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Obstacles To Bariatric Surgery Provision In Adolescents In England & Scotland

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**OBSTACLES TO BARIATRIC SURGERY PROVISION
IN ADOLESCENTS IN ENGLAND & SCOTLAND**

A Thesis Submitted to the Yale University School of Medicine
in Partial Fulfillment of the Requirement for the
Degree of Doctor of Medicine

By

Kristel Carrington

2012

ABSTRACT

Obesity is an epidemic of global proportions and contributes significantly to the burden of chronic disease and disability. Bariatric surgery is the only effective treatment for morbid obesity. Patients not only lose weight but see vast improvement in obesity related comorbidities. Childhood obesity is one of the most serious public health challenges of the 21st century. England, Scotland and the US have some of the highest rates of childhood obesity, with increasing rates of obesity related comorbidities seen in this population. In adolescents, bariatric surgery has been shown to be safe and effective. England and Scotland have significantly lower rates of surgery provision compared to the US. This is particularly true in adolescents. This appears due to barriers that effectively ration surgery amongst those who are eligible. This mismatch between eligibility and receipt of surgical care is related to multiple factors, including the ways in which the health care system considers patients for surgery and delivers surgical care. These barriers include inconsistent application of guidelines, lack of resources, and prejudice toward the obese for the “self inflicted” nature of their disease. As a result, access to surgery is highly variable. The concept of personal responsibility has been central to social, legal, and political approaches to obesity. Policy in the UK places heavy emphasis on obesity prevention and lifestyle choices but this neglects those who are currently in need of surgical treatment.

England and Scotland need to acknowledge the under-provision of bariatric surgery and its potential consequences. Increasing surgery for obese adolescents may prevent them from becoming obese adults and may also be cost effective for the NHS. Increasing physician training in this procedure, enforcing evidence-based guidelines, and initializing specialized bariatric surgery programs for adolescents would help to address the under provision of surgery. Also, discrimination toward the obese should be acknowledged and governments must ensure that policy reflects medical evidence, not attitudes.

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Introduction

Childhood obesity is one of the most serious public health challenges of the 21st century (1). Its prevalence has increased at an alarming rate. The World Health Organization estimates that across the globe, 42 million children under the age of five are obese (1). Levels are rising all in many countries and as the numbers of overweight & obese increase, it imposes a considerable economic burden on society (2). Over the history of this epidemic, the US had reported the greatest prevalence of obesity among developed nations, with levels of obesity amongst men and women over 30% (3). However, England saw a 400% increase in obesity over the past three decades now with nearly 25% of men and women classified as obese (4) and Scotland nearly matches the US with 27% adults meeting criteria for obesity (5). On present trends, obesity will soon surpass smoking as the greatest cause of premature loss of life (4) as more and more children are being diagnosed with obesity related co-morbidities that up until a few years were only seen in the adult population (6, 7).

Bariatric surgery has been proven to be an effective treatment for morbid obesity (8)(9). Results have been very positive with people not only losing weight but seeing improvement in many of the obesity related comorbidities they have (10). It has also been reported that if more surgeries were performed, it may save healthcare systems money (2, 11). With so many children becoming obese, bariatric surgery is being considered more and more as a treatment option for this population. For patients who meet criteria for surgery, this procedure can be a life-altering and life-saving intervention. However, internationally there exist a number of obstacles to accessing surgery for patients who could clearly benefit from the procedure.

The UK lags significantly behind the US in the amount of surgeries performed with about 4000 procedures performed in 2009 (12). Only a small percentage of those who qualify for surgery actual get it (13). This is especially true in adolescents with cases being isolated and scattered. This mismatch between eligibility and receipt of surgical care is related to multiple factors, including the ways in which the health care system considers patients for surgery and delivers bariatric surgical care. My project examines the obstacles to accessing surgery in the setting of a system of universal healthcare. Through collaboration between Yale University and Keele University in the England, I was able to research political and ethical issues surround bariatric surgery provision in that particular system. In the US, it is well known that income, education level, insurance status, and access to healthcare have been shown to be significant factors in receiving both basic medical care and advanced interventions. Where morbid obesity is concerned socioeconomic factors play a major role in determining who does and does not undergo bariatric surgery, despite medical eligibility. Significant disparities according to race, income, education level, and insurance type continue to exist with most procedures performed on white, affluent, privately insured patients (3).

Childhood obesity rates are as high in England and Scotland as the US and in all three countries, the level of surgery provision cannot keep up with the demand. However, the US and its insurance companies are more accepting of the surgical approach to obesity and in comparison it performs a large volume of surgeries every year (14). The UK operates under the National Health Service (NHS), a system of universal healthcare in which the government bears the cost of health services for its citizens. In a system so dissimilar from our own, discussions of rationing and disparities in access to

care occur in a very different context. Considering that England and Scotland have an obesity problem comparable to the US, this project aimed to investigate the obstacles to increasing bariatric surgery provision for those eligible in a system that provides free healthcare for its citizens.

In adolescents, obesity surgery has been proven to be safe and effective. Most obesity programs for youth focus on educational and behavioral interventions with limited overall success (4, 15). More adolescents should receive surgery if they meet the eligibility criteria. The government needs to address what barriers exist to accessing care and act to dissolve them. This research speaks to the need to standardize access to bariatric surgery in both the adult and the pediatric population. The following discussion will provide an in depth analysis of obstacles to obesity surgery in England & Scotland in the pediatric population. The analysis will examine the scope of the obesity crisis, policy guidelines in place as well as the complex provision practices that shape patients' access to this particular medical service. This paper also discusses the ethical concerns about providing surgery in this population, especially in context of the broader principles of healthcare rationing.

Aims & Objectives

In comparing the policy guidelines and provision practices of these countries, this paper focuses on several important factors:

- (1) The scope of the child obesity problem in England and Scotland with mention of treatment options and their efficacy.
- (2) Provide a brief overview of the structure of the National Health Service (NHS) in England and Scotland with a subcontext describing the ethical theories commonly used in resource allocation decisions.
- (3) Summarize the trends in access to bariatric surgery in the UK in light of the policy guidelines in place.
- (4) Address the current challenges to service provision and how they create barriers to access these countries.
- (5) Discuss the ethical, medical, and legal considerations surrounding provision of care in the pediatric population.
- (6) Concluding statements and recommendations that may inform policy organizations and aid in confronting the challenges to increasing obesity surgery.

Materials and Methods

This paper serves to be an analytical study on the policy issues, provision practices, and ethical concerns surrounding obesity surgery in children in England and Scotland. The aim is to explore the barriers to providing equitable access to bariatric surgery in the population of obese children. Sources of data consist of policy documents, primary literature, and informal interviews. The policies were founded in policy documents

produced by the relevant government or medical organizations of the respective countries. In addition, several informal interviews were held with medical professionals, leading bariatric surgeons and a policy official from the Scottish Health Department. Interviewees were found via their respective organizations and clinics and were identified by means of primary known contacts with help from my advisor. These interviews addressed topics such as government policy, the barriers that create unequal access to surgery, negative attitudes on increasing provision of bariatric surgery, and what specific concerns exist for providing obesity surgery in the adolescent population. By studying the information provided by these policy documents and interviews, it has provided insight into the complex nature of the childhood obesity phenomenon and the many challenges to providing treatment. My conclusions are based on analysis from these sources and the goal is to make recommendations on future policy that could help to increase provision for both adults and adolescents.

Scope of the Problem

Within the UK, England and Scotland have seen increases in rates of overweight and obesity over several decades. Prevalence of obesity in adults is measured each year as part of the annual Health Survey for England (16). In the adult population, 24% of those aged 16 or over in England were classified as obese in 2007; an overall increase from 15% in 1993. (16) In Scotland, 2009 almost two-thirds of men aged 16-64 (66.3%) and more than half of women (58.4%) were overweight (17).

In adults, overweight and obesity is commonly assessed by using body mass index (BMI) defined as the weight in kilograms divided by the square of the height in meters (kg/m^2) (1, 18). A BMI over $25 \text{ kg}/\text{m}^2$ is defined as overweight, and a BMI of over $30 \text{ kg}/\text{m}^2$ as obese. BMI is used to calculate the degree of obesity and to determine the health risks associated with it. These markers provide common benchmarks for assessment. Obesity in children is different from obesity in adults in some important respects. It is difficult to develop a simple index for the measurement of overweight and obesity in children and adolescents because their bodies undergo a number of physiological changes as they grow (19). It is not appropriate to apply the adult BMI cut off points to children as the relationship between weight and height is age dependent. To determine whether children are within the healthy weight range their BMI is compared to the BMI percentiles of the UK 1990 reference curves (19). Children whose BMI is above the 85th percentile are classified as being above the healthy weight range (20) In the United States, the 85th and 95th centiles of body mass index for age and sex based on nationally representative survey data have been recommended as cut off points to identify overweight and obesity (19)

The rates of childhood obesity have more than tripled in the last 30 years(18, 21). **See figure 1.** England, Scotland, and the US have significantly high rates of childhood obesity in comparison to other countries. National agencies continue to monitor obesity and overweight in children, revealing steady increases. In 2005 the England's government established the National Childhood Measuring Program (NCMP) which weighs and measures children's weights at the start of primary school, termed "reception" all the way through year 6 (22). The program gathers population level data to allow analysis of trends in weight. The key findings for 2008/09 were that: in reception, more than one in five (22.8%) of the children measured were either overweight or obese. In Year 6, this rate was nearly one in three (32.6%). The percentage of obese children in Year 6 (18.3%) is nearly double than that in reception (9.6%). Apparently, the problem exists upon entering primary school and only worsens as children get older.

