

# Obesity Value Dossier Brief

Outlining the Burden and Treatment Options for Obesity and the Clinical and Economic Benefits of Bariatric Surgery Worldwide

## Statement of purpose

The purpose of this report is to address the challenges faced by society worldwide as a result of the rising obesity pandemic; to analyse the current prevention methods and potential treatments for this debilitating disease; and to call for international collaboration to alleviate the devastating impact of obesity and its associated comorbidities on both patient lives and healthcare budgets

*Johnson & Johnson*

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## Introduction

The alarming rise in the worldwide incidence of obesity has resulted in almost 30% of the world's population being considered overweight or obese,<sup>1</sup> placing an unsustainable burden on patients and healthcare systems.<sup>2</sup> Obesity has a devastating impact on the individual, drastically increasing the risk of developing additional diseases, including type 2 diabetes and leading to a significantly reduced life expectancy.<sup>3,4</sup>

Obesity in children is also rising far too rapidly and there is an undeniable trend that obese children typically grow up to become obese adults.<sup>5</sup> Accordingly, effective prevention of obesity is critical for the next generation. However, in the past 33 years no national success stories have been reported.<sup>1</sup> In this dossier, we overview the scale of the obesity problem, the role of prevention and treatment, and the need for collaborative action between policy makers and the healthcare sector.

While dietary and lifestyle changes have not been able to demonstrate any lasting effects on patient weight,<sup>6,8</sup> bariatric surgery, has consistently been shown to lead to more pronounced and lasting weight loss compared with conventional, non-surgical treatments.<sup>7,9</sup> The benefits of bariatric surgery also extend to resolving the many comorbidities of obesity, such as type 2 diabetes.<sup>7,9</sup> Unsurprisingly then, bariatric surgery has been shown to be cost-effective and even cost-saving in a number of developed countries.<sup>10-13</sup>

Many of the patients that are eligible for bariatric surgery are unaware of, or do not have access to, this effective treatment.<sup>14</sup> Here we highlight the various legislative and social barriers to bariatric surgery and provide our recommendations for solving this global health emergency. The consequences of inaction, whether drastically growing levels of morbidity and mortality, or the increasing, unsustainable strain on national healthcare systems,<sup>3</sup> are too severe to ignore and we must build a collaborative framework in order to ease the immense individual and societal burden of obesity.

### Summary

Obesity and its associated diseases have become a global health emergency of pandemic proportions, placing an unsustainable burden on patients and healthcare systems.

Current methods of prevention and treatment are vastly inadequate to cope with the looming threat of obesity.

Bariatric surgery provides a highly effective treatment option for suitable patients, with positive effects on patient health and economic factors, however awareness and access needs to be substantially improved.

# Section 1:

## Obesity, the Growing Burden of Getting Bigger

### The Scale of the Problem

Obesity, recently branded as “the new smoking”,<sup>15</sup> is one of the greatest challenges facing public health of our time. The implications for public health services are huge, not only because of obesity per se but because obesity increases the risk for an array of obesity-related comorbidities, including type 2 diabetes, cardiovascular disease and cancer.<sup>16</sup> Currently, almost 30% of the world’s population are overweight or obese. In terms of obesity alone, it is estimated that over 500 million adults worldwide are obese,<sup>17</sup> including 20% of men and 23% of women in Europe.<sup>18</sup> Moreover, this prevalence is rising with rates having doubled or tripled in many countries since 1980.<sup>19</sup> In 19 of 34 OECD countries, the majority of the population are now overweight or obese.<sup>19</sup> Worryingly, a recent survey of policy makers found that many are uninformed of the extent of this serious issue, with 66% and 84% unaware of their country’s obesity and overweight rates, respectively.<sup>20</sup>

Traditionally, obesity is measured with reference to a patient’s body mass index (BMI) which is calculated by dividing a patient’s weight by the square of their height (given in the units kg/m<sup>2</sup>). Depending on the patient’s BMI value, their level of obesity is categorised into different classes (Table 1).

Classification	BMI ( kg/m <sup>2</sup> ) Principal Cut-off Points
Underweight	< 18.5
Normal range	18.5–24.9
Overweight	25.0–29.9
Obese	≥ 30.0
Obese Classe I (Mild)	30.0–34.9
Obese Classe II (Moderate)	35.0–39.9
Obese Classe III (Morbid)	≥40.0

**Table 1:** The international classification of adult underweight, overweight and obesity according to BMI.<sup>21</sup>

Class III (morbid) obesity is the most severe level of obesity and is associated with the highest risk of comorbidity development and mortality.<sup>22</sup> Obesity cannot be viewed solely in isolation, as excess weight is thought to be a contributory factor in 75% of type 2 diabetes cases, 50% of hypertensive disease incidence and 33% of ischaemic heart and stroke disease cases.<sup>3</sup> Adults aged 35 to 59 years with a BMI of 40–50 kg/m<sup>2</sup> are 5 times more likely to die from ischaemic heart disease, 6.5 times more likely to die from stroke and 22.5 times more likely to die from type 2 diabetes than those with a BMI of 22.5–25 kg/m<sup>2</sup>.<sup>22</sup> Overall, morbidly obese patients have a drastically reduced life expectancy (9 years for women and 12 years for men).<sup>4</sup> Moreover, the risk of mortality is associated with the duration of disease,<sup>23</sup> suggesting that those who fail to lose excess weight continue to increase

