Evidence and issues in addressing cost-effectiveness in treating obesity

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Abstract

Healthcare systems that provide care free of charge at the point of care must evaluate health interventions for effectiveness and cost-effectiveness. This is as true for treatments for obesity as it is for any disease area, and the same money cannot be spent at the same time on obesity and other disease areas necessitating these evaluations. Cost–utility analyses carried out to inform payers typically ask whether a new health intervention makes people live longer and/or better than the existing standard of care. The costs associated with one versus another intervention, including the costs and benefits of all downstream sequelae, comprise the incremental cost-effectiveness ratio. Uncertainties exist because estimates of life-long treatment rely on the results of short-term clinical studies.

Keywords Bariatric surgery; cost–utility analyses; incremental cost-effectiveness; MRCP; obesity; quality-adjusted life-year

Why obesity treatments require health economic analyses

A health system must offer cost-effective treatments for obesity (as for all disease areas) because it cannot feasibly provide all therapies, to all people, at any price. Health technology appraisal addresses whether a technology (essentially any intervention) works, and whether it reflects good value for money. When health budgets are limited (as all health budgets are), payers should not offer treatments when more effective, better value options exist – even if these are in another disease area. Countries such as the UK, where the National Health Service (NHS) provides care 'from cradle to grave', must relate price (as but one component of all costs) and outcome.

Regulators and payers, and payers' approach to cost–utility analyses

For an obesity drug, a regulatory agency may ask a manufacturer whether a new drug lowers body weight, often proven against a placebo, and is safe. By contrast, an agency such as the National Institute for Health and Care Excellence (NICE), which provides guidance to the payer NHS England, asks whether the drug makes people live longer and/or live better compared with existing treatments. NICE prefers a generic endpoint for effectiveness, because what the NHS spends on obesity it cannot spend elsewhere. It is difficult to compare the value of disease-specific endpoints, for example, body weight in obesity, with a sustained virological response in hepatitis.

Because living longer and/or better ('utility') reflects effectiveness across diseases, many cost-effectiveness analyses employ the quality-adjusted life-year (QALY) as a generic measure of effectiveness. The difference in total costs (price plus all downstream consequences and costs) divided by the difference in the anticipated number of QALYs gives the incremental cost-effectiveness ratio (ICER); this reflects what the health service would pay for one QALY's worth of health benefits. Traditionally, England deems a technology with an ICER of <£20,000–30,000 to be cost-effective.

The 'perspective' (of who pays and who benefits) is that of the NHS, even though, arguably, society would benefit from a lower prevalence of obesity. NICE to date values cost-effectiveness over affordability, but recognizes that a cost-effective treatment for obesity, which is highly prevalent, will be associated with a big bill to the health service.

Disease modelling

Few trials in obesity measure length of life (or even quality of life or costs), meaning that economists have to develop disease models that simulate the treated 'natural history' of disease. These models relate the changes observed in study outcomes to anticipated long-term quality of life, length of life and costs. The models simulate treatments in hypothetical, yet representative, populations; they generate results for each treatment, and compare them to estimate cost-effectiveness.

Issues in cost–utility analyses of treatment for obesity

Many issues exist when estimating cost-effectiveness. For example, the costs and benefits of treating obesity may be life-long, yet trials last for only a defined (generally short) period; thus, whether short-term benefits seen in trials translate to long-term benefits in real life is a major source of uncertainty. Trials of one-off treatments such as bariatric surgery capture the whole period of treatment (the surgery), but little of the period of follow-up. Bariatric surgery improves blood glucose levels in diabetes mellitus, but it is not clear how long this lasts.

In addition, surgical trials are likely to be unblinded, leading to the possibility that people's behaviour is influenced by knowing their treatment, and this may influence the trial outcome. Supplementing and validating trial evidence with observational studies of drugs or surgery risks the possibility that treated people differ fundamentally from untreated people in a way that itself improves the outcomes (known as confounding). There are few methodologically sound studies that determine quality of life and assign it a numerical value. This includes studies of the disutilities associated with adverse outcomes from drugs or bariatric surgery.

Examples of cost–utility analyses in the UK

In 2004, the NHS Research and Development Health Technology Assessment (R&D HTA) Programme reviewed treatments for obesity.[1] Using Cochrane Collaboration methods to review the

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Competing interests: none declared.

evidence, and developing a Markov model to examine diet and exercise in people with obesity and glucose intolerance, the group concluded that targeting high-risk groups with drugs or surgery for obesity resulted in a cost per QALY or 'no more than £13,000'. The authors concluded that surgery in even higher risk individuals (those with morbid obesity) was even more cost-effective.

They suggested that metformin use, insofar as it was associated with both weight loss and possible cardiovascular protection and was a low-price drug, could be cost-saving, meaning the long-term benefits were positive and the long-term costs negative. The authors concluded that diet plus exercise had a similar cost-effectiveness to treatment with drugs.

An NHS R&D HTA study from 2009[2] addressed the clinical and cost-effectiveness of bariatric surgery by developing an economic model for three populations: patients with morbid obesity (body mass index (BMI) $\geq$40 kg/m^2 undergoing adjustable gastric banding (AGB) or gastric bypass; patients with moderate to severe obesity (BMI $\geq$30 and $<$40 kg/m^2) with type 2 diabetes mellitus undergoing AGB; and patients with moderate obesity (BMI $\geq$30 and $<$35 kg/m^2) undergoing AGB. Outcomes were extrapolated to 20 years after surgery. Although the authors deemed surgery (compared with no surgery) to be cost-effective in all populations, the authors deemed the actual ICER estimates 'unlikely to be reliable'.

In a clinical guideline from 2014, NICE performed cost-effectiveness analyses on two key areas: very low-calorie diets for reducing weight, and bariatric surgery in overweight or obese people with recent-onset type 2 diabetes mellitus.[3] The guidelines, backed by economic analyses, advocated 'multicomponent interventions' including behavioural interventions, physical activities, diets and pharmacological interventions, but 'only after trying dietary, exercise and behavioural approaches'. The guidelines gave the option to use drugs to maintain weight loss, and encouraged clinicians to stop treatment in people who had not reached weight loss targets.

NICE recently addressed the use of naltrexone–bupropion for managing overweight and obesity but did not recommended its use.[4] The technology appraisal committee was aware that trial evidence showed naltrexone–bupropion plus lifestyle measures to be more effective than lifestyle measures alone, but it recognized that the treatment's long-term effectiveness was unknown. Specifically, the committee recognized that the cost-effectiveness of naltrexone–bupropion depended on the degree of weight gain after stopping treatment. The committee knew that the manufacturer's model did not account for episodes of re-treatment, a likely scenario for many people.

The committee recognized that, in the company's model, the company considered that obesity increased the risk for only three diseases: type 2 diabetes mellitus, stroke and myocardial infarction. It acknowledged that obesity increases the risk of many other conditions and, without these in the model, the committee could not gauge the true cost-effectiveness of naltrexone–bupropion.

Generalizing cost-effectiveness studies to another setting

If a treatment for obesity is cost-effective in one place, is it cost-effective in another? In general, estimates from cost-effectiveness analyses are poorly generalizable from one setting to another. Although a technology may be as effective in one population as in another, the difference in absolute effectiveness, the costs[5] and the country-specific difference in valuing health-related quality of life are not. ◆

KEY REFERENCES

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