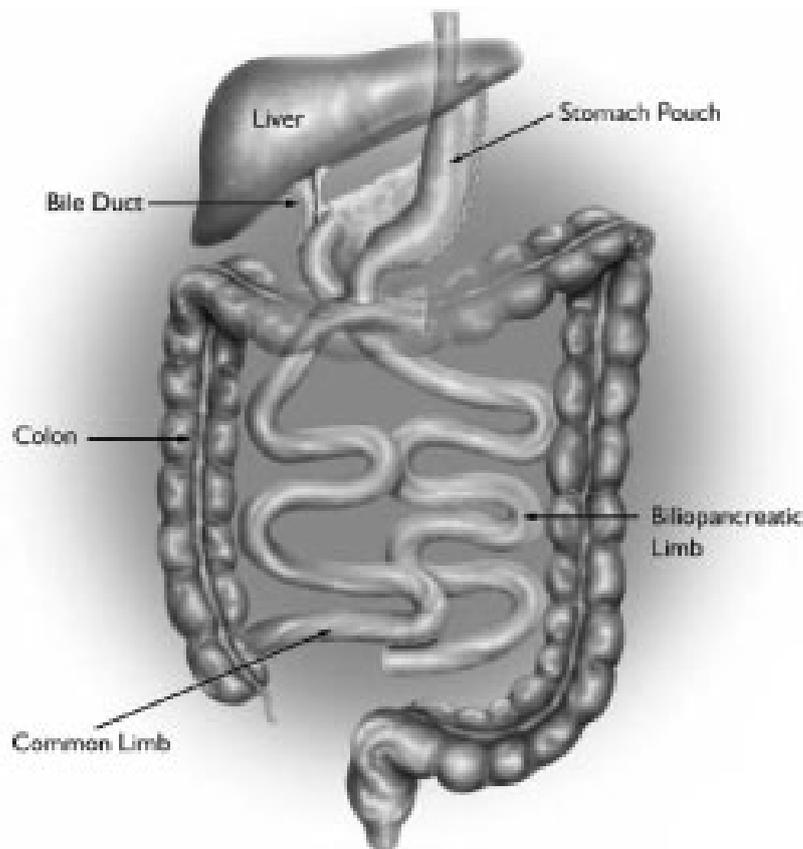


Figure 4 Diagrammatic Representation of a Bilio-pancreatic Diversion with Duodenal Switch

The DS is a modification of the BPD designed to prevent ulcers, increase the amount of gastric restriction, minimize the incidence of dumping syndrome and reduce the severity of protein-calorie malnutrition. The DS works through an element of gastric restriction as well as malabsorption. The stomach is cut vertically, leaving a tube of stomach that empties via the preserved pylorus into a very short (2 - 4 cm) segment of duodenum. The malabsorptive component is essentially identical to that of the BPD. The duodenum is tolerant of stomach acid and therefore is much more resistant to ulceration compared to the small intestine. The BPD involves an anastomosis

between the stomach and the intestine, the DS involves an anastomosis between the duodenum and the intestine. The intestine is sewn to the end of the duodenum which remains in continuity with the stomach. The other side of the duodenum will carry all the bile and pancreatic secretions. There is a lack of a “dumping syndrome”.

However, dumping syndrome may help patients avoid eating sugary and high fat foods which would adversely affect weight loss (Hess & Hess, 1998; Marceau et al., 1998). Malabsorption of fat soluble vitamins, iron deficiency and protein-calorie malnutrition are complications associated with this procedure (Hess & Hess, 1998; Marceau et al., 1998).

Micro-nutritional Implications following Bariatric Surgery

There is substantial clinical evidence of nutritional deficiencies following bariatric surgery (Ledoux et al., 2006; Czerwińska, Marcinowska-Suchowierska, Walicka, Lisik & Wierzbicki, 2007; Folope, Coëffier & Déchelotte, 2007; Toh, Zarshenas & Jorgensen 2009). The nutritional deficiencies that occur after bariatric surgery depend significantly on the type of surgery performed.

Restrictive procedures such as gastric banding are the least likely to cause nutritional deficiencies. However, deficiencies may occur because of the limitation of food intake and food avoidance. Ledoux et al (2006) established that just over half of patients with LAGB became intolerant to meat, which has a high protein and micro-nutrient density (Ledoux et al. 2006).

Restrictive / malabsorptive procedures such as RYGB and malabsorptive / restrictive procedures such as BPD have a greater tendency to result in serious nutritional problems due to the extensive surgically induced anatomical changes in the gastrointestinal tract.

The most commonly reported micro-nutrient deficiencies are of iron, vitamin B₁₂, calcium and vitamin D (Malinowski, 2006). Although there is good evidence for deficiencies to occur in magnesium (Dolan, Hatzifotis, Newbury, Lowe & Fielding, 2006); zinc (Cominetti, Garrido & Cozzolino, 2006); selenium (Dolon et al., 2006); copper (Griffith, Liff, Ziegler, Esper & Winton, 2009); vitamin A (Dolon et al., 2004); vitamin B₁ particularly with persistent vomiting (Chang, Adams-Hurst & Provost, 2004); vitamin E (de Luis, Pacheco, Izaola, Terroba, Cuellar & Martin, 2008); vitamin K (de Luis et al., 2008) and folate (Gasteyger, Sutter, Calmes, Gaillard & Giusti, 2006). Iron, vitamin B₁₂, vitamin D and calcium deficiencies following bariatric surgery will be examined in more detail.

Iron

After both purely restrictive and mixed restrictive and malabsorptive procedures, patients are at risk of iron deficiency and anaemia, which are the most commonly reported nutritional complications following bariatric surgery (Bloomberg, Fleishman, Nalle, Herron & Kini, 2005). However, patients following the mixed restrictive and malabsorptive procedures are more at risk and their pathogenesis are due to a combination of factors:-

1. The reduced capacity of the gastrointestinal tract to reduce dietary Fe^{3+} into the more absorbable Fe^{2+} ion due to the reduction in gastric hydrochloric acid production.
2. The bypass of the duodenum and proximal jejunum, the chief site of iron absorption in the gastrointestinal tract.
3. Intolerance to heme rich foods (Bloomberg et al., 2005).

In restrictive procedures, the incidence has been reported as high as 32% for iron deficiency and 46% for anaemia, four years after vertical banded gastroplasty (Kalfarentzos, Kechagias, Soulikia, Loukidi & Mead, 2001).

Vargas-Ruiz, Hernández-Rivera and Herrera (2008) established that iron deficiency was seen in 40.0% patients at two years and 54.5% of patients at three years, following RYGB. At the two year follow-up, 46.6% of the patients had already developed anaemia and 63.6% at three years.

Skroubis et al., (2002) established that at two years post BPD 15.2% of patients had low ferritin levels. Varma et al. (2008) found that patients having undergone BPD with DS had a significantly lower hemoglobin ($P = 0.02$), relatively lower ferritin levels and required more additional parenteral iron treatment after the initial resolution of anemia ($P = 0.001$) when compared with proximal RYGB patients

presenting with anaemia requiring parenteral treatment.

Both iron deficiency anaemia and anaemia of chronic inflammation present with low serum iron levels (Ausk & Ioannou, 2008). Most studies reporting anaemia after bariatric surgery lack serum ferritin determinations, so that the relative contribution of inflammation to anaemia cannot be assessed (von Drygalski & Andris, 2009). Also, a significant number of anaemias after bariatric surgery remain unexplained and may be attributable to less frequently seen micro-nutrient deficiencies such as copper, fat soluble vitamins A and E, or an imbalance in zinc intake (von Drygalski & Andris, 2009). Menstruating or pregnant women and adolescents are particularly predisposed toward developing iron deficiency and microcytic anaemias after bariatric surgery (Love & Billett, 2008).

Therefore, pre-operative assessment of the haematological status of patients is recommended (Ernst et al., 2009). The American Association of Clinical Endocrinologists [AACE], The Obesity Society [TOS] and the American Society for Metabolic and Bariatric Surgery [ASMBS] (2008) recommended that post operatively iron status should be monitored in all bariatric surgical patients for life and then appropriately treated. AACE / TOS / ASMBS (2008) proposed that oral administration of ferrous sulphate, fumarate or gluconate (320 mg twice a day) may be needed to prevent iron deficiency in patients who have undergone malabsorptive / restrictive procedures. Intravenous iron infusion with iron dextran, ferric gluconate or ferric sucrose may be needed if oral iron supplementation is ineffective at correcting the iron deficiency (Varma et al., 2008).

Vitamin B₁₂

It may be considered that restrictive procedures do not place the obese patient at increased risk of vitamin B₁₂ deficiency, since the gastrointestinal tract remains intact. However, these patients are often nutritionally compromised prior to their surgery. Additionally, 65% of LAGB patients experience food intolerance. Milk, dairy products, meat, meat products, fish and fish dishes are the main contributors of vitamin B₁₂ (Henderson, Gregory, Irving & Swan, 2003) and these are the food groups often causing difficulty (Ledoux et al., 2006).

However, deficiencies in vitamin B₁₂ are more widely associated with mixed restrictive and malabsorptive procedures. In a paper by Toh et al. (2009), 11% of patients one year post their proximal RYGB were vitamin B₁₂ deficient. In a study by Vargas-Ruiz et al. (2008), it was established that vitamin B₁₂ deficiency was observed in 33.3% at two years and in 27.2% at three years, of the 30 RYGB patients studied. This occurred despite multi-vitamin supplementation being prescribed to all patients. In the normal gastrointestinal tract acid and peptic hydrolysis in the stomach helps liberate the vitamin. In the duodenum, the vitamin binds to intrinsic factor, released from the parietal cells of the antrum of the stomach. The combined intrinsic factor and vitamin B₁₂ is absorbed in the terminal ileum. Obviously, this process is interrupted following mixed restrictive and malabsorptive procedures. Skroubis et al. (2002) used linear regression from the data of the first six months after surgery to predict the time of onset of vitamin B₁₂ deficiency. The researchers predicted that following proximal RYGB, deficiency was most likely to occur at 10.7 months post operatively, and with the BPD with DS, at 7.9 months after the operation.

Vitamin D

Bone mineral metabolism in obese individuals generally and specifically in patients having undergone all types of bariatric surgery is a complex topic.

Olmos, Vazquez, Amado, Hernandez and Macias (2008) demonstrated a rise in 25-dihydroxycholecalciferol following vertical banded gastroplasty, suggesting its release from adipose tissue as vitamin deposits are reduced, particularly as their subjects were not supplemented.

Slater et al. (2004) identified 63% distal RYGB patients as having vitamin D deficiency four years post operatively. Despite supplementation, Hamoui et al. (2003) found that although subjects' median vitamin D levels rose post operatively, deficiency was still present in 17% distal verses 10% proximal RYGB patients, one year after surgery.

Ybarra et al. (2005) demonstrated that the rates of vitamin D deficiency before and after bariatric surgery were not significantly different. This suggests that pre- and post operative factors contribute to vitamin D deficiency. It is not just the fact that vitamin D is primarily absorbed in the jejunum and ileum that influences deficiency.

There is a close interplay between calcium, vitamin D and parathyroid hormone (PTH). Coates, Fernstrom, Fernstrom, Schauer & Greenspan (2004) demonstrated that following proximal RYGB despite supplementation, vitamin D levels remained low, with elevated PHT levels, six - nine months following surgery. de Campos et al. (2008) demonstrated that eight years after RYGB, without supplementation, 90% of their 77 patients had vitamin D deficiency and elevated PTH.

Newbury, Dolan, Hatzifotis, Low and Fielding (2003) established that 50% post BPD patients had low vitamin D levels, three years after surgery, despite supplementation.

Goldner et al. (2009) demonstrated that vitamin D replacement as high as 5,000

i.u./day (125 µg/day) is safe and necessary in many patients to treat vitamin D deficiency following RYGB. Clay, Cohen and Preen (2007) suggested that a once yearly intramuscular dose of vitamin D of 600,000 i.u. (15,000 µg) was a simple and safe method to normalise vitamin levels after BPD.

Davies, Baxter and Baxter (2007) concluded that patients most at risk of developing bone mineral density problems after surgery were patients with a BMI greater than 50 kg / m², post menopausal women, patients who experienced the greatest weight loss after surgery and patients who had high bone turnover prior to surgery.

calcium

In both the obese and in patients having undergone bariatric surgery, bone mineral metabolism is a complex topic.

Calcium deficiency has been reported as high as 25%, nine - eighteen months post operatively (Hamoui et al., 2003), to only 2% (Youssef et al., 2007), following mixed restrictive and malabsorptive procedures. The cause of this deficiency is thought to be ingested food bypassing the principle sites of calcium absorption, which are the duodenum and proximal jejunum. The defective absorption of fat soluble vitamin D, which promotes calcium absorption may also have a role. This relative lack of calcium stimulates the production of PTH which causes an increased production of 1, 25–dihydroxycholecalciferol and increases reabsorption of calcium from bone. Raised PTH levels have been determined in 53.3% of patients two years post operatively (Youssef et al., 2007). Research by DiGiorgi et al. (2009) demonstrated that if both LAGB and proximal RYGB patients were supplemented with 1200 mg calcium and between 800 – 1200 i.u./day (20 – 30 µg / day) vitamin D per day, they could improve their bone metabolism abnormalities related to obesity. Furthermore, adequate supplementation for proximal RYGB patients may attenuate the increased risk for bone loss associated with malabsorption from the bypass (DiGiorgi et al. 2009). Considering malabsorptive / restrictive procedures, Newbury et al. (2003) established that 26% of 82 patients had hypocalcaemia and elevated PTH, three years after BPD, despite 83% taking multi-vitamin supplementation.

Clinical Practice with regard to Vitamin and Micro-nutrient Supplementation

In a survey of 109 bariatric surgeons, back in 1999, Brolin and Leung established that after all types of RYGB, 96% of surgeons prescribed multi-vitamins, 63% gave iron and 49% gave vitamin B₁₂. Whilst after BPD, 96% of surgeons gave multi-vitamins, 67% gave iron, 42% gave vitamin B₁₂, 97% gave calcium, 63% gave fat-soluble vitamins and 21% gave protein supplements. The bariatric surgeons were asked to estimate nutritional deficiencies after all types of RYGB. They estimated 16% iron, 12% vitamin B₁₂, 14% anaemia and 3% calcium. They estimated the nutritional deficiencies after BPD as 26% iron, 11% vitamin B₁₂, 21% anaemia, 18% protein, 16% calcium, and 6% fat-soluble vitamins.

Gasteyger, Suter, Gaillard and Giusti (2008) supplemented all RYGB patients with a standardized multi-vitamin and mineral preparation between the first and the sixth post operative months. It contained the following daily amounts of vitamins and minerals 3 µg vitamin B₁₂, 5 µg vitamin D₃, 120 mg calcium and 8 mg iron amongst other vitamins and micro-nutrients. Three months after RYGB, 34% of these patients required at least one specific supplement in addition to the multi-vitamin and mineral preparation to treat deficiency. At six and 24 months, this proportion increased to 59% and 98%, respectively. At two years vitamin B₁₂ was the most frequently prescribed supplement (80%: 1 mg/day), followed by iron (60%: 80 mg/day), calcium + vitamin D₃ (60% Calcium: 1000 mg/day and vitamin D₃: 0.02 mg/day).

Malone (2008) following her review of the common nutritional deficiencies after bariatric surgery concluded that healthcare professionals, especially those who practiced outside large bariatric centres, must be aware of the supplements required by patients who have had bariatric surgery. Many patients fail to attend or are not offered

lifelong follow up from their surgery team and are managed by their primary healthcare teams and community pharmacists. These teams need to be aware of the selection of multi-vitamin and nutritional supplements that are required in this group of patients.

In 2007 the result of the work by the Bariatric Scientific Collaborative Group, the Inter-disciplinary European Guidelines on Surgery of Severe Obesity were published. The recommendation for patients undergoing “food limiting” operations such as LAGB were that “supplement of vitamin and micro-nutrients should compensate for their possible reduced intake”. Also stating “metabolic and nutritional status should be regularly monitored to prevent vitamin deficiencies and allow appropriate supplementation”. The European Guidelines for patients undergoing proximal RYGB were that “vitamin and micro-nutrient supplements (oral) should routinely be prescribed to compensate for their possible reduced intake and absorption”. Additionally, “laboratory tests should be carried out annually” and “as a result of those tests it may be necessary to correct deficits by parenteral administration of vitamins and micro-nutrients” (2007).

The European Guidelines (2007) for patients undergoing ‘limiting absorption of nutrients’ operations such as BPD or distal RYGB are:-

- “laboratory tests are necessary to evaluate the evolution of metabolic and nutritional status and to adapt supplementation and drug treatment accordingly,
- lifelong daily vitamin and micro-nutrient supplementation (vitamins should be administered in a water soluble form),
- vitamin A, D, E and K,

- calcium supplementation (preferably in calcium citrate), recommended total intake 2 g/day,
- supplement of vitamins and micro-nutrients should compensate for their possible reduced intake and according to laboratory values,
- in a preventive regimen the supplementation can be administered orally,
- for correction of deficits, the supplementation should be administered parenterally, except for calcium.”

In 2008, the American Bariatric Surgical Medical Guidelines for the clinical practice for the peri-operative, nutritional, metabolic and non-surgical support of the bariatric surgery patient were published by the AACE / TOS / ASMBS. These American Guidelines provided more detailed recommendations with regard to the nutritional supplementation of the post bariatric surgical patient.

Recently, specially formulated bariatric vitamin and micro-nutrient supplements have been emerging on the UK market, predominately from America, such as “Bariatric Advantage” and “Vita4Life”.

What Vitamin and Micro-nutrient Supplementation Recommendations are being Made in the UK?

There is a strong body of evidence about the nutritional implications of bariatric surgery. However, there is a sparsity of evidence about the vitamin and micro-nutrient supplementation recommendations made to bariatric patients in the UK. In light of the nutritional consequences and the European Guidelines about supplementation, this area warranted further research. It was felt that the European Guidelines should be used as the benchmark to measure the recommendations to this group of patients in the UK.

Therefore, research to determine the clinical recommendations made by UK registered dietitians to patients about vitamin and micro-nutrient supplementation, following bariatric surgery was justified. Determination of the nutritional adequacy of the recommended products, by UK registered dietitians, compared with European Guidelines should be undertaken.

To conclude, there were two hypotheses of this piece of research.

Firstly, that the recommendations made by UK registered dietitians meet the European Guidelines (2007) following “food limiting” bariatric procedures in that “supplement of vitamin and micro-nutrients should compensate for their possible reduced intake”.

Secondly, the recommendations made by UK registered dietitians meet the European Guidelines (2007) following “limiting absorption of nutrients” bariatric procedures, namely lifelong daily vitamin and micro-nutrient supplementation, vitamin A, D, E and K, and calcium supplementation, to a recommended total intake 2 g/day.

Chapter 2

Method

Rationale for Participant Selection

The British Dietetic Association (BDA), the professional association for dietitians, aimed to inform, protect, represent, and support the 6500 membership. Most were qualified dietitians holding a degree or postgraduate diploma recognised for Registration by the Health Professions Council (HPC).

One of the specialist interest groups of the BDA was 'Dietitians in Obesity Management UK' (DOMUK). The aspiration of DOMUK was to be a practical resource for dietitians, to provide opportunities to network and develop new skills, ensuring that dietitians provided the best advice and support for people wanting to manage their weight. Membership numbered 200 in 2009 / 2010. The email addresses of all the members were held by the Members' Secretary of the group. There were forty members of the surgical sub group of DOMUK.