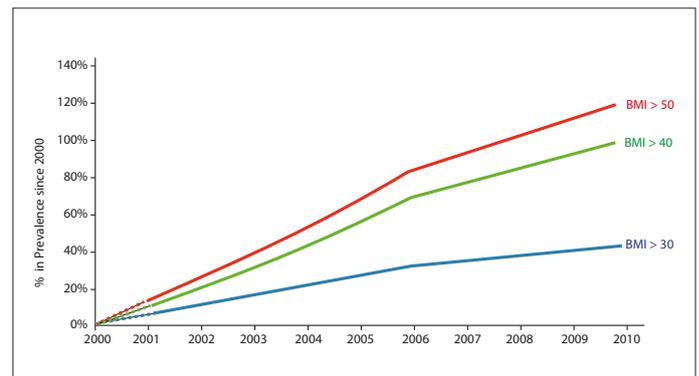
their risk for premature mortality.

The devastating personal impact of obesity is also increasing, as evidenced by a doubling in the number of quality-adjusted life years lost due to obesity in the USA from 1993 to 2008.<sup>24</sup> The psychosocial status of patients is also concerning, with anxiety disorders diagnosed in 48% and personality disorders diagnosed in up to 72% of obese individuals.<sup>25</sup> Obesity’s burden is also observed in employment and productivity, as obese individuals take more days off work due to illness, claim more in disability benefits and tend to be less productive than individuals of normal weight.<sup>19</sup> Overall, it is clear that obesity negatively impacts the overall quality, productivity and longevity of an individual’s life.

### The Budgetary Burden

Globally, obesity costs are estimated to account for between 0.7% and 2.8% of a country’s total healthcare expenditure.<sup>26</sup> When costs associated with being overweight are included, the upper limit of this range increases to 9.1%.<sup>26</sup> In Europe, obesity and overweight account for 2.8% of total hospital costs, 1.9–4.7% of total healthcare costs and 0.47–0.61% of gross domestic product.<sup>27</sup> In Germany, the current annual cost of obesity is estimated to exceed €20 billion,<sup>28</sup> and in the UK, the annual cost of obesity was estimated to be £15.8 billion in 2007.<sup>29</sup> Projecting towards the future, the costs for treating obesity in the UK are projected to reach £49.9 billion by 2050.<sup>29</sup>

Medical expenditure is related to the severity of obesity, with costs increasing with each BMI point.<sup>30</sup> This is particularly concerning considering that, since 2000, the sharpest rise in obesity rates have been recorded in the highest BMI groups<sup>31</sup> (Figure 1).



**Figure 1:** There has been a notable increase in the prevalence of obesity since 2000, with the greatest increases in the highest BMI groups.<sup>31</sup>

Per capita healthcare costs for class III obese patients in the USA are 47% higher than class I obese patients, 65% higher than overweight patients and 81% higher than the general non-obese population.<sup>30</sup> With regard to comorbidities, the medical expenditure of a patient with type 2 diabetes is 2 to 4 times greater than for a patient without diabetes.<sup>32</sup> In the UK, spending on type 2 diabetes alone for the year 2010/11 was £8.8 billion in direct

costs (costs attributable to healthcare) and £13.0 billion in indirect costs (which factor in lost work productivity and informal care), representing 10% of annual health resource spending.<sup>33</sup> By the year 2036, direct costs and indirect costs for type 2 diabetes are estimated to rise to £16.9 and £15.1 billion respectively, accounting for 17% of annual health resource spending.<sup>33</sup> On an international scale, the total spending on the treatment for the direct costs of type 2 diabetes across France, Germany, Italy, Spain, and the UK was estimated at €90 billion in 2010.<sup>34</sup> Looking to the future, total worldwide costs for diabetes are projected to reach 678 billion international dollars by 2035.<sup>35</sup> These staggering figures highlight the fact that the current obesity pandemic is both a clinical and financial emergency.

Conventional treatments for obesity, such as lifestyle interventions relating to diet and exercise and pharmacotherapy, have been shown to lead to minimal weight reduction.<sup>6, 7, 36-41</sup> In addition, only 20% of obese patients on dietary treatment maintain a weight loss of  $\geq 10\%$  after three years.<sup>6</sup> Consequently, obese patients that fail conventional therapy may be treated with bariatric surgery, which provides greater weight loss in comparison.<sup>9, 42-57</sup> Despite this, bariatric surgery is currently only considered a last resort treatment option.<sup>58</sup> As demonstrated within this report, bariatric surgery is a clinically proven, cost-effective intervention that tackles both the patient's weight and their comorbid burden, thus dramatically improving overall health, wellbeing and quality of life in patients that have failed conventional treatment.

