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Identifying Barriers to **Appropriate Utilization of** Metabolic/Bariatric for the Treatment of Type 2 Diabetes: Results from a Policy Lab

RUNNING TITLE: Identifying Barriers to Appropriate Use of Metabolic/Bariatric Surgery

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ABSTRACT

Despite increasing recognition of the efficacy, safety and cost-effectiveness of bariatric/metabolic surgery in the treatment of *type 2 diabetes*, few patients who may be appropriate candidates and may benefit from this type of surgery avail themselves of this treatment option. To identify conceptual and practical barriers to appropriate use of surgical procedures, a Policy Lab was hosted at the 3rd World Congress on Interventional Therapies for *type 2 diabetes* on September 29, 2015. Twenty-six stakeholders participated in the Policy Lab, including academics, clinicians, policymakers, industry leaders and patient representatives. Participants were provided with a summary of available evidence about the cost-effectiveness of bariatric/metabolic surgery and the costs of increasing utilization of bariatric/metabolic surgery, using U.K. and U.S. scenarios as examples of distinct healthcare systems. There was widespread agreement among this group of stakeholders that bariatric/metabolic surgery is a legitimate and cost-effective approach to the treatment of type 2 diabetes in obese patients. Four “building blocks” were identified to facilitate policy changes: 1) communicating the scale of the costs and harms associated with rising prevalence of type 2 diabetes, 2) properly articulating the role of bariatric/metabolic surgery for certain population groups 3) identifying new funding sources for bariatric/metabolic surgery and 4) incorporating bariatric/metabolic surgery into the appropriate clinical pathways. Although more research is needed to identify specific clinical scenarios for prioritization of bariatric/metabolic surgery, the case appears to be strong enough to engage relevant policy makers and practitioners in a concerted discussion of how to better utilize metabolic surgical resources in good diabetes practice.

MAIN TEXT

Introduction

Type 2 diabetes comprises 90% of diabetes cases around the world (1). According to the most recent estimates by the International Diabetes Federation's (IDF), 8.3% of adults in the world – 382 million people – currently have diabetes, and the number is set to rise beyond 592 million in less than 25 years (2). The disease is a leading cause for myocardial infarction, stroke, blindness, kidney failure and amputations (3). Due to its costly complications, diabetes places a significant financial burden on national healthcare systems.

In cases where diet, exercise, and medications have proved to be insufficient, bariatric/metabolic surgery can be an alternative to treat obesity and *type 2 diabetes* (4). In fact, many of the patients who undergo this type of surgery enjoy sustained remission of the disease, which is generally considered irreversible and inevitably progressive. Randomized clinical trials demonstrate that bariatric/metabolic surgery can achieve better control of hyperglycemia and greater reduction of cardiovascular risk factors compared to conventional medical therapies and lifestyle interventions (5,6). However, despite increasing recognition of the efficacy, safety and cost-effectiveness of bariatric/metabolic surgery, there appear to be numerous potential barriers to the appropriate use of surgical procedures for those patients who may benefit.

To address the challenges and opportunities that bariatric/metabolic surgery offers to diabetes care and research, the World Congress on Interventional Therapies for *Type 2 Diabetes* was set up as an international forum where clinicians, scientists and policy makers discuss available evidence on the use and study of bariatric/metabolic surgery and new device-based interventions. The third congress in this series was held in September 2015 in London to critically discuss the latest evidence on bariatric/metabolic surgery, including clinical outcomes, mechanisms of action and implications for healthcare policies (7). A specific aim of the congress was to identify and address potential barriers that may prevent access to surgical treatment of obesity and diabetes in eligible patients.

The Policy Institute at King's College London was invited to undertake a Policy Lab exercise during the congress, with the intent to bring together clinicians, academics, senior policy officials and patient representatives. The specific goals of the Policy Lab included the following: 1) to provide the latest evidence on cost-effectiveness of bariatric/metabolic surgery as a treatment option for obesity and diabetes, 2) to identify

barriers to appropriate utilization of bariatric/metabolic surgery as part of the mix of interventions to address the rising burden of *type 2 diabetes* and 3) to develop health policy initiatives that may improve access to surgical treatment when indicated. Policy Lab participants were provided with a summary of available evidence about the cost effectiveness of bariatric/metabolic surgery and the costs of increasing the proportion of patients who would be appropriate candidates to receive bariatric/metabolic surgery procedures. This paper is structured as follows. First, we describe the ‘Policy Lab.’ . Second, we present existing evidence on the global healthcare costs of diabetes, the evidence on the cost-effectiveness of bariatric/metabolic surgery, and our own calculations of the costs and benefits of meeting potential demand for bariatric/metabolic bariatric surgery in England and the U.S. based on published data. Third, we report the views expressed by participants in the ‘Policy Lab’ and relevant policy implications which emerged.

What is a Policy Lab?