In NICE Guidance 43 (2006) it was recommended for individuals undergoing bariatric surgery that:-

“Regular, specialist post operative dietetic monitoring should be provided, and should include:

- information on the appropriate diet for the bariatric procedure
- monitoring of the person's micro-nutrient status
- information on patient support groups
- individualised nutritional supplementation, support and guidance to achieve long-term weight loss and weight maintenance,

- the person commits to the need for long-term follow-up.”

Bariatric surgery undertaken within the NHS (be it in NHS or private hospitals) should follow these recommendations. Unfortunately, there was no guarantee that surgery, undertaken in the private sector, for self paying patients follow them. Since it was recommended that dietitians monitor and individualise nutritional supplementation, it was felt that this group of health care professionals should be asked to partake in the study. One of the study objectives was to determine the clinical recommendations made by UK registered dietitians to patients about vitamin and micro-nutrient supplementation following bariatric surgery. DOMUK, being a specialist interest group in obesity became the most obvious group of the profession to survey. The Chair and the Members’ Secretary gave their permission to survey the membership on 13th March 2009.

Questionnaire Development

In order to determine what clinical recommendations were being made by UK registered dietitians to patients about vitamin and micro-nutrient supplementation following bariatric surgery, a self constructed questionnaire was developed. Baseline retrospective information on number of patients the dietitian consulted with last year and whether the patients that the dietitian consulted with were seen in the NHS or private sector was asked. The two main types of procedures, as classified by the European Guidelines on Surgery of Severe Obesity (2007), being “food limiting” or “nutrient absorption limiting” procedures were used to determine current vitamin and micro-nutrient supplementation recommendations. Therefore, the questionnaire contained both quantitative and qualitative information. The questionnaire required both tick box and free text responses. The pilot self constructed questionnaire, which

was self-reporting, was completed by five Committee members of DOM on 13th March 2009 . Minor alterations were made and the amended questionnaire was piloted with three work colleagues, employed as specialist bariatric dietitians on 17th April 2009. No further alterations were required. Completion time of the questionnaire was approximately ten minutes.

Ethical Approval

A hard copy of the application to the University of Chester's Faculty of Applied and Health Sciences Research Ethics Committee was submitted for the Committee meeting to be held on 22nd April 2009 (see Appendix A). Unfortunately, due to the high number of applications, this application was deferred until the Committee meeting held on 6th May 2009. An electronic response from the Committee was received on 14th May 2009 (Appendix B). This stated that the application had been "agreed and that there were no ethical objections to this study taking place. However, a number of clarifications and amendments were noted. Before approval can be given, the applicant must respond to the following:

- The title should indicate what was being investigated
- Question 2 of the questionnaire should ask "what percentage?"
- Wording needed to be refined."

It was agreed that the applicant's response would be reviewed by the lead reviewer and Chair of the Committee, in order to reach a decision. The applicant used a template to amend the application (Appendix C). This was emailed to the Research Co-ordinator on 14th May 2009 and he presented to the lead reviewer and Chair of the Committee on 15th May 2009. A hard copy of the formal confirmation of the approval of the Research Ethics Committee was received on 19th June 2009 (Appendix D).

Procedure

The author created a free account with SurveyMonkey.com, a web survey provider. The company employed a multiple layered security system with the latest firewall and intrusion prevention technology and pledged to keep the information collected confidential. The questionnaire was transposed onto the provider's questionnaire template. Completion of the survey by respondents was voluntary and anonymous. This was indicated, along with further information about the purpose of the survey in both a covering letter and participant information sheet. The covering letter contained the link to the on-line participant information sheet and questionnaire (Appendix E), which was emailed to the Members' Secretary of DOMUK. The Members' Secretary accessed the questionnaire via the link in the covering letter and completed a questionnaire to ensure that all were functioning as expected. The author contacted SurveyMonkey.com who deleted that response. Both the author and the Members' Secretary were satisfied the link and collation of responses was satisfactory. The Members' Secretary distributed the covering letter via email to the membership on 3rd July 2009. One month was allowed for the completion of the questionnaire. SurveyMonkey.com held the completed responses in the author's account which was automatically redirected to the author's University of Chester email address. HPC Standards of conduct, performance and ethics were adhered to (HPC, 2008).

Vitamin and Micro-nutrient Content of Recommended Products

One objective of the study was to determine the nutritional adequacy of the vitamin and micro-nutrient supplementation recommendations made by UK registered dietitians. The nutritional composition of the products named in the free text responses in the questionnaire was ascertained by accessing the manufacturers'

websites. If the information was not provided on the website then the manufacturers were contacted via email and asked to provide nutritional composition data on the product.

Analysis of the Questionnaire Responses

Only the responses to the quantitative questions were subjected to statistical analysis using SPSS 16.0 for Windows. Responses to Question One were ordinal scale data, having only one feature of the real number series; order. This data type was categorical. For analysis the code “1 = 1 – 20 patients”; “2 = 21 – 50 patients”; “3 = 51 – 100 patients” and “4 = 100+ patients” seen was used. The descriptive statistics generated for this question was measures of central tendency, being median and measure of variability being range. The responses to Question Two were of ratio scale data. This is the most complex form of data type, having order, distance and origin. The descriptive statistics generated for this question measures of central tendency being mean, if the distribution was normal or median if the distribution was skewed. The Shapiro-Wilk test was used to determine whether the distribution of percentages was significantly different from a normal distribution; a significant value indicated a deviation from normality, but this test was affected by large samples, in which small deviations from normality yield significant results (Field, 2005). Therefore, Coakes and Steed (2007) recommend that the Shapiro-Wilk test was used if the sample size was less than 100. The measure of variability would be standard deviation if normally distributed or range if not.

The number of patients the respondents consulted with last year was calculated using the lower figures in the caseload banding for both NHS and private / self pay patients. The measurement scale for the responses to Question Three and Question Seven was

nominal, which is the most primitive form of measurement and represents none of the real number features. The code “1 = no” and “2 = yes” was used to analyse these results. The descriptive statistics generated for this question was measures of central tendency being mode and the measure of variability being range.

The free text responses to the Questions Four, Five, Six, Eight, Nine and Ten of the questionnaire were tabulated.

The nutritional composition of the vitamin and micro-nutrient supplements named in the free text responses to Questions Four, Five, Six, Eight, Nine and Ten were tabulated from information provided from the products’ website or directly from the manufacturer.

To determine the nutritional adequacy of the products recommended by UK dietitians compared with European Guidelines, the descriptive statistics generated from the responses to Questions Three and Seven would be used to determine the compliance of the responding members of DOMUK to the European Guidelines (2007) for both “food limiting” and “nutrient absorption limiting” bariatric procedures, in terms of nutritional supplementation.

Additionally, the naming of specified vitamins and micro-nutrients from the free text responses to Questions Four, Five, Six, Eight, Nine and Ten were used to determined the compliance with the European Guidelines (2007), pertaining to “nutrient absorption limiting” bariatric procedures. The calcium content of the named products, with the stated dose was calculated to determine the daily calcium content of the recommendations made by UK registered dietitians who were members of DOMUK, who responded to the questionnaire.

Chapter 3

Results

Respondents Completed Questionnaires

The SurveyMonkey output can be found in Appendix F.

Statistical Analysis

This was conducted using SPSS 16.0 for Windows. The SPSS output can be found in Appendix G.

Response Rate

The questionnaire was e-distributed to all 200 members of the BDA's Specialist Interest Group DOMUK. Of this group there was a surgical interest sub-group with forty members. All members had one month to complete the questionnaire. Only completed responses were collated by the web survey provider, SurveyMonkey.com. There were twenty one completed questionnaires. This was 10.5% of the DOMUK membership.

Caseload Frequency

The first question completed by the respondents was to elicit the range of numbers of bariatric patients (caseload) that the dietitian had consulted with during the previous year. This data was categorical (see Table 1).

Table 1 Number of Bariatric Patients seen Last Year by the Survey Respondents

<u>Numbers of Patients Seen</u>	<u>Frequency</u>	<u>Valid Percent</u>
1-20	3	15
21-50	4	20
51-100	4	20
100+	9	45
Total	20	100

Forty five percent (n=9) of the respondents had seen over 100 patients in the previous year.

The data was ordinal level data and hence median was used as the measure of central tendency. In Table 2, the code “1 = 1 - 20 patients”; “2 = 21 - 50 patients”; “3 = 51 - 100 patients” and “4 = 100+ patients” was used. Therefore, the median category of patients seen was 51-100 patients last year, by the respondents (Table 2). The measure of variability was range, being from 1-20 patients to over 100 patients being seen last year.

Table 2 Descriptive Statistics for the Number of Bariatric Patients seen Last Year by the Survey Respondents

	<u>Descriptive Statistics</u>
Valid	20
Missing	1
Median	3 (51-100 patients)
Range	3

Percentage of NHS and Private Patients Seen by Respondent Dietitians

The registered dietitians were asked to state what percentage of their bariatric caseload was seen in the NHS and in the private / self pay sector. This data was ratio scale. Mean was the measure of central tendency, unless the data was not normally distributed, when median was used. The measure of variability would be standard deviation if the data was normally distributed, or range if not.

The Shapiro-Wilk test was used to determine whether the distribution of scores was significantly different from a normal distribution, when the sample size was less than 100, as it was in this case (Coakes & Steed, 2007). It can be seen from Table 3 that the distribution was not normal, since the significance for the Shapiro-Wilk test was $p=0.000$ for both NHS and private sector patients. If the value was less than $p=0.05$, then the sample was not normally distributed. Therefore, it can be concluded that the sample was not normally distributed (Coakes & Steed, 2007).

Table 3 The Tests of Normality of the Distribution of the Percentage of NHS and Private Patients seen by UK Registered Dietitians

	<u>Shapiro-Wilk</u>
	<u>Significance</u>
Percentage NHS	0.000
Percentage Private	0.000

Table 4 Descriptive Statistics for the Percentage of Responding Dietitians' Caseload that were NHS and Private / Self Pay Patients

	<u>Percentage NHS %</u>	<u>Percentage Private %</u>
Valid	20	20
Median	85	15
Range	100	100

Therefore, the median value was used to describe the measure of central tendency. The median for percentage of patients that were seen by the responding dietitians that were treated in the NHS was 85%, with the measure of variability, being range was 0% to 100% (Table 4). Likewise for the median percentage of patients seen by the responding dietitians that were treated in the private sector was 15%, with a range from 0% to 100% (Table 4). However, of the dietitians who saw the highest number of patients (100+ patients) last year, 56% of those patients were seen in the NHS, whilst 44% of those patients were seen in the private sector. Dietitians who consulted with between 51-100 patients last year, 34% of those patients were NHS and 66% were self pay patient. Dietitians who saw between 21-50 patients last year, 98% of

those patients were NHS and only 2% were self pay. Whilst dietitians who consulted with the lowest number of bariatric patients (1-20 patients) last year, 60% were NHS patients and 40% were self pay patients.

Table 5 Percentage of the Responding Dietitians' Bariatric Caseload that were seen in the NHS

<u>Valid</u>	<u>Frequency</u>	<u>Valid Percent %</u>
0	4	20
2	1	5
5	1	5
30	1	5
50	1	5
60	1	5
80	1	5
90	2	10
99	1	5
100	7	35
Total	20	100

Thirty five percent of all the patients seen by the responding dietitians were seen by dietitians exclusively consulting NHS patients (Table 5).

Table 6 Percentage of the Responding Dietitians' Bariatric Caseload that were seen in the Private / Self Pay Sector

<u>Valid</u>	<u>Frequency</u>	<u>Valid Percent %</u>
0	7	35
1	1	5
10	2	10
20	1	5
40	1	5
50	1	5
70	1	5
95	1	5
98	1	5
100	4	20
Total	20	100

Twenty percent of all the patients seen by the responding dietitians were seen by dietitians exclusively consulting private / self pay patients (Table 6).

The respondents consulted with just under 1200 patients last year. Using the lower figures in the caseload banding, 650 patients were seen by the respondents last year in the NHS. Using the lower figure in the caseload banding, 540 patients were seen in the private / self pay sector by the respondents last year.

**Do UK Registered Dietitians Recommend Vitamin and Micro-nutrient
Supplementation to Patients Post Food Limiting Procedures?**

Respondents were asked if they recommended vitamin and micro-nutrient supplementation to patients following the two main types of procedures, as classified by the European Guidelines on Surgery of Severe Obesity (2007). This was a simple yes / no response, so the data was nominal level data, were “1 = no” and “2 = yes”. Therefore, the measure of central tendency was the mode value. Consulting Table 7 it was seen that the mode for recommendations for vitamin and micro-nutrient supplementation following food limiting bariatric procedures was “2”, being yes supplements were recommended. However, the range for food limiting procedures was 1 – 2, that was some dietitians (n = 2) were not recommending vitamin and micro-nutrient supplementation to patients following food limiting procedures.

Table 7 Descriptive Statistics for Recommendations for Vitamin and Micronutrient
Supplementation following Food Limiting Bariatric Procedures

	<u>Descriptive Statistics</u>
Valid	19
Missing	2
Mode	2 (Yes)
Range	1

Do UK Registered Dietitians Recommend Vitamin and Micro-nutrient Supplementation to Patients Post Limiting Absorption of Nutrient Procedures?

Consulting Table 8, it can be seen that all UK registered dietitians recommended vitamin and micro-nutrient supplementation to their patients following nutrient absorption limiting bariatric surgery, since the mode is 2 (yes) and there was no range.

Table 8 Descriptive Statistics for Recommendations for Vitamin and Micro-nutrient Supplementation following Limiting Absorption of Nutrients Bariatric Procedures

	<u>Descriptive Statistics</u>
Valid	20
Missing	1
Mode	2 (Yes)
Range	0

Percentage of UK Registered Dietitians who Meet the Vitamin and Micro-nutrient European Guidelines following Food Limiting Procedure

It can be seen for Table 9 that 10% of UK registered dietitians who responded to the survey were not recommending vitamin and micro-nutrient supplementation to patients who have undergone food limiting bariatric procedures, but 90% of the responding dietitians did recommend supplements.

Table 9 The Frequency and Percentage of UK Registered Dietitians that Recommended Vitamin and Micro-nutrient Supplementation Following Food Limiting Bariatric Procedures

	<u>Frequency</u>	<u>Valid Percent %</u>
Valid No	2	10.5
Yes	17	89.5
Total	19	100

Percentage of UK Registered Dietitians who Meet the Vitamin and Micro-nutrient European Guidelines following Food Limiting Procedure

It can be seen from Table 10 that all the responding UK registered dietitians recommended vitamin and micro-nutrient supplementation following nutrient absorption limiting procedures.

Table 10 The Frequency and Percentage of UK Registered Dietitians that Recommended Vitamin and Micro-nutrient Supplementation Following Nutrient Absorption Limiting Bariatric Procedures

	<u>Frequency</u>	<u>Valid Percent %</u>
Valid Yes	20	100
Total	20	100

Table 11 Tabulated Free Text Responses to the Question of What Vitamin and Micro-nutrient Supplementation UK Registered Dietitians Recommended to their Patients following Food Limiting Bariatric Procedures

<u>RD</u>	<u>Number Patients Seen</u>	<u>Percent-age NHS (%)</u>	<u>Percent-age Private (%)</u>	<u>Recom'nd Suppls. Food Limiting Procedure</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>
1	1-20	0	100	No	-	-	-	-	-	-
2	100+	60	40	No	-	-	-	-	-	-
3	100+	0	100	Yes	Sanatogen Gold / Centrum	1 tablet a day	For life	-	-	-
4	-	-	-	Yes	Forceval / Centrum / Supermarket A-Z multivitamin & mineral	1 tablet a day	Lifelong	-	-	-

Table 11 Tabulated Free Text Responses to the Question of What Vitamin and Micro-nutrient Supplementation UK Registered Dietitians

Recommended to their Patients following Food Limiting Bariatric Procedures (continued)

<u>RD</u>	<u>Number</u> <u>Patients</u> <u>Seen</u>	<u>Percent-</u> <u>age NHS</u> <u>(%)</u>	<u>Percent-</u> <u>age</u> <u>Private</u> <u>(%)</u>	<u>Recom'nd</u> <u>Suppls.</u> <u>Food</u> <u>Limiting</u> <u>Procedure</u>	<u>Recommended</u> <u>Product</u>	<u>Dose</u>	<u>Duration</u>	<u>Recommended</u> <u>Product</u>	<u>Dose</u>	<u>Duration</u>
5	51-100	0	100	Yes	Sanatogen Gold A-Z / Centrum	Standard Dose	Active weight loss period	-	-	-
6	100+	0	100	Yes	General multi vitamin with mineral	One a day	Ideally from pre op diet, for life	Calcichew	One a day	Lifelong post op
7	100+	90	10	Yes	Any complete vit and mineral	1 tablet od	Life long	-	-	-

Table 11 Tabulated Free Text Responses to the Question of What Vitamin and Micro-nutrient Supplementation UK Registered Dietitians Recommended to their Patients following Food Limiting Bariatric Procedures (continued)

<u>RD</u>	<u>Number Patients Seen</u>	<u>Percent-age NHS (%)</u>	<u>Percent-age Private (%)</u>	<u>Recom'nd Suppls. Food Limiting Procedure</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>
8	100+	50	50	Yes	Forceval / Sanatogen Gold	1 daily	Life	-	-	-
9	100+	100	0	Yes	Multivitamin and mineral suppl, complete A-Z	1 tablet per day	At least 6 months post op. Reassess thereafter	Variable upon nutritional status and bloods post op. Iron, folate, zinc, calcium, vitD	-	-

Table 11 Tabulated Free Text Responses to the Question of What Vitamin and Micro-nutrient Supplementation UK Registered Dietitians Recommended to their Patients following Food Limiting Bariatric Procedures (continued)

<u>RD</u>	<u>Number</u> <u>Patients</u> <u>Seen</u>	<u>Percent-</u> <u>age NHS</u> <u>(%)</u>	<u>Percent-</u> <u>age</u> <u>Private</u> <u>(%)</u>	<u>Recom'nd</u> <u>Suppls.</u> <u>Food</u> <u>Limiting</u> <u>Procedure</u>	<u>Recommended</u> <u>Product</u>	<u>Dose</u>	<u>Duration</u>	<u>Recommended</u> <u>Product</u>	<u>Dose</u>	<u>Duration</u>
10	21-50	90	10	Yes	Over the counter multi vitamin and mineral A-Z complete	1 daily	6 months	-	-	-
11	51-100	30	70	Yes	Forceval / Centrum / Sanatogen Gold	1 daily	Life	-	-	-
12	51-100	5	95	Yes	Sanatogen Gold	1 tablet / day	Depends on patient	-	-	-

Table 11 Tabulated Free Text Responses to the Question of What Vitamin and Micro-nutrient Supplementation UK Registered Dietitians Recommended to their Patients following Food Limiting Bariatric Procedures (continued)

<u>RD</u>	<u>Number Patients Seen</u>	<u>Percent-age NHS (%)</u>	<u>Percent-age Private (%)</u>	<u>Recom'nd Suppls. Food Limiting Procedure</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>
13	1-20	100	0	Yes	As suggested by centre where procedure done	As suggested by centre where procedure done	As suggested by centre where procedure done	-	-	-