## Section 2:

# Tackling the Epidemic – Prevention for the Next Generation

### Current Prevention Efforts

A substantial part of the future burden of obesity is derived from the fact that current rates of childhood obesity are also rising far too rapidly and there is an undeniable trend that obese children typically grow up to become obese adults.<sup>5</sup> If no action is taken, 90% of today's children could be overweight or obese by 2050.<sup>59</sup> Accordingly, effective prevention of obesity is critical for the next generation.

However, prevention is also highly important for the current generation as a large segment of today's population will continue to gain weight excessively if we do not act now, thus further exacerbating the burden (Figure 1). Indeed, prevention strategies focu-

sing on management of weight gain and weight loss for all ages are emerging at the local and national level across Europe.<sup>60</sup> For example, in Germany, the In Form initiative aims to encourage healthy eating and physical activity nationwide.<sup>61</sup> The Ensemble Prévenons l'Obésité Des Enfants (EPODE) initiative, which started in France and focusses on the prevention of childhood obesity now has programs in several European countries, including Belgium, Greece and Spain.<sup>62</sup> Finally, in the UK, healthy living campaigns such as Change4Life<sup>63</sup> and 5-A-Day<sup>64</sup> promote balanced healthy diets and active lifestyles to maintain a healthy weight in order to reduce obesity and the risk of its related metabolic diseases.

However, campaigns such as these have been deemed only 'partially successful', particularly due to their poor penetrance to the social demographics most at risk of obesity.<sup>65</sup> National governments have recently begun to take more drastic measures, with the Danish government initiating (and subsequently scrapping) a tax on saturated fat,<sup>66</sup> and the UK government recently signing a deal with food manufacturers to limit to the amount of saturated fat in food.<sup>67</sup> Despite these efforts, in the light of ever-increasing rates of obesity, diabetes and cardiovascular disease, no national success stories have been reported in the last 33 years.<sup>1</sup> Thus, it is clear that current efforts at the individual, medical and governmental level are failing to control the delicate balance of weight gain and weight loss in our Westernising world.

### The Need for Further Action

Current estimates for the future burden of obesity paint a dire picture. For example, 60% of men and 50% of women in the UK are predicted to be obese by 2050,<sup>29</sup> with claims that these shocking figures are underestimates of the true scale of the problem.<sup>68</sup> Consequently, immediate action is required in order to prevent the burden from growing even further. While prevention efforts that focus on promoting healthy lifestyles remain a necessary tool for the next generation, in the short-term, society's inability to halt and reverse the rise in obesity will further exacerbate the strain on national healthcare systems, potentially leading to bankruptcy.<sup>2</sup> Thus, in addition to producing more extensive and impactful prevention strategies, effective treatment of current obesity sufferers to reduce the collective burden of the disease is of utmost importance. Through collaboration on a transnational scale, the parallel implementation of preventative measures for the future and treatment for the present can give us the impetus desperately needed to finally halt the growing obesity pandemic.

## Section 3:

### Taking Action on Obesity

#### The Need for Coordinated Action

There is a desperate need for coordinated action by policy makers and the healthcare sector in order to tackle the obesity emergency. Through better treatment, education and prevention, the staggering rise in disease incidence can be halted and national healthcare systems can be relieved of the immense burden that they already bear.

#### Johnson & Johnson is Committed to Tackling Obesity

Johnson & Johnson (J&J) is the world's largest and most diverse medical devices and diagnostics company, and the world's sixth largest consumer health company, biologics company and pharmaceuticals company.<sup>69</sup> As part of its credo, J&J prioritises ethical actions and scientific advancement<sup>70</sup> and is committed to tackling the global issue of obesity and access to its treatment. As part of this commitment, J&J is involved in a number of programs encouraging healthy eating and exercise. As part of its Gateway to a Healthy Community™ Healthier Kids initiative,<sup>71</sup> J&J is involved in encouraging physical activity amongst school children in high risk communities in four US-cities.<sup>72</sup> In addition, J&J also provides grants to outstanding community-based nonprofit organisations, such as La Vida Buena to provide health and nutrition education to underserved populations.<sup>73</sup>

#### Johnson & Johnson Supports Meaningful Studies into Obesity

J&J is also involved in studies focusing on the scientific advancement of obesity treatments. Ethicon Endo-Surgery, a J&J subsidiary, sponsors the Metabolic Applied Research Strategy (MARS) initiative, a collaborative research programme focused on understanding the physiologic and metabolic changes following bariatric surgery, aiming to further explore the mechanisms that make this proven treatment so effective.<sup>49</sup> Ethicon is also the primary supporter of the STAMPEDE trial which compares diabetes outcomes between bariatric surgery and conventional medical therapy.<sup>44</sup> In light of the study findings and a large body of additional evidence supporting the use of bariatric surgery for obesity and diabetes (discussed below),<sup>9, 42-57</sup> J&J is committed to reducing barriers that prevent patients from accessing this effective treatment. Furthermore, J&J aims to continue to provide evidence to healthcare professionals and change physician perception and acceptance of bariatric surgery in order to address the currently unmet treatment need for a means to tackle the global burden of obesity.