Making decisions about healthcare policies is a complex task and can require an understanding of the needs of the target communities, of the evidence base for a range of available interventions and an assessment of the attitudinal, resource and logistical contexts that can affect the implementation of such policies. We prepared a ‘Policy Lab’ (8) in which individuals of appropriate expertise debated available scientific evidence and identified effective means by which such evidence can inform policy and practice. The Policy Lab brought together twenty-six stakeholders, including academics, clinicians, policymakers, industry leaders, and patient representatives, with the goal of discussing bariatric/metabolic surgery as a treatment option for *type 2 diabetes* and the potential barriers to increased access to its use in practice. (Figure 1)

Prior to the meeting, the organizing committee and the moderators of the Policy Lab researched available evidence and summarized data about the current cost of diabetes for healthcare systems, clinical- and cost-effectiveness of bariatric/metabolic surgery for *type 2 diabetes* and its uptake in high-income countries. We also assessed the number of potentially eligible patients who currently have access to bariatric/metabolic surgery in two countries, England and US, as examples of two distinct types of healthcare systems, and estimated the costs and benefits of increasing access to the surgery. These data were summarized and presented to participants of the Policy Lab during the congress. Participants considered the case for an increased provision of bariatric/metabolic surgery to help address the challenge of *type 2 diabetes*. Specifically, they were asked to

identify obstacles to increasing the use of bariatric/metabolic surgery and propose actions that could help overcome such obstacles.

The global healthcare cost of diabetes

In 2015 the global healthcare cost of diabetes was estimated to be \$673 billion or 12 percent of all global healthcare costs, but healthcare expenditures for diabetes vary dramatically by region and by country (2). The world's richest regions, North America and Europe, account for 75 percent of global healthcare expenditures for diabetes. In the U.S., mean annual healthcare expenditures per person with diabetes are \$10,942 and in the United Kingdom, they are \$4,373 (2) (and estimated to account for 10 percent of the NHS budget (9)). Assuming constant per capita healthcare expenditures for diabetes, the global cost of diabetes is projected to increase by 19% to approximately \$802 billion by 2040 (2). The reasons for the increasing costs of diabetes include population growth, aging of the population, and increasing prevalence of diabetes.

Economic development is associated with increased access to healthcare and increased per capita healthcare expenditures. In high-income countries, substantial resources are used for antihyperglycemic therapy, blood pressure, and lipid lowering therapies and for the treatment of diabetic complications and comorbidities. In low- and middle-income countries, a greater proportion of resources are used for antihyperglycemic therapy and less for the treatment of chronic complications and comorbidities (10). With economic development, more individuals receive antihyperglycemic therapy and treatment for cardiovascular risk factors, complications, and comorbidities. A recent global systematic review revealed that the direct costs of diabetes are closely and positively associated with a country's per capita gross domestic product (GDP) such that every additional dollar in per capita GDP corresponds with an average increase in diabetes expenditures of approximately 4 U.S. cents (10). Treatment for late and expensive complications of diabetes such as end-stage renal disease (ESRD) have also been shown to be strongly associated with national economic wealth or GDP. In low and middle income countries ESRD treatment rates are negligible or extremely low. (11) Treatment rates increase progressively with GDP per capita, and are substantially larger in high income countries. These data suggest that with global economic growth, access to care and the increase in healthcare costs attributable to diabetes and its complications will be substantially greater than hitherto projected and will be unsustainable unless action is

taken to slow the epidemic of *type 2 diabetes*. There is an urgent need to implement interventions to delay or prevent the development of *type 2 diabetes* and to slow the progression of its complications and comorbidities.

Cost effectiveness of bariatric/metabolic surgery for patients with type 2 diabetes

For the Policy Lab, evidence was gathered from two, recent, systematic reviews which included international evidence on the cost-effectiveness of bariatric/metabolic surgery in people with *type 2 diabetes* who are also obese (Table 1). The reviews were commissioned by the UK's NIHR Health Technology Assessment (HTA) programme (12) and the National Clinical Guidelines Centre (NCGC) and were published in 2009 and 2015. Across both reviews, four studies were identified which met the NCGC quality criteria (13,14,15,16) (eight further economic evaluations were excluded on quality or scope grounds by the NCGC). All four studies used probabilistic decision analytic modelling to estimate the incremental costs and benefits of bariatric/metabolic surgery when compared to non-surgical management in patients with *type 2 diabetes* in periods of up to 40 years. Modelled populations lived in Australia (16), the UK (13,14) and USA.(15)

Input data on clinical effectiveness, including diabetes remission rates, typically came from published RCTs which had a maximum of two years follow-up. (17,18) Input data on costs came from relevant literature or providers of health system information, including the UK's Health and Social Care Information Centre. Three of the studies concluded that bariatric/metabolic surgery had a very high likelihood (95%-100%) of being cost-effective within any reasonable threshold of what would be considered value for money in healthcare (in a high-income country context). Nevertheless, there was considerable variability in the estimated incremental cost-effectiveness ratios (ICERs) between studies, due to differences in the modelling approach, input parameters and assumptions made. The fourth study concluded bariatric/metabolic surgery dominated the non-surgical comparator, in that it was both less costly and more effective.