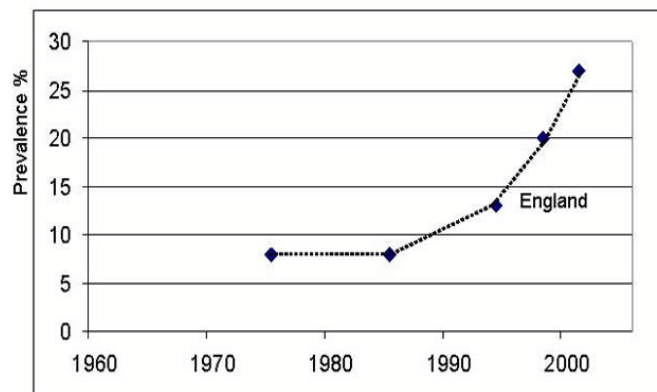


Figure 1: Trends in overweight children in England over last 3 decades. Source: National Childhood Measurement Program

In Scotland, children's weights are recorded through the Scottish Health Survey (17). The most recent report, published in 2009, found that: prevalence of obesity in adults has continued to increase each year reaching 26.9% for men and 27.6 % for

women. The proportion of children with a BMI above the healthy range increased significantly with age, from 24.3% of children aged 2-6, to 30.8% of those aged 7-11, and to 35.2% of those aged 12-15. Almost 30% of all children were overweight or obese. See **Figure 2.**

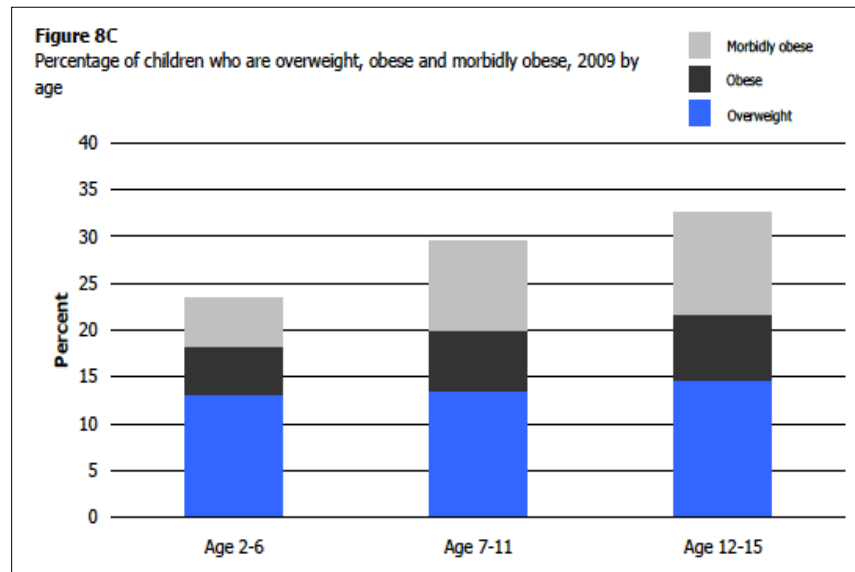


Figure 2: Percentage of children who are overweight, obese and morbidly in Scotland.

The Obesogenic Environment

The causes of obesity are under considerable investigation by biomedical, behavioral, and social scientists. Studies have looked at the maternal diet, genetics, food ingredients, energy intake, and exercise (23). The underlying cause of obesity seems inherently simple. Weight gain occurs when energy intake exceeds energy expenditure. Many report that energy expenditure in society has declined over the past few decades (21), contributing to the problem. At the same time, environmental factors have combined to make it increasingly easy for people to consume more calories than they

need (23, 24). In reality, obesity's etiology is multi-factorial, much more complex and is influenced by genetic, social, cultural, psychological, environmental and economic circumstances (24-26). We are living in an "obesogenic" environment (24). This term describes an environment that encourages the overconsumption of energy-dense foods. These foods are highly calorific and are becoming increasingly available. While evidence suggests that people are, generally speaking, aware of what constitutes a healthy diet (4), there are multiple barriers to their putting this into practice. Consider the influence of the food industry, which uses sophisticated advertising and marketing campaigns to promote their products; especially to children (24). Food promotion occurs in shops, restaurants, and schools. School is an important environment that can shape the health habits of youth, both in aspects of both nutrition and physical activity. Unhealthy options for school lunch and in vending machines make it difficult for young people to choose a healthy diet (27).

Of paramount consideration is the influence of parents in the causes, consequences, and treatment of childhood obesity. There is countless research on how genetics play a role. Studies have indicated that children with overweight parents are at increased risk of being overweight themselves (28). Also, keep in mind that eating habits of the parents strongly influence development of their children's eating habits and weight status (29). Parents have responsibility for their children's diets as they control the provision and selection of food. Some reports suggested that less households in England are preparing meals at home and relying more on commercial foods (4). In Scotland, obesity prevalence was higher in households where parents were obese or overweight (17). These are only some of the complex factors that make it difficult for both adults and

children to make healthier food choices. While unhealthy diet and physical inactivity are the fundamental physical drivers of obesity, they cannot be examined in isolation.

Understanding why people who are obese make unhealthy choices requires an understanding of the commercial, environmental, and social policy drivers of obesity.

Health professionals are aware that the rising trends in excess weight among children and adolescents will put a heavy burden on health services(30) as well as increase their risk of developing severe comorbidities at younger ages.

Health Risks of Morbid Obesity

There is a growing body of evidence that links childhood obesity with a number of immediate and long term physiological and psychological health risks (7, 31-33).

Childhood obesity is a risk factor for a number of chronic diseases in adult life including heart disease, diabetes, certain cancers, and osteoarthritis (31). Other conditions such as hypertension, pseudotumor cerebri, and sleep apnea are all potential consequences of childhood obesity (7, 32, 33). As severely overweight children become adults, the risks of weight-related complications in adulthood increase (34). Some disease can become manifest during childhood such as alterations glucose metabolism and fatty infiltration of the liver (7). Type 2 diabetes already appears to be a sizable and growing problem among U.S. children and adolescents (6, 35). Formerly a disease diagnosed in adults, its frequency has markedly increased in the pediatric age group over the past two decades (6, 35). In 2005, between 8% and 45% of newly presenting children and adolescents in the U.S. had type 2 diabetes (7). Predictions from US data imply that type 2 DM may become the most common form of newly diagnosed diabetes in adolescents youth within 10 years (6) For the European countries, there are few population-based incidence and

prevalence data concerning type 2 DM in children & adolescents (36). In the UK, a recent report reviewed first hospital admissions with a diagnosis of type 2 DM in patients <18 yrs of age indicated a significant rise between 1996-2004 (35).

Contracting type 2 DM at a young age means having a lifetime to develop the severe complications of the disease which include cardiovascular problems, blindness, kidney failure, stroke, and damage to the nervous system(4) Dietz et al found that in both men and women who are obese during adolescence, rates of cardiovascular disease and diabetes were increased(32). Metabolic syndrome is another obesity related condition typically seen in adults that has been emerging more and more in children (36). The term describes a combination of medical disorders that increase one's risk of developing cardiovascular disease and type 2 diabetes. The syndrome affects 25% of US adults and is present in as many as 30% of obese adolescents.(7) Adolescent health has implications for the health of future populations. Obese children are likely to remain obese throughout their adult lives, have poor health, and decreased life expectancy through increased risk of associated diseases. (34)(37) Studies show that 50%-77% of children and adolescents who are obese carry their obesity into adulthood. The risk increases to 80% if just one parent is also obese (38). Government reports have predicted that levels of obesity among children and young people will only continue to rise into the future (30).

Obesity's toll is not only physical. The first problems caused by obesity are likely to be emotional and psychological (33)}. Obese children become targets of early and systemic discrimination. Low self esteem and behavioral problems were commonly associated with obesity (4, 33). Furthermore, rates of anxiety and depression are three to four times higher among obese individuals (4). Overweight adolescents are likely to

experience social isolation, ridicule from their peers, anxiety and depression (39).

Childhood obesity also has adverse effects on social and economic outcomes in young adulthood. (33) Among women who were obese during adolescence, adverse psychosocial consequences include completion of fewer years of education, higher rates of poverty, and lower rates of marriage and household income. (31)

Economic Impact

We must also examine obesity's burden to society by exploring its economic impact on the healthcare system. Not surprisingly, the economic burdens of obesity are rising in proportion its prevalence and associated comorbidities (40, 41). In England and Scotland, as obesity prevalence rises, the cost can be measured through both its direct and indirect effects.

In 2001 the National Audit Office (NAO) investigated the management of obesity in the NHS. Direct costs of obesity arise from consultations, drugs and treatments of diseases attributable to obesity (42). The big three cost drivers are hypertension, coronary heart disease, and diabetes (42). NAO estimated that obesity cost the NHS around £480 million in 1998 and the indirect costs associated with obesity were estimated to be about £2 billion. In 2002, the direct cost of treating obesity was estimated at £1-1.1 billion(4). At that time, surgery was the least common option for referral by GPs. GPs would often send their patients to the dietician for further management. Using the framework of the NAO report, another study estimated the true cost of obesity to the NHS Scotland. There, the total cost of managing obesity and related diseases is estimated at more than £171 million (43). **See figure 3.** Of this total, 10% was due to GP visits,

60% to medicine prescribed and 30% to hospital care. Policy makers estimated that this figure could reach over 3 billion by the yr 2030 (44).

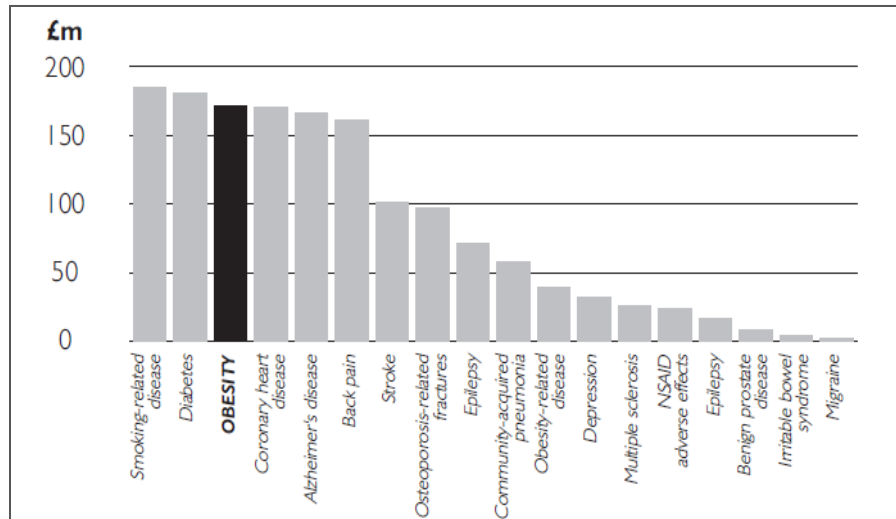


Figure 3: Cost of obesity in relation to other diseases in Scotland.

Obesity's effect is much wider than the costs directly related to health issues. The indirect costs contribute a larger burden to society as a whole. Indirect costs of obesity are defined in terms of lost output in the economy due to sickness, absence, or death of workers (2). Obesity has been shown to adversely affect employment, production levels (via increased absence from work or school and premature death) and mental wellbeing (45). The House of Commons Health Select Committee estimated that the total annual cost of obesity and overweight for England was nearly £7 billion (4). This total includes direct costs of treatment, the cost of dependence on state benefits, and indirect costs such as loss of earnings and reduced productivity. In Scotland, obesity costs the government a significant amount in the employment sphere. Lost earnings directly attributable to obesity were estimated to be £2.4-2.6 billion (2). The costs of obesity are likely to rise in

the next few decades. Along with it, future costs of diabetes, coronary heart disease, and stroke are predicted to rise significantly (30).