Table 11 Tabulated Free Text Responses to the Question of What Vitamin and Micro-nutrient Supplementation UK Registered Dietitians Recommended to their Patients following Food Limiting Bariatric Procedures (continued)

<u>RD</u>	<u>Number</u> <u>Patients</u> <u>Seen</u>	<u>Percent-</u> <u>age NHS</u> <u>(%)</u>	<u>Percent-</u> <u>age</u> <u>Private</u> <u>(%)</u>	<u>Recom'nd</u> <u>Suppls.</u> <u>Food</u> <u>Limiting</u> <u>Procedure</u>	<u>Recommended</u> <u>Product</u>	<u>Dose</u>	<u>Duration</u>	<u>Recommended</u> <u>Product</u>	<u>Dose</u>	<u>Duration</u>
14	100+	100	0	Yes	Don't currently name a particular brand but recommend chewable / suckable / liquid / effervescent multi vit & mineral	-	-	-	-	-

Table 11 Tabulated Free Text Responses to the Question of What Vitamin and Micro-nutrient Supplementation UK Registered Dietitians Recommended to their Patients following Food Limiting Bariatric Procedures (continued)

<u>RD</u>	<u>Number</u> <u>Patients</u> <u>Seen</u>	<u>Percent-</u> <u>age NHS</u> <u>(%)</u>	<u>Percent-</u> <u>age</u> <u>Private</u> <u>(%)</u>	<u>Recom'nd</u> <u>Suppls.</u> <u>Food</u> <u>Limiting</u> <u>Procedure</u>	<u>Recommended</u> <u>Product</u>	<u>Dose</u>	<u>Duration</u>	<u>Recommended</u> <u>Product</u>	<u>Dose</u>	<u>Duration</u>
15	21-50	100	0	Yes	Complete multivitamin and mineral – none specified	As per tablet directions	Ongoing until balanced intake established	-	-	-
16	1-20	80	20	-	-	-	-	-	-	-
17	51-100	100	0	Yes	Forceval	1 cap daily	Until dietary intake adeq.	-	-	-

Table 11 Tabulated Free Text Responses to the Question of What Vitamin and Micro-nutrient Supplementation UK Registered Dietitians Recommended to their Patients following Food Limiting Bariatric Procedures (continued)

<u>RD</u>	<u>Number Patients Seen</u>	<u>Percent-age NHS (%)</u>	<u>Percent-age Private (%)</u>	<u>Recom'nd Suppls. Food Limiting Procedure</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>
18	21-50	100	0	Yes	Forceval	1 tablet	Every day for life	-	-	-
19	100+	2	98	Yes	Multivitamin and mineral	One a day or what is specified on the label	Life	-	-	-

Table 11 Tabulated Free Text Responses to the Question of What Vitamin and Micro-nutrient Supplementation UK Registered Dietitians Recommended to their Patients following Food Limiting Bariatric Procedures (continued)

<u>RD</u>	<u>Number Patients Seen</u>	<u>Percent-age NHS (%)</u>	<u>Percent-age Private (%)</u>	<u>Recom'nd Suppls. Food Limiting Procedure</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>
20	100+	99	1	Yes	A to Z or Complete multivitamin with minerals (don't recommend specific brands as yet)	Daily	Only in initial weight loss phase	-	-	-
21	21-50	100	0	-	-	-	-	-	-	-

Table 12 Tabulated Free Text Responses to the Question of What Vitamin and Micro-nutrient Supplementation UK Registered Dietitians Recommended to their Patients following Nutrient Absorption Limiting Bariatric Procedures

<u>RD</u>	<u>Number Patients Seen</u>	<u>Percent-age NHS (%)</u>	<u>Percent-age Private (%)</u>	<u>Recom'nd Suppls. Nutrient Absorpt. Limiting Procedure</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>
1	1-20	0	100	yes	General one a day multi vit and mineral supp	-	Lifelong	-	-	-
2	100+	60	40	yes	Sanatogen Gold / Centrum / Boots multi vitamin and mineral	1	Lifelong	-	-	-

Table 12 Tabulated Free Text Responses to the Question of What Vitamin and Micro-nutrient Supplementation UK Registered Dietitians Recommended to their Patients following Nutrient Absorption Limiting Bariatric Procedures (continued)

<u>RD</u>	<u>Number Patients Seen</u>	<u>Percent-age NHS (%)</u>	<u>Percent-age Private (%)</u>	<u>Recom'nd Suppls. Nutrient Absorpt. Limiting Procedure</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>
3	100+	0	100	Yes	Multivitamin and mineral like Sanatogen Gold / Centrum	1 tablet a day	For life	Calcium Vitamin D Vitamin B12 injections	800 mg 5µg 1 mg	2 x day 2 x day Every 3 months first 2 yrs

Table 12 Tabulated Free Text Responses to the Question of What Vitamin and Micro-nutrient Supplementation UK Registered Dietitians Recommended to their Patients following Nutrient Absorption Limiting Bariatric Procedures (continued)

<u>RD</u>	<u>Number</u> <u>Patients</u> <u>Seen</u>	<u>Percent-</u> <u>age NHS</u> <u>(%)</u>	<u>Percent-</u> <u>age</u> <u>Private</u> <u>(%)</u>	<u>Recom'nd</u> <u>Suppls.</u> <u>Nutrient</u> <u>Absorpt.</u> <u>Limiting</u> <u>Procedure</u>	<u>Recommended</u> <u>Product</u>	<u>Dose</u>	<u>Duration</u>	<u>Recommended</u> <u>Product</u>	<u>Dose</u>	<u>Duration</u>
4	-	-	-	Yes	Forceval / Centrum / Supermarket A-Z multivitamin & mineral	1 tablet a day	Lifelong	-	-	-

Table 12 Tabulated Free Text Responses to the Question of What Vitamin and Micronutrient Supplementation UK Registered Dietitians Recommended to their Patients following Nutrient Absorption Limiting Bariatric Procedures (continued)

<u>RD</u>	<u>Number Patients Seen</u>	<u>Percent-age NHS (%)</u>	<u>Percent-age Private (%)</u>	<u>Recom'nd Suppls. Food Limiting Procedure</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>
5	51-100	0	100	Yes	As restrictive procedure (Sanatogen Gold A-Z / Centrum)	As per restrictive procedure(Standard Dose)	As per restrictive procedure (Active weight loss period)	Extra B12 injection, Ca, D	As per physician	Life

Table 12 Tabulated Free Text Responses to the Question of What Vitamin and Micro-nutrient Supplementation UK Registered Dietitians Recommended to their Patients following Nutrient Absorption Limiting Bariatric Procedures (continued)

<u>RD</u>	<u>Number Patients Seen</u>	<u>Percent-age NHS (%)</u>	<u>Percent-age Private (%)</u>	<u>Recom'nd Suppls. Nutrient Absorpt. Limiting Procedure</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>
6	100+	0	100	Yes	General multi vitamin with mineral	One a day	From pre op diet for life	Calcichew/Adcal D3 Ferrous sulphate or gluconate as indicated by routine bloods	One a day	Lifelong Until Hb resolves, often lifelong

Table 12 Tabulated Free Text Responses to the Question of What Vitamin and Micro-nutrient Supplementation UK Registered Dietitians Recommended to their Patients following Nutrient Absorption Limiting Bariatric Procedures (continues)

<u>RD</u>	<u>Number Patients Seen</u>	<u>Percent-age NHS (%)</u>	<u>Percent-age Private (%)</u>	<u>Recom'nd Suppls. Nutrient Absorpt. Limiting Procedure</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>
7	100+	90	10	Yes	Complete vit and mineral	1 tablet 1 x day	Life long	Vitamin B12 injections	1 mg	3 monthly

Table 12 Tabulated Free Text Responses to the Question of What Vitamin and Micro-nutrient Supplementation UK Registered Dietitians Recommended to their Patients following Nutrient Absorption Limiting Bariatric Procedures (continued)

<u>RD</u>	<u>Number Patients Seen</u>	<u>Percent-age NHS (%)</u>	<u>Percent-age Private (%)</u>	<u>Recom'nd Suppls. Food Limiting Procedure</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>
8	100+	50	50	Yes	Forceval / Sanatogen Gold	1 daily	Life	Calcium Calcium	1000mg R- e-Y 2000m BPD and DS	Life Life

8								Vitamin B12 injections	May be for BPD, not DS	Life
cn't								Iron	Depends on results	Depends on results
								Additional selenium and zinc	Depends on results	Depends on results
								AquaEDKS for BPD and DS	-	-

Table 12 Tabulated Free Text Responses to the Question of What Vitamin and Micronutrient Supplementation UK Registered Dietitians Recommended to their Patients following Nutrient Absorption Limiting Bariatric Procedures (continued)

<u>RD</u>	<u>Number Patients Seen</u>	<u>Percent-age NHS (%)</u>	<u>Percent-age Private (%)</u>	<u>Recomm- end Suppls. Food Limiting Procedure</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>
9	100+	100	0	Yes	Multivitamin and mineral suppl, complete A-Z	1 tablet per day	Life-long	Iron supplements	Depends on which iron salts they are prescribed but we aim	Usually life-long

9 cn't								<p>Calcium</p> <p>B12 IM injection</p>	<p>to ensure patients receive ~65 mg per day</p> <p>1000mg / day</p> <p>1 mg every 3 months</p>	<p>Life-long</p> <p>Life-long</p>
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Table 12 Tabulated Free Text Responses to the Question of What Vitamin and Micro-nutrient Supplementation UK Registered Dietitians Recommended to their Patients following Nutrient Absorption Limiting Bariatric Procedures (continued)

<u>RD</u>	<u>Number Patients Seen</u>	<u>Percent-age NHS (%)</u>	<u>Percent-age Private (%)</u>	<u>Recomm- end Suppls. Food Limiting Procedure</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>
10	21-50	90	10	Yes	Multi vitamin and mineral A-Z complete or Forceval	1 daily	For life	Calcium	1000mg	Life
								Vitamin D3	800 IE units	Life
								Vit B12 injections	Inj. 1 mg	3-4mnths

Table 12 Tabulated Free Text Responses to the Question of What Vitamin and Micro-nutrient Supplementation UK Registered Dietitians Recommended to their Patients following Nutrient Absorption Limiting Bariatric Procedures (continued)

<u>RD</u>	<u>Number Patients Seen</u>	<u>Percent-age NHS (%)</u>	<u>Percent-age Private (%)</u>	<u>Recom'nd Suppls. Nutrient Absorpt. Limiting Procedure</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>
11	51-100	30	70	Yes	Depends on procedure in DS and bypass Standard multivitamin and minerals as with band	1 daily bypass 2 daily DS	Life	Calcium Vitamin D	2 daily bypass, 4 daily DS 2 bypass, 4 daily DS	Life Life

Table 12 Tabulated Free Text Responses to the Question of What Vitamin and Micro-nutrient Supplementation UK Registered Dietitians Recommended to their Patients following Nutrient Absorption Limiting Bariatric Procedures (continued)

<u>RD</u>	<u>Number Patients Seen</u>	<u>Percent-age NHS (%)</u>	<u>Percent-age Private (%)</u>	<u>Recom'nd Suppls. Nutrient Absorpt. Limiting Procedure</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>
12	51-100	5	95	Yes	Sanatogen Gold	1 tablet / day	Indefinitely	-	-	-

Table 12 Tabulated Free Text Responses to the Question of What Vitamin and Micro-nutrient Supplementation UK Registered Dietitians Recommended to their Patients following Nutrient Absorption Limiting Bariatric Procedures (continued)

<u>RD</u>	<u>Number Patients Seen</u>	<u>Percent-age NHS (%)</u>	<u>Percent-age Private (%)</u>	<u>Recom'nd Suppls. Nutrient Absorpt. Limiting Procedure</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>
13	1-20	100	0	Yes	As suggested by centre where procedure done	As suggested by centre where procedure done	As suggested by centre where procedure done	-	-	-

Table 12 Tabulated Free Text Responses to the Question of What Vitamin and Micro-nutrient Supplementation UK Registered Dietitians Recommended to their Patients following Nutrient Absorption Limiting Bariatric Procedures (continued)

<u>RD</u>	<u>Number Patients Seen</u>	<u>Percent-age NHS (%)</u>	<u>Percent-age Private (%)</u>	<u>Recom'nd Suppls. Nutrient Absorpt. Limiting Procedure</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>
14	100+	100	0	-	-	-	-	-	-	-
15	21-50	100	0	Yes	Lap banding only carried out at present first line	-	-	-	-	-
16	1-20	80	20	Yes	Forceval	od	Continue	Calcichew	500mg	Continue

Table 12 Tabulated Free Text Responses to the Question of What Vitamin and Micro-nutrient Supplementation UK Registered Dietitians Recommended to their Patients following Nutrient Absorption Limiting Bariatric Procedures (continued)

<u>RD</u>	<u>Number Patients Seen</u>	<u>Percent-age NHS (%)</u>	<u>Percent-age Private (%)</u>	<u>Recom'nd Suppls. Nutrient Absorpt. Limiting Procedure</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>
17	51-100	100	0	Yes	Forceval	1 cap daily	Lifelong	Calcichew D3 forte Others depending on blood results eg B12 inj	2 tablets daily	Lifelong

Table 12 Tabulated Free Text Responses to the Question of What Vitamin and Micro-nutrient Supplementation UK Registered Dietitians Recommended to their Patients following Nutrient Absorption Limiting Bariatric Procedures (continued)

<u>RD</u>	<u>Number Patients Seen</u>	<u>Percent-age NHS (%)</u>	<u>Percent-age Private (%)</u>	<u>Recom'nd Suppls. Nutrient Absorpt. Limiting Procedure</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>
18	21-50	100	0	Yes	Forceval	1 tablet	Every day for life	Spatone	1 sachet per day	When ferritin levels are low

Table 12 Tabulated Free Text Responses to the Question of What Vitamin and Micronutrient Supplementation UK Registered Dietitians Recommended to their Patients following Nutrient Absorption Limiting Bariatric Procedures (continued)

<u>RD</u>	<u>Number Patients Seen</u>	<u>Percent-age NHS (%)</u>	<u>Percent-age Private (%)</u>	<u>Recomm- end Suppls. Food Limiting Procedure</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>
19	100+	2	98	Yes	Multivitamin and mineral	One a day or whatever is specified on the label	Life	Calcium Iron	One a day or what is specified on the label	Life

									One a day or whatever is specified on the label	Until serum ferritin, folate and B12 is in range or patient chooses to stop due to constp'n
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Table 12 Tabulated Free Text Responses to the Question of What Vitamin and Micronutrient Supplementation UK Registered Dietitians Recommended to their Patients following Nutrient Absorption Limiting Bariatric Procedures (continued)

<u>RD</u>	<u>Number Patients Seen</u>	<u>Percent-age NHS (%)</u>	<u>Percent-age Private (%)</u>	<u>Recomm- end Suppls. Food Limiting Procedure</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>
20	100+	99	1	Yes	A to Z or Complete multivitamin with minerals (don't recommend specific brands as yet)	Daily	Lifelong	Vit B12 injections	Once every 4 months approx.	Lifelong

Table 12 Tabulated Free Text Responses to the Question of What Vitamin and Micronutrient Supplementation UK Registered Dietitians Recommended to their Patients following Nutrient Absorption Limiting Bariatric Procedures (continued)

<u>RD</u>	<u>Number Patients Seen</u>	<u>Percent-age NHS (%)</u>	<u>Percent-age Private (%)</u>	<u>Recomm- end Suppls. Food Limiting Procedure</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>	<u>Recommended Product</u>	<u>Dose</u>	<u>Duration</u>
21	21-50	100	0	Yes	Sanatogen A-Z complete crushed with water	Once per day	Until able to take whole then switch to any multivitamin preparation	Vitamin B12 injections	Once every 3 months	For life

Vitamin and Micro-nutrient Recommendations Made by UK Registered

Dietitians Post Food Limiting Procedures

The results of the free text response to the question about what vitamin and micro-nutrient supplementation UK registered dietitians recommended to their post food limiting bariatric procedures varied from 10% dietitians not recommending any supplementation to a general complete vitamin and micro-nutrient supplement and possibly iron, folate, zinc, calcium and vitamin D depending on bloods post operation (see Table 11). The Bariatric Scientific Collaborative Group produced the Inter-disciplinary European Guidelines on Surgery of Severe Obesity in 2007. In this document the recommendation was made that patients undergoing ‘food limiting’ operations, such as LAGB, was that a “supplement of vitamin and micro-nutrients should compensate for their possible reduced intake”. The recommendation that ‘food limiting’ operations, such as proximal RYGB, was that a “supplement of vitamin and micro-nutrients should compensate for their possible reduced intake and absorption”. Two respondents did not recommend supplementation to this group of patients.

Recommended Products

There were seventeen free text responses to the question about what vitamin and micro-nutrient supplement the dietitian recommended to his / her patients undergoing food limiting procedures. One respondent did not make any recommendation, but stated “as suggested by centre where procedure done”. However, there was no clarification as to what that centre recommended. The remaining sixteen respondents who stated that they recommended supplements to this group of patients, made the following free text responses to the question about which product they recommended: “Forceval” (n=5); “Sanatogen Gold” (n=5); “Centrum” (n=4); “Supermarket A-Z

multi vitamin and mineral” (n=1). Seven respondents recommended a supplement, but were none specific, suggesting “any complete”; multivitamin and mineral, complete”; “over the counter multi-vitamin and mineral complete”; “multi-vitamin and mineral”; “complete multi-vitamin and mineral”; “multi-vitamin and mineral” and “A – Z or complete multi-vitamin with mineral”. Some dietitians made two or three responses.

Dosage Recommendations

The dosage recommendation varied from giving none, to “one daily”; “as per tablet direction”; “what is specified on the label”; one Forceval tablet (actually presented in capsule form) or “daily”.

Duration of Supplementation

The information on duration of supplementation was variable. Eight respondents recommended supplementation for life, whilst others recommended for “active weight loss period”; at least six months post operation”; “depends on patients”; “as suggestion by centre where procedure done”; “ongoing until a balanced intake established”; “until dietary intake adequate” or “only in initial weight loss phase”.

Additional Recommendations

The Inter-disciplinary European Guidelines on Surgery of Severe Obesity (2007) also recommend for patients undergoing ‘food limiting’ operations are that “metabolic and nutritional status should be regularly monitored to prevent vitamin deficiencies and allow appropriate supplementation”. Only two respondents suggested that additional supplementation may be required one stating “Calcichew, one a day, lifelong post operation” whilst the other more comprehensively stated “variable upon nutritional

status and bloods post operation, iron, folate, zinc, calcium, vitamin D”.

Consequence of Caseload on Recommendations

The number of patients that the dietitians consulted with last year has no bearing on the type of response. Nine dietitians consulted with over one hundred patients last year. One dietitian who saw over one hundred patients last year did not recommend supplementation to patients who had food limiting procedures. Another dietitian whose caseload was greater than one hundred patients gave vague advice “don’t currently name a particular brand but recommend chewable / suckable / liquid / effervescent multi-vitamin and mineral” with no recommendation on dosage or duration. However, it was the dietitian whose caseload was over one hundred that stated that bloods and nutritional status may indicate the need for iron, folate, zinc, calcium or vitamin D. Of the two dietitians whose caseloads of bariatric patients were low (between one and twenty patients last year), one did not recommend supplementation and the other was not aware of the supplementation that his / her patients were taking stating “as suggested by centre where procedure done”.