## Section 4:

### An Effective Solution Exists

#### The Obesity Treatment Landscape

Alongside prevention methods focusing on the next generation, there is a desperate need for effective treatment options for those patients who already bear an unacceptably high burden. The singular failure of conventional therapy, which includes lifestyle interventions such as dietary modification, exercise and pharmacotherapy,<sup>36, 37, 39-41</sup> only increases this urgency. Bariatric surgery is the most promising treatment currently available for tackling the obesity epidemic, having consistently been shown to lead to more pronounced and lasting weight loss in addition to conferring a number of other health and social benefits compared with conventional, non-surgical treatments.

#### The Mechanisms of Bariatric Surgery

The regulation of weight is controlled by a delicate hormone balance and whilst some hormones indicate satiety, others signal the physiological need to eat and it is this balance that has been found to be unregulated in obese persons.<sup>74</sup> This ultimately means that weight loss following an initial gain in weight is extremely difficult to achieve simply by changing the way we eat.

Bariatric surgery was originally developed as a surgical intervention designed to restrict food intake or cause the malabsorption of ingested calories, which was thought to work via a predominantly mechanical mechanism to allow the patient to lose weight. However, it quickly became apparent that the effects of bariatric procedures were not exclusively limited to weight loss; it was noted as far back as 1995 that obese patients with type 2 diabetes experienced significant improvements in fasting blood sugar levels, an indicator of diabetes, from within a single day after bariatric surgery, well before any weight loss.<sup>52</sup> Although the exact mechanisms by which bariatric surgery works are yet to be elucidated, gut signalling is thought to be altered leading to a change in the production of gut hormones that have effects ranging from altering our perception of hunger/satiety (eg. controlling food intake), to changing the levels of insulin production (eg. regulating control of blood glucose).<sup>49</sup> Regardless of the exact mechanisms, the beneficial effects bariatric surgery confers to the patient with regard to both weight loss and comorbidity resolution are undeniable.

#### The Unrivalled Clinical Effectiveness of Bariatric Surgery

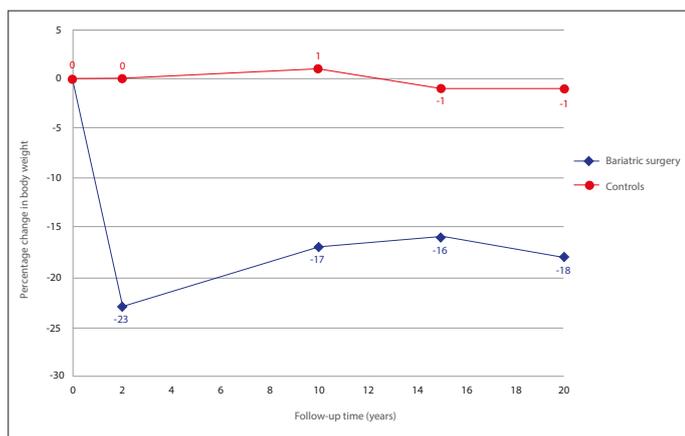
"[Bariatric surgery is] the most effective treatment for morbid obesity in terms of long-term weight loss, improves comorbidities and quality of life, and in the long term decreases overall mortality" (The European Association for the Study of Obesity, 2008)<sup>75</sup>

The need for an effective treatment option for obesity is crucial given its high burden of disease and far-reaching consequences; bariatric surgery shows a great potential to fulfil this need. The clinical benefits associated with bariatric surgery are significant, with increased weight loss, high resolution of comorbid condi-

tions, decreased mortality and improved overall quality of life well- documented within the literature. A recent systematic review and meta-analysis found that 94% of included studies demonstrated a statistically significant advantage favouring surgery over conventional therapy including in weight loss, diabetes remission and clinical biomarker reductions.<sup>53</sup> These results are further validated by a recent Cochrane review in which surgical procedures were found to be associated with greater improvements in weight loss outcomes and reductions in comorbidities such as diabetes, metabolic syndrome and sleep apnoea compared to non-surgical interventions.<sup>9</sup>

### Improved Weight Loss Outcomes

One very long-term study, the Swedish Obese Subjects (SOS) study, which follows over 4,000 obese participants, has reported a sustained weight loss of approximately 20% associated with bariatric surgery compared to matched controls with conventional care at approximately 0% (Figure 2).<sup>54</sup> A recent systematic review and meta-analysis found that bariatric surgery was associated with a significantly reduced BMI and a sustained mean excess weight loss of 69.4% at 10+ years.<sup>45</sup> Furthermore, effective weight control has been reported in wider patient populations; bariatric surgery was found to be associated with a significantly greater weight loss, in addition to improved glycaemic control, compared to controls in a number of studies of non-morbidly obese patients with diabetes.<sup>50</sup>



**Figure 2:** Mean percentage weight change from baseline amongst patients in the control and bariatric surgery groups during 20 years of follow up.<sup>54</sup>

### Reduced Mortality Risk

Obesity has a number of severe consequences, the most serious being the risk of premature death, which is significantly increased. In morbidly obese patients, life expectancy is drastically reduced by 9 years for women and 12 years for men.<sup>4</sup> The risk of mortality is associated with the duration of disease,<sup>23</sup> suggesting that those that fail to benefit from conventional therapy continue to increase their risk for mortality until an effective treatment

strategy is initiated. Bariatric surgery has been shown to significantly lower the long-term mortality compared to controls<sup>55</sup> and to decrease the relative risk of death by 89%<sup>46</sup> while carrying a similar mortality rate as other surgeries (including hip replacement), with a short-term mortality rate of 0.48% and a long-term mortality rate of 0.35%.<sup>76</sup> This low mortality rate is also much lower than the risk of death in cardiac surgery (3.1%)<sup>77</sup> which, due to the many associated cardiovascular health issues with increased weight, may be a consequence of obesity left being untreated.