Bariatric Surgery in Adolescents- The Evidence

As the prevalence of obesity and its related comorbidities increases among adolescents, physicians are increasingly faced with the dilemma of determining the best treatment strategies for affected patients (38). The complex nature of this public health crisis makes management difficult for individuals and families. The growing problem of obesity along with the evidence for it as a harbinger of adult disease raise questions about the role of pharmacotherapy and bariatric surgery in pediatric populations.

Based on surgical techniques originating in the 1950s bariatric surgery has developed considerably and has increased in popularity in recent years. In the late 1960s, the early experiences with surgical treatment for adult obesity were first published (46). Although effective for weight loss, early operations such as the jejunoileal by pass, were associated with an unacceptable number of significant long-term complications and mortality (47). Subsequently, the use of minimally invasive techniques led to a huge reduction in the morbidity and mortality associated with the open versions of the procedures (47). In obese patients, a range of bariatric procedures has been performed, but the two most common surgeries performed in adolescents are roux-en-y gastric bypass and adjustable gastric banding (48). Roux-en-y gastric bypass involves dividing the stomach to create a small stomach pouch, which restricts intake and diverts nutrients from the proximal stomach to the mid jejunum (49). In gastric band surgery, an inflatable silicon ring is placed around the upper portion of the stomach. This creates a smaller stomach, which makes people feel full sooner and reduces the amount they eat. Gastric

banding is a nondiversion operation, achieving weight loss by restriction of nutrient intake alone (50). See **figure 4**.

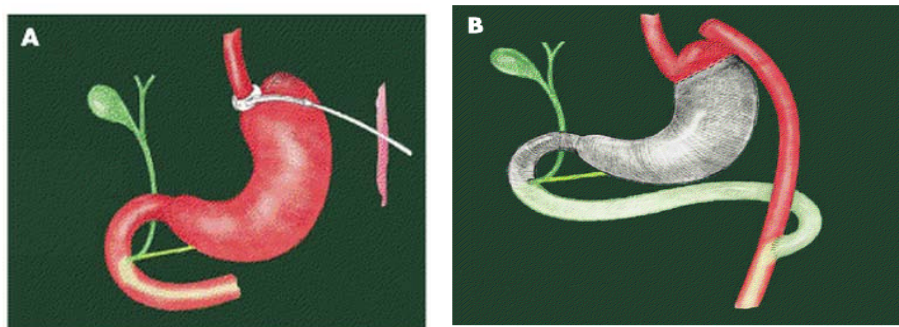


Figure 4: Diagrammatic representation of (a) adjustable gastric banding and (b) a gastric bypass with horizontal gastric stapling with Roux gastrojejunostomy

It was not until the 1970s and 1980s that bariatric procedures for adolescents with severe obesity were first reported (51, 52). These early operations caused extreme malabsorption with significant side effects such as liver and renal damage and multiple nutrient deficiencies (47, 52). These complications understandable made the medical community wary about performing this procedure in the pediatric population. However, a recent study looking at national trends in the US identified that the population-based, annual, bariatric surgery case volume increased threefold between 2000 to 2003 in adolescence, although only 700–800 cases were performed in total, which is <1% of all bariatric procedures performed during that time (53). This paradigm shift has occurred in part because of the use of laparoscopy and the realization that non surgical approaches are of limited effectiveness for severe obesity (53).

In the UK, obesity tends to be managed within the primary care sector of the NHS through advice on lifestyle modification (12)(54). Surgery is usually considered for people with complications of morbid obesity when all other measures have failed.

Education on lifestyle modifications remain the cornerstone of pediatric obesity therapy as well. Conventional treatment of childhood obesity has proven to be time consuming, difficult, frustrating, and expensive. Although numerous short-term successes have been noted, long-term weight reductions are modest (15). Very few procedures have been carried out on adolescents, though there have been isolated cases that garnered media attention (55). Much of the information available on obesity surgery in adolescents comes from the US.

In one study, Obrien et al (56) compared the outcomes of laparoscopic adjustable gastric banding (LAGB) with an optimal lifestyle program on adolescent obesity that involved reduced energy intake and increased activity. They hypothesized that surgery would induce more weight loss and provide greater health benefits and better improvement in the quality of life than the optimal application of available lifestyle approaches. Each group consisted of 25 patients. A total of 21 patients in the bariatric surgery group (84%) but only three subjects in the lifestyle group (12%) achieved the primary outcome measure of a loss of at least 50% of excess weight. Results revealed that LAGB patients had lost a mean of 35kg, which represents a mean loss of 28% of total body weight. In comparison, subjects in the lifestyle group lost a mean of 3kg, which represents a mean loss of 3% of total body weight.(56) Despite a comprehensive, behaviorally focused intervention, those in the lifestyle group were not able to achieve sustained long term weight loss.

Surgery is not only effective for weight loss but is also proven to treat many obesity related comorbidities (8, 10, 56-58). At the start of the O'Brien study, nine participants (36%) in the LAGB group and ten (40%) in the lifestyle group had metabolic

syndrome. At two years follow-up, none of the LAGB group had metabolic syndrome compared with 4 of the 18 patients (22%) in the lifestyle group. Those who underwent gastric banding also showed significant improvements in quality of life in the domains of physical functioning, general health, self-esteem, and family activities, whereas those who participated in the nonsurgical intervention did not. A recent review of 18 trials involving 1,891 subjects concluded that surgical management of obesity yielded an average of 28-30kg more weight loss than medical management after 2 years, with marked amelioration of obesity-related diseases such as diabetes, hypertension, and hypertriglyceridemia (49).

Lawson and colleagues (59) performed a retrospective study looking at 1 year outcomes in 36 adolescents who had RYGBP between the ages of 13 and 21 from three pediatric surgical centers and compared the results with 12 nonsurgical patients who participated for at least 1 year in a pediatric weight management program. Mean BMI in the surgical group was 56.6kg/m². Postoperatively, mean BMI fell by 20.7 kg/m². In the nonsurgical cohort, BMI decrease was only 1.2kg/m². Surgical patients demonstrated significant decreases in triglycerides, total cholesterol, fasting glucose, and fasting insulin. One of the important findings is that BMI values 1 year after RYGBP still range from overweight to obese. None of the patients attained normal weight during this time frame. This finding is consistent with adult bariatric results and is useful information for counseling adolescents about realistic postoperative expectations and a reminder that surgery is not a quick fix.

Although substantial and sustained weight loss follows bariatric surgery, limited data are available regarding long term mortality after surgery. RCT data evaluating

mortality and obesity related comorbidity endpoints are lacking. Available studies have certain methodologic limitations. Much of the evidence comes from observational studies and relatively short-term (<5 years) RCTs performed in experienced centers. Because of this, some argue that the reported results may overestimate the benefits of surgery and underestimate the risks. Adams and colleagues (57) addressed this question in a retrospective 18 year cohort study comparing 7925 who underwent gastric bypass surgery to 7925 matched controls. They examined mortality from all causes as well as obesity related diseases. When comparing death from coronary artery disease, diabetes, and cancer, patients who underwent gastric bypass had lower mortality rates (57).

While bariatric surgery is not cheap (prices for private surgery can range from £5000 -£8000 for the AGB to £9500 - £15000 RYGB), evidence indicates that it is a more cost effective intervention for weight loss than non-surgical options (11, 60, 61). The cost-effectiveness of bariatric surgery compared with non-surgical management appears to be particularly favorable in patients with type 2 diabetes (62). New data shows that morbidly obese people with T2DM who undergo bariatric surgery fully recover the costs of surgery in 2-3 years (63). This is in part due to a decrease in need for obesity related medications. Conclusions about cost effectiveness are somewhat limited due to lack of long term data. Some argue that bariatric current cost analyses might overestimate the economic attractiveness of surgery (62). Bariatric surgery is more costly than nonsurgical approaches, however given the direct and indirect costs of obesity related conditions, the NHS may in fact save money by investing in more surgeries for those eligible, especially if levels of obesity increase. Analysis by the government's Foresight program shows that over half of the UK adult population could be obese by

2050 (30) and NHS costs attributable to overweight and obesity are projected to double to £10 billion per year by 2050. Based on present trends, obesity will soon surpass smoking as the greatest cause of premature loss of life (4).

Access to Bariatric Surgery in the UK

NHS structure

To gain a better understanding of the challenges of obesity surgery provision, it is necessary to provide a brief description of how the National Health Service works in England and Scotland. An in depth description of the system's structure and its intricacies is beyond the scope of this paper. Rather, this is meant to provide a basic overview of how the NHS functions in order to better understand the context of healthcare inequities in this particular system. First, note that in the UK, England, Scotland, Wales, and Northern Ireland each have their own individual NHS structure. The basic idea, however, is the same: universal coverage for all citizens. Only England and Scotland's respective healthcare systems will be discussed.

The NHS is a healthcare system funded through national taxation. Since its launch in 1948 the NHS has grown to become the world's largest publicly funded health service (64). The system was born out of an ideal that healthcare should be available to all and that principle remains at its core (64, 65). With that, the promotion of equity is also one of the principal aims of the NHS. It is a tiered system with several agents of government in control of different aspects of healthcare provision. Each country in the UK shares this

basic structure, with comparable names of organizational bodies that perform similar functions in the healthcare system. See **figure 5**.

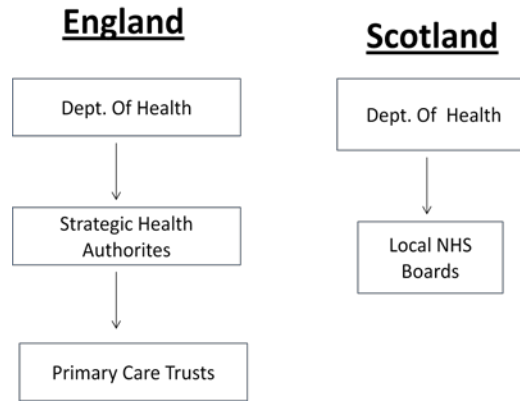


Figure 5: Basic organizational structure of NHS in England and Scotland.