For obese patients with established diabetes, a U.S. study by Hoerger et al. (2010) reported an ICER of \$13,000 per QALY for banding surgery and \$12,000 per QALY for bypass surgery (both were compared to non-surgical management over a lifetime). Relative to patients with established diabetes, bariatric surgery led to more life years and lower ICERs in patients with newly diagnosed diabetes (\$11,000 for banding and \$7,000 for

bypass).¹ (15) The UK study by Picot et al. (2012) estimated an ICER of £1,634 (\$2,428) per QALY for banding surgery in obese patients with early onset *type 2 diabetes* over a 20 year period. Over a two year period, i.e. avoiding the need to extrapolate data beyond the follow-up period of the RCT, the ICER was estimated to be £20,159 (\$29,954) per QALY.² Although higher, since the cost-savings arising from resolution of *type 2 diabetes* in the surgical intervention group had yet to materialize, this was nonetheless still within the boundaries of cost-effectiveness thresholds (at least in the UK). (14)

Costs and benefits of meeting potential demand for bariatric/metabolic surgery in England and U.S.

We used published data on the prevalence of obesity and *type 2 diabetes* (see Tables 2 and 3) to estimate that 1.3m adults with a BMI greater than 30kg/m² in England (19-24), and 10.1m in the US (25-30), are living with *type 2 diabetes* (of these, 590,000 in England and 5.5m in the US were people with a BMI greater than 35kg/m²). Incidence data were used to estimate that there are 120,000 additional cases of *type 2 diabetes* amongst people with BMI greater than 30kg/m² each year in England, and 860,000 additional cases each year in the US (of these, 54,000 in England, and 470,000 in the US, were people with a BMI greater than 35kg/m²).

When compared to data on the annual number of diabetic patients who are treated with metabolic surgery in England and the US (around 1,500 people in England, Table 2, and 41,000 in the US, Table 3), only a small proportion of patients who might be eligible for surgery currently receive surgery. The number of *type 2 diabetes* patients currently treated each year with bariatric surgery is equivalent to 1.2% of the estimated number of new cases of *type 2 diabetes* amongst people with BMI greater than 30kg/m² in England, or 4.8% in the US..

We estimated the potential costs and benefits of treating more obese diabetic patients with bariatric/metabolic surgery using published data (Tables 2 and 3) on the costs and benefits of treatment. We considered both obese people with incident diabetes who are likely to become eligible for surgery each year, as well as potential existing cases (i.e. people in the general population with *type 2 diabetes* and a BMI greater than 30kg/m² or 35 kg/m² who have not previously accessed treatment).

¹ In the study by Hoerger et al, all costs were reported in 2005 US \$

² In the study by Picot et al, all costs were measured in 2010 UK £ and have been converted to 2010 US \$ using yearly average currency exchange rates: www.irs.gov/Individuals/International-Taxpayers/Yearly-Average-Currency-Exchange-Rates accessed 21.03.16

During the Policy Lab we presented a scenario in which 70% of people with *type 2 diabetes* and a BMI greater than 30kg/m² were considered by their doctors to be eligible for treatment, and 5% of them went on to choose surgery. Accordingly, we estimated that the current annual number of people with *type 2 diabetes* treated with bariatric/metabolic surgery would need to increase six-fold in England (to around 9,000 per annum), and by more than 60 per cent in the US (to around 65,000 per annum), if the potential demand for bariatric/metabolic surgery (from both new and existing cases of obese-diabetics) were to be addressed over a ten year period (see Table 4). In this scenario, the additional annual ‘upfront’ cost of bariatric/metabolic surgery would be £35.8m (\$52.6m) in England and \$686 million in the US (in 2015 prices). Thus, despite the evidence on the cost-effectiveness of bariatric/metabolic surgery and the large costs already associated with treating diabetes (described above), these ‘upfront’ costs may represent a challenge to limited healthcare budgets. Nevertheless, the cost-effectiveness estimates in the study by Picot et al. (2012) suggest that, in the scenario where a policy of increased bariatric/metabolic surgery is sustained for a ten year period, health gains would be in excess of 50,000 QALYs in England and 580,000 QALYs in the US (with associated incremental costs, which account for cost savings arising from diabetes remission in treated patients, of £93.7million (\$137.6m) in England and \$8.2billion in the US (in 2015 prices)). We altered the assumptions on which these estimates are based to provide a range of alternative scenarios (see Table 4). For example, should the potential demand for bariatric/metabolic surgery (both new existing cases of obese-diabetics) be addressed over a shorter (one- or five- year) period, or if more than 5 per cent of the eligible population chose surgery, then annual costs and capacity requirements would inevitably rise substantially further.

Building blocks towards policy change

Policy change does not follow from provision of research and evidence alone. Much work is often needed for evidence to reach the decision-makers (31). Often the first step is identifying the relevant policy community for the intended policy and practice change, whether at the national or local decision-making level. In the case of diabetes care, the target may include national health policy, including clinical guidelines, but also local practice and patient advocacy groups. Decision makers at all levels will need to consider how to find sufficient funding to implement change, to gain the support of key stakeholders, and, crucially, to balance expenditure on immediate treatment needs with investment in longer term preventative strategies. Secondly, given that

decisions are taken at different tiers, change requires carefully targeted interventions of appropriate scale. In our Policy Lab we identified four ‘building blocks’ for policy and practice change that may facilitate increased uptake of bariatric/metabolic surgery for *type 2 diabetes*: 1) communicating the scale of the costs and harms associated with diabetes, 2) articulating the potential role of bariatric/metabolic surgery for certain population groups, 3) identifying the cost-effectiveness arguments that may support expanding the use of bariatric/metabolic surgery and 4) changing both the available resources and processes for incorporating bariatric/metabolic surgery into the appropriate clinical pathways. We discuss each in turn below.