NHS or Private Sector Patients

Whether the patients were seen in the NHS or the private sector, had no bearing on the recommendations made. The dietitian whose caseload was over one hundred patients who stated that nutritional status and blood tests may indicate the need for iron, folate, zinc, calcium and vitamin D was consulting in the NHS, whereas the dietitian who recommended supplementation ideally pre-operatively, as well as post operatively for life and the need for extra calcium was working in the private sector. Very small caseloads (less than twenty patients last year) were held by two dietitians, one in the

NHS and the other in the private sector. The one in the private sector did not recommend supplementation, whilst the other, working in the NHS, did but did not know what his / her patients were taking stating “as suggested by centre where procedure done”.

Vitamin and Micro-nutrient Recommendations Made by UK Registered Dietitians Post Limiting Absorption of Nutrients Procedures

All UK registered dietitians recommended vitamin and micro-nutrient supplementation to nutrient absorption limiting bariatric patients in their care according to the response (see Table 10). However, the range of the recommendations made was vast, from some recommending a “general one a day multi vitamin and mineral supplement” to one recommending “Forceval / Sanatagen Gold and extra calcium, vitamin B₁₂ injections, iron, selenium, zinc and vitamins A, E, D and K” (See Table 12).

The European Guidelines on Surgery of Severe Obesity (2007) recommendations for vitamin and micro-nutrient supplementation for patients undergoing ‘limiting absorption of nutrients’ operations were:-

- “lifelong daily vitamin and micro-nutrient supplementation (vitamins should be administered in a water soluble form),
- vitamin A, D, E and K,
- calcium supplementation (preferably in Calcium citrate), recommended total intake 2 g/day”.

Recommended Products

Eighteen of the twenty respondents who stated that they recommended supplements to this group of patients, made the following free text responses to the question about which product they recommended: “ Forceval” (n=6); “ Sanatogen Gold” (n=5); “Centrum” (n=4); “Sanatogen A-Z” (n=1); “Boots multi-vitamin and mineral” (n=1); “Supermarket A-Z multi-vitamin and mineral” (n=1), whilst eight respondents recommended none specified general multi-vitamin and mineral supplements. Six respondents offered two or three products that they recommended. One respondent stated that he / she did recommend supplementation to this group of patients but it was “as suggested by the centre where the procedure done”, whilst the other respondent who stated that they recommended supplementation to this group of patients was not actually consulting with patients undergoing these types of procedures stating “Lap banding only carried out at present first line”.

Dosage Recommendations

Eighteen out of the twenty respondents who recommended supplementation to this patient group recommended one tablet per day, but one respondent also recommended two tablets daily for patients having undergone DS procedures. One respondent gave no dosage recommendation and one stated “as suggested by centre where procedure done”.

Duration of Supplementation

Fifteen respondents of the nineteen recommending supplementation to this patient group recommended life long supplementation, with one also recommending from “the pre-op diet”. One respondent recommended supplementation during the “active weight loss period”; one recommending “continue”; one stating “as suggested by centre where procedure done” and one did not state any duration of supplementation.

Additional Supplementation

Four UK registered dietitians did not recommend any other supplement to patients undergoing limiting absorption of nutrients procedures.

Calcium

Ten of the twenty respondents who recommended supplementation to this group recommended additional calcium. The individual dietitians made the following recommendations: “800mg calcium 2 x day”; “extra Ca, as per physician, life; “Calcichew / Adcal D₃, one a day, lifelong”; “Calcium 1000mg R-e-Y, Life” and “Calcium 2000mg BPD and DS, life”; “Calcium 1000mg / day, life-long”; calcium 1000mg, life”; “Calcium 2 daily bypass, 4 daily DS, life”; “Calcichew, 500mg, continue”; “Calcichew D₃ forte, 2 tablets daily, lifelong” and “calcium, one a day, life”.

Vitamin D

Seven dietitians recommended extra vitamin D. The individual dietitians made the following recommendations: “Vitamin D, 5 µg, 2 x day”; “extra Ca, as per physician, life”; “Calcichew / Adcal, one a day, lifelong”; “AquaAEDKS for BPD and DS”; “Vitamin D₃, 800IE units, life”; “Vitamin D, 2 daily bypass, 4 daily DS, life”; “Calcichew D₃ forte, 2 tablets daily, lifelong”.

Vitamin B₁₂

Nine dietitians recommended vitamin B₁₂ injections. The individual dietitians made the following free text responses: “Vitamin B₁₂, 1mg, every 3 months for first 2 years”; “extra B₁₂ injections, as per physician, life”; “Vitamin B₁₂ injections, 1 mg, 3 monthly”; “Vitamin B₁₂ injections, maybe for BPD, not DS, Life”; “B₁₂ IM injections, 1mg every 3 months, life-long”; “Vitamin B₁₂ injections, injection 1 mg, every 3-4 months”; “others depending on blood results e.g. B₁₂ inj”; “Vitamin B₁₂ injections, once every 4 months approx., lifelong” and “Vitamin B₁₂ injections, once every 3 months, for life”.

Iron

Five UK registered dietitians recommended additional iron to patients who had undergone nutrient absorption limiting bariatric procedures. The individual dietitians' free text responses were: “Ferrous sulphate or gluconate as indicated by routine bloods, Until Hb resolves, often needed lifelong”; “Iron, depends on results, depends on results”; “iron supplements, depends on which iron salts they are prescribed but we aim to ensure patients receive ~65 mg per day, usually life-long”; “Spatone, 1 sachet per day, when ferritin levels are low”; “iron, one a day or whatever is specified on the

label, until serum ferritin, folate and B₁₂ is in range or patient chooses to stop due to constipation”.

Other Vitamins and Micro-nutrients

One dietitian also recommended “additional selenium and zinc, depending on results and AquAEDKs for BPD and DS” but with no dose or duration advice.

Consequence Caseload on Recommendations

The number of patients that the dietitians consulted with last year has a bearing on the type of response. Eight dietitians consulted with over one hundred patients last year.

Seven out of those eight dietitians made additional recommendations to that for general vitamin and micro-nutrient supplementation. However, one dietitian who saw over one hundred patients last year did not recommend any additional supplementation to patients who had limiting absorption of nutrient procedures.

However, the dietitian who gave the most comprehensive advice had a caseload of over 100 patients. Of the three dietitians whose caseloads of bariatric patients were low (between one and twenty patients last year), one only recommended a “general one a day multi-vitamin and mineral”, one was not aware of the supplementation that his / her patients were taking, stating “as suggested by centre where procedure done” and the third one recommended “Forceval, once a day, with 500 mg calcium, continue”.

NHS or Private Sector Patients

Whether dietitians consulted wholly or predominantly in the NHS or private sector had little bearing on the comprehensiveness of the free text responses. The dietitian who did not state the supplementation that his / her patients were taking offering “as suggested by the centre where the procedure done” consulted exclusively in the NHS, whereas the dietitian who gave the most comprehensive advice was consulting equal numbers of NHS and private / self pay patients.

Nutritional Composition of Recommended Products

The range of nutritional composition of the vitamin and micro-nutrient supplements named in the free text responses varied widely as can be seen in Appendix H, Tables 13 – 21.

Iron

The iron content varied from none in the Biocare product (sold through Asda as an example of supermarkets own brand) to 14 mg in Centrum and Sanatogen Gold A-Z.

Vitamin B₁₂

Vitamin B₁₂ content of the vitamin and micro-nutrient supplements recommended by UK registered dietitians ranged from 30 µg in the BioCare product, to 1 µg in the Boots and Centrum supplement.

Calcium

The calcium content of the named supplements ranged from 6 mg in the Biocare product to 230 mg in the Boots supplement.

The European Guidelines recommend supplementing nutrient absorption limiting patients with 2 g calcium per day. Half the dietitians recommended additional calcium to their bariatric patients, but only two dietitians' recommendations met the 2 g as recommended by European Guidelines, being 2200 mg calcium and 2000 mg plus calcium in "standard multi-vitamin and minerals" (between an extra 6 to 230 mg).

Vitamin A

There was 10900 µg (1 i. u. = 0.6 mcg carotene equivalents) in AquADEKs and only 400 µg in Boots Complete A-Z Vitamins.

Vitamin D

AquADEKs contains 20 µg (1 i. u. = 0.025 mcg vitamin D), but Boots own label and Centrum contained only 5 µg.

Vitamin E

The range of vitamin E content of the recommended products was from 10 mg in the Boots, Centrum, Forceval and Sanatogen Gold A-Z products, to 100 mg (1 i. u. = 0.67 mg D- α -tocopherol) in AquADEKs.

Vitamin K

The Vitamin K content of the named products range from 700 µg in AquAEDKs to none in Forceval.

Chapter 4

Discussion

Hypotheses

The two hypotheses of this piece of research were that the recommendations made by UK registered dietitians met the Bariatric Scientific Collaborative Group's Inter-disciplinary European Guidelines on Surgery of Severe Obesity (2007), in terms of nutritional supplementation, following the two main classifications of bariatric surgery type.

The first hypothesis was that a “supplement of vitamin and micronutrients should compensate for their possible reduced intake and absorption” should be recommended to patients undergoing ‘food limiting’ operations. Ninety percent of UK registered dietitians who were members of DOMUK and who responded to the survey were recommending vitamin and micro-nutrient supplementation to this group of patients in their care.

The second hypothesis was that:

- “lifelong daily vitamin and micro-nutrient supplementation (vitamins should be administered in a water soluble form),
- vitamin A, D, E and K,
- calcium supplementation (preferably in Calcium citrate), recommended total intake 2 g/day”,

were recommended to patients undergoing ‘limiting absorption of nutrients’

operations, in accordance with European Guidelines (2007). Only five percent (n = 1) of UK registered dietitians who were members of DOMUK and who responded to the survey were meeting these guidelines for patients in their care. All respondents did recommend vitamin and micro-nutrient supplementation to this group of patients. Therefore, both hypotheses of this piece of research, being that the recommendations made by UK registered dietitians met the Bariatric Scientific Collaborative Group's Inter-disciplinary European Guidelines on Surgery of Severe Obesity (2007), in terms of nutritional supplementation, were rejected.

The nutritional content of the vitamin and micro-nutrient supplements recommended by UK registered dietitians varied.

Representative Sample

Twenty one completed questionnaires were returned via SurveyMonkey. Responses were only received from 10.5% of the DOMUK membership. However, due to the specialist nature of the survey, it was likely that most of the respondents would have been members of the surgical sub-group. If this was the case the response rate would have been an improved 53%. Therefore, the survey may have been improved by asking respondents to identify if they were members of the surgical sub-group.

At least a third of patients treated in the NHS last year would have been advised by responding dietitians. No comment could be made on the proportion of patients in the private sector that were advised by the responding dietitians, due to lack of data on the surgical activity in this sector, because of the commercially sensitive nature of that information.

The validity of the survey findings with respect to the advice offered to NHS patients could have been improved if a free text response to the number of patients seen last year had been used.

Food Limiting Procedures

The Bariatric Scientific Collaborative Group in 2007 published guidelines for patients following food limiting procedures, to ensure the nutritional adequacy of patients' intake post operatively. The most common restrictive procedure in the UK was the LAGB, this being the gold standard purely restrictive procedure (NICE, 2006).

Fortunately, restrictive procedures such as LAGB are the least likely to cause nutritional deficits. However, deficiencies may occur, because of the limitation of food intake and food avoidance (Ledoux et al. 2006; Kalfarentzos et al., 2001). The European Guidelines (2007) also included mixed restrictive / malabsorptive procedures such as proximal RYGB in this category of surgical procedures. The European Guidelines (2007) recommend routine supplementation of vitamins and micro-nutrients to compensate for possible reduced intake and absorption.

Ten percent (n=2) of dietitians who were consulting with patients who had undergone food limiting procedures did not recommend supplementation following the patients' surgery. One of the dietitians had only consulted with between one and twenty patients last year, but the other had advised over one hundred patients last year.

Reassuring 90% (n=18) of the respondents had recommended vitamin and micro-nutrient supplementation to the patients they consulted who had undergone food limiting bariatric procedures.

The specificity of the advice given to this group of patients on vitamin and micro-nutrient supplementation was poor. Seven respondents recommended a supplement, but were none specific, suggesting "any complete", "multi vitamin and mineral" or words to that effect. The dosage recommendation varied from giving none, to "one daily"; "as per tablet direction"; "what is specified on the label"; "one Forceval tablet" (actually presented in capsule form) or "daily". The European Guidelines (2007) do

not specify the type of supplement of vitamins and micro-nutrients that should be recommended or prescribed to compensate for the patients' possible reduced intake and absorption. However, one would have to question the proficiency of a healthcare professional who recommended a nutritional supplement or requested an authorised prescriber to prescribe a nutritional supplement (such as Forceval), but made no comment or gave vague advice on the dosage of that product.

Likewise, the information on duration of supplementation was equally variable. Eight respondents recommended supplementation for life, whilst others recommended for "active weight loss period", "at least six months post operation" or "until dietary intake adequate". The European Guidelines do not give any recommendation on the duration of the vitamin and micro-nutrient supplementation for this type of procedure, but that follow-up should be annually. Nutritional deficiencies occur following proximal RYGB ((Skroubis et al., 2002; Toh et al., 2009) and patients experience difficulties following LAGB in achieving a balanced, dietary intake (Ledoux et al., 2006). The majority of respondents only recommending a short duration of supplementation may expose the patient to the long term risk of nutritional deficiencies.

Regular monitoring of the nutritional status is essential to detect any deficiencies that may arise in the post bariatric patient. The European Guidelines state that "metabolic and nutritional status should be monitored to prevent vitamin deficiencies and allow appropriate supplementation". Although the questionnaire did not specifically ask about monitoring of nutritional status, it would have been expected that UK registered dietitians would have tempered their responses of recommended vitamin and micro-nutrient supplementation to the nutritional status of the patients in their care. NICE Guidance 43 (2006) states that regular, specialist post operative dietetic monitoring

should be provided, which should include monitoring of the person's micro-nutrient status and individualised nutritional supplementation following bariatric surgery. Only one dietitian stated that his / her recommendations were "variable upon nutritional status and bloods post operation".

Iron Status with Food Limiting Procedures

Four years after purely restrictive surgery, nearly a half of patients may develop iron deficiency anaemia (Kalfarentzos et al., 2001) and the majority of patients undergoing this type of surgery are pre-menopausal women who are particularly predisposed to developing iron deficiency anaemia (Love & Billett, 2008; Cunneen, 2008).

Therefore, the risk of developing iron deficiency and iron deficiency anaemia is raised.

Patients having undergone mixed restrictive and malabsorptive procedures are more at risk of developing iron deficiency and iron deficiency anaemia due to a combination of factors (Bloomberg et al., 2005). The risk of developing this nutritional deficiency as a result of this type of bariatric surgery is high, with nearly two thirds of RYBG patients developing anaemia, three years after their surgery (Vargas-Ruiz et al., 2008).

Although the European Guideline (2007) recommend a multi-vitamin and micro-nutrient supplement, Malone (2008) suggests that patients should choose "a multi-vitamin preparation with iron and that ideally contains vitamin C", which may enhance absorption in the daily supplement. However, the American Guidelines (2008) are more specific, recommending as routine that all RYBG patients be supplemented with 40 – 65 mg per day elemental iron.

The iron content of the products recommended by UK registered dietitians had a wide variation. A supermarket own brand, produced by BioCare, contained no iron, Forceval contained 12 mg iron, whereas Centrum and Sanatogen Gold contained 14 mg iron. These levels are well below the American recommendations. All the supplements named by the UK registered dietitians contained vitamin C. Centrum, Sanatogen Gold and Forceval containing 60 mg vitamin C, with the BioCare product containing 243 mg.

Therefore by making the general recommendation, such as “Supermarket A-Z multi-vitamin and mineral” may be placing the patient at risk of developing iron deficiency anaemia, since it may not contain iron. UK registered dietitians must make themselves aware of the nutritional composition of the products that they are recommending to patients in their care.

Only one dietitian stated that additional iron may be required depending on nutritional status, but offered no dosage. The European Guidelines (2007) make no dosage recommendations, but the American Guidelines (2008) recommend 320 mg twice a day of ferrous fumarate, sulphate or gluconate daily to treat iron deficiency.

The European Guidelines (2007) indicate that depending on laboratory results, parenteral administration of vitamins and micro-nutrients may be required to correct deficits. Varma et al. (2008) reiterates this statement by suggesting intravenous iron infusion with iron dextran, ferric gluconate or ferric sucrose may be needed if oral iron supplementation is ineffective at correcting the iron deficiency.

Vitamin B₁₂ Status with Food Limiting Procedures

It is considered that restrictive procedures such as LAGB do not place the obese patient at increased risk of vitamin B₁₂ deficiency, since the gastrointestinal tract remains intact. However, deficiencies in vitamin B₁₂ are more widely associated with mixed restrictive and malabsorptive procedures such as proximal RYGB, which the Europeans Guidelines (2007) group along with purely restrictive procedures such as LAGB. The American Guidelines group all RYBG and malabsorptive / restrictive procedures such as BPD together for nutritional supplementation recommendations. Following malabsorptive procedures, due to the surgically induced anatomical changes in the gastrointestinal tract, the normal physiological process is interrupted which may account for the development of vitamin B₁₂ deficiency. A third of RYGB patients have been shown to be vitamin B₁₂ deficient, despite general multi-vitamin supplementation, two years after their operations, (Vargas-Ruiz et al., 2008). The European Guidelines only recommend a multi-vitamin and micro-nutrient supplement, although the American Guidelines recommend a prophylactic oral dose of crystalline vitamin B₁₂ 350 µg or more per day. The vitamin B₁₂ content of the vitamin and micro-nutrients supplements recommended by UK registered dietitians ranged from 30 µg in the BioCare product, to 1 µg in the Boots and Centrum supplement. There was a wide discrepancy between the dose of vitamin B₁₂ that UK registered dietitians were recommending to the patients in their care and the dose that has been established to maintain serum values within the reference range. Skroubis et al. (2002) predicted the time of onset of vitamin B₁₂ deficiency following proximal RYGB to occur just less than a year after their operation. Eight respondents recommended supplementation for life, whilst others recommended for “active weight loss period”, “at least six months post operation” or “until dietary intake adequate”.

Considering the anatomical changes to the gastrointestinal tract, patients who have undergone proximal RYGB are at lifelong risk of developing vitamin B₁₂ deficiency. Only recommending supplementation for such time periods as for “active weight loss period” or “ongoing until a balanced intake established”, may not be of sufficient duration to prevent deficiency developing.

The European Guidelines (2007) recommend annual laboratory tests to evaluate nutritional status and as a result of these tests, possibly parenteral administration of vitamins and minerals, but with no dosage recommendations. The American Guidelines (2008) recommend that if vitamin B₁₂ sufficiency cannot be maintained with oral supplementation, then 1000 µg vitamin B₁₂ monthly or 1000 – 3000 µg every six to twelve months should be administered parenterally. No dietitian made reference to the possible need for parenteral supplementation of vitamin B₁₂ following the European grouping of food limiting procedures.

Vitamin D Status with Food Limiting Procedures

There is a close interplay between vitamin D, calcium and PTH. It has been established that following European Guidelines classed 'food limiting procedures' such as proximal RYGB, vitamin D deficiency has been demonstrated, from as early as six – nine months after surgery (Coates et al, 2004).