NHS England

Management of NHS at a national level: Department of Health

The Department of Health controls the NHS in England. It passes primary legislation for the health service and is responsible for the overall health and well being of UK citizens. One member of the cabinet, the Secretary of State has general responsibility for the work of the Dept of Health and NHS improvement. He is responsible for setting national standards, securing resources, setting overall direction and leading transformation of the NHS.

Strategic Health Authorities (SHA 's)

Strategic Health Authorities manage the NHS in local areas and serve as an intermediate tier of management lying between the Dept of Health and clinicians. There are 10 SHAs in England. They are responsible for developing strategies for local health services and ensuring high quality performance. They develop plans for improving the

health service in local areas and they assist the development of local strategies to achieve central targets and objectives (64).

Primary Care- Primary Care Trusts (PCTs)

Primary Care Trusts are local organizations in charge of the actual provision of health care services. There are 152 PCTs in England. They are responsible for planning and securing these services and for improving the health of the local population. They are the main route for the funding of primary and secondary care (e.g. hospitals, dental, ophthalmic and pharmaceutical treatment and nursing care) and directly control most of the NHS budget; about 80% (66). In theory PCTs have considerable power to influence the quality of care provided by hospitals and general practitioners (GPs). PCTs enter NHS contracts with other NHS bodies using service level agreements. Since certain changes implemented in 2002 (67), PCTs have been the dominant purchasers of NHS services from hospitals, community health services and GPs. This offers PCTs considerable influence over the range of services to be provided, quality of care, how inadequate clinical standards should be identified and reported, the remedial steps to taken and, generally, the duty to enhance the quality of care to patients. Finally, private insurance does exist but unlike many other countries, private health care makes only a minimal contribution to care in the UK.

NHS Scotland

Scotland has a similar tiered organizational structure with differences in organizational titles and functions.

Scottish Health Department

The Scottish Executive Health Department (SEHD) allocates a budget for primary care and hospital services to each of the 14 NHS Boards (68). NHS Boards are boards of governance and have a statutory obligation to account for the quality of care they deliver to patients. Healthcare in Scotland is the responsibility of the Scottish Government, through the Deputy First Minister and Cabinet Secretary for Health and Wellbeing.

Local NHS Boards

The Scottish model of delivery is based around NHS Boards, responsible for all healthcare services in their geographical area. These 14 geographically-based boards are directly funded by and accountable to Scottish Department of Health. Hospitals within a given geographical area are directly managed by the corresponding NHS Board. Their requirements include: developing local health plans that address the health priorities and health care needs of the resident population; resource allocation; performance management of local NHS system, and operational management.

FUNDING THE NHS

As mentioned, the NHS is funded by the taxpayer. Financing healthcare through taxation means the overall level of resources is constrained by what the government judges the economy can afford. Within the NHS, PCTs are allocated funds directly from the Department of Health {{ }}. It allocates funds to PCTs on the basis of the relative needs of their respective populations. Population size varies amongst PCTs. Their share of the resources is based on their share England's population, so PCTs that serve larger areas get more funding and vice versa. A weighted capitation formula is used to determine each PCT's target share of available resources, to enable them to commission similar levels of health services for populations in similar need. The underlying principle

of the weighted capitation formula is to distribute resources based on the relative need of each area for health services. The current formula is based on the utilization of health care services and has the following components:

- Hospital and community health services
- HIV/AIDS
- GP practice infrastructure, e.g. practice staff wages, premises and equipment
- general practice prescribing
- GP remuneration (64).

The components of the formula are used to adjust each primary care trust's "crude" population according to their relative need for health care and the unavoidable geographical differences in the cost of providing healthcare. The weighted capitation formula is regularly reviewed. Geographically, attempts have been made to give a "fair" allocation to different parts of the England, bearing in mind differences in morbidity and mortality, labor costs and other factors. PCTs are subject to a statutory duty not to exceed their financial allocations and PCT board members may be dismissed by the Secretary of State for failure to comply with this duty. Given that demand for health care is always likely to exceed the resources invested in the NHS, PCTs must identify priorities amongst the various demands made upon them. PCTs are subject to pressure from patients, doctors, the press and government. Hostile newspaper headlines may prompt forthright telephone calls from the Department of Health with instructions as to how a local matter should be resolved (64). So, although in theory, priority setting is a responsibility delegated to PCTs, external factors can still influence their decision making.

To support decisions on priorities, measurements of outcome rather than process were required. An economic perspective led to the development of the 'quality adjusted life years' (QALYs) (69), which is a measure used in cost-utility analysis to calculate

cost effectiveness of a particular medical intervention. It is a health status index measuring disease burden by including both quality *and* quantity of life lived. The general idea is that a beneficial health care activity is one that generates a positive amount of QALYs, and that an efficient health care activity is one where the cost per QALY is as low as it can be (70). Comparisons can be made between interventions, and priorities can be established based on those interventions that are relatively inexpensive (low cost per QALY) and those that are relatively expensive (high cost per QALY).

The financing of the NHS in Scotland is similar to England. Funding is provided on a capitation basis for each health board. As described above the NHS Boards are responsible for funding both primary and secondary care. The funds available to Scotland's 14 NHS Boards are determined during an annual spending review process (71). NHS Scotland uses a formula¹ and also has a resource allocation committee to allocate funds on a basis that supposed to be fair, equitable, and reflect the relative need of each NHS Board. It is up to the boards to decide how to spend their allocation in a way that best meets the needs of its resident population (71).

The NHS constitution

Every NHS has a constitution. It sets out rights to which patients, public and staff are entitled. It works in partnership with other organizations in the interest of patients, local communities, and the wider population. Underpinning the NHS is a set of core principles, which include provision of a comprehensive service, available to all based on

¹ The Arbutnott Formula- implemented in 2002, it assesses each NHS Board's relative need for funding, using information about its population size and characteristics that influence the need for healthcare in terms of hospital services, community services and GP prescribing.

clinical needs, not on an individual's need to pay (70). It aspires to the highest standards of excellence and professionalism and is committed to providing the most effective, fair, and sustainable use of finite resources (65). It also professes a wider social duty to promote equality through the services it provides and to pay particular attention to groups or sections of society where improvement in health and life expectancy are not keeping pace with the rest of the population (65).

The NHS constitution affirms ideal principles of quality, access, and fairness in the distribution of healthcare. Many countries strive to achieve this but the task is difficult given the increasing demands on healthcare. The new demands for medical care and seemingly uncontrollable costs have placed great burdens on both public and private health care systems. The complex changes which have occurred in systems around the world raise ethical dilemmas regarding the allocation of scarce health resources. (72) Once it is established what a society should spend overall on health care, then it must also be decided who should have that care, and on what basis it should be allotted. Resource constraints require judgments about which medical needs are more important to meet than others. Fairness in the distribution of healthcare is a critical part of resource allocation decisions (73). Rooted in discussions of resource rationing is the ethical principle of distributive justice, a concept concerning fairness in the allocation of resources amongst society (74). In the following section, I will describe a few basic principles of distributive justice and how they are applied to healthcare. It is not the aim to review all principles of justice discussed in the literature but rather to present the main ethical theories that underpin healthcare allocation discussions.

Distributive Justice in Healthcare

John Rawls was one of the first philosophers to speak on the principles of justice and his work has been used by many to apply his principles to healthcare. Rawls's main idea centers on the idea of *justice as fairness* (75). He conceptualizes an "original position", that is a hypothetical state of nature in which

"no one knows his place in society, his class or social status, nor does any one know his fortune in the distribution of natural assets and abilities, his intelligence, strength, etc." (75)

The idea is that the people of this idealistic world choose the principles of justice through a "veil of ignorance". This veil is essentially one that blinds people to all facts about themselves that might cloud what a notion of justice is. According to Rawls, ignorance of these details about oneself will lead to principles that are fair to all. If an individual does not know how he will end up in his own conceived society, he is likely not going to privilege any one class of people, but rather develop a scheme of justice that treats all fairly. The veil of ignorance is intended to encourage individuals to take steps to correct inequalities that are in place because of chance (74, 75)

Rawls defined justice in two principles. The first principle addresses an equal claim by all citizens to equal rights and freedoms. The second principle has two parts. The first part of the second principle states that there must be equality of opportunity provided by social structures so all citizens may have the same chance of gaining income, wealth, position, and social advantages. The second part of the second principle states that inequalities will be tolerated only when such inequalities work to the advantage of society's most disadvantaged. Rawls' theory of justice has been appealing in healthcare ethics because it corresponds to the altruism of most healthcare providers of offering care to those who demonstrate need regardless of their behavior or socioeconomic status (74).

While Rawls' work was not directly related to healthcare, many philosophers have used his model to apply it to healthcare and how resources should be fairly distributed (73, 74, 76, 77).

Several principles of justice have been applied to healthcare(78): Need principles, maximizing principles, and egalitarian principles (78). Need principles require that healthcare be distributed in proportion to need. Things get complicated because different definitions of need lead to quite different substantive rationing principles. Need can be seen in terms of immediate threat to life, immediate pain & suffering, and potential to benefit from an intervention. Maximizing principles require that health care should be distributed so as to bring about the best possible consequences. This principle is broadly utilitarian in focus and enters the realm of cost-utility discussions in healthcare rationing (72). According to egalitarian principles, health care resources should be allocated so as to reduce inequalities in health as well as equalizing people's opportunity for lifetime health. The aim of a responsible government is to balance these principles and to try to bring everyone as close as possible to a decent minimum level of health (79). Sometimes these principles can be conflicting given the complexities of a society's healthcare needs (80). A frequent criticism of use of the QALY is that it places a higher priority on efficiency than medical need(81) (maximization vs need). What needs focus is not whether particular distribution mechanisms are unethical but whether they are structured and work in morally acceptable ways, and lead to morally acceptable results (76). Given that health services will always be in short supply in relation to potential demand, the question is whether services are structured and organized in ways that will promote people's fair and equitable access to care. Healthcare must be planned in ways that try to

achieve justice, fairness, and equality. There will always be potential conflicts between different moral concerns at different levels but justice requires that all societies meet healthcare needs fairly under reasonable resource constraints (77, 82).

Norman Daniels has written extensively on issues of fairness in healthcare and he frames an argument for universal healthcare by using Rawls' principles. He defines the moral significance of health in terms of the preservation of equal opportunity (73). Daniels draws on studies of the social determinants of health to argue that health inequalities are unjust if they result from socially controllable factors affecting the population (83). According to Daniels, healthcare is of special importance, because it helps to preserve our status as fully functioning citizens. It protects normal functioning, which in turn protects the range of opportunities open to individuals. Disease and disability, by impairing normal functioning, restrict the range of opportunities open to individuals. By keeping people close to normal functioning, healthcare preserves for people the ability to participate in the political, social, and economic life of their society (73). According to Daniels, this relationship between healthcare and the protection of opportunity suggests that the appropriate principle of distributive justice for regulating the design of a healthcare system is a principle protecting equality of opportunity (83, 84).