1 Communicating the scale of the global diabetes challenge

Policy change requires policymakers and practitioners to be motivated to act; this is contingent on evidence that changes in policy and practice will improve outcomes, reduce costs and/or or reduce harms. In the case of *type 2 diabetes* there appears to be a growing awareness of the magnitude of the problem globally. However, participants at Policy Lab noted that there is still a need to present a more detailed breakdown of the costs of diabetes, including better data on the prevalence of and costs of diabetes complications (such as retinopathy, renal disease and neuropathy) and to improve awareness of the wider social and economic costs and harms associated with the disease.

2. Articulating the role of bariatric/metabolic surgery for the treatment of diabetes

Once the case for action has been made, the next stage involves articulating the specific role that metabolic/bariatric surgery can play in the treatment of *type 2 diabetes* among certain population groups. The guidelines of the National Institute for Clinical Excellence (NICE) in England and Wales have already recommended that bariatric/metabolic surgery be considered for patients with a BMI of 30Kg/m² or above with recent-onset (less than ten years) *type 2 diabetes*. For patients with a BMI of 35 Kg/m² or above the level of recommendation is stronger, suggesting that these patients should be offered expedited assessment for bariatric/metabolic surgery (32). These guidelines reflect NICE’s interpretation of existing clinical evidence on the efficacy of bariatric/metabolic surgery vs non-surgical interventions in the treatment of *type 2 diabetes*. In the US, third party payors such as CMS will reimburse for specific cases of metabolic/bariatric surgery with

requirements for co-payment and prior medical intervention (33) and recent recommendations also recommend considering surgery for BMI over 30kg/m².(34)

The typical arguments against surgery generally focus on the advantages of investing in prevention over providing a relatively costlier treatment, or employing low-cost lifestyle therapeutic approaches (e.g. diet and physical activity) over the more invasive and (initially) expensive surgical approach. However, while devoting more resources to preventative efforts and encouraging early and lasting healthy lifestyle changes is objectively the most logical way to tackle the epidemic of diabetes, it is similarly obvious that prevention is no longer possible for individuals with already established disease and that for some of them lifestyle interventions may be relatively ineffective (35). It is this group that constitute the gap between those who are candidates for bariatric/metabolic surgery vs those that received it identified earlier. Articulating this distinction clearly will be important in making the case for surgery.

3. Identifying the cost-effectiveness arguments for bariatric/metabolic surgery

The third building block involves furthering the understanding of the cost-effectiveness of bariatric/metabolic surgery versus other interventions. With pressures on public expenditure and competing budgetary priorities, value-for-money is highly salient in public policy. The Policy Lab participants considered the existing evidence on the cost-effectiveness of bariatric/metabolic surgery to be reasonably robust, with good evidence that the cost per QALY gained is at least comparable (and may be lower) for bariatric/metabolic surgery than for other approved interventions. (14,15) However, it was recognised that the completion of longer-term studies would be beneficial in building a more holistic picture of the evolution of the costs of bariatric/metabolic surgery over time, including rates of initial diabetes remission and risk of subsequent relapse and the impact of surgery on existent diabetes complications.

4. Changing the available resources and processes for incorporating bariatric/metabolic surgery

These first three building blocks relate to the interactions between the academic and policy communities – the evidence research communities must marshal and articulate for decision-makers to catalyse policy change. However, structural and political barriers to change may remain and identifying these may be an important step

towards change. Policy Lab participants identified three sets of such barriers: those related to resources, those regarding understanding, and those associated with processes.

The availability of resources may be particularly pertinent – despite recognition of bariatric/metabolic surgery’s demonstrated cost-effectiveness. Meeting the substantial up-front costs of greater uptake of the treatment was viewed as a significant barrier to expanding provision in an environment of tight healthcare budgets, particularly in the UK context. The potential for treatment to be concentrated in Centres of Excellence was seen as one way of controlling delivery costs, while participants also suggested that alternative sources of finance could be sought, including from the private sector, to overcome short-term resource constraints, although we have not sought evidence that supports these suggestions within the scope of this study. The idea that up-front costs are a barrier to uptake may reflect some misconceptions, identified by participants, about bariatric/metabolic surgery. Bariatric/metabolic surgery, it was argued, is still largely conceived as a weight-loss intervention and; as such, it may be perceived as an extremely expensive option when compared to other (low-cost) weight-reduction interventions (e.g. diet and lifestyle modifications). Furthermore, bariatric/metabolic surgery may be mistakenly considered solely as a means to prevent future obesity-related complications rather than as a therapy for established disease, which is particularly true when the surgery is used to treat diabetes. This misconception may be a significant barrier to policy changes; in fact, expediting access to what is perceived to be a costly, preventive intervention might not be felt as a priority at a time of tight healthcare budgets.