### Comorbidity Resolution

In addition to significantly improved weight loss outcomes, bariatric surgery has also been shown to have beneficial effects on a number of obesity-related metabolic diseases:

### Type 2 Diabetes Remission

Studies have found that 75–95% of patients achieved diabetes remission within 2 years of bariatric surgery, in stark contrast to conventional medical therapy alone, with which no patients achieved remission.<sup>51, 57</sup> This finding is validated by a recent meta-analysis, which found that bariatric surgery patients were approximately 10–16 times more likely to achieve diabetes remission than those receiving conventional medical therapy over an average follow-up period of approximately 1.5 years.<sup>53</sup> These high rates of diabetes remission have been shown to be sustained at 5 years<sup>42</sup> and data suggest that earlier surgical intervention leads to more durable diabetes remission.<sup>78</sup> Moreover, bariatric surgery has been shown to have a preventative effect on the development of diabetes, reducing the risk by approximately 80%.<sup>79</sup> In addition, bariatric surgery has been shown to improve levels of clinical markers of diabetes, such as overall glycaemic control,<sup>48, 80</sup> significantly reduced haemoglobin A1c,<sup>44, 53</sup> and decreased fasting plasma glucose levels within 6 months.<sup>47</sup> Currently, the diabetes burden is staggeringly high and expected to continue rising with 592 million type 2 diabetes sufferers predicted by 2035.<sup>35</sup> It is therefore imperative that an effective treatment is available to achieve control and remission of the disease.

### Improved Cardiovascular Outcomes

Cardiovascular disease is the number one cause of death globally and represents 30% of worldwide deaths,<sup>81</sup> clearly indicating the need for control of this deadly threat. In the SOS study, incidence of both cardiovascular deaths and events was significantly reduced following bariatric surgery compared with conventional therapy, and sustained in the long-term to approximately 15- years follow-up.<sup>56</sup> Furthermore, a retrospective cohort study of almost 16,000 obese subjects from 1996 to 2009 found that bariatric surgery was associated with a 65% reduction in major macrovascular and microvascular events in moderately and severely obese patients with type 2 diabetes.<sup>82</sup>

### **Beneficial Effects on Other Clinical Comorbidities**

The far-reaching effects of bariatric surgery have also been documented to have a benefit on further comorbidities such as cancer, non-alcoholic fatty liver disease (NAFLD) and obstructive sleep apnoea (OSA). Patients who underwent bariatric surgery were found to have had significantly fewer physician/hospital visits for all cancer diagnoses at 2.0%, compared with controls at 8.45%.<sup>43</sup> Bariatric surgery has additionally been shown to confer a favourable impact on the progression of NAFLD<sup>83, 84</sup> and to be a broadly effective therapy for reducing the symptoms of OSA compared with intensive lifestyle changes.<sup>85, 86</sup> The extensive benefits associated with bariatric surgery are clear, having been shown to not only achieve clinically beneficial weight loss, but also to act on a variety of the far-reaching consequences of obesity.

### **Improved Quality of Life and Self-Esteem**

Patients report much higher levels of self-esteem following bariatric surgery, with approximately 50% of patients with reduced self-esteem cured and further 40% improved at a 4-year follow up.<sup>87</sup> Levels of depression, the impact of weight on day-to-day living and overall quality of life is also significantly improved following bariatric surgery compared with non-surgical alternatives.<sup>88, 89</sup> The effectiveness of bariatric surgery on all aspects of a patient's life may help them overcome the psychological issues that are so often intertwined with obesity,<sup>90-92</sup> and empower them in all aspects of their life.

### **Surgery**

Given its power to improve weight loss, comorbidity resolution and psychosocial outcomes for the individual, bariatric surgery has the potential to empower governments by curtailing the rising healthcare costs of obesity. There is growing evidence that bariatric surgery is a cost-effective and, in some cases, cost-reducing intervention for patients suffering with obesity and its associated metabolic diseases. Although linked with higher upfront costs compared to conventional treatment, bariatric surgery leads to a greater improvement in both physical and mental health, reducing the number of hospital visits, medications and productivity lost to illness. It would therefore be highly shortsighted to ignore this effective obesity treatment option in light of the enormous growing economic burden of obesity.