Policy makers try to achieve balance between utilitarian and egalitarian principles all while trying to achieve fairness and justice in the distribution of healthcare. Unfortunately, there is no consensus on how to achieve a perfect balance between these principles. People have diverse moral and religious views about many matters, so there will be disagreements about what constitutes a fair allocation of resources to meet

competing healthcare needs. Governments try to make decision fair but ultimately, there is always some inequality to be felt in the system because healthcare is not the only important good.

England and Scotland make their rationing decisions through organizations dedicated to evidenced based medicine that provide national guidelines for physicians regarding best practice for certain health conditions. In England, that organization is the National Institute for Health & Clinical Excellence (NICE). When the NHS was established in 1948, evidenced based standards were not incorporated into clinical practice. Studies during the 1990s showed that the results of clinical research were poorly incorporated into routine care and that inappropriate variations in the standards of clinical practice abounded (70, 85). As medical knowledge grew, attitudes changed. Medical practice based on evidence, rather than on anecdote and opinion, gained credence. In 1997, parliament announced the establishment of NICE, with a remit to include guidance on treatments, drugs and other technologies. NICE profoundly changed the way that England and Wales evaluated health interventions. It exists to give health professionals advice on providing their patients with the highest clinical standards of care. It is the independent organization providing national guidance on the use of specified medicines and treatments and the care and treatment of NHS patients with specified diseases. NICE also publishes reports and approves evidence based guidelines.

In September 2006 NICE was asked to launch a new program to help the NHS identify interventions that are not effective, to help it make better use of its resources by reducing spending on ineffective treatments that did not improve patient care or represent good value for money. NICE does this through technology appraisals (86). Technology

appraisals are recommendations on the use of new and existing medicines and treatments within the NHS (86). Technology appraisals would be undertaken where clinical evidence suggested that current practice is no longer appropriate or effective and does not improve patient care. NICE also uses the QALY to help evaluate clinical and cost effectiveness of an intervention and to ensure that its judgments are fair (87).

Technologies are considered clinically effective if, in normal clinical practice they confer an overall health benefit, taking account of any harmful effects, when compared with relevant alternative treatments. If a treatment costs greater than £20,000-£30,000 it would not be considered cost effective (87).

Affordability, in this sense, is a matter for the government when deciding the annual budget for the NHS. NICE must be able to judge whether something should or should not be purchased from within the resources made available to the NHS. Even though legally there can be no blanket ban to entirely exclude a medical procedure from funding (79), not all forms of health care are equally well-funded. This is a consequence of the local allocation of health budgets, where the PCTs decide for a particular geographical area which healthcare provisions will receive funding. As a consequence, the kinds of health care available for individual patients may vary considerably between geographical areas (88). Scotland's equivalent, the Scottish Intercollegiate Guidelines Network (SIGN) was as precursor to NICE in England. It was formed in 1993 with an objective to improve the quality of health care for patients by reducing variation in practice and outcome, through the development and dissemination of national clinical guidelines containing recommendations for effective practice based on current evidence (89).

Policy issues surrounding obesity surgery in the adult/pediatric population

In England, NICE published guidance on the use of bariatric surgery in 2002.(90, 91, 91) The guidance recommended surgery for people with a BMI either equal or greater than 40kg/m², or between 35kg/m² and 40kg/m² in the presence of significant comorbid conditions that could be improved by weight loss. This guideline also recommends surgical intervention as a first line option for people with BMI equal to or greater than 50kg/m². NICE has recommended that surgery should be available as a treatment option for those who meet all of the following criteria:

- they are aged 18 years or over
- they have been receiving treatment in a specialist obesity clinic at a hospital
- they have tried all other appropriate non-surgical treatments to lose weight but have not been able to maintain weight loss
- there are no specific medical or psychological reasons why they should not have this type of surgery
- they are generally fit enough to have an anaesthetic and surgery
- they should understand that they will need to be followed-up by a doctor and other healthcare professionals such as dieticians or psychologists over the long-term (91).

NICE recommends that eligible patients have surgery to aid weight loss only after they have had a full assessment by a specialist and other healthcare professionals involved in their care. In 2006 NICE revised its guidelines on the management of obesity and included recommendations for adolescents (92). Surgery is not generally recommended for children or young people. **See figure 6.** Bariatric surgery is considered for young people only in exceptional circumstances, and if:

- they have achieved or nearly achieved physiological maturity
- they have a BMI of 40 kg/m² or more, or between 35 kg/m² and 40 kg/m² and other significant disease (for example, type 2 diabetes, high blood pressure) that could be improved if they lost weight
- all appropriate non-surgical measures have failed to achieve or maintain adequate clinically beneficial weight loss for at least 6 months
- they are receiving or will receive intensive specialist management
- they are generally fit for anaesthesia and surgery

- they commit to the need for long-term follow-up.

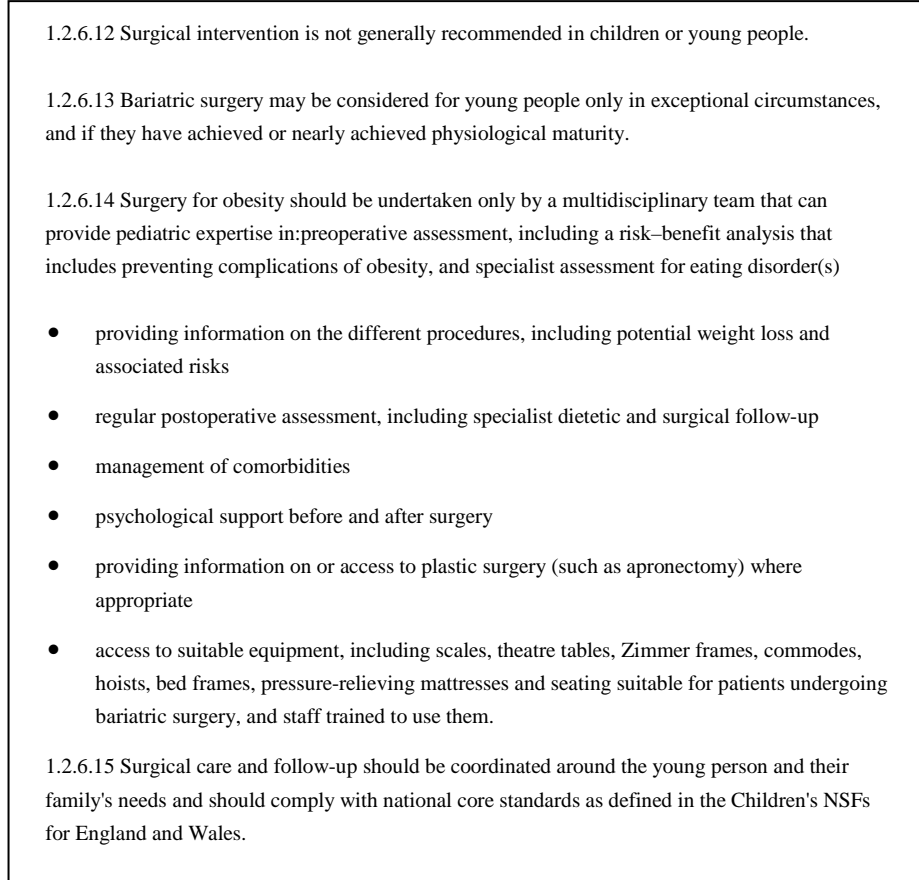


Figure 6: NICE criteria for obesity surgery in adolescents.

In Scotland, the guidelines for overweight and obese adults needing surgery mirrors that in England. For adolescents, SIGN recommends surgery for post pubertal adolescents with very severe to extreme obesity that may have serious obesity-related morbidity that requires weight loss (93). SIGN also specifies that weight loss should be limited to older children. For younger overweight and obese children, weight maintenance is an acceptable goal and allows a gradual decline in BMI.

Status of Bariatric Surgery in England & Scotland

The UK has lagged significantly behind the US in the amount of bariatric surgical procedures performed each year (90, 94). However, laparoscopic surgery has increased exponentially in England over the past decade. See **Figure 7**. Growth in the rate of performance of bariatric surgery increased rapidly after 2002 (21, 90). Obesity surgeries increased from 72 in 1996 to 347 in 2004. This is a relatively small number of operations compared to 7,176 procedures carried out between 1987 & 1996 in Sweden, 1,000 bariatric operations per month in France, and 72,177 procedures carried out in the USA in 2002 (54). The reasons for the rapid expansion in provision of bariatric surgery in recent include publication of the NICE guidelines and increased advocacy in the surgical community for surgery. An anticipated delay in changes to everyday practice regularly follows the implementation of such a guideline, given the requirement for training and expansion of services. In addition, agreement must be sought from primary care trusts that obesity surgery will be funded (54)

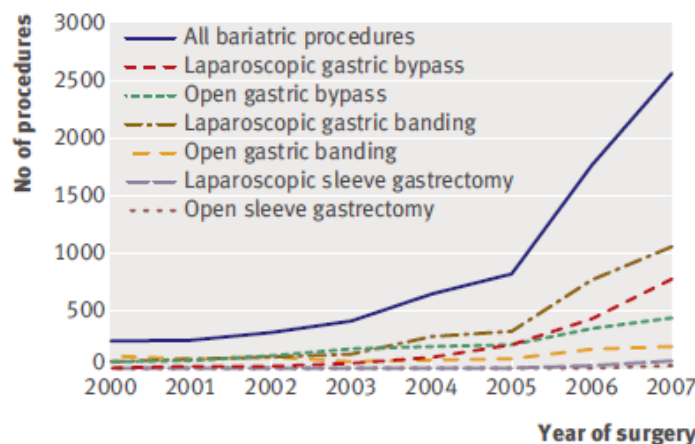


Figure 7: Changes in type of operation over time and trends in uptake of laparoscopic surgery.