Increasing understanding both of the severity of challenges associated with rising prevalence of diabetes and the process of surgery and its outcomes among the clinical and patient communities was also seen by Policy Lab participants as important for increasing uptake of bariatric/metabolic surgery. While current guidelines on obesity treatment already recommend bariatric/metabolic surgery for certain groups of patients with *type 2 diabetes* (26, 36) it is likely that very few general practitioners (primary care physicians) are aware of this recommendation; as a result, most diabetes care providers may not refer eligible patients to surgery. There may also be misconceptions among doctors about the risk of bariatric/metabolic surgery (37) and inadequate knowledge of the improved outcomes of modern, minimally invasive surgical techniques that have helped to reduce the incidence of surgical complications. Better coverage of these topics in medical education and

training courses for all healthcare workers could help rectify this. Improved understanding among healthcare workers is likely to filter down to patients suffering from *type 2 diabetes*.

Finally, according to the participants, processes matter, including how services are commissioned, delivered and incentivised. Participants noted a common complaint related to the poor or patchy provision of specialist pre-surgery services and the lack of coordination between preparation for bariatric/metabolic surgery, surgery itself and follow-up care. It was suggested that the creation of multidisciplinary teams could bring coherence to the system and prevent bottlenecks from emerging. Bariatric/metabolic surgery also does not appear to be integrated into the established clinical care pathway for *type 2 diabetes* in England- for example, while bariatric/metabolic surgery is a recommended option for treating diabetes in the clinical pathway for obesity treatment, there is no reference to bariatric/metabolic surgery in either the previous or recently updated NICE guidelines on the management of *type 2 diabetes*. (38) Including bariatric/metabolic surgery in diabetes treatment algorithms may help increase its visibility for relevant clinicians and improve access to surgery for eligible patients who opt for this surgery. This was the aim of the 2nd Diabetes Surgery Summit (DSS-II), which was held in conjunction with the 3rd world congress on interventional therapies for type 2 diabetes in September 2015 (report to be published in Diabetes Care).

Reframing the concept of bariatric/metabolic surgery

The Policy Lab hosted at the 3rd World Congress on Interventional Therapies for *type 2 diabetes* provided evidence of agreement among stakeholders that bariatric/metabolic surgery is an appropriate and cost-effective approach to the treatment of *type 2 diabetes* in some groups of patients. Given the evidence and challenges, participants identified four ‘building blocks’ to facilitate changes in policy and practice and adequately increase appropriate uptake of bariatric/metabolic surgery for the treatment of diabetes: 1. communicating the scale of the costs and harms associated with rising rates of type 2 diabetes, 2. articulating the role of metabolic/bariatric surgery for certain populations 3. identifying where/how resources might be found to fund bariatric/metabolic surgery and 4. changing the available resources and processes for incorporating bariatric/metabolic surgery into the appropriate clinical pathways.

One further issue that arose in discussions in the Policy Lab was that the name of “bariatric” may negatively influence people’s understanding of the role of surgery in diabetes and its potential benefits. In fact, surgery is generally viewed by many as a risky and worrying undertaking, to be avoided if at all possible. Conceiving surgery solely as a weight-loss intervention, as implied in the name “bariatric”, may be viewed as extremely risky compared to alternative, conservative weight loss interventions (diet and lifestyle modifications). Placing these concerns alongside the potential burden of inadequately controlled *type 2 diabetes* may be helpful on this point. Further, obesity itself carries many connotations that may affect clinicians and others’ inclination to recommend it. In fact, surgery could be seen as a drastic step to address a challenge that many consider avoidable through self-control and weight loss. This issue may be addressed by properly using terms such as “metabolic” or “diabetes” surgery when gastrointestinal operations are offered with the primary intent to treat fully developed *type 2 diabetes*. We also noted above the importance of including bariatric/metabolic surgery in clinical guidelines for diabetes care as opposed to just in guidelines for obesity treatment.

Conclusions

This paper has provided new calculations on the proportion of potentially eligible obese-diabetics who currently receive metabolic/bariatric surgery in light of new guidelines which recommend considering surgery for diabetic patients with a BMI over 30kg/m².⁽³⁴⁾ This updates previous estimates provided by the American Society for Metabolic and Bariatric Surgery (35). Although more research is needed to identify specific clinical scenarios for prioritization of surgical treatment in patients with type 2 diabetes, the case appears to be strong enough to engage relevant policy makers and practitioners in a concerted discussion of how to extend appropriate use of bariatric/metabolic surgery as part of the of the mix of approaches to address the growing burden of *type 2 diabetes*.

Authors Contribution:

JKR led the Policy Lab, presented its findings and contributed to writing the manuscript. SH coordinated the various tasks in the project including review of evidence, organization and design of the Policy Lab, reporting, and contributed to writing the manuscript. RH provided analytical support in preparing for the Policy Lab and contributed to writing the manuscript. AM estimated the costs and benefits of increased utilization of bariatric

surgery and reviewed the cost-effectiveness literature. WHH contributed to writing the manuscript and participated in the Policy Lab discussions. FR conceived the idea of a study to inform policy discussions for the world congress, obtained funds through an educational grant, assisted with appraisal of evidence, participated in the Policy Lab, and contributed to writing the manuscript.

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Professor Rubin is the guarantor of this work, had full access to all the data, and takes full responsibility for the integrity of data and the accuracy of data analysis.