It has been shown that downstream savings associated with bariatric surgery may begin to accrue from just 12–25 months following surgery.<sup>93, 94</sup> Another recent study has found that bariatric surgery may save €13,244 per patient lifetime,<sup>95</sup> and a cost-utility analysis in Spain similarly found savings of €13,994 with bariatric surgery, treatment with which was almost the half the cost compared with no intervention over a lifetime.<sup>96</sup> In a Scottish study, annual savings following bariatric surgery in 88 patients were achieved across several hospital departments: £11,452 was saved on medications, £16,420 on hospital admissions and £2,532 on outpatient clinic visits, leading to a total annual saving of £30,404 per annum.<sup>97</sup>

Furthermore, two studies carried out over a 5-year timeline reported a higher effectiveness and lower costs associated with bariatric surgery in diabetic patients compared with conventional treatment in four key European countries.<sup>10, 11</sup> It has further been shown that bariatric surgery is cost-effective throughout the obesity spectrum, remaining cost-effective from mildly obese patients without any comorbidities, and becoming cost-saving in morbidly obese patients suffering from a range of related metabolic diseases.<sup>98</sup>

Bariatric surgery has been demonstrated to be highly cost-effective in the resolution of type 2 diabetes in the vast majority of patients and may lead to a reduction in medication intake and further associated costs. Pharmaceutical use has been found to be drastically reduced following bariatric surgery, with average monthly savings of \$182.10 per patient on medicine intake for a range of metabolic diseases including type 2 diabetes, hypertension and sleep apnoea.<sup>99</sup> Costs for anti-diabetic agents, antihypertensive agents and dyslipidemic agents remained lower 6 years following surgery.<sup>100</sup> It is also important to consider the saving of costs associated with treating events of long-term complications (eg. treatment of heart attack, stroke, kidney disease, blindness, amputation or kidney dialysis).<sup>33</sup>

Patients undergoing bariatric surgery experience a number of meaningful changes in all aspects of their life, from improved self-esteem to increased mobility, conferring a greater ability to return work and contribute to the economy.<sup>101, 102</sup> One study found that bariatric surgery was associated with a 32% increase of patients in paid work, with an increase in the number of weekly hours worked and an associated decrease in state benefits claimed.<sup>102</sup> It is, therefore, clear that bariatric surgery has a multitude of economic effects ranging from savings at the governmental and hospital level, to the ability for a patient to remain financially self-sufficient and regain control in their health.

### **Increasing Inclusivity of International Guidelines**

In recent years, guidelines for the indication of bariatric surgery have opened up to become more inclusive in light of the overwhelming clinical<sup>9, 42-57, 80</sup> and economic<sup>10-12, 93-95, 97-100, 102, 103</sup> evidence in its favour and the failure of conventional treatment to have a substantial and sustained effect. Bariatric surgery is typically recommended for those with class II obesity provided they suffer from associated metabolic diseases such as diabetes or high blood pressure, and for patients with a class III obesity in whom all appropriate non-surgical measures have been unsuccessful.<sup>104</sup>

International guidelines have recently been updated to extend the recommendation of bariatric surgery as a treatment option to patients with class I obesity and uncontrolled diabetes,<sup>35</sup> reflecting the growing evidence supporting the use of bariatric surgery in a wider populations. However, while this is a welcome development, there are still a number of challenges patients encounter that limit their access to this effective treatment, as discussed in detail below.

## Section 5:

# Barriers to Effective Obesity Solutions

**“[I]n the countries with the highest bariatric surgery uptake less than 2% of eligible patients are treated annually”  
(International Diabetes Federation, 2011)<sup>14</sup>**

Bariatric surgery has consistently been shown to be a clinically<sup>9, 42-57, 80</sup> and financially<sup>10-12, 93-95, 97-100, 102, 103</sup> superior treatment option when compared with conventional therapies such as diet, exercise and pharmacotherapy. In spite of this evidence, the number of eligible patients undergoing bariatric surgery is low.<sup>14, 58</sup> There are several reasons for this, including restrictive national guidelines that are slow to adapt to international recommendations,<sup>105</sup> a lack of implementation of existing guidelines<sup>58, 106</sup> and also the societal stigma that is associated with both obesity itself and the use of surgery as a treatment option for obesity.<sup>107, 108</sup> Accordingly, there is a vital need for collaboration between policy makers and the healthcare sector to ensure that patients and doctors alike are informed and have access to a treatment that is capable of relieving us of the immense burden of obesity.

### Restrictive National Guidelines

Key elements of the current international recommendations state that bariatric surgery is indicated for patients with either class III obesity alone or class II obesity with comorbidities that would also benefit from surgical intervention.<sup>104, 109</sup> As mentioned previously, these recommendations for bariatric surgery have recently become more inclusive for patients with class I obesity and type 2 diabetes.<sup>104, 109</sup> However, this is yet to be fully implemented across Europe at the national guideline level<sup>105, 110</sup> and thus a large proportion of obese people are still restricted to less effective non-surgical interventions.<sup>36, 37, 39-41</sup> For example, in Switzerland, patients with a BMI of 35 are all eligible for bariatric surgery, however, patients with a BMI between 30-35 and type 2 diabetes are not included,<sup>110</sup> whereas in Denmark, patients without any comorbidities are only eligible for bariatric surgery with a BMI of over 50.<sup>20</sup> In a number of European countries including France, Spain, Italy and Scotland, bariatric surgery is only recommended for patients with a BMI above 40, or with a BMI above 35 and one or more severe comorbidities (including diabetes).<sup>20, 105, 111</sup> Prior to July 2014, this was also the case in England and Wales.<sup>112</sup> However, these guidelines are being reviewed to potentially include patients with a BMI between 30 and 35 and type 2 diabetes, in line with the international recommendations.<sup>112</sup> This would be a welcome change and may help reverse the worrying reports of patients deliberately exacerbating their obesity in order to get access to this potentially life-saving treatment.<sup>113</sup>