Despite the proven effectiveness of obesity surgery, there have been delays with implementation of a nationwide strategy for bariatric surgery in the UK. Population access to obesity surgery across England appears to be highly variable and does not reflect estimated regional differences in morbid obesity (12, 95). Around 1 million people meet NICE criteria with around 240,000 wanting surgery, yet only 4300 operations happened in 2009 (12). **See figure 8.** This is a problem well recognized by many professional medical groups (95). The Royal College of Surgeons has raised concerns that not enough bariatric surgery is being carried out by the NHS. Surgeons have called for consistency and transparency across the NHS so that patients are clear about what they are entitled to (95). They are urging the Department of Health to invest in a long term strategy to ensure that patients have equal access to treatment. Alberic Fiennes, President-elect of the British Obesity and Metabolic Surgical Society (BOMSS), shared this opinion:

“We recognize the difficulties faced in dealing with a ‘new’ disease of epidemic proportions but to limit surgery to the most severely obese is unfair and short-sighted and against basic professional ethics. It is also contrary to strategies that are standard for diseases that overwhelm resources.”(96)

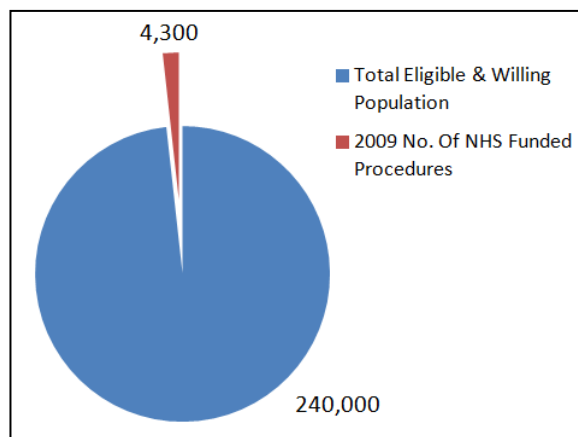


Figure 8: Changes in type of operation over time and trends in uptake of laparoscopic surgery.

While environmental solutions are clearly key to tackling obesity at a population level, the NHS also has an important role to play in the treatment of obesity, but evidence suggests that this has not been as high a priority for PCTs as it should have been (4). A 2001 National Audit Office report concluded that there was little NHS activity related to the management of obesity outside general practice (42). Bariatric surgery is increasing, but is not uniformly available across the country and a significant proportion is funded privately (11). This is something that warrants further investigation if equality in service provision is to be provided. In Scotland only 0.8 % of those eligible and willing to have weight-loss surgery receive treatment, compared with 1.2% in England, 5.5% in Sweden and 9% in the United States (97). More than 100 gastric band operations were carried out in Scotland in the past few years (98). This increase also reveals wide variation in provision of surgery similar to England. For example, one such health board, NHS Grampain performed 89 surgeries between 2008-9, whereas in that same period another board NHS Glasgow carried out 198 and another NHS Lanarkshire only 5 or fewer, and another had none (99). Of course, the population of obese in certain regions will influence the demand in a particular area though it seems that established bariatric centers are only available in few locations in Scotland. It is well acknowledged that the level of investment is extremely low, such that these services are not having an impact on a national level. Most Scottish health boards do not offer it and the few that do often say they are overwhelmed by demand (100). Experts agree that to save some of the colossal and rising costs of obesity, a lot more investment is needed for treatment (101).

Challenges to increasing surgery provision in England & Scotland

Practical Challenges

Despite having national guidelines in place, there are multiple barriers within the NHS that impede increasing obesity surgery provision to patients. The most glaring challenge is that for clinical guidelines adherence is not mandatory. According to Adrienne Cullum², “NICE doesn’t enforce implementation of the guidelines. It only monitors who employs the guidelines and collects data from that” (Cullum, A, phone interview, 11/10/2010).

Official statistics from a recent report from the Office of Health Economics (13) suggest that PCTs are either not following the guidance or interpreting it stringently. The report details the results of an exercise looking at trends in obesity, current provision of bariatric surgery in England with particular reference to the NICE clinical guidelines for obesity, and potential economic benefits that could be achieved through adherence to the NICE guideline.

PCTs were surveyed to elicit details of the current practices and policies for provision of bariatric surgery. Returns from the questionnaire suggest that adherence to the NICE guideline is inconsistent and suboptimal. Some PCTs responding to the questionnaire said that they do not follow the NICE guidelines at all. Of particular significance was the wide variety in the BMI cut-offs specified in the responses to suitability for referral to surgery. BMI cut offs ranging from 35 to 60 were listed for surgical referral. **See Figure 9.** Other examples of stringent criteria include needing to have recorded evidence that all non surgical options have failed; documented

² Adrienne Cullum, PhD- Trustee for Association for the Study of Obesity. Was a technical lead on the 2006 NICE guidance on obesity.

participation in a lifestyle program that has failed, or evidence that patient has received non surgical obesity management for 6 months-1 year.

<u>PCT</u>	<u>Criteria for patient funding of bariatric surgery</u>
Bedfordshire	BMI over 40 with type 2 diabetes and/or severe sleep apnoea (hypertension is not an allowable comorbidity for surgery), are aged 18-60 and who have been receiving intensive obesity management of at least 6 months.
Calderdale	NICE Guideline criteria plus patient must have been severely obese for 5 years or more and actively involved in a non-surgical weight reduction program for that time. Priority will be given to patients with symptomatic coronary heart or peripheral vascular disease and non-insulin dependent diabetes.
Dudley	BMI over 60 or over 50 with serious comorbidities (ischemic heart disease, T2DM, OSA, severe HTN, TIA or stroke)
Warwickshire	One year intensive management in specialist obesity clinic setting. BMI over 45 with type 2 diabetes or over 50 with comorbidities or over 65 without comorbidities.

Figure 9: Examples of how eligibility criteria varies across PCTS.
<http://www.bospa.org/information.aspx?page=46>

Adherence was generally suboptimal and the number of procedures commissioned by PCTs ranged from 1 to 194 in 2009-10 indicating a wide variation in practice. The inconsistency between national guidelines and implementation at the local level presents a huge obstacle for the obese patient. PCTs are using their own their own criteria that differs from the NICE guidelines; criteria which have no foundation in the evidence .By raising the threshold BMI, they limit the number of patients who are eligible for surgery irrespective of the guidance and also create a perverse incentive to gain more weight in order to qualify for surgery. A consultant surgeon, Bob Marshall, shared his experience with one primary care trust:

“The current situation is that the PCT will only fund initial consultations and work up for patients with a BMI of 50 or more and who also have some comorbidity. If we

consider that these patients are suitable for surgery, then we have to reapply for PCT funding. Anyone with a BMI under 50 will not get funding on the NHS. If these other people want to pursue bariatric surgery then it has to be done privately.” (102)

Other surgeons are concerned that surgery provision is not driven by clinical need (94). At times, procedures are not offered to the patients that would most benefit from them and those who are refused end up fighting with the NHS in court. Thomas Condiff is one such patient (103). With a weight of 308 lbs (140kg), a BMI 43, and complications from type 2 DM which include vision loss in one eye and chronic kidney disease, Mr. Condiff more than qualifies for bariatric surgery. However, he was refused the operation because he fell below the threshold set by his local PCT, which demands a BMI of at least 50 to be considered for surgery. Mr. Condiff is challenging the decision in appeals court. His quality of life has only worsened during his battle with the NHS. He can no longer stand or walk for more than a short time and needs help with activities of daily living. He is urging the NHS to grant the appeal and consider the impact on his life and his family. The PCT in question, NHS North Staffordshire, makes its decisions for exceptional funding on the medical condition of the patient, and does not consider their personal circumstances. In this particular case, that reasoning seems illogical given the fact that his personal circumstances are a result of his medical condition. This case again highlights the regional differences in funding for surgery. Especially troubling is that the over-arching Department of Health has made no effort to investigate why certain PCTs have generated their own criteria and there has been no push to standardize criteria across England.

The implementation of NICE guidance by NHS bodies is ostensibly less comprehensive and timely than desired. The availability of funds to execute the guidance

can clearly be a factor and is often cited by PCTs as an obstacle to increasing provision (104, 105). However the most significant issue identified was weaknesses in local financial management of PCTs. These weaknesses include the fact that PCTs do not routinely identify costs and savings associated with guidance making it difficult to assess financial impact and affordability. In addition, Implementation of NICE guidance is not routinely integrated into financial planning and budgeting processes (104). Also when it comes to rationing resources and examination of priorities, it appears that some PCTs view bariatric surgery as a low priority. For example, NHS East Lancashire (106) put out a policy document that clarifies PCT commissioning intentions regarding procedures and treatments which are considered low priority. These procedures include those that “are requested for aesthetic purposes and/or for which there is a lack of evidence and are considered of low priority” Bariatric surgery is listed as a low priority intervention and is not normally funded. There is a multitude of evidence of surgery’s effectiveness but it is still grouped in this category.

There are disturbing trends in both private and NHS sectors. As surgery is considered a low funding priority, the patient must overcome extra hurdles to pay for the procedure which is why many surgeries are paid for privately or patients go outside of the UK to pay for cheaper procedures abroad (94, 107). Doctors are increasingly seeing patients who have received operations privately but have developed complications or have not been provided with the appropriate support and follow-up. Laparoscopic gastric banding is technically less challenging than other bariatric operations; unfortunately, this has resulted in some surgeons ‘dabbling’ in this operation without expertise in weight management (108). Also, there are several troubling trends within the NHS. First, there is

the danger of proliferation of small units that do not have the appropriate expertise or infrastructure to provide the best care. Second, laparoscopic gastric banding is offered as the only operation in some centers where other operations are more appropriate. Third, with increasing competition within the NHS, there is a tendency to cut corners and not provide the appropriate staffing for a successful bariatric practice (12).

In Scotland, there are also regional differences in number of surgeries performed. Problems include lack of guidance implementation and a the need for a comprehensive, organized referral processes (109). No nationally agreed patient pathway exists for patients undergoing bariatric surgery in Scotland. Some patients are referred from primary care, other from endocrinologists or cardiologists, or orthopedists. As such, patients will receive varied care dependent upon which practitioner they see and how aggressive they are in trying to treat the obesity. Obesity is managed mainly in general practice, with most common approach being advice on weight control and diet provided by GPs. Other options, such as drug therapy, referral to specialist weight loss clinics, behavioral therapy, etc are also considered but hampered by a general lack of knowledge and resources within this sector to allow appropriate clinical care pathways to be established (110).

Lack of physician training is another recognized challenge to increasing obesity surgery in the UK (12, 111). Most surgeons practicing bariatric surgery in the UK are upper GI surgeons who are self taught or have attended international bariatric surgery courses. In the UK, there are currently 2 US bariatric fellowship trained surgeons (12).