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Figures

Figure 1. Distribution of participant roles at the Policy Lab

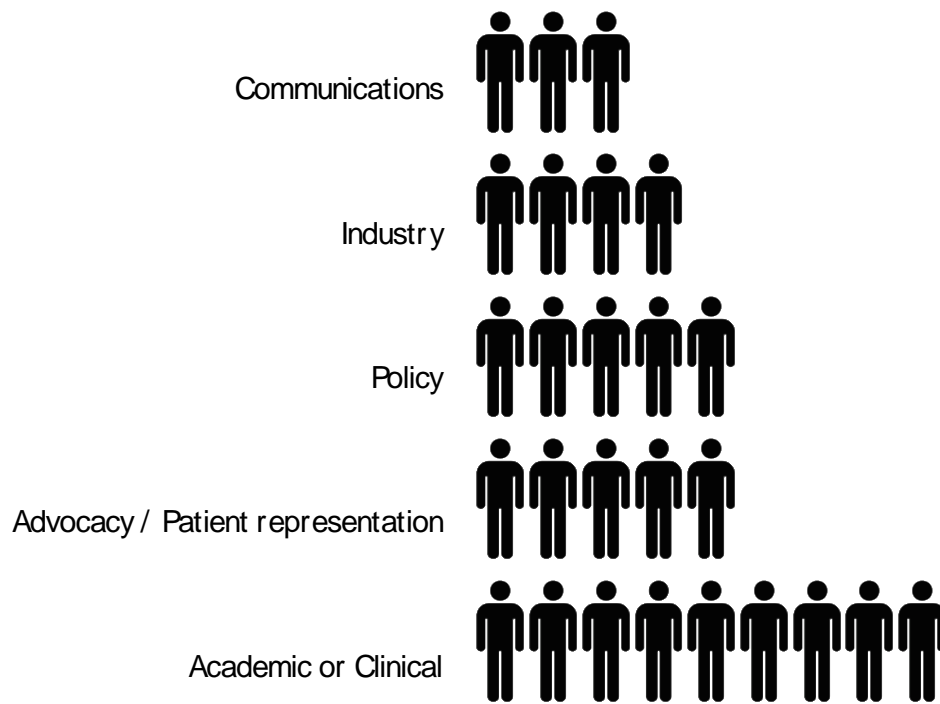


Figure 2. Flow chart to demonstrate how estimates for cost model were calculated (England example)