While the potential inclusion of class I obese patients with type 2 diabetes within national indications for bariatric surgery is a step in the right direction, access to this effective treatment should not be denied to any class I obese patient associated with a significant comorbidity simply on the basis of their BMI. This is due to the fact that the BMI scale is considered to be a poor health risk predictor.<sup>114</sup> Crucially, the use of BMI does not take into account where the fat is distributed in the body (eg. fat that is

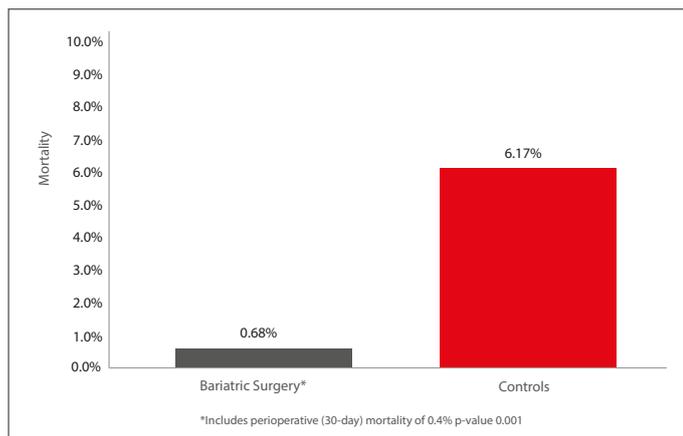
located in the legs vs fat that surrounds the liver) which is a more accurate indicator of poor health than simple putting weight and height into a formula.<sup>114, 115</sup> Accordingly, bariatric surgery should be considered in all class I obese patients, provided they have a clinically and individually assessed high comorbid burden and/or they have been unable to achieve sufficient weight loss after a reasonable period of non-surgical therapy.<sup>114</sup>

### Inconsistencies in Guideline Implementation

Even in the event that a patient is deemed eligible according to the existing guidelines, there appears to be a large degree of inconsistency in their application. For example, even in the countries with the highest treatment uptake, only 2% of eligible patients undergo bariatric surgery.<sup>14</sup> In the UK, the degree of implementation of the current guidelines varies considerably, as does the attainment of the conservative benchmark rate for a bariatric surgical service of 0.01% operations per capita (25 cases/year for an average primary care trust of 250,000 patients).<sup>116</sup> This is highlighted by the finding that, for primary care trusts in England, the rate of bariatric procedures in hospitals per 100,000 ranged from 0.4 to 41.3 (93-fold variation).<sup>106</sup> Under existing England and Wales guidelines, 1 million people are currently eligible for bariatric surgery, however, only approximately 9,000 people undergo bariatric surgery every year.<sup>58</sup> Increasing this number, even marginally, can improve our ability to tackle obesity's immense global burden by giving more patients access to a treatment that is both clinically sound<sup>9, 42-57, 80</sup> and financially viable.<sup>10-12, 93-95, 97-100, 102, 103</sup>

One reason for the lack of eligible patients' progression to bariatric surgery appears to be the need to pay for surgical treatment up front.<sup>58</sup> This is in contrast to medical therapies which are comparably less expensive up front, thereby offsetting costs. Ultimately though, the cost per year of an obese patient (often getting more obese) remains significantly higher for medical therapy than for surgery, which has even been shown to be cost saving within 12-25 months.<sup>93, 94</sup> Furthermore, when calculated on a wider scale, carrying out the treatment on a mere 25% of patients who are already eligible is estimated to produce a net gain of over £1 billion to the English and Welsh economy within 3 years.<sup>113</sup> Non evidence-based cost-citing is also a factor in Germany where reimbursement from insurance companies is handled on a case-by-case basis<sup>117</sup> and there is a general reluctance on behalf of insurance companies to fund bariatric surgery other than as a last resort.<sup>117, 118</sup> The principally cited reasons for this reluctance are cost and the perceived dangers associated with the surgical procedures. However, as mentioned above, bariatric surgery is considered to be both cost-effective and cost-saving within a short amount of time<sup>93, 94</sup> and, therefore, citing costs as a reason for not implementing evidence-based guidelines<sup>104, 109</sup>

is not clinically or financially justified. Furthermore, while there are risks associated with any surgical intervention, the incorporation of the large body of evidence supporting the clinical effectiveness of bariatric surgery into international recommendations demonstrates that the risks associated with this treatment are vastly outweighed by its benefits (Figure 3).