Although the European Guidelines (2007) do not propose a recommended dose for vitamin D, the American ones do (2008). In that document, it is suggested that patients having undergone all RYGB have a routine vitamin D supplement of 10 – 20 µg vitamin D per day. The vitamin D content of the supplements recommended by the UK registered dietitians ranged from 5 - 10 µg per day. No dietitian recommended additional vitamin D. This again highlights the need for UK registered dietitians to know the nutritional composition of the products that they are recommending to patients in their care.

However, the need for annual laboratory blood testing to determine vitamin D status of patients following food limiting procedures must be undertaken. Although not specifically asked about in the survey, only one dietitian cited this in his / her response and he / she suggested that additional vitamin D may be required following the results of these tests. The dietitian offered no dosage advice, however, Goldner et al. (2009) demonstrated that vitamin D replacement as high as 125 µg / day is safe and necessary in many patients to treat vitamin D deficiency following RYGB.

calcium Status Following Food Limiting Procedures

In both the obese and in patients having undergone bariatric surgery, bone mineral metabolism is a complex topic. In the European Guidelines classified “food limiting” procedures, up to one in four patients may become calcium deficiency, following proximal RYGB (Hamoui et al., 2003). The cause of this deficiency is thought to be ingested food bypassing the principle sites of calcium absorption, which are the duodenum and proximal jejunum and the defective absorption of fat soluble vitamin D, which promotes calcium absorption.

Supplementation with 1200 mg calcium and between 20 – 30 µg vitamin D per day in both LAGB and proximal RYGB patients improved bone metabolism abnormalities associated with obesity and attenuated the increased risk for bone loss associated with malabsorption from the bypass (DiGiorgi et al., 2009).

Only two dietitians recommended additional calcium to this group of patients, but the dose recommended by one was only 500 mg calcium per day, whilst the other offered no dosage advice. The European Guidelines (2007) make no recommendation for level of calcium supplementation to this group of patients, but the American ones do, being 1200 – 2000 mg calcium per day (2008). No dietitians’ recommendations met this level of supplementation, with the range of level of supplementation being from six – 230 mg in the general multi-vitamin and micro-nutrient to 506 – 730 mg from the dietitian recommending additional calcium. At this level of supplementation, patients are continuing to be at risk of the bone metabolism abnormalities associated with obesity, let alone the increased risk of bone loss associated with RYGB.

Consequence of Caseload on Recommendations Made

The number of patients that the dietitians consulted with last year has no bearing on the type of response. One dietitian who saw over one hundred patients last year did not recommend supplementation to patients who had food limiting procedures whilst it was the dietitian whose caseload was over one hundred that gave the most comprehensive response to supplementation following food limiting procedures.

Summary of the Survey Findings with regard to Food Limiting Bariatric Procedures

Most UK registered dietitians (90%) were recommending vitamin and micro-nutrient supplementation to the patients who had undergone food limiting bariatric procedures, which included LAGB and proximal RYGB, as defined by the European Guidelines (2008).

However, there is a risk of developing nutritional deficiencies following these procedures. Iron deficiency and iron deficiency anaemia (Kalfarentzos et al., 2001; Bloomberg et al., 2005), vitamin B₁₂ deficiency (Malone, 2008) as well as altered bone mineral metabolism have been reported following these procedures.

Although most UK registered dietitians were meeting the European Guidelines, in that they were recommending vitamin and micro-nutrient supplementation, patients in their care may be at risk of developing nutritional deficiencies due to the nutritional content of the products that they were recommending.

The European Guidelines (2007) state “metabolic and nutritional status should be regularly monitored to prevent vitamin deficiencies and allow appropriate supplementation”, to tailor supplementation to the individual. (The pedantic author would propose this statement should include “micro-nutrient deficiencies” since iron

deficiency anaemia is not a vitamin deficiency). NICE Guidance 43 (2006) also state that regular, specialist post operative dietetic monitoring should be provided, which should include monitoring of the person's micro-nutrient status and individualised nutritional supplementation. Although monitoring was not specifically asked about in the survey, only one respondent (5%) stated that his / her recommendations were dependent on such findings. In light of the evidence surrounding nutritional deficiencies following restrictive and mixed restrictive and malabsorptive bariatric surgery, detection of and tailoring vitamin and micro-nutrient supplementation to treat any deficiency are essential (Gasteyger et al., 2008).

Nutrient Absorption Limiting Procedures

The Bariatric Scientific Collaborative Group in 2007 published guidelines for patients following nutrient absorption limiting procedures, to ensure the nutritional adequacy of patients' intake post operatively. This group of procedures include BPD and distal RYGB. The extensive surgically induced anatomical changes in the gastrointestinal tract results in these procedures having a greater tendency to result in serious nutritional problems.

The European Guidelines (2007) for patients undergoing these types of bariatric procedures include:-

- “lifelong daily vitamin and micronutrient supplementation (vitamins should be administered in a water soluble form),
- vitamin A, D, E and K,
- calcium supplementation (preferably in Calcium citrate), recommended total intake 2 g/day,

were recommended to patients undergoing ‘limiting absorption of nutrients’ operations. Only one UK registered dietitian who was a member of DOMUK and who responded to the questionnaire was meeting these guidelines for patients in his / her care.

All UK registered dietitians recommended vitamin and micro-nutrient supplementation to nutrient absorption limiting bariatric patients in their care. The one dietitian who met all the recommended guidelines for this type of procedure stated that he / she recommended “Forceval / Sanatagen Gold and extra calcium, vitamin B₁₂ injections, iron, selenium, zinc and vitamins A, E, D and K”. Four respondents only recommended a general, multi vitamin and mineral supplement. Ninety percent of the

respondents (n=18) recommended one tablet per day although one respondent did also recommend two tablets daily for patients having undergone DS. One respondent gave no dosage recommendation and one stated “as suggested by centre where procedure done”.

Eighty percent (n=15) of respondents recommended lifelong supplementation to this patient group. The European Guidelines state that supplementation should be for life after this type of procedure.

Considering the body of evidence about the serious risk of nutritional deficiencies following malabsorptive / restrictive procedures such as BPD, the fact that 20% of respondents were not recommending life-long supplementation was a concern.

The European Guidelines (2007) state that “laboratory tests are necessary to evaluate the evolution of metabolic and nutritional status and to adapt supplementation and drug treatment accordingly”. Although the survey did not specifically ask about monitoring of nutritional status, it would have been expected that UK registered dietitians would have tempered their responses of recommended vitamin and micro-nutrient supplementation to the nutritional status of the patients in their care. NICE Guidance 43 (2006) states that regular, specialist post operative dietetic monitoring should be provided, which should include monitoring of the person’s micro-nutrient status and individualised nutritional supplementation following bariatric surgery. Only four dietitians made mention of the need for specific supplementation to be determined by the result of blood tests.

Iron Status following Nutrient Absorption Limiting Bariatric Procedures

Patients are at risk of developing iron deficiency anaemia following malabsorptive / restrictive procedures such as BPD (Skroubis et al., 2002) and pre-menopausal women are particularly predisposed toward developing iron deficiency following bariatric surgery (Love & Billett, 2008).

Although the European Guidelines do not specify the oral dose of iron recommended to patients following nutrient absorption limiting procedures, the American Guidelines recommend routine supplementation of this group of patients with 40 – 65 mg elemental iron per day, with up to 320 mg twice a day of ferrous sulphate, fumarate or gluconate possibly being required to prevent iron deficiency in patients who have undergone malabsorptive / restrictive procedures, especially menstruating women.

The iron content of the general vitamin and micro-nutrient supplements recommended by the all the respondents ranged from none to 14 mg iron per day. Twenty five percent (n=5) of UK registered dietitians recommended additional iron to patients who had undergone nutrient absorption limiting bariatric procedures. The recommendation of one respondent met the 65 mg iron per day as per the American Guidelines, whilst another recommended just 5 mg per day. This is far below the level recommended by the American Guidelines and could place the patients in their care at risk of developing iron deficiency anaemia.

Four of the five dietitians who recommended extra iron to this group of patients stated that dosage was depended on blood results, which was in accordance with the European Guidelines.

The European Guidelines (2007) go on to suggest that for the correction of any such deficit that may arise, the supplementation should be administered parenterally.

Varma et al., (2008) suggested that intravenous iron infusion with iron dextran, ferric gluconate or ferric sucrose may be needed if oral iron supplementation is ineffective at correcting the iron deficiency.

Vitamin B12 Status following Nutrient Absorption Limiting Bariatric

Procedures

Although the deficiency of vitamin B₁₂ with BPD is less common, due to the stomach production of acid and intrinsic factor remaining unaffected (Malone, 2008), the risk of developing vitamin B₁₂ deficiency is still present (Dolan et al., 2004). Just eight months after surgery unsupplemented BPD patients can expect to become vitamin B₁₂ deficient (Skroubis et al., 2002).

There is no European Guideline (2007) on the recommended dose of vitamin B₁₂, but American Guidelines (2008) recommend equal to or greater than 350 µg vitamin B₁₂ per day orally, prophylactically. The vitamin B₁₂ content of the vitamin and micro-nutrients supplements recommended by UK registered dietitians ranged from 30 µg in the BioCare product, to 1 µg in the Boots and Centrum supplement. There was a wide discrepancy between the dose of vitamin B₁₂ that UK registered dietitians were recommending to the patients in their care and the American Guidelines. No dietitian recommended extra oral vitamin B₁₂. Patients are possibly being placed at extra risk of developing vitamin B₁₂ deficiency because of the low doses of the supplement they were being advised to be take following their surgery.

The European Guidelines recommend blood testing at one, four and twelve months and thereafter annually (2007) following nutrient limiting bariatric procedures.

Depending on the results of these tests, parenteral administration of vitamins and minerals should be undertaken to correct deficits. The European Guidelines offer no

recommended intramuscular dose to treat vitamin B₁₂ deficiency, but the American Guidelines recommend 1000 - 3000 µg parenterally, every six months to twelve months, if vitamin B₁₂ sufficiency cannot be maintained by means of oral supplementation. Forty five percent of dietitians (n=9) recommended vitamin B₁₂ injections for this group of patients. It may be that sufficiency could be maintained by a larger oral dose, such as the American recommendation, mitigating the need for the four responding UK registered dietitians recommending 1 mg, three monthly injections. Only one of these respondents highlighted the need for blood tests to determine the need of vitamin B₁₂ supplementation.

Vitamin D Status following Nutrient Absorption Limiting Bariatric Procedures

Bone mineral metabolism is a complex issue following bariatric surgery. Malone (2008) reported that the general consensus was that patients were likely to develop problems with bone mineral density and metabolism after bariatric surgery, especially with malabsorptive procedures, such as BPD. The patients most at risk were patients with a BMI greater than 50 kg / m², post menopausal women, patients who experience the greatest weight loss after surgery and patients who had high bone turnover prior to surgery (Davies et al., 2007).

The European Guidelines recommend that patients who have undergone nutrient absorption limiting procedures should be supplemented with vitamin D, although no dose was proposed. The American Guidelines (2008) recommend that patients having undergone BPD, BPD with DS or RYGB have a routine vitamin D supplement of 10 – 20 µg vitamin D per day. Depending on the general supplement that the responding dietitians recommended to their patients, the dose varied from 5 – 10 µg vitamin D per day. The majority of dietitians who responded to the questionnaire were not

recommending additional vitamin D, despite the European Guidelines highlighting the need to do so. Thirty five percent of respondents (n = 7) were recommending extra vitamin D. The dietitians' recommended dosage ranged from 10 µg - 40 µg per day, in addition to the vitamin D in the general supplement (ranging from 5 mcg - 10 mcg vitamin D depending on product). Patients may well be ingesting a quarter of the American recommended dose, thus placing patients in their care at risk of deficiency, if they are taking a lower dose vitamin D preparation. This again highlights the need for UK registered dietitians to know the nutritional composition of the products that they are recommending to patients in their care.

The European guidelines recommend blood testing at one, four and twelve months and thereafter annually (2007) following nutrient limiting bariatric procedures such as BPD. Depending on the results of these tests, parenteral administration of vitamins and minerals should be undertaken to correct deficits. The European Guidelines offer no recommended dose to treat vitamin D deficiency, however, the Americans ones suggest that between 1250 and 3750 µg vitamin D₂ daily may be needed in cases of severe malabsorption. The recommended treatment guidelines for vitamin D deficiency is 50000 i.u. (1250 µg) vitamin D₂ intramuscularly, weekly for four to six weeks, then maintained with 1000 i.u. (25 µg) orally, daily (Holick, 2007).

calcium Status following Nutrient Absorption Limiting Bariatric Procedures

Bone mineral metabolism is a complex issue following bariatric surgery. Normally, passive calcium absorption continues throughout the gastrointestinal tract. However, due to the extensive anatomical change following bariatric surgery, the absorption of calcium is limited. BPD is often the surgical procedure of choice for heavier patients, with the greatest weight loss achieved after surgery (NICE, 2006). Hence, this group of patients are at most risk of developing bone mineral density problems as a result of their surgery (Davies et al., 2007).

Just under fifty percent (n = 9) of the responding dietitians were only recommending calcium within the general vitamin and micro-nutrient supplement, which ranged from six - 230 mg depending on product.

The European Guidelines recommend an extra 2 g of calcium per day, preferably in the citrate form (2007), whereas the American Guidelines recommend between 1200 – 2000 mg calcium per day, to this group of patients. Although just over fifty percent of the respondents (n=10) recommended additional calcium to this group of patients, the recommended dosage ranged from 500 mg to 2000 mg extra calcium per day in addition to the calcium within the general vitamin and micro-nutrient supplement.

Only two dietitians were meeting the European recommended level of calcium supplementation. The citrate form of the calcium salt was recommended as patients often have low dietary intakes, hypochlorhydria and low vitamin D levels (Malone, 2008).

The European guidelines recommend blood testing at one, four and twelve months and thereafter annually (2007) following nutrient limiting bariatric procedures such as BPD. Depending on the results of these tests, parenteral administration of vitamins and minerals should be undertaken to correct deficits, with the exception of calcium.

Other Vitamins and Micro-nutrients

There is good evidence for other vitamin and micro-nutritional deficiencies occurring as a result of malabsorptive / restrictive procedures (Malone, 2009). One dietitian recommended additional selenium and zinc, depending on blood results. That dietitian also recommended extra vitamins A, E and K to this group of patients.

Consequence of Caseload on Recommendations Made

The number of patients that the dietitians consulted with last year had a bearing on the type of response, with six out of those eight dietitians who consulted with over one hundred patients last year making two or more additional recommendations to that for general vitamin and micro-nutrient supplementation. The dietitian who gave the most comprehensive advice had a caseload of over 100 patients. Of the three dietitians whose caseloads of bariatric patients were low (between one and twenty patients last year), only additional calcium was recommended by one of them.

Summary of the Survey Findings with regard to Nutrient Absorption Limiting Bariatric Procedures

Unfortunately, only one UK registered dietitian who was a member of DOM and responded to the questionnaire met the European Guidelines on the supplementation of patients with vitamins and micro-nutrients following nutrient limiting bariatric procedures such as BPD. It is well recognised that due to the extensive surgical induced anatomical changes occurring in this type of procedure, patients are at risk of developing nutritional deficiencies (Hess & Hess, 1998; Marceau et al., 1998; Scopinaro et al, 1996).

Deficiencies in iron (Skroubis et al., 2002) and vitamin B₁₂ (Dolan et al., 2004) have been reported along with the abnormal bone mineral metabolism in patients following malabsorptive / restrictive procedures (Newbury et al., 2004).

This increased risk is ameliorated by the more specific vitamin and micro-nutrient supplementation guidelines produced by the European Bariatric Scientific Collaborative Group (2007). Unfortunately the survey findings suggest that the advice provided to this group of patients, by UK registered dietitians is placing them at risk of developing nutritional deficiencies.

The European Guidelines (2007) recommend nutritional status be determined at one, four and twelve months and then annually thereafter and that supplementation should be adapted depending on the results of these tests. NICE Guidance 43 (2006) also state that regular, specialist post operative dietetic monitoring should be provided, which should include monitoring of the person's micro-nutrient status and individualised nutritional supplementation. Although monitoring was not specifically asked about in the survey, only five respondents (25%) stated that his / her recommendations were dependent on such findings. In light of the evidence

surrounding nutritional deficiencies following malabsorptive / restrictive bariatric surgery, detection of and tailoring vitamin and micro-nutrient supplementation to treat any deficiency are essential (Gasteyger et al., 2008).

Micro-nutritional Implications of Obesity

There is growing evidence about the generally poor micro-nutrient status in obese individuals. Deficiencies of magnesium, zinc, folate, selenium, vitamin B6, vitamin E and thiamine have been identified (Ernst et al., 2009; Farhanghi et al., 2009). Up to a third of pre-bariatric surgery patients have been demonstrated to have iron deficiency anaemia (Skroubis et al., 2002; Flancbaum, Belsley, Drake, Colarusso & Tayler, 2006), with nearly a fifth of morbidly obese individuals having vitamin B₁₂ deficiency (Ernst et al., 2009). Abnormalities of bone mineral metabolism have also been established in the obese (Goldner et al., 2009; Hamoui et al., 2004).

Therefore, morbidly obese patients may well present for surgery in a nutritionally compromised state, prior to the nutritional insult imposed on them as a result of bariatric procedures involving a degree of restriction of food ingestion or malabsorption.

Neither the European or American Guidelines recommend nutritional supplementation prior to surgery. However, one UK registered dietitian commented in the free text response that he / she recommended vitamin and micro-nutrient supplementation ideally from the patients' pre - operation diet, for both food limiting and nutrient absorption limiting procedures. In light of the compounding evidence regarding the deleterious nutritional state morbidly obese patients may present for surgery, it may be prudent to advise this group of patients to supplement their diet with additional vitamins and micro-nutrients from their pre-surgical consultation.

Implications of the Survey Findings on Professional Dietetic Practice

The range of advice offered to patients following their surgery, by UK registered dietitians who are members of DOMUK and who responded to the survey was wide. Many patients are being exposed to the risk of developing nutritional deficiencies. Increasing the knowledge of dietitians who advise bariatric patients on the type, dosage and duration of supplementation will be an outcome from this survey, through dissemination of these findings.

However, as Malone (2008) suggests, all healthcare professionals, especially those who practiced outside large bariatric centres, must be aware of the supplements required by patients who have had bariatric surgery. Many patients fail to attend or are not offered lifelong follow up from their surgical team and are managed by their primary healthcare teams, who need to be aware of the selection of vitamin and micro-nutrient supplements that are required.

Conclusion

Reassuringly, the majority of UK registered dietitians were meeting the European Guidelines for food limiting procedures. However, only one respondent met the European Guidelines for nutrient absorption limiting procedures. Therefore, the hypotheses for this piece of research are rejected.

The European Guidelines group both LAGB and proximal RYGB as food limiting procedures. There is strong evidence that patients who have undergone all types of RYGB are at a greater risk of developing nutritional deficiencies, such as iron, vitamin B₁₂, calcium and vitamin D, than patients who have undergone purely restrictive procedures such as LAGB. The risk of developing nutritional deficiencies

following nutrient absorption limiting procedures such as BPD and distal RYGB is high. The American Guidelines group all types of RYGB along with BPD and BPD with DS as requiring the same prophylactic supplementation.

Although there is the proviso that patients undergoing all types of bariatric surgery should have annual blood tests to detect deficiencies in the European Guidelines, the evidence is that general vitamin and micro-nutrient supplementation would not meet their nutritional needs (Gasteyger et al., 2008). Following exploration of the specially formulated bariatric vitamin and micro-nutrient supplements that are emerging on the UK market, the recommendation of these supplements by UK registered dietitians may prove to be more appropriate to ensure the nutritional needs of patients are met.