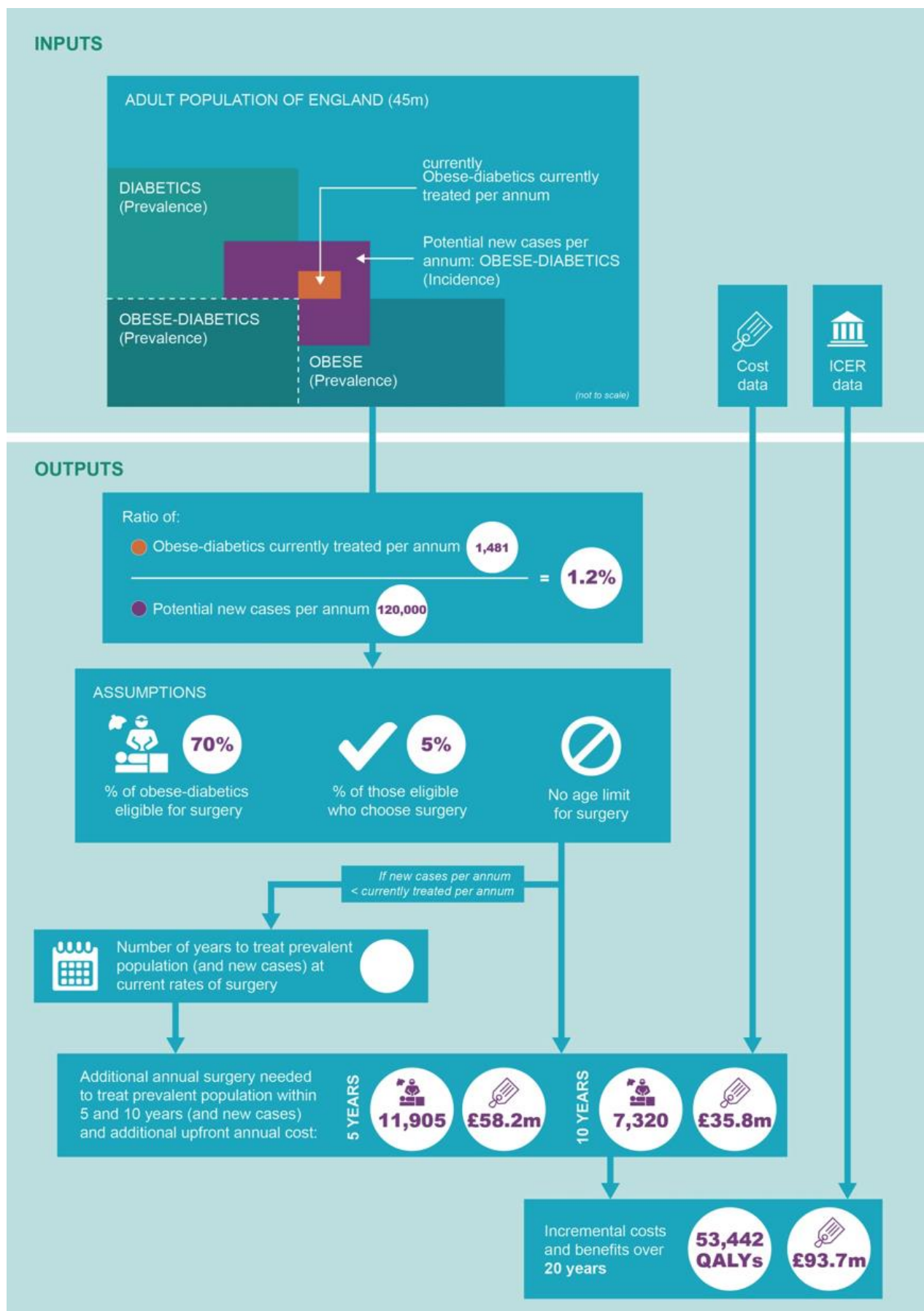
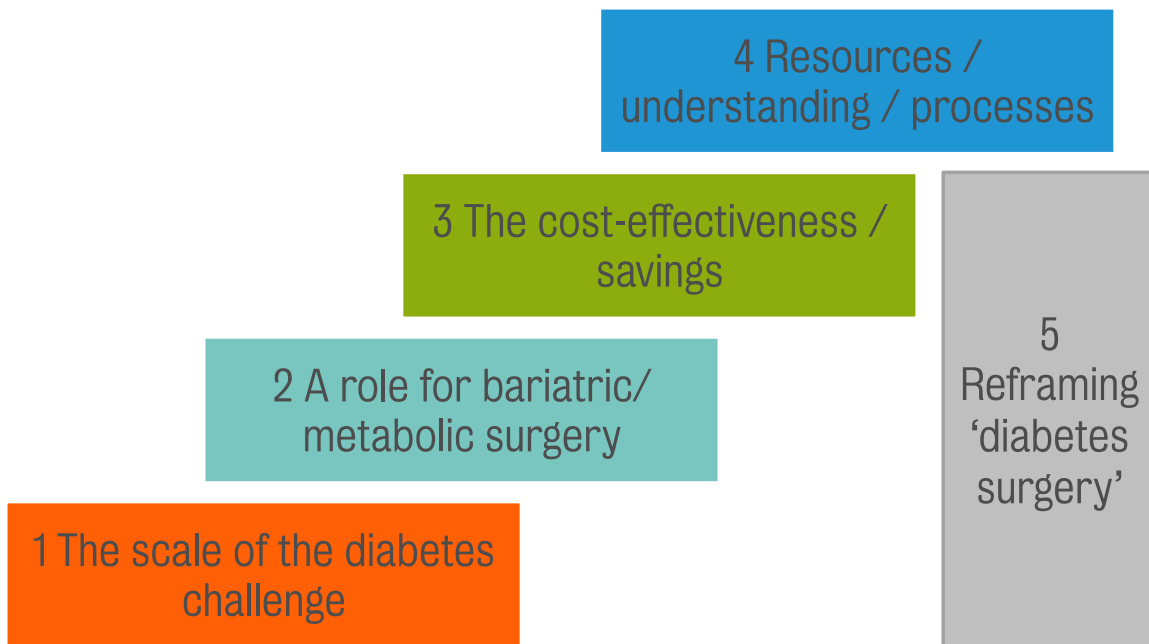


Figure 3. Building blocks of policy change for appropriate utilization of surgery in treatment of type 2 diabetes



Tables

Table 1: Evidence from two studies on the cost-effectiveness of bariatric/metabolic surgery in patients with type 2 diabetes

	England [14]	US [15]
INTERVENTION		
Description	Laparoscopic adjustable gastric banding surgery	Gastric bypass surgery
Upfront cost	£4,546 ³ (\$6,754)	\$23,871 (all costs were measured in 2005 US \$)
Total lifetime cost	£35,055 (\$52,088) (including surgery, consumables, inpatient stay, dietitian, therapy, re-operations) (20 years)	\$99,944 (including follow-up care visits, long-term complications, revisional surgery, diabetic related medicine)
Total lifetime QALYs	11.49 (20 years)	9.38
COMPARATOR		
Description	Non-surgical weight loss programme (including low calorie diet for 6 months)	Standard care for type 2 diabetes
Total lifetime cost	£33,262 (\$49,423) (including regular contact with physician, pharmacotherapy, Optifast, Orlistat) (20 years)	\$79,618 (including diabetic related medicine)
Total lifetime QALYs	10.39 (20 years)	7.68
COST-EFFECTIVENESS		
ICER	£1,634 (\$2,428) per QALY gained* Probability that intervention is cost-effective at £30,000 (\$44,577)/QALY threshold = 100%	\$12,000 per QALY gained Probability that intervention is cost-effective at \$30,000/QALY threshold = 95%
	Notes: *Resolution of type 2 diabetes in the intervention group (compared to non-intervention group) made the greatest contribution to the reduction in the ICER from £20,159 (\$29,954) at 2 years (i.e. without extrapolation of RCT data) to £1,634 (\$2,428) at 20 years [15]	

¹ ICER: incremental cost effectiveness ratio

² QALY: quality adjusted life year

³ In the study by Picot et al, all costs were measured in 2010 UK £ and have been converted to 2010 US \$ using yearly average currency exchange rates: www.irs.gov/Individuals/International-Taxpayers/Yearly-Average-Currency-Exchange-Rates accessed 21.03.16