However, the number of bariatric surgery fellowships and courses offered in the UK is rising. According to David Kerrigan³, a leading bariatric surgeon in England

“there needs to be more training of surgeons in bariatric surgery. I don’t believe that there aren’t enough surgeons, there just aren’t enough that are trained to perform this surgery” (Kerrigan, D. Informal interview, 12/7/2010)

Disregard for evidenced-based guidance, lack of resources, poor referral process, and a need for more surgeons trained in this intervention encompass only some of the challenges to increasing access to surgery.

Hidden Challenges

There are multiple hidden barriers to access in the adolescent population, mainly driven by attitudes toward the obese and concerns about surgery in youth (112-114).

There seems to be professional resistance to perform this procedure on someone under the age of 18 and there are many reasons for this. The pediatric weight loss surgical patient requires unique considerations that make treatment less straightforward than treating adults and several ethical issues emerge when discussing this intervention in adolescents (38, 114-117).

First and foremost, with any surgical procedure, understanding of the risks involved is paramount. The desire to have a body that is socially acceptable may interfere with a deep understanding of the operative risks, and in the case of the Roux-en-Y gastric bypass, its irreversible nature (117). The risk profile for RYGB and the LAGB has been well established in large clinical series of adult patients and in smaller numbers of adolescent patients (49, 118). For RYGB, the major early postoperative complications include anastomotic leak, massive bleeding, and pulmonary embolism. Other

³ David Kerrigan, MD. Medical director of Gravitas, an obesity surgery center in England.

complications include wound infection, anastomotic stricture, marginal ulceration, incisional hernias, symptomatic cholelithiasis, and remote weight regain (115). In addition, the long-term nutritional risks for deficiencies of calcium, vitamin D, iron, folate, and B vitamins require that patients adhere to strict micronutrient supplementation.

Troublesome symptoms of dumping, particularly after eating sweet foods, nausea and vomiting, and diarrhea may be recurring problems for some patients, and all will have more frequent bowel movements (118). The postoperative risks following placement of the LAGB relate to mechanical and infectious complications (119). The LAGB can become malpositioned, with slippage of the band from its proper location, either in the early or late postoperative period. Patients can experience painful symptoms of gastric obstruction or more serious signs of erosion of the band into the gastric wall. Because the band is a foreign body, it carries the risk of infection, either within the abdominal cavity or abdominal wall. Removal of the device is usually necessary for infectious complications, and repositioning or removal and replacement of the band is required for slippage.

A primary concern is when is the best time to surgically intervene in pediatric obesity cases? Many argue that morbidly obese individuals should be the adult age before undergoing obesity surgery (120). Optimal timing often depends on the severity of the patient's obesity related comorbidities and whether the patient has failed more conservative options. The longer an individual is obese, the higher the risk of comorbidities (7). Since many obesity-related diseases take years to develop, the suggestion exists of a need for earlier intervention. Higher BMI criterion exposes the adolescent to a higher degree of risk for operative complications and death. According to

Cuttler and colleagues (121), the link between pediatric and adult obesity is age dependent. Childhood obesity becomes the dominant predictive factor for adult obesity after age 10 years, with approximately 80% of children 10 years or older with a BMI above the 95th percentile carrying their obesity into adulthood. For the severely obese adolescent, treatment delayed may be treatment denied and in some cases a crisis invited (122). Another concern over the timing of bariatric surgery is due to the potential compromise of growth and development in children who undergo this procedure too young. There is rapid neuroendocrine, skeletal, and psychosocial maturation during adolescence, and it is unknown how these growth processes are affected by restrictive or malabsorptive surgical procedures (38). The accelerated growth of adolescence requires adequate nutrition, and bariatric surgery performed before the growth spurt could potentially compromise growth. While bariatric surgery is not considered to drastically impair linear growth if at least 95% of adult stature has been attained, it is not yet known whether and to what extent bariatric surgery may adversely affect bone mineral density and increase the risk of brittle bone fractures later in life(38, 123). So, if a patient is particularly young, the surgical team is left with a dilemma: Wait until the patient is more physiologically mature, creating the possibility of worsening comorbidities or intervene earlier but risk the metabolic complications and their effects in the patient's future growth.

Additionally, while some adolescents may be considered physiologically mature enough to undergo bariatric surgery, psychological readiness is not as easy to assure (116). The legal and ethical issue raised here is whether the patient has decisional capacity and is able to participate in autonomous decisions. Assent for surgery must be

obtained from the child/adolescent patient, and informed permission must be obtained from the parents before surgery. The patient and family members must clearly understand the potential benefits as well as risks associated with the procedure. The role of adults in decisions regarding pediatric obesity is particularly important because children are not always in control of the food available to them. It may be questioned whether parents who have been unable to successfully treat overweight youth by lifestyle changes are likely to adhere to the critically important dietary and activity plans needed postoperatively for life-long success (124). For these reasons, clinicians must be careful to focus on the best interests of the obese child and help parents to make sound decisions on behalf of their child. Decisional capacity is not determined strictly by chronologic age (38). Some agree that children under age 13 years do not have the capacity to make decisions regarding such a serious intervention as bariatric surgery (116, 120) yet there are those who consider the age range of 8-14 years to be appropriate for assent (113). These ethical considerations regarding developmental capacity to give consent suggest that intensive treatments should focus on older children and adolescents.

Because obesity is acknowledged as a cause of major morbidity and mortality, prevention of obesity is a target health policy in many countries. Both the English and Scottish governments recognize that part of solving the obesity problem involves preventing the rest of the population from becoming overweight. Both governments have laid out numerous policies to combat the problem including improving school nutrition, menu labeling, even proposing controversial measures such as taxing foods high in fat or sugar content (125). Programs developed in the UK have been largely focused on tackling obesity through improving education, diet, and raising physical activity levels

(27, 30, 42). Most of the scientific evidence shows that nutrition lessons, exercise recommendations, and industry self regulation have not slowed the rise of obesity (25, 26). This is not to say that lifestyle changes are not as important for secondary prevention, but they are rarely enough. While many may agree with the above, they seem to have a hard time applying this knowledge to obesity. While every politician, non-government organization and legions of health workers are campaigning for more efforts on preventing obesity, where does this leave those who need treatment now? It is important that the medical problem of pediatric obesity be clearly distinguished from the cultural value placed on being thin. Otherwise, attempts to reduce obesity may be viewed as enhancement therapies rather than efforts to treat a disease (39). In the case of obesity, this focus on prevention reflects an underlying prejudice to those who are obese (25, 94, 110).

It is more than half a century since obesity was introduced into the international classification of diseases (126). Yet even now it is not fully recognized as a disease even by some members of the medical profession (110). Despite the frequency of encounters between clinicians and patients who are obese, many providers hold negative attitudes toward obese individuals. A number of studies demonstrate that obese patients report negative clinical experience, poor treatment, and stigmatizing behavior by health care providers (110). In 2006, Soonwalla and colleagues (107) conducted a survey of 748 UK surgeons which showed that 93 of them felt that surgery should rarely be used in the management of obesity. Alarming, over 10% of the surgeons actually condemned bariatric surgery despite evidence of its effectiveness. 63 surgeons held the opinion that bariatric surgery should not be funded by the NHS and the reasons they gave were that:

obesity is a psychological problem for which surgery is not appropriate, surgery is not effective enough for it to be used in this disease, and the condition is self-inflicted and treatment for it should be paid for by the patient. In children, it is even more contentious.

Michael Craig⁴, a lead policy official in Scotland concludes that

“ it is an issue of whether surgeons are comfortable doing it on someone who is very young. It’s viewed as a very radical approach, an easy way out. GPs are even hesitant about using drugs in kids. Surgery has to be the ultimate, absolute, last resort.” (Craig, Michael, personal communication, 11/30/2010)

These beliefs can shape the clinical interaction, making it harder for obese patients to get the care they need. David Kerrigan believes

“GP ignorance is a huge barrier to providing surgery. GPs either keep prescribing drugs or just tell people to lose weight the ‘right’ way. It makes patients feel dissociated from the medical profession”. (Kerrigan, David. Personal communication 12/7/2010)

For many, losing weight is difficult. It has been shown that fewer than 5% of people who attempt diet and exercise recommendations succeed (127), yet, in the UK prevention measures are promoted as a treatment option.

Surgical treatment of obesity is often felt to be controversial to lay people, the media, health politicians, and professionals (128). Specifically, the idea that obesity is self inflicted underlies the continued myopic focus on prevention as well as the negative “antifat” attitudes society holds toward the obese. The term “antifat” refers to prejudice, bias, belief, phobia, and stigma held about the concept of fatness and demonstrated toward people whose bodies are considered too large (39). It is wrong to be fat in western society because being fat is viewed as unhealthy and unattractive. These attitudes have been attributed to the belief that fatness is caused by self indulgence, gluttony, and laziness. Subsequently, as these are vices of the individual, treatment and prevention

⁴ Michael Craig- Public Health Advisor for Food Nutrition and Healthy Weight. Scotland.

approaches were, and still are largely focused on individual behavior. Much of the ethical discussion regarding obesity is centered on two frames: (1) that obesity is an issue of personal responsibility and thus is a matter for the affected individual to handle and (2) that obesity is a legitimate illness that causes disability and should be treated as such (26, 129, 130). Sometimes the personal responsibility argument is used as a justification for rationing healthcare (131) but this is often perceived as contrary to intuitions of justice and compassion in medicine (132).

On one hand of the argument, people don't like the idea of using scarce sources on treatment of disease that is supposedly self inflicted when they could alternatively be spent on to cure those conditions for which no one is to blame (133). On the other hand, there are those that disagree with denying potentially life-saving care to someone because of lifestyle choices. Many conditions requiring expensive medical treatment are caused by behaviors that are socially accepted (74). Thus singling out socially disapproved behaviors as less deserving of treatment reflects social prejudice rather than logic (25, 74). It is unfair to impose penalties on only some. Some may overeat; others smoke, drink, engage in adventure sports, sunbathe excessively or pursue an overly ambitious and stressful professional career (134). Which responsibilities are acceptable for blame and which ones are not? The desire to hold individuals responsible for choices that affect their health is disproportionately applied to the obese. Should we deny treatment to alcoholics suffering from liver disease? Or smokers suffering from lung cancer or COPD? If obesity is known to be a significant predictor of severe illness and premature death and there exists a treatment scientifically proven to be clinically effective and cost-effective, then it should be provided within that healthcare system (25, 26, 129). Within

all modern societies healthcare authorities are facing difficult priority setting problems and the question is; should responsibility based arguments be accepted as relevant to meeting healthcare rationing fairly and legitimately (131, 135)? Although people may be held responsible for their choices in the sense of criticism for negligence or high risk behavior, this does not imply that they are not entitled to any assistance. Issues of what people are to be held responsible for should be distinguished from issues of how deserving they are of medical care (136).