List of References

Adams, T. D., Gress, R.E., Smith, S. C., Halverson, R. C., Simper, S. C., Rosamond, W. D., Lamonte, M. J., Stroup, A. M. & Hunt, S. C. (2007). Long-term mortality after gastric bypass surgery. *New England Journal of Medicine*, 357: 753–761.

American Association of Clinical Endocrinologists (AACE), the Obesity Society (TOS) and the American Society for Metabolic and Bariatric Surgery (ASMBS). (2008). American Bariatric Surgical Medical Guidelines for the clinical practice for the peri-operative, nutritional, metabolic and non-surgical support of the bariatric surgery patient. *Endocrine Practice*; Vol 14: 3.

Avenell, A., Brown, T. J., Mcgee, M. A., Campbell, M. K., Grant, A. M., Broom, J., Jung, R. T. & Smith, W. C. S., (2004a). What are the long term benefits of weight reducing diets in adults? A systematic review of randomized controlled trials. *Journal of Human Nutrition and Dietetics*, 17: 317-335.

Avenell, A., Brown, T. J., Mcgee, M. A., Campbell, M. K., Grant, A. M., Broom, J., Jung, R. T. & Smith, W. C. S., (2004b). What interventions should we add to weight reducing diets in adults with obesity? A systematic review of randomized controlled trials of adding drug therapy, exercise, behaviour therapy or combinations of these interventions. *Journal of Human Nutrition and Dietetics*, 17: 293-316.

Avenell, A., Broom, T. J., Poobalan, A., Aucott, L., Stearns, S. C., Smith, W. C. S., Jung, R. T., Campbell, M. K. & Grant, A. M., (2004). Systematic review of the long term effects and economic consequences of treatments for obesity and implications for health improvement. *Health Technology Assessment*, 8: 1-182.

Ausk, K., J. & Ioannou, G. N. (2008). Is obesity associated with anaemia of chronic disease? A population based study. *Obesity*, October; 16(10): 2356-2361.

Bensimhon, D. R., Kraus, W. E. & Donahue, M. P. (2006). Obesity and physical activity: a review. *American Heart Journal*, 151: 598-603.

Bloomberg, R., Fleishman, A., Nalle, J. E., Herron, D. M. & Kini, S. (2005). Nutritional deficiencies following bariatric surgery. *Obesity Surgery*, Vol 15: 145-154.

Boudreau, R. & Hodgson, A. (2007). Laparoscopic adjustable gastric banding for weight loss in obese adults: clinical and economic review. *Health Technology Assessment (HTA) Database. Canadian Agency for Drugs and Technologies in Health (CADTH)*. Retrieved from the CADTH Web site:
<http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?View=Full&ID=32007000541>

Brolin, R. E. & Leung, M. (1999). Survey of vitamin and mineral supplementation after gastric bypass and biliopancreatic diversion for morbid obesity. *Obesity Surgery*, April; 9(2): 150-154.

Bromley, C., Sprogston, K. & Shelton, N. (Eds.). (2005). *The Scottish Health Survey, 2003*. Edinburgh: The Stationary Office.

Chang, C. G., Adams-Hurst, B. & Provost, D. A. (2004). Acute post gastric reduction surgery (APGARS) neuropathy. *Obesity Surgery*, 14: 182-189.

Clay, T. D., Cohen, L. & Preen, D. B. (2007). Once yearly 'megadose' intramuscular vitamin D (600,000 i. u.): A simple, safe and effective method to normalise vitamin D levels after BPD surgery. *Surgery for Obesity and Related Disorders; Vol 3; 3*: 354.

Clegg, A., Colquitt, J., Sidhu, M., Royle, P. & Walker, A. (2003). Clinical and cost effectiveness of surgery for morbid obesity: a systematic review and economic evaluation. *International Journal of Obesity, Vol 2*: 1167–1177.

Coates, P. S., Fernstrom, J. D., Fernstrom, M. H., Schauer, P. R. & Greenspan, S. L. (2004). Gastric bypass surgery for morbid obesity leads to an increase in bone turnover and a decrease in bone mass. *The Journal of Clinical Endocrinology and Metabolism, Vol 89: No 3*, 1061-1065.

Cominetti, C., Garrido, A. B. & Cozzolino S. M. F. (2006). Zinc nutritional status of morbidly obese patients before and after roux-en-y gastric bypass: A preliminary report. *Obesity Surgery, Vol 16*: 448-453.

Coakes, S. J. & Steed, L. G. (2007). *SPSS version 14.0 for windows: Analysis without anguish*. Queensland: Wiley.

Cunneen, S. A. (2008). Review of meta-analytic comparisons of bariatric surgery with a focus on laparoscopic adjustable gastric banding. *Surgery for Obesity and Related Disorders*. May-June; 4 (3 Suppl): S47-55.

Czerwińska, E., Marcinowska-Suchowierska, E., Walicka, M., Lisik, W. & Wierzbicki, Z. (2007). The influence of bariatric surgery on calcium homeostasis and biochemical markers of bone turnover in patients with morbid obesity. *Endokrynol Pol*, Mar-Apr; 58 (2): 130-8.

Davies, D. J., Baxter, J. M. & Baxter, J. N. (2007). Nutritional deficiencies after bariatric surgery. *Obesity Surgery*; 17: 1150-1158.

Dawson-Hughes, B., Heaney, R., Holick, M., Lips, P., Meunier, P. J. & Vieth, R. (2005). Estimates of optimal vitamin D status. *Osteoporosis International*, 16: 713-716.

de Campos, C. D., Dalcanale, L., Pajecki, D., Garrido, A. B. & Halpern, A. (2008). Calcium intakes and metabolic bone disease after eight years of roux-en-y gastric bypass. *Obesity Surgery*, 18: 386-390.

- de Luis, D. A., Pacheco, D., Izaola, O., Terroba, M. C., Cuellar, L & Martin, T. (2008). Clinical results and nutritional consequences of biliopancreatic diversion: three years of follow-up. *Annals of Nutrition and Metabolism*, 53 (3-4): 234-239.
- DiGiorgi, M., Daud, A., Inabnet, W. B., Schrope, B., Urban-Skuro, M., Restuccia, N. & Bessler, M. (2008). Markers of bone and calcium metabolism following gastric bypass and laparoscopic adjustable gastric banding. *Obesity Surgery*, Sep; 18(9):1144-1148.
- Dixon, J. B., O'Brien, P. E., Playfair, J., Chapman, L., Schachter, L. M., Skinner, S., Proietto, J., Bailey, M. & Anderson, M. (2008). Adjustable gastric banding and conventional therapy for type 2 diabetes: a randomized controlled trial. *Journal of American Medical Association*, 299: 316–323.
- Dolan, K., Hatzifotis, M., Newbury, L., Lowe, N. & Fielding, G. (2004). A clinical and nutritional comparison of biliopancreatic diversion with and without duodenal switch. *Annals of Surgery*, Vol 240: 51- 56.
- Ernst, B., Thurnheer, M., Schmid, S. M. & Schultes, B. (2009). Evidence for the necessity to systematically assess micro-nutrient status prior to bariatric surgery. *Obesity Surgery*, Jan; 19(1): 66 -73.

- Farhanghi, M. A., Mahboob, S. & Ostadrahimi, A. (2009). Obesity induced magnesium deficiency can be treated by vitamin D supplementation. *Journal Pakistan Medical Association*, Apr; 59(4): 258-261.
- Field, A. (2005). *Discovering Statistics Using SPSS*. Second Edition (and Sex, Drugs and Rock 'n' Roll). London; Sage.
- Flancbaum, L., Belsley, S., Drake, V., Colarusso, T. & Tayler, E. (2006). Pre-operative nutritional status of patients undergoing Roux-en-Y gastric bypass for morbid obesity. *Journal of Gastrointestinal Surgery*, Jul-Aug; 10(7): 1033-1037.
- Folope, V., Coëffier, M. & Déchelotte, P. (2007). Nutritional deficiencies associated with bariatric surgery. *Gastroenterology Clinical Biology*, Apr; 31(4): 369-377.
- Fried, M., Hainer, V., Basdevant, A., Bushwald, H., Deitel, M., Finer, N., Greve, J. W. M., Horber, F., Mathus-Vliegen, E., Scopinaro, N., Steffen, R., Tsigos, C., Weiner, R. & Widhalm, K. (2008). Interdisciplinary European Guidelines on Surgery of Severe Obesity. *Obesity Facts*, 1: 52-59.
- Gasteyger, C., Suter, M., Calmes, J. M., Gaillard, R. C. & Giusti, V. (2006) Changes in body composition, metabolic profile and nutritional status 24 months after gastric bypass. *Obesity Surgery*, 16: 243-250.

Gasteyger, C., Suter M., Gaillard, R. C. & Giusti, V. (2008). Nutritional deficiencies after Roux-en-Y gastric bypass for morbid obesity often cannot be prevented by standard multi-vitamin supplementation. *American Journal of Clinical Nutrition*, Vol. 87, No. 5, 1128-1133.

Goldner, W. S., Stoner, J. A., Lyden, E., Thompson, J., Taylor, K., Larson, L., Erickson, J. & McBride, C. (2009). Finding the optimal dose of vitamin D following Roux-en-Y gastric bypass: a prospective, randomized pilot clinical trial. *Obesity Surgery*, Feb; 19(2): 173-179.

Government Office for Science. (2007). *Foresight - Tackling Obesities: Future Choices – Project Report*. 2nd Edition. London: Department of Innovation Universities and Skills.

Griffith, D. P., Liff, D. A., Ziegler, T. R., Esper, G. J. & Winton, E. F. (2009). Acquired copper deficiency: a potentially serious and preventable complication following gastric bypass surgery. *Obesity*, April; 17(4): 827-831.

Hamoui, N., Anthone, G. & Crookes, P.F. (2004). Calcium metabolism in the morbidly obese. *Obesity Surgery*, 14: 9-12.

Hamoui, N., Kim, K., Anthone, G. & Crookes, P. F. (2003). The significance of elevated levels of parathyroid hormone in patients with morbid obesity before and after bariatric surgery. *Archives of Surgery*, Vol 138: 891-897.

- Health Professions Council [HPC]. (2008). Standards of conduct, performance and ethics. HPC; London.
- Henderson, L., Gregory, J., Irving, K., & Swan, G. (2003). *The National Diet and Nutritional Survey: Adults Aged 19 to 64 years, Volume 2*. London: The Stationery Office.
- Hess, D. S. & Hess, D. W. (1998). Biliopancreatic diversion with a duodenal switch. *Obesity Surgery*, 8; 267-282.
- Holick, M. (2005). The vitamin D epidemic and its health consequences. *Journal of Nutrition*, 135: 2739S-48S.
- Holick, M. (2007). Vitamin D Deficiency. *New England Journal of Medicine*; 357: 266 – 281.
- James, W. P. T., Astrup, A., Finer, N., Hilsted, J., Kopelman, P., Rossner, S., Saris, W. H. M. & Van Gaal, L. F. (2000). Effect of sibutramine on weight maintenance after weight loss: a randomized trial. *Lancet*, 356: 2119-2125.
- Information Services Division. (2009). *Inpatient, Day Case and Outpatient Activity, 2007*. Scotland: NHS. Retrieved from NHS National Services Scotland Web site: <http://www.isdscotland.org/isd/4150.html>

Kalfarentzos, F., Kechagias, I., Soulikia, K., Loukidi, A. & Mead, N. (2001). Weight loss following vertical banded gastroplasty: intermediate results of a prospective study. *Obesity Surgery*, 2001; 11(3):265-270.

Knight, I. (1984). *The heights and weights of adults in Great Britain*. London: OPCS :HMSO.

Kopelman, P. (2007). Health Risks Associated with Overweight and Obesity. Short Science Review. Foresight Tackling Obesities: Future Choices. *Obesity Reviews*, 8(s1); 37-40.

Ledoux S., Msika S., Moussa F., Larger E., Boudou P., Salomon L, Roy C. & Clerici C. (2006). Comparison of Nutritional Consequences of Conventional Therapy of Obesity, Adjustable Gastric Banding, and Gastric Bypass. *Obesity Surgery*, 16, 1041-1049.

Love, A. L. & Billett, H. H. (2008). Obesity, bariatric surgery, and iron deficiency: true, true, true and related. *American Journal of Hematology*, May; 83(5): 403-409.

Madan, A. K., Orth, W. S., Ticanansky, D. S. & Ternovits, C. A. (2006). Vitamin and Trace Mineral Levels after Laparoscopic Gastric Bypass. *Obesity Surgery*, 16, 603-606.

- Malinowski, S. S. (2006). Nutritional and metabolic complications of bariatric surgery. *American Journal of Medical Science* April; 331(4):219-225.
- Malone, M. (2008). Recommended nutritional supplements for bariatric surgery patients. *Annals of Pharmacotherapy*, Vol 42; 1851-1858.
- Marceau, P., Hould, F. S., Simard, S., Label, S., Bourque, R. A., Potvis, M. & Biron, S. (1998). Biliopancreatic diversion with duodenal switch. *World Journal of Surgery*, 22: 947-954.
- McNulty, S. J., Ur, E. & Williams, G. (2005). A randomized trial of sibutramine in the management of obese type 2 diabetic patients treated with metformin. *Diabetes Care*, 26: 125-131.
- McPherson, K., Marsh, T. & Brown, M. (2007). Modelling Future Trends in Obesity and the Impact on Health. *Foresight Tackling Obesities: Future Choices*.
- National Institute for Health and Clinical Excellence. (2006). *Obesity guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children*. London: NICE Clinical Guideline 43.
- Newbury, L., Dolan, K., Hatzifotis, M., Low, N. & Fielding, G. (2003). Calcium and vitamin D depletion and elevated parathyroid hormone following biliopancreatic diversion. *Obesity Surgery*, Dec; 13 (6) 893 – 895.

Northern Ireland Statistics and Research Agency. (2007). *Health and Social Wellbeing Survey, 2006*. Retrieved from Northern Ireland Statistics and Research Agency Web Site: <http://www.nisra.gov.uk>

Olmos, J. M., Vazquez, L. A., Amado, J. A., Hernandez, J. L. & Macias, J. G. (2008). Mineral Metabolism in obese patients following vertical banded gastroplasty. *Obesity Surgery*, 18: 197-203.

Scopinaro, N. Gianetta, G. E. & Civalleri, D. (1996). Bilio-pancreatic diversion for obesity at eighteen years. *Surgery*, 119: 261-268.

Sjostrom, L., Narbro, K., Sjostrom, C. D., Karason, K., Larsson, B., Wedel, H., Lystig, T., Sullivan, M., Bouchard, C., Carlsson, B., Bengtsson, C., Dahlgren, S., Gummesson, A., Jacobson, P., Karlsson, J., Lindroos, A. K., Lonroth, H., Naslund, I., Olbers, T., Stenlof, K., Torgerson, J., Agren, G. & Carlsson, L. M. (2007). Effects of bariatric surgery on mortality in Swedish obese subjects. *New England Journal of Medicine*, 357:741-752.

Sjostrom, L., Rissanen, A., Andersen, T., Boldrin, M., Golay, A., Koppeschaar, H. P. F. & Krempf, M. (1998). Randomized placebo controlled trial of orlistat for weight loss and prevention of weight regain in obese patients. *Lancet*, 352: 167-172.

Skroubis, G., Sakellaropoulos, G., Pougouras, K., Mead, N., Nikiforidis G., & Kalfarentzos, F. (2002). Comparison of nutritional deficiencies after Roux-en-Y gastric bypass and biliopancreatic diversion with Roux-en-Y gastric bypass. *Obesity Surgery*, 12: 551-558.

Slater, G. H., Ren, C. J., Siegel, N., Williams, T., Barr, D., Wolfe, B., Dolan, K. & Fielding, G. A. (2004). Serum fat soluble vitamin deficiency and abnormal calcium metabolism after malabsorptive bariatric surgery. *Journal Gastrointestinal Surgery*, Jan; 8 (1): 48-55.

The Information Centre (2008). *Lifestyle Statistics for Health and Social Care*.

London: The Information Centre. Retrieved from Welsh Assembly Government Web Site:

<http://www.ic.nhs.uk/statistics-and-data-collections/health-and-lifestyles>

Thomas, B. & Bishop, J. (2007). *Manual of Dietetic Practice*. Fourth Edition. Oxford: Blackwell Publishing.

Toh, S. Y., Zarshenas, N. & Jorgensen, J. (2009). Prevalence of nutrient deficiencies in bariatric patients. *Nutrition*, May 30.

Tice, J. A., Karliner, L., Walsh, J., Petersen, A. J. & Feldman, M. D. (2008). Gastric banding or bypass? A systematic review comparing the two most popular bariatric procedures. *American Journal of Medicine*, 121 (10): 885-893.

Vandenbroeck, I. P., Goossens, J. & Clemens, M. (2007). Obesity Systems Atlas.

Foresight Tackling Obesities: Future Choices.

Vargas-Ruiz, A. G., Hernández-Rivera, G. & Herrera, M. F. (2008). Prevalence of iron, folate and vitamin B12 deficiency anemia after laparoscopic Roux-en-Y gastric bypass. *Obesity Surgery*, Mar; 18(3):288-293.

Varma, S., Baz, W., Badine, E., Nakhli, F., McMullen, H., Nicastro, J., Forte, F., Terjanian, T. & Dai, Q. (2008). Need for parenteral iron therapy after bariatric surgery. *Surgery for Obesity and Related Disorders*, Nov-Dec; 4(6): 715-719.

von Drygalski, A. & Andris, D. A. (2009). Anemia after bariatric surgery: more than just iron deficiency. *Nutrition in Clinical Practice*, Apr-May; 24(2): 217-226.

Welsh Assembly Government. (2008). *Welsh Health Survey, 2007*. Retrieved from

Welsh Assembly Government Web Site:

<http://wales.gov.uk/topics/statistics/theme/health/health-survey/results/?lang=en>

Wilding, J. (2007). Treatment Strategies for Obesity. Short Science Review. *Foresight Tackling Obesities: Future Choices. Obesity Reviews*, 8(s1): 137-144.

World Health Organisation. (2000). *Obesity: Preventing and Managing the Global Epidemic*. Report of a WHO Consultation. WHO Technical Report Series 894. Geneva:WHO.

World Health Organisation. (1997). *International Statistical Classification of Disease and Related Health Problems*. Chapter IV: Endocrine, nutritional and metabolic diseases 10th Revision Version for 1997. Geneva: WHO.

World Health Organisation. (2007). *International Statistical Classification of Disease and Related Health Problems*. Chapter IV: Endocrine, nutritional and metabolic diseases 10th Revision Version for 2007. Geneva:WHO.

Wortsman, J., Matsuoka, L. Y., Chen, T. C., Lu, Z. & Holick, M. (2000). Decreased bioavailability of vitamin D in obesity. *American Journal Clinical Nutrition*, 72: 690-693.

Ybarra, J., Snachez-Hernandez, J., Gich, I., deLeiva, A., Rius, X., Rodriguez-Espinosa, J. & Perez, A. (2005). Unchanged hypovitaminosis D and secondary hyperparathyroidism in morbid obesity after bariatric surgery. *Obesity Surgery*, 15: 330-335.