Table 2: Published estimates of the prevalence and incidence of type 2 diabetes and obesity, and cost and benefits of bariatric surgery (England)

Variable	Value	Source/justification		
Population prevalence and incidence				
Prevalence of type 2 diabetes in adult population	5.6%	6.2% (doctor diagnosed, i.e. excluding undiagnosed, type 1 and type 2 diabetes) [20], of which 90% is type 2 diabetes [9]		
Incidence of diabetes	515 /100,000 /year	[21]		
Proportion of type 2 diabetics with BMI>35	23.6%	National Diabetes Audit 2012/13 [22]		
Proportion of type 2 diabetics with 30>BMI>35	28.9%			
Assumptions about appropriate utilisation of bariatric surgery				
Proportion suitable for surgery	70%	Based on National Diabetes Audit 2012/13 which says 70% of obese diabetics receive “usual care” / tier 3 intervention [22]		
Proportion who choose surgery	5%	Expert opinion		
Age range of adults who are suitable for surgery	All ages over 18 years	Expert opinion		
Published estimates of current utilisation				
Numbers treated	6,170	Estimates provided by the National Bariatric Surgery Registry based on 2012/13 HES data (we assumed this referred only to England). [23] We multiplied data on 11 months (n=5,656) by 12/11. Another study also provided a similar estimate. [24]		
Proportion of those patients treated who have type 2 diabetes	24%	[24]		
Published estimates of costs and benefits of surgery				
“Upfront” cost	£4,892 (\$7,184)	Laparoscopic adjustable banding. Adjusted for 2015 prices using £4,546 in 2010.[14]		
Incremental costs	£1,928 (\$2,831)	Laparoscopic adjustable banding 20 year incremental costs and QALYs for patients with type 2 diabetes (£1,792 in 2010) (LGBP or other surgery not available) Estimates are for 30>BMI<40		
Incremental QALYs	1.10			

Table 3: Published estimates of the prevalence and incidence of type 2 diabetes and obesity, and cost and benefits of bariatric/metabolic surgery (US)

Variable	Value	Source/justification		
Population prevalence and incidence				
Prevalence of type 2 diabetes in adult population	8.1%	National Health Interview Survey 2014: 9.0% (type 1 and type 2) [25], of which we assumed 90% is type 2 diabetes [9]		
Incidence of diabetes	690 /100,000 /year	National Health Interview Survey 2014 [26]		
Proportion of type 2 diabetics with BMI>35	27.7%	NHANES data [ref]		
Proportion of type 2 diabetics with 30>BMI>35	23.2%			
Assumptions about appropriate utilisation of bariatric surgery				
Proportion suitable for surgery	70%	Based on estimates for England described in Table 2		
Proportion who choose surgery	5%	Expert opinion		
Age range of adults who are suitable for surgery	All ages over 18 years	Expert opinion		
Published estimates of current utilisation				
Numbers treated	124,838	2008. Excludes outpatient procedures. [27]		
Proportion of those patients treated who have type 2 diabetes	33%	[27]		
Published estimates of costs and benefits of surgery				
“Upfront” cost	\$28,161	Bypass surgery (includes all first year costs) Adjusted for 2015 prices using \$23,871 in 2005 [ref.]		
Incremental costs of treatment	\$23,979	Bypass surgery Adjusted for 2015 prices using \$20,326 in 2005 [ref.]		

Incremental QALYs	1.70	Bypass surgery [ref.] Figures relate to people with established type 2 diabetes and BMI>35 (thus a conservative estimate of QALY gains compared to newly diagnosed diabetics)		
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Table 4: Estimates of costs and benefits of meeting appropriate utilization for bariatric/metabolic surgery in England and the US

		England			US		
Scenario: Proportion choosing surgery		1%	5% (base case)	20%	1%	5% (base case)	20%
Additional upfront annual cost of clearing the 'backlog' in 1 year		£41.7m (\$61.2m)	£237.7m (\$349.0m)	£972.4m (\$1.4bn)	\$1.3bn	\$9.7bn	\$42.1bn
Lifetime incremental cost of clearing the backlog		£16.4m (\$24.1m)	£93.7m (\$137.6m)	£383.2m (\$562.7m)	\$854m	\$8.2bn	\$35.9bn
Lifetime incremental QALYs of clearing the backlog		9,385	53,442	218,655	60,554	582,907	2.5m
Time taken to treat existing obese diabetics in the population (i.e. the 'backlog') if no change in uptake of surgery		14 years	Never*	Never*	2 years	32 years	Never*
Additional annual surgery needed to clear the 'backlog' within 1, 5 and 10 years	1 year	8,532	48,584	198,777	35,620	342,887	1.5m
	5 year	1,196	11,905	52,063	0	59,740	362,550
	10 years	279	7,320	33,724	0	24,347	220,976

*never since the number of new cases presented each year exceeds the number currently treated

All monetary values in this table were measured in 2015 UK £ or 2015 US \$. 2015 UK £s have been converted to 2015 US \$ using yearly average currency exchange rates: www.irs.gov/Individuals/International-Taxpayers/Yearly-Average-Currency-Exchange-Rates accessed 21.03.16