**Figure 3:** Bariatric surgery leads to a reduction in mortality rates over a 5 year period, which translates to a decrease in the relative risk of death by 89%.<sup>46</sup>

### Stigmatisation of Patients

Another key barrier for the acceptance of bariatric surgery is the social stigma attached to obesity. In addition to being a barrier to patients in and of itself, the delayed acceptance of the international guidelines and subsequent implementation of national guidance on a local level are also potential consequences of the stigma that surrounds this disease.

Patients who are considering surgery or have already undergone surgery are subject to considerable outside perceptions from their peers including that they are “lazy” and “sloppy”.<sup>108</sup> This stigmatisation does not only occur on a social level but also occurs at the policy maker level, who may see obesity as “gluttony”.<sup>107</sup> In a policy maker survey of 11 countries (7 in Europe), 79% of policy makers believed that individuals were ‘very’ responsible for reducing obesity levels, and only 37% placed this level of responsibility onto either society or the government.<sup>20</sup> Furthermore it is clear that many family doctors do not view obesity as a disease that needs treatment and monitoring, as highlighted by the missing data in a study of over 4,000 obese patients; 27% of obese controls had missing values for blood pressure and 68% had missing cholesterol data, compared to 1% and 26%, respectively, of bariatric surgery patients.<sup>119</sup>

Accordingly, delays in the uptake of guidelines as well as implementation of these guidelines can, in part, be attributed to the fact that some highly-educated decision makers perceive obese patients as people who are unable or unwilling to help themselves.<sup>107</sup> This ignores the fact that hormonal dysregulation is a key feature of a disease that extends beyond simply overeating.<sup>74</sup> It

is imperative that the stigmatisation of obese patients is brought to an end, particularly in light of the overwhelming evidence for the effectiveness of bariatric surgery<sup>9, 42-57, 80</sup> coupled with the lack of effectiveness of conventional treatment.<sup>36, 37, 39-41</sup> This is especially true at the policy maker level where it is simply not feasible to allow personal prejudices to interfere with the adoption and implementation of guidelines that are both cost-saving and clinically effective.

### Variations in Patient Care

Currently, patient pathways for bariatric surgery vary centre-by-centre, with each employing a different set of criteria, treatment options and post-surgery care. There is a vital need to have a universally recommended patient pathway for bariatric surgery, suitable for use in most care settings. This will allow patients and healthcare professionals to make clear and informed decisions that ensure access to optimal treatment. Surgeons specialising in this surgical area are also likely to become better practiced, as indicated by the mortality rate decreasing to just 0.13% when performed at a Bariatric Surgery Centre of Excellence.<sup>120</sup> Consequently, as the risks associated with surgery fall with time and greater surgical expertise is acquired, the evidence in favour of bariatric surgery as the most effective treatment for obesity will grow even further. Finally, clinical endocrinologists should have a central role in the perioperative decision-making for patients undergoing bariatric surgery.<sup>121</sup> This is due to the fact that clinical endocrinologists will already be treating obese patients as part of their comorbidity treatment regime for type 2 diabetes. Thus, by facilitating collaboration during the perioperative decision-making, we can ensure that the root cause of the patient’s problems (excess weight) is attacked and managed in such a way that the key obesity-related comorbidities can be treated simultaneously.

# Conclusion

The pandemic of obesity is of increasing concern, with the prevalence of both obesity and its associated comorbidities increasing at an alarming rate worldwide. The disease's burden on individual patients, healthcare systems and resources is clearly apparent. In addition to implementing prevention strategies for the next generation, current treatment must be improved in order to immediately tackle the ever-growing burden. Bariatric surgery for both obesity and its comorbidities such as type 2 diabetes has been consistently demonstrated to be a superior treatment option for obese patients in comparison to currently available, conventional treatments.

Clinical benefits compared with conventional treatment include a greater weight loss and a reduction in mortality rates, as well as improved glycaemic control and remission in patients with type 2 diabetes. It has further been shown to be a cost-effective and in some cases even cost-saving option, associated with long-term savings on medication and healthcare resource use, both for treating the weight-loss itself, and also for treating related diseases.

Bariatric surgery therefore represents a highly effective and economically viable option for the treatment of obesity and its comorbidities. However, several barriers to treatment –restrictive national guidelines which lag behind international recommenda-

tions, incomplete implementation of existing guidelines, and stigmatisation of obese patients – prevent patients from accessing bariatric surgery despite its proven effectiveness. Accordingly, it is imperative that bariatric surgery is given the recognition it deserves and that existing barriers are brought down to ensure that eligible patients are given access to this effective treatment in order to ease their individual and the collective burden.

## Key Points

1. Collaborative action must be taken in order to tackle the rising pandemic of obesity.
2. Prevention is critical for the next generation and should be coordinated with the use of existing, effective, treatment options to immediately ease the current burden of obesity.
3. By developing a clear and consistent patient pathway for proven obesity treatments, we can ensure an effective approach towards reducing the heavy weight of this disease on individuals and nations alike.

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