Youssef, Y., Richards, W. O., Sekhar, N., Kaiser, J., Spagnoli, A., Abumard, N. & Torquati, A. (2007). Risk of secondary hyperparathyroidism after laparoscopic gastric bypass surgery in obese women. *Surgical Endoscopy and Other Interventional Techniques*, 21: 1393-1396.

Zaninotto, P., Wardle, H., Stamatakis, E., Mindell, J. & Head, J. (2006). *Forecasting Obesity to 2010*. National Centre for Social Research. London: National Centre for Social Research.

Appendix 1

List of References

- Bloomberg, R., Fleishman, A., Nalle, J. E., Herron, D. M. & Kini, S. (2005).
Nutritional deficiencies following bariatric surgery. *Obesity Surgery*, Vol 15:
145-154.
- Department of Health. (2008). *Health Survey for England*. National Centre for Social
Research Department of Epidemiology and Public Health at the Royal Free
and University College Medical School. London: The Stationery Office.
- Davies, D. J., Baxter, J. M. & Baxter, J. N. (2007). Nutritional deficiencies after
bariatric surgery. *Obesity Surgery*, 17, 1150 – 1158.
- deCampos, C. D., Dalcanale, L., Pajacki, D., Garrido, A. B. & Halpern, A. (2008).
Calcium intakes and metabolic bone disease after eight years of roux-en-y
gastric bypass. *Obesity Surgery*, 18: 386-390.
- Fried, M., Hainer, V., Basdevant, A., Buchwald, H., Deitel, M., Finer, N., Greve, J.,
Horber, F., Mathus-Vliegen, E., Scopinaro, N., Steffen, R., Tsigos, C., Weiner,
R. & Widhalm, K. (2007) Inter-disciplinary European guidelines on surgery of
severe obesity. *International Journal of Obesity*, 31, 569-577.

Hamoui, N., Kim, K., Anthone, G. & Crookes, P. F. (2003). The significance of elevated levels of parathyroid hormone in patients with morbid obesity before and after bariatric surgery. *Archives of Surgery*, Vol 138: 891-897.

National Institute for Health and Clinical Excellence. (2006). *Obesity: guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children*. NICE clinical guideline 43. London: National Institute for Health and Clinical Excellence.

The Information Centre. (2009). *Lifestyle Statistics for Health and Social Care*. London: The Information Centre.

Vargas-Ruiz, A.G., Hernandez-Rivera, G. & Herrera M. F. (2008). Prevalence of iron, folate and vitamin B12 deficiency anaemia after laparoscopic roux-en-y gastric bypass. *Obesity Surgery* 18: 288-293

World Health Organisation. (2007). *International Statistical Classification of Disease and Related Health Problems. Chapter IV: Endocrine, nutritional and metabolic diseases*. 10th Revision. Version for 2007. Geneva: WHO.

Appendix E

**e-letter sent to all DOMUK members with [surveymonkey.com](https://www.surveymonkey.com) link.
Information Sheet for Participants of this survey and questionnaire as seen by
respondants.**

Appendix 3

Centre for Exercise and Nutrition Science
University of Chester
Parkgate Road
Chester
CH1 4BJ

April 2009

Dear Dietitian

I've been a registered dietitian for nearly twenty years and like you, have an interest and am employed in obesity treatment and prevention.

To further my knowledge and skills in this important field, I am reading a masters degree in weight management at the University of Chester.

I am particularly concerned about the nutritional adequacy of the diets of post bariatric surgery patients. For my masters degree dissertation I am looking at the vitamin and micronutrient supplementation recommendations we make to patients following their surgery.

I wondered if you would be willing to follow the link to SurveyMonkey and to spend a few minutes completing the short questionnaire? There is a brief information sheet for participants, providing further information about my study in this attachment.

Thank you in anticipation. I hope to report my findings to a DOM meeting and publish my research, on completion of my studies, so that my work will be of benefit to our profession.

With kind regards

Yours sincerely

Catherine Towers
RD

Centre for Exercise and Nutrition Science
University of Chester
Parkgate Road
Chester
CH1 4BJ

1st July 2009

Dear Dietitian

I've been a registered dietitian for nearly twenty years and like you, have an interest and am employed in obesity treatment and prevention.

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I am particularly concerned about the nutritional adequacy of the diets of post bariatric surgery patients. For my masters degree dissertation I am looking at the vitamin and micronutrient supplementation recommendations we make to patients following their surgery.

I wondered if you would be willing to spend a few minutes completing a short survey? If so please click on this link:

http://www.surveymonkey.com/s.aspx?sm=w8JNITppjOZ8RuYb6aC2xQ_3d_3d

There is a brief information sheet for participants, providing further information about my study, with the survey on the next page.

Thank you in anticipation. I hope to report my findings to a DOM meeting and publish my research, on completion of my studies, so that my work will be of benefit to our profession.

With kind regards

Yours sincerely

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I wondered if you would be willing to spend a few minutes completing a short survey? If so please click on this link:

http://www.surveymonkey.com/s.aspx?sm=w8JNITppjOZ8RuYb6aC2xQ_3d_3d

There is a brief information sheet for participants, providing further information about my study, with the survey on the next page. Please return your completed survey to my email address:

Thank you in anticipation. I hope to report my findings to a DOM meeting and publish my research, on completion of my studies, so that my work will be of benefit to our profession.

With kind regards

Yours sincerely

Catherine Towers
RD

1. Default Section

1. How many new bariatric patients did you see last year?

- 1 - 20
 21 - 50
 51 - 100
 100 +

2. What percentage of the patients that you see are:

NHS
patients

Self pay
patients

3. Do you recommend vitamin and micronutrient supplementation to your patients after food limiting procedures (like laparoscopic adjustable gastric bands)?

- Yes (Please go to Qu 4, 5 & 6) No (Please go to Qu 7)

4. What are your recommendations for food limiting procedures?

Type or Name of Product

Dosage

Duration

5. What are your recommendations for food limiting procedures?

Type or Name of Product

Dosage

Duration

6. What are your recommendations for food limiting procedures?

Type or Name of

Product

Dosage

Duration

7. Do you recommend vitamin and micronutrient supplementation to your patients after nutrient absorption limiting procedures (like gastric bypass or BPD)?

Yes (Please go to Qu 8, 9 & 10) No (Please go to the End)

8. What are your recommendations for nutrient absorption limiting procedures?

Type or
Name of
Product

Dosage

Duration

9. What are your recommendations for nutrient absorption limiting procedures?

Type or
Name of
Product

Dosage

Duration

10. What are your recommendations for nutrient absorption limiting procedures?

Type or
Name of
Product

Dosage

Duration

Appendix F

Raw Data from completed Questionnaires from SurveyMonkey.com Account

Appendix 4

Information Sheet for Participants of the Survey of Vitamin and Micronutrient Supplement Advice to Patients Post Bariatric Surgery by UK Dietitians

What is the purpose of the study?

To determine which nutrition supplements, if any, Registered Dietitians are recommending to their post bariatric surgery patients.

Why have I been chosen?

The reason you have been asked is because you are a member of the British Dietetic Association's Specialist Interest Group 'Dietitians in Obesity Management' (DOM).

Do I have to take part?

No! The survey is voluntary, but it would help my research if as many members of DOM completed the questionnaire.

What will happen to me if I take part?

All you need to do is follow the links to SurveyMonkey and complete the short questionnaire.

What are the possible benefits of taking part?

The more dietitians that reply, the more accurate the survey results are of what we are recommending to our patients.

What are the possible risks of taking part?

There are no risks to taking part. The survey is anonymous and it is not a test of your knowledge or competence as a dietitian!

Are the results confidential?

Yes. The results will be collated by SurveyMonkey, who have a strict confidentiality policy. Your responses cannot be traced back to you.

What will happen to the results?

I will present my findings to a DOM meeting and hope to get my paper published, to further our professions knowledge.

Who is organising and funding the research?

I am organising the research, with supervision from Dr Fallows at the University of Chester. I am funding the research myself and have no conflicts of interest with any organisations.

Who can I contact for further information?

Catherine Towers	Dr Stephen Fallows
MSc Student	Research Co-ordinator
Centre for Exercise and Nutrition Science	Centre for Exercise and Nutrition Science
University of Chester	University of Chester
Parkgate Road	Parkgate Road
Chester	Chester
CH1 4BJ	CH1 4BJ

Who can I complain to?

Professor Sarah Andrew
Dean of Applied and Health Sciences,
University of Chester, Parkgate Road, Chester CH1 4BJ

Flow Chart to Clarify the Method for Sending Information and Blank Questionnaire on 'Micro-Nutrient Supplementation Post Bariatric Surgery', to Dietitians in Obesity Management Members and for the Return of Completed Questionnaires to Student for Analysis

www.domuk.org



Click on 'List serv'
(list serv can post message to all group members by sending single email to a single email address)



Post Letter of Invitation to Participants (Appendix 3) with Participants' Information Sheet (Appendix 4)



Copy and Paste a link to www.surveymonkey.com where blank non-validated questionnaire (Appendix 6) is situated



Participants complete questionnaire on line, which is voluntary and anonymous.
Consent will be presumed by completion of questionnaire



Completed questionnaires automatically redirected back to towers@catterall2.wanadoo.co.uk

Appendix 6
Vitamin and Micronutrient Supplementation Post Bariatric Surgery

Questionnaire

- 1 How many new bariatric patients do you see each year?

Number	Tick
1 – 20	
21 – 50	
51 – 100	
100 +	

- 2 Are the patients you see

Patient Type	Tick
All NHS	
All self pay	
A mixture of both	

Thinking about the patients that you see, do you recommend vitamin and micronutrient supplementation after the procedure and if so what products?

3 For food limiting procedures (like laparoscopic adjustable gastric band)?

	Tick	Action
Yes		Please go to Qu 3a
No		Please go to Qu 4

3a What are your recommendations:

Type or Name of Product(s)	Dose mg/day	Duration

4 For nutrient absorption limiting procedures (bilo-pancreatic diversion)?

	Tick	Action
Yes		Please go to Qu 4a
No		End

7a What are your recommendations:

Type or Name of Product(s)	Dose mg/day	Duration

Thank you for your help.

INPATIENTS DATA REQUEST SPECIFICATION FORM

Please note that the fields marked with an asterisk (*) are mandatory. If these fields are not completed your information request may be delayed.

For help and information on any field, highlight the field and press the F1 key.

*Requester's Name:

*Organisation Name:

Organisation Address:

*Tel No: Fax No:

*E-Mail Address:

Date Required (dd/mm/yyyy): Previous Request Number (if applicable):

*Group Patient Data By (Select all that apply):

Total:	<input checked="" type="checkbox"/>
NHS Trusts:	<input type="checkbox"/>
Hospital Sites:	<input type="checkbox"/>
Local Health Board Resident Population:	<input type="checkbox"/>
Local Health Board GP Registered Population:	<input type="checkbox"/>
Ward of Residence:	<input type="checkbox"/>

*Patient Coverage: Welsh Trusts - All patients

*Patient Classification: All Cases

*Admission Method: All Admissions (Inc Maternity)

*Activity Count Currency: Patients

Admission/Discharge Based Analysis: N/A

Diagnosis Criteria: None

Diagnosis Details Morbid obesity, Class III obesity, NICE guidance43

Procedure Criteria: With a principal procedure

Procedure Details laparoscopic adjustable gastric band, gastric bypass, sleeve gastrectomy, BPD with DS

*Time Period Criteria: Please Select:

From (dd/mm/yyyy): To (dd/mm/yyyy):

Split Data By (Select all that apply):

Months:	<input type="checkbox"/>
Quarters:	<input type="checkbox"/>
Sex:	<input type="checkbox"/>
Age Bands:	Please Select:
Other Please Specify:	<input type="text" value="yearly"/>

Data Items Required:

The following data items are considered confidential: Name, Address, Full Postcode, DOB, CRN, GP Code, Consultant Code and Consultant Name.

Just case numbers

***Purpose of Data:**

To complete the introduction to my master degree dissertation on the nutritional implications of bariatric surgery.

Changes to Original Request (if applicable):

Any Other Information:

Many thanks

*Specification Agreed By: Catherine Towers

*Date (dd/mm/yyyy): 21/05/2009

Information Requests are usually analysed and quality assured within seven days, however particularly large analyses may take longer.

Microsoft Excel Spreadsheet (.xls) is the standard output format however particularly large outputs may be Microsoft Access Databases (.mdb); this is dependent on file size. If the information is required in a different format please indicate this in the *Any Other Information* field above.

If a completed specification form is not returned within seven days it will be assumed the information is no longer required.

For further information or help on completing this form please e-mail pdit.requests@hsw.wales.nhs.uk or alternatively telephone (029) 2050 2363



Application for Ethical Approval of Proposed Research Study

Applicant name: Catherine Towers

Department: Centre for Exercise and Nutrition Science

New Application

OR

Resubmission

Study Title: Vitamin and Micronutrient Supplementation Post Bariatric Surgery

Version number / Date: 1 / 31.03.2009

Date of meeting: 22.04.09

(Details of meeting dates can be found on IBIS – please check before completing)

FREC reference number:

(Previous applicants can type their FREC reference number. The Secretary of the Faculty's Research Ethics Committee will complete this in the case of new applications only)

- *Please read the accompanying guidance notes before completing this application form, which can be found on IBIS.*
- *Submit **ONE** paper copy of your application (including **all** appendices) to Mrs. Jess Hitchcock, FREC Secretary, Centre for Public Health Research, University of Chester, Parkgate Road, Chester, Cheshire, CH1 4BJ, United Kingdom.*
- *You are also asked to submit an electronic copy of your application (including **all** appendices) to j.hitchcock@chester.ac.uk. If possible, this should include the completed signature pages.*
- *Please **do not** staple your application, nor the associated appendices as they will need to be photocopied – use a paper clip.*



Applicant's Checklist

Title of Study: Vitamin and Micronutrient Supplementation Post Bariatric Surgery
Lead researcher: Catherine Towers

- This document **MUST** be completed and submitted as part of the application form. Please ensure **ONE** copy of each document, as detailed below, is attached as an appendix to the application. **ALL** appendices **MUST** have dates and version numbers clearly marked.
- Indicate 'yes/no' as applicable, and continue your document list on the continuation sheet if necessary

Document	Enclosed?	Appendix number(s)	Version	Date
FREC Application Form	Mandatory		1	March 09
List of references	Mandatory	1	1	
Summary C.V. for lead researcher	Mandatory	2		
Letter(s) of invitation to participants	Y <input checked="" type="checkbox"/> / N <input type="checkbox"/>	3	1	March 09
Participant information sheet(s) [PIS]	Y <input checked="" type="checkbox"/> / N <input type="checkbox"/>	4	1	March 09
Participant consent form(s)	Y <input type="checkbox"/> / N <input checked="" type="checkbox"/>			
Information sheets or letters for other relevant personnel	Y <input type="checkbox"/> / N <input checked="" type="checkbox"/>			
Written permission(s) from relevant personnel (e.g. to use facilities for research purposes)	Y <input checked="" type="checkbox"/> / N <input type="checkbox"/>	5	1	April 09
Interview schedule(s) or topic guide(s) for participants	Y <input type="checkbox"/> / N <input checked="" type="checkbox"/>			
Validated questionnaire(s)	Y <input type="checkbox"/> / N <input type="checkbox"/>			
Non-validated questionnaire(s)	Y <input checked="" type="checkbox"/> / N <input type="checkbox"/>	6	1	March 09
Copies of advertisement material for recruiting research participants, e.g. posters, newspaper adverts, website entries. For video or audio cassettes, please also provide the printed script.	Y <input type="checkbox"/> / N <input checked="" type="checkbox"/>			
Risk assessment form(s)	Y <input type="checkbox"/> / N <input checked="" type="checkbox"/>			
Other (please specify on the following sheet, as necessary)	Y <input type="checkbox"/> / N <input type="checkbox"/>			



Part 1: Introduction

<p>1. Title of research project Vitamin and Micronutrient Supplementation Post Bariatric Surgery</p>

<p>2. Lead researcher (The Applicant) <i>NB. A copy of a current summary CV (maximum 2 sides of A4) for the lead researcher must be submitted with this application.</i></p>

Name of Applicant	Catherine Towers
Status (for example: MSc. student; PhD student; researcher; other – please specify)	MSc Student
Address for correspondence	
Telephone number	
Email	
Qualifications	BSc Hons Nutrition and Dietetics, Diploma in Management Studies
Programme (if a student)	MSc Weight Management

<p>3. Details of other researchers who will work on the project <i>NB. A copy of a current summary CV (maximum 2 sides of A4) for additional researchers must be submitted with this application.</i></p>

Name	
Status (for example: student, tutor, researcher, statistician)	
Institution	
Address	
Telephone Number	

Name	
Status (for example: student, tutor, researcher, statistician)	
Institution	
Address	
Telephone Number	

--



4. **If this is a postgraduate student project (taught or research students) please state who will act as academic supervisor(s) for the project.**

Dr Stephen Fallows

*Please provide a brief summary of their **relevant** qualifications, training and experience in the space below. You do not need to submit a C.V. for your academic supervisor.*

C.V. on file.

5. **Please state what preparation and training the Applicant has received in research methods**

Full attendance on the Research Methods and Data Analysis Module code XNM209, Centre for Exercise and Nutrition Science, University of Chester

6. **Good research practice**

Please confirm that the research will be carried out in accordance with the University of Chester's guidelines as outlined in the Research Governance Handbook, and state which other professional codes of conduct you will abide by (if applicable).

I confirm that I will conduct my research in accordance with the University of Chester's Research Governance Handbook and the Health Professions Council's Standards of conduct, performance and ethics.

7. **Confirmation of exclusivity**

I confirm that this application has NOT been submitted to any OTHER Research Ethics Committee.

Check here

If this is a resubmitted application to FREC, please indicate the date of the meeting at which the original (1st submission) application was first reviewed:



Part 2: The research

1. Type of research proposed

Please indicate whether the proposed research is:

- Quantitative** **Qualitative** **Both**

2. Outline of the research

Please provide a brief outline of the proposed research under the sub-headings provided.

i. Aims/objectives

To determine the clinical recommendations made by UK registered dietitians to patients about vitamin and micronutrient supplementation following bariatric surgery.

To ascertain the vitamin and micronutrient content of products recommended by UK registered dietitians.

To determine the nutritional adequacy of the products recommended by UK registered dietitians, compared with European guidelines.

ii. Hypotheses and/or research question(s) to be addressed

It has been hypothesised that the recommendations made by UK registered dietitians meet the European guidelines following:

Food limiting bariatric procedures for:

- vitamin supplementation
- micronutrient supplementation

Nutrient absorption limiting bariatric procedures for:

- vitamin supplementation
- micronutrient supplementation.

iii. Rationale (to include a brief synopsis of the background to the research)

iv. Since 2007, obesity has been classified as a disease by the World Health Organisation (WHO)[Who, 2007]. The health consequences of this disease are many, including development of type 2 diabetes, hypertension, coronary heart disease and some cancers. The WHO define morbid obesity as having a body mass index (BMI) equal to or greater than 40 kg/m² (WHO, 2007). The prevalence of morbid obesity has increased over the last decade in England. In 1996, only 0.4% of all men over 16 years of age were morbidly obese, rising to 1.3% in 2007. Likewise for women over the age of 16 years, rates rose



from 1.4% in 1996 to 2.2% in 2007 (Department of Health, 2008).