Revisiting Norman Daniels' arguments, he rejects attempts at making people bear the cost of risky lifestyle choices for several reasons. Assessing responsibility is administratively burdensome, costly, intrusive, demeaning, liberty and privacy infringing, and may "victim blame" already disadvantaged groups.

"too much emphasis on personal responsibility ignores egalitarian considerations central to democratic equality. Our health needs, however they arise, interfere with our ability to function as free and equal citizens. We must meet these needs however they have arisen, since capabilities can be undermined by both lifestyle choices and condition beyond one's control"(73).

Furthermore, personal responsibility cannot wholly be applied to adolescents as they are often not fully responsible for their health choices. Many lifestyle interventions strive to incorporate the parents of overweight children as much as possible given the magnitude of parental influence on health choices (27)

Attitudes toward obesity are important determinants of attitudes toward bariatric surgery. Those attitudes also influence policy aimed at treating the obese and overweight population. How issues are presented in public discussion, is important to which policy approaches are adopted (26). History teaches that discrimination against socially undesirable groups leads to societal and governmental neglect of the stigmatized group's health problem (25). Discrimination can lead to inaction and can impede efforts to solve

health disparities. Society and government tend to blame the victims and enact and interpret legislation based on the theory that the people are not taking appropriate responsibility for their own health. Obese individuals internally suffer from weight bias but also suffer because society blames them for their illness and thus relinquishes responsibility of addressing the other underlying causes of their obesity (24, 25, 74). Discrimination against stigmatized groups perpetuates the disparities already prevalent in their lives. Due to this discrimination, the condition of obesity is not being addressed on par with nonstigmatized medical conditions.

Historically, those in power have advocated education and/or prevention as a solution to the health problem of the stigmatized group; neither of which actually addresses the cause of the increased incidence of disease and both of which results in increased discrimination. Even policy makers often take removing causes of illness as an ideal of treatment. For example, the NAO report- “as a lifestyle issue, the scope for policy to affect such changes in a direct way is very limited. The department of health cannot be expected to cure the problem” (42), perhaps hinting that “the problem” is the lack of self control of the obese individual. On the NHS obesity page it states: “the best way to treat obesity is to reduce the amount of calories in your diet and exercise more” In responding to a request to fund more surgery, the Department of Health suggested that other more important health strategies would have to wait if WLS was funded. The very emotive phrase was used "well do you want to take funding away from a cancer patient?" Interestingly this appears to have filtered down to local press, trusts and medical professionals so that some fear increasing investment in obesity surgery would decrease investment in cancer (44). Ironic in light of the evidence that WLS leads to a decrease in

several cancers (9). Recently, the Department of Health boasted a “new approach” and a “new ambition” in tackling obesity that only continues to focus on prevention and “asking the public to take responsibility for their own lifestyle choices.” (137)

Ignoring their plight and focusing all resources on prevention perpetuates the wide held notion that obesity is entirely preventable and that anyone who has obesity has obviously “failed” at doing the right thing and therefore simply deserves no better (138). What message could be more powerful in cementing the already widespread bias and discrimination against individuals struggling with this condition? Continuing to channel all efforts into prevention and ignoring the plight of the millions who need treatment now only promotes this prejudice and discrimination against people with obesity. Treating obesity requires the same attention and commitment of resources as we devote to other chronic diseases. Obesity bias may influence policy makers’ reluctance to increase access to surgery. Lifestyle choices that promote good health are often constrained by socioeconomic factors those choices that increase risk of disease are influenced by the availability of bad options that are a basic part of the social structure in many western societies (24, 74). All people take risks that may seem avoidable from the perspective of others. Since social policies are often responsible for the social and economic inequalities that produce these health effects, we are forced to look upstream from the point of medical delivery and ask about fairness of the distribution of these goods.

Justice requires coherence of the health care system so that obesity and bariatric surgery are treated similarly to other chronic conditions and treatments; especially those also considered to be a result of lifestyle choices. We must disconnect the question of assigning responsibility from decision about entitlement to treatment or status in

prioritization decisions (77). We need to achieve a goal of treating people's needs however they have arisen, while recognizing, but not exaggerating the role of personal responsibility.

Discussion

The UK is experiencing an epidemic of obesity affecting both adults and children. Against a background of rising prevalence, halting the upward trend of obesity presents a major challenge. Part of the solution lies in preventing people from becoming overweight and obese, as much as helping those who are already obese. England and Scotland have lagged behind other western countries in the number of surgeries performed every year yet they have some of the highest rates of obesity within the European Union (16). Surgery has increased significantly in recent years due to its recognized need and publication of evidenced-based guidelines recommending use of surgery for morbidly obese patients. Despite proven clinical and cost-effectiveness, supply is not meeting the demand and healthcare systems are becoming increasingly overwhelmed by the burdens associated with obesity (2, 42, 43, 45). Practical barriers as well as obesity bias hinder progress toward creating policy that will increase fair and equal access to bariatric surgery.

England and Scotland's practical challenges encompass varied implementation of clinical guidance, a poorly organized referral process, financial constraints placing surgery as a low priority treatment option for obesity, and the need for more trained obesity surgeons. These barriers have resulted in a varied and unequal provision of

surgery across the UK. Eligible patients are being denied access to surgery. Such a distribution of resources deviates from the ethical principles upheld in the NHS constitution and violates the broader principles of distributive justice. Exacerbating the problem is an underlying stigmatization of the obese which often results in bariatric surgery and its public funding being questioned on ethical arguments relating to the “self-inflicted” nature of the disease. As such, treatment proposals tend to focus on obesity prevention and individual behavior in order to address personal responsibility for one’s lifestyle choices. Health is affected both by personal behavior and factors generally beyond immediate individual control. This is especially true in children, who are not in total control of their diet and lifestyle choices.

The public provision of obesity surgery should not be rationed differently from other surgical or medical interventions. Because supply outweighs demand some rationing is inevitable but resources should be prioritized to those most likely to benefit. With that, any rationing done should be done according to the same principles and procedures that are used to ration other cost-effective treatments for serious diseases. Within the NHS, bariatric surgery should be publicly funded. Implementation of national guidelines is the responsibility of each PCT and health board and is an essential part of clinical governance. Mechanisms should be in place to review care provided against the guideline recommendations and the reasons for any differences should be assessed and addressed.

As more medical professionals acknowledge the need for surgery, many have proposed plans for what an ideal adolescent bariatric surgical service should look like. As surgeries in the adolescent population have increased, there is increasing interest in

developing comprehensive adolescent bariatric surgery programs (112). Even with the recognized need for this service, information is lacking in the this age group to guide decision regarding optimal patient selection, choice of procedure, and postoperative management (120, 139) . Physicians are faced with the task of delineating clear, realistic, and restrictive guidelines for using this approach. For adequate obesity treatment service, many recommend a tiered approach to weight loss management (140, 141). The first level of this tiered approach would be primary care and lifestyle interventions. Higher levels of care would be for patients with more severe illness, receiving more intensive treatments, and the final level being bariatric surgery in a specialty service (141). Ideally, adolescents who undergo bariatric surgery should be treated consistently, at regional centers of excellence with ongoing clinical data collection and targeted research (142). They should be referred to centers with multidisciplinary teams in meeting the unique physical and psychological needs of adolescents (143, 144). Additional expertise in pediatrics, endocrinology, GI, cardiology, nutrition, psychiatry, and orthopedics should be readily available. In addition to that, meticulous long term medical supervision is needed as well.

Conclusion

Pediatric obesity is a public health priority that requires a concerted societal response. We must take into account the magnitude of the problem, the fact that children are not fully responsible for their own health choices, and the recognition that obesity reflects a combination of genetic, behavioral, and environmental influences. It is generally agreed that if no action is taken now, the costs of the health problems resulting

from such alarming rates of obesity will not only harm children, but it will also cause significant problems for the NHS down the line. For severely obese adolescents who have failed organized attempts to lose weight and who have serious or life threatening comorbidities, surgery may provide the only practical alternative for achieving healthy weight and for avoiding the physical and psychological effects of morbid obesity.

The causes of obesity are diverse, complex, and underpinned by what are now entrenched societal norms. They are problems for which no one simple solution exists. Obesity cannot be viewed simply as a health issue, nor will it be solved by reliance on individual behavior change. It is important to recognize that obesity is both a medical condition and a lifestyle disorder and both factors have to be seen within a context of the individual, family, and societal functioning (4, 23, 24). By instructing individuals to make changes (eat more veggies, less junk), without changing the environment to make these changes possible, education alone can be considered a form of victim blaming. For a large cohort of adolescents, prevention efforts are too late and treatment is needed. Treatment must be prioritized alongside prevention.

Look forward, the English NHS is currently in the midst of drastic changes to the health care system structure and is set for radical alteration by the 2012/2013 year (145). Commissioning groups, that include GPs, will be tasked with allocating significant amounts of public. SHAs and PCTs will be eliminated. Given the views of unfair and unethical access to obesity surgery, many worry whether the present situation is likely to get worse with the cuts on spending. What is encouraging is that both England and Scotland seem to be addressing issues of surgery provision and are making efforts to tackle some of the barriers. A UK bariatric surgery registry was established whose aim is

to provide a nationwide online record of patient outcomes from which an evidence base can eventually be established. Over 1,000 patient records were entered within the first 12 weeks after launch (12). As far as physician training, there is currently an expanding generation of young surgeons at the resident level who are seeking bariatric surgery training with established UK bariatric surgeons, and this will subsequently lead to an increase in the number of trained surgeons. There is also an increased desire by NHS hospitals to gain international accreditation through medical organizations to ensure a high quality of service is provided to UK patients. Within Scotland, the size of the problem and distribution of surgical experience provide an opportunity to establish a coherent service. Different models of care are already active (99). For example, North of Scotland Planning Group proposed the establishment of a formal bariatric surgery/obesity management subgroup to plan and implement a regional network of obesity management services that would include the surgery (98). The next step would be to see how effective these programs are and whether they can be incorporated into a broader standardized treatment program across the country for the morbidly obese. Increasing awareness to the benefits of surgery to patients, PCTs, health boards, and the media will ensure that bariatric surgery in the UK continues to grow and prosper. More broadly, a successful approach to stopping the obesity epidemic will require multidisciplinary collaboration and investment. Without changes to social policy that impact that the living environment as a whole, there is little likelihood that policy focused on promotion of healthy choices will result in sustainable change and yield benefits to improve the life chances of adolescents in the UK.

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