- v. In 2006, the National Institute for Health and Clinical Excellence (NICE)[NICE, 2006] recommended bariatric surgery as a treatment option for people suffering with morbid obesity, or for people with a BMI between 35 kg/m² and 40 kg/m² and other significant disease that would improve if they lost weight. NICE recommend that people must have tried, but failed to achieve or maintain adequate, clinically beneficial weight loss for at least 6 months. Additionally, the person has been or will receive intensive management in a specialist obesity service; is fit for anaesthesia and committed to long term follow-up. Bariatric surgery is recommended as a first line option for people with a BMI greater than 50kg/m².
- vi. The National Health Service has treated 40% more patients with morbid obesity by bariatric surgery in the last year, with 2,724 procedures being performed in the NHS in 2007 / 2008 (The Information Centre, 2009). The number of procedures performed in the private sector, both in the UK and on UK citizens abroad, is unknown.
- vii. Numerous short, medium and long term vitamin and micronutrient deficiencies, as a consequence of bariatric surgery, are well documented in the literature. (Davies, Baxter & Baxter, 2007; Bloomberg, Fleishman, Nalle, Herron & Kini, 2005). Vargas-Ruiz, Hernandez -Rivera and Herrera (2008) established following gastric bypass, 26.6% of patients become anaemic after one year, rising to 63.3% after three years. Hamoui, Kim, Anthone and Crookes (2003) reported that as many as 25% post bariatric patients become calcium deficient 9-18 months after their operations. De Campos, Dalcanale, Pajacki, Garrido and Halpern (2008) demonstrated that eight years after surgery, without supplementation, 90% of their 77 patients had become vitamin D deficient.
- viii. There are European guidelines (Fried et al., 2007) regarding vitamin and micronutrient supplementation post bariatric surgery. There are specific requirements on the amount of calcium that patients who have undergone nutrient absorption limiting procedures should take on a daily basis. A one sampled T Test will be performed, comparing this level with the amounts being recommended by UK registered dietitians.
- ix. Registered dietitians have a vital role to play in ensuring the nutritional adequacy of patients' intakes following bariatric surgery (NICE, 2006). The results of this survey will establish that UK registered dietitians are ensuring the nutritional adequacy of their patients' diets.
- x. ***Study design (to include sample size, with justification; recruitment and sampling strategy, with inclusion/exclusion criteria; and so on)***



A survey of the members of the specialist interest group of the British Dietetic Association (BDA), Dietitians in Obesity Management (DOM) will be conducted by a web survey provider (SurveyMonkey.com). SurveyMonkey.com is survey tool on the web. The company employs a multiple layered security system with the latest firewall and intrusion prevention technology. They pledge to keep the information collected confidential.

The self constructed questionnaire, which will be in a self –reporting format, will be piloted on the Committee of DOM. Following appropriate amendments, it will when be distributed to the 260 members of DOM via the DOM listserv with the covering letter, participant information sheet and link to SurveyMonkey.com.

Manufacturers of the products named in the responses in the questionnaires will be contacted by email and asked to provide nutritional composition data on those products.

xi. Method(s) for data collection (to include duration of participation anticipated for each participant)

Completion on line of one questionnaire with expected participant completion time of 10 minutes.

Manufacturers of the products named in the responses in the questionnaires will be contacted via email and asked to provide nutritional composition data on those products.

xii. Description of site(s)/facilities required

Home office with internet facilities

xiii. Proposed method(s) of data analysis

There is a mixed level of data. Therefore, only non-parametric testing will permitted on this data.

Descriptive statistics that will be used are mode, median and range.

To compare the difference between two variables Chi-Squared test will be performed.

To test the association between two variables, Chi-Squared test will be performed.

The one sampled T-Test will be used on the ratio data of nutritional content of the recommended product verses European guidelines.

3. Summary of the ethical issues

Please summarise what you think are the ethical issues inherent in this study. The questions that follow will give you an opportunity to demonstrate how you will manage these issues in the conduct of your research.

Completion of the questionnaire is voluntary and anonymous. All



responses received by SurveyMonkey.com are treated confidentially.

An ethical issue may result from the findings if the European guidelines as to the nutritional supplementation of post bariatric surgery patients are not being met, by UK registered dietitians. This could be addressed by training, if required. The author has already agreed with the Chair of DOM that she will present the findings from the survey at a future DOM meeting.

4. What are the potential adverse effects, risks or hazards for research participants?

None.

5. What is the potential for discomfort, distress, inconvenience or changes to the lifestyle of research participants?

If the findings identify that recommendations made by UK registered dietitians do not meet European guidelines, then training would be recommended.

6. Are there any particular requirements or abstentions that will be imposed upon the participant (for example: multiple attendance sessions or visits, abstention from alcohol, tobacco and so on)?

No.

7. What are the potential benefits for research participants?

To confirm that their recommendations are in line with European guidelines.

The author has already agreed to present her findings to a future meeting of DOM and would be looking to publish her paper in official journal of the British Dietetic Association 'Journal of Human Nutrition and Dietetics'.

The British Obesity and Metabolic Surgery Society will also be contacted with an offer to present her findings to one of their meetings.

8. What is the potential for adverse effects, risks, hazards, pain, discomfort, distress or inconvenience for *researchers themselves*?

None.



- 9. Please indicate whether any payment or reimbursement is intended to be made to research participants and, if so, the amounts in question. (This should include any reimbursement of expenses.)**

No.

- 10. Please state the relationship, if any, which may/will exist between the researcher(s) and potential participants. (For example, will any of the participants be students, subordinates or colleagues of the investigator, or staff members of the University?)**

All are UK registered dietitians and all are members of the British Dietetic Associations Specialist sub group Dietitians in Obesity Management.



11. Will informed consent be obtained from the research participants?

No, informed consent will not be obtained. Completion of the questionnaire is voluntary and so consent will be presumed through completion of the questionnaire.

Give details of who will take consent and how it will be done, including how long participants will have to decide whether or not to take part.

Not applicable.

Children

Can you confirm that, where the participant is 16 or over, consent to participate in the research will be obtained from the young person him/herself?

Not applicable.

Can you confirm that, where the child is under the age of 16 years, but is judged to have the maturity and capacity to understand the nature of the research, that his/her consent will be sought?

Not applicable.

Please state the manner in which any apparent objection to participation by a child subject will be handled.

Not applicable.

Please state whether and how parental consent, or the consent of the legal guardian or the order/declaration of the court, will be sought, in relation to the participation of child subjects in the research.

Not applicable.

NB. Copies of the consent form(s) and participant information sheet(s) [PIS] to be used **must** accompany this application.

12. How will participants who may not adequately understand verbal explanations or written information given in English be enabled to consent?

Not applicable. The completion of the questionnaire on-line will be voluntary and so consent will be presumed if the questionnaire is completed.

13. Please state what measures will be taken to ensure that participants are able to withdraw from the research at any time without explanation or fear of reprisal should they so wish.

Not applicable.



14. Please state what measures will be taken to protect the confidentiality of participants' data. Who will have control and act as custodian of the data generated by the research?

You should consider data in hard copy form, electronic form and audio/audio-visual form. You should explain how you will protect the anonymity of participants during the data collection process, during the analysis and at the end of the research project. (Applicants are advised to consult the University's Research Governance Handbook for further information).

No personal data will be collected by the questionnaire. The process is totally voluntary and anonymous.

Who will have access to the data generated by the study?

Only the applicant and dissertation supervisor will have access to the generated data.

Can you confirm that the data will be retained in accordance with the University's Research Governance Handbook, which states that "data generated in the course of research should be kept securely in paper or electronic format as appropriate for a minimum of ten years from the date of final publication"?

Yes, I confirm data will be stored for a minimum of 10 years.

15. Vulnerable groups

Please indicate whether participants belong to any of the following groups:

- children under 16
- pregnant women
- the elderly
- persons suffering from mental disorder
- adults with learning disabilities
- prisoners
- young offenders
- other vulnerable groups

Please state what special or additional arrangements, if any, will be applied, particularly in relation to participant information sheets and gaining informed consent, to safeguard the interests of such participants.

Not applicable.

Please explain why it is necessary to conduct research involving such participants, and whether the required data could be obtained by any other means.

Not applicable.

Please state whether, and if so, how participation in the proposed research may/will be of personal benefit to individual participants



Not applicable.

16. Disclosure statement

If you are working with vulnerable adults or children (under the age of 18 years old), please state whether or not you have applied for and received a disclosure statement from the Criminal Records Bureau (or equivalent, in the case of research conducted overseas).

Yes No

If 'yes', please give the disclosure number and date this was received.

Disclosure number:

Date received:

Part 3: Financial and other arrangements

- 1. Please state any financial or other interests the Applicant, his/her department/centre, supervisor or employer has in relation to the conduct of this research.**

No financial interests. The applicant is a registered dietitian working with bariatric patients.

- 2. Please state the amount of payment, if any, that will be paid to the investigator (over and above any normal salary).**

None.

- 3. What additional costs will be incurred through the conduct of the research to the University and how are these to be met? Please state whether funding for the research has been secured.**

None.

- 4. Do you confirm that the necessary arrangements have been, or will be made to comply with the requirements of the UK Data Protection Act 1998 with regard to the computer storage and processing of participants' personal information and generally to ensure confidentiality of such data supplied and generated in the course of the research.**

No personal information will be obtained from the participants.



5. (a) What arrangements are in place for monitoring the conduct of the research?

Monitoring the conduct of the research will be by regular review with the dissertation supervisor.

(b) What arrangements are in place for dealing with complaints or adverse effects of participating in the research?

In the participant information sheet, contact details are provided in the event of the participant requiring further information, or to complain or compliment the research. Any complaints would be addressed to Professor Sarah Andrew, Dean of Applied and Health Sciences, in the first instance.

Part 4: Signatures

For employees of the University

This form must be signed by the Applicant's line manager to confirm that s/he understands the purpose of the research, is in agreement with it and is aware of all the implications including time necessary to conduct the research:

Name: Insert name of line manager here
(Line manager of the applicant)

Department/Centre: Insert Department/Centre here

Signed: _____

Date:

For postgraduate students of the University

This form must be signed by the Applicant's academic supervisor to confirm that s/he has discussed this application with the student, has read it and fully supports it.

Name: Dr Stephen Fallows
(Academic supervisor)

Department/Centre: Centre for Exercise and Nutrition Science

Signed: _____



Date:

Applicant's signature

The information in this application is, to the best of my knowledge, accurate and I take full responsibility for it.

I undertake to abide by the ethical principles embodied in the good practice guidelines identified in this application.

If the research is approved, I undertake to adhere, without deviation, to the study as outlined in this application.

I am aware of my responsibility to be up-to-date and compliant with the requirements of the law and relevant guidelines relating to data security.

I understand that personal data about me as a researcher and this application will be held by the Faculty Research Ethics Committee and that this will be managed according to the principles established in the Data Protection Act.

Name: Catherine Towers

Signed: _____

Date: 08/04/09

- ***Please ensure that your line manager/academic supervisor has seen and agreed to support this proposal, and that all the relevant signatures have been obtained before submitting your application. Failure to have all the required signatures will result in your application being returned to you, which may delay your review.***
- ***Applicants should note that it is their responsibility to submit their proposal in sufficient time if working to tight/strict deadlines. This includes allowing sufficient time prior to submission for the supervisor to read, provide feedback and agree to support the application.***
- ***Applicants should note that their application and ALL appendices should be emailed to j.hitchcock@chester.ac.uk in addition to submitting a paper copy.***
- ***The Committee aims to respond to all applicants within 15 working days of the application being reviewed at an FREC meeting. Please do not contact the FREC before this time.***
- ***Feedback on your application and the Committee's decision will be emailed to you, to the address given on this form, in addition to a formal written response being sent from the FREC Chair to the address given on this form.***
- ***Further information can be found on the FREC's IBIS pages - http://ganymede.chester.ac.uk/index.php?page_id=244264&group=2***



**Vitamin and Micronutrient Supplement Advice Given to Post Bariatric Surgery
Patients by UK Dietitians**

Questionnaire

1 How many new bariatric patients do you see last year?

Number	Tick
1 – 20	
21 – 50	
51 – 100	
100 +	

2 What percentage of the patients you see are:

Patient Type	Tick
NHS	
Self pay	

Thinking about the patients that you see, do you recommend vitamin and micronutrient supplementation after the procedure and if so what products?

3 For food limiting procedures (like laparoscopic adjustable gastric band)?

	Tick	Action
Yes		Please go to Qu 3a
No		Please go to Qu 4

3a What are your recommendations:

Type or Name of Product(s)	Dosage	Duration

4 For nutrient absorption limiting procedures (bilo-pancreatic diversion)?

	Tick	Action
Yes		Please go to Qu 4a
No		End

4a What are your recommendations:

Type or Name of Product(s)	Dosage	Duration

Thank you for your help.

Appendix I

Written permission from SurveyMonkey.com

Boots Complete A-Z Vitamins

Table 13 The Nutritional Composition of Boots Complete A-Z Vitamins

Nutrient	Content
Vitamin A	400 µg RE
Vitamin D	5.0 µg
Vitamin E	10 mg
Vitamin C	60 mg α -TE
Thiamin (Vitamin B ₁)	1.4 mg
Riboflavin (Vitamin B ₂)	1.6 mg
Niacin (Vitamin B ₃)	18 mg NE
Vitamin B ₆	2.0 mg
Folic Acid	200 µg
Vitamin B ₁₂	1.0 µg
Biotin	150 µg
Pantothenic Acid	-
Vitamin K	30 µg
Calcium	230 mg
Iron	14 mg
Magnesium	60 mg
Zinc	15 mg
Iodine	150 µg

Table 13 The Nutritional Composition of Boots Complete A-Z Vitamins (continued)

Nutrient	Content
Chromium	25 µg
Copper	0.75 mg
Manganese	0.5 mg
Molybdenum	25 µg
Selenium	25 µg
Lutein	0.5 mg

Recommended Dose: One tablet daily

Centrum

Table 14 The Nutritional Composition of Centrum

Nutrient	Content
Vitamin A	800 µg
Vitamin D	5 µg
Vitamin E	10 mg
Vitamin C	60 mg
Vitamin B ₁ (Thiamin)	1.4 mg
Vitamin B ₂ (Riboflavin)	1.6 mg
Niacin	18 mg
Vitamin B ₆	2 mg
Folic Acid	200 µg
Vitamin B ₁₂	1 mcg
Biotin	150 µg
Pantothenic Acid	6 mg
Vitamin K	30 µg
Calcium	162 mg
Phosphorus	125 mg
Iron	14 mg
Magnesium	100 mg
Zinc	7.5 mg

Table 14 The Nutritional Composition of Centrum (continued)

Nutrient	Content
Iodine	150 µg
Copper	700 µg
Manganese	2.5 mg
Potassium	40 mg
Chloride	36.3 mg
Chromium	25 µg
Molybdenum	25 µg
Selenium	25 µg
Lutein	250 µg

Recommended Dose: One tablet daily

Forceval

Table 15 The Nutritional Composition of Forceval

Nutrient	Content
Vitamin C	60 mg
Vitamin A	2500 i.u.
Vitamin D ₂	400 i.u.
Vitamin B ₁	1.2 mg
Vitamin B ₂	1.6 mg
Vitamin B ₆	2 mg
Vitamin B ₁₂	3.0 µg
Vitamin E	10 mg
d-Biotin	100 µg
Nicotinamide	18 mg
Pantothenic Acid	4 mg
Folic Acid	400 µg
Calcium	100 mg
Iron	12 mg
Copper	2 mg
Phosphorus	77 mg
Magnesium	30 mg
Potassium	4 mg
Zinc	15 mg

Table 15 The Nutritional Composition of Forceval (continued)

Nutrient	Content
Iodine	140 µg
Manganese	3 mg
Selenium	50 µg
Chromium	200 µg
Molybdenum	250 µg

Recommended Dose: One capsule per day.

Sanatogen Gold A-Z (Complete)

Table 16 The Nutritional Composition of Sanatogen Gold A-Z (Complete)

Nutrient	Content
Vitamin A	800 µg RE
Vitamin D	5 mg
Vitamin E	10 mg α -TE
Vitamin C	60 mg
Thiamin (Vitamin B ₁)	1.4 mg
Riboflavin (Vitamin B ₂)	1.6 mg
Niacin	18 mg NE
Vitamin B ₆	2 mg
Folic Acid (folacin)	200 µg
Vitamin B ₁₂	1 µg
Biotin	150 µg
Pantothenic Acid	6 mg
Vitamin K	20 µg
Calcium	200 mg
Phosphorus	145 mg
Iron	14 mg
Magnesium	100 mg
Zinc	15 mg

Table 16 The Nutritional Composition of Sanatogen Gold A-Z (Complete)

[continued]

Nutrient	Content
Iodine	150 µg
Copper	1000 mg
Manganese	1 mg
Chromium	25 µg
Selenium	50 µg
Potassium	40 mg
Chloride	36 mg

Recommended dose: One tablet per day

Supermarket Multi-Vitamin and Mineral (Asda)

BioCare Product Information per Daily Intake (One Tablet)

Table 17 The Nutritional Composition of BioCare's General Adult Vitamin and Mineral Supplement

Nutrient	Content
Vitamin C	243 mg
Pantothenic Acid (Vitamin B ₅)	100 mg
Niacin (Vitamin B ₃)	50 mg
Vitamin E	50 mg
Thiamine (Vitamin B ₁)	25 mg
Riboflavin (Vitamin B ₂)	25 mg
Vitamin B ₆	25 mg
Magnesium	22 mg
Inositol	12 mg
P.A.B.A. (para amino benzoic acid)	10 mg
Potassium	8.9 mg
Zinc	8.5 mg
Calcium	6 mg
Vitamin A	600 µg
Folic Acid	400 µg
Manganese	300 µg

Table 17 The Nutritional Composition of BioCare's General Adult Vitamin and Mineral Supplement (continued)

Nutrient	Content
Molybdenum	98.7 µg
Selenium	50 µg
Chromium	50 µg
Iodine	37.8 µg
Biotin	35 µg
Vitamin B ₁₂	30 µg
Vitamin D ₂	6.25 µg

Recommended Dose: One capsule taken daily.

AquAEDKs

Table 18 The Nutritional Composition of AquAEDKs

Nutrient	Content
Vitamin A(as β -carotene)	18167 iu
Vitamin C	75 mg
Vitamin D ₃	800 iu
Vitamin E (D- α -tocopherol)	150 iu
Vitamin E (mixed tocopherols)	80 mg
Vitamin K ₁	700 μ g
Vitamin B ₁	1.5 mg
Vitamin B ₂	1.7 mg
Niacin	20 mg
Vitamin B ₆	1.9 mg
Folic Acid	200 μ g
Vitamin B ₁₂	12 μ g
Pantothenic Acid	12 mg
Zinc	10 mg
Selenium	75 μ g
Beta carotene	10 mg
Coenzyme Q10	10 mg

Recommended Dose: Two capsules per day.

Calcichew

Table 19 The Nutritional Composition of Calcichew

Nutrient	Content
Calcium	500 mg

Adcal D₃

Table 20 The Nutritional Composition of Adcal D₃

Nutrient	Content
Calcium	600 mg
Colecalciferol	10 mcg

Calcichew D₃ Forte

Table 21 The Nutritional Composition of Calcichew D₃ Forte

Nutrient	Content
Calcium	500 mg
Colecalciferol	10 mcg

Spatone

Table 22 The Nutritional Composition of Spatone

Nutrient	Content
Iron	5 mg

Recommended dose: Three sachets per day.