**The relevant perspective of economic evaluations informing local decision makers: an exploration in weight loss services**

**Running title:** Evaluative perspective for local decision makers

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Since 2013 obesity services in the UK NHS have focussed on a tiered structure, with tiers 3 (specialist weight management services) and 4 (primarily bariatric surgery) commissioned by Clinical Commissioning Groups (CCGs) and widely reported as cost-effective and recommended by National guidelines. However, CCGs have been reluctant to fully conform to the guidance. We explore how the different evaluative perspective of those generating evidence from local decision makers has contributed to this failure of the CCGs to provide services considered cost-effective. We explore four elements where the conventional economic evaluation framework, as applied by NICE, differ from the reality faced by local decision makers: the cost-effectiveness threshold, the implications of decision uncertainty and budgetary excess, the valuation of future costs and outcomes, and the scope of included costs. We argue that the failure of the conventional framework to reflect the reality faced by local decision makers is rendering much of the existing literature and guidance inappropriate to the key commissioners. Our analysis demonstrates that it is not reasonable to assume that the framework of economic evaluation used to inform national guidance applies to local decision makers, such as in the commissioning of weight loss services. This failure is likely to apply to the majority of cases where evidence is generated to inform National decision makers but commissioning is at a local level.

Key Points for Decision Makers:

* Economic evaluation methodology has been developed extensively to focus on a national decision maker’s perspective, failing to reflect the different reality faced by those commissioning at a local level.
* We consider the areas where the conventional NICE style framework does not reflect the local experience, highlighting the limited relevance of published research and national guidance at the point of commissioning.
* Local decision makers must be careful in their adoption of national guidance and published recommendations without a consideration of the relevance of the underlying perspective of the analysis. In turn national guidance and research should better reflect the different focus of local decision makers.
1. **Introduction**

The shift in policy in the UK to a tiered treatment pathway in the management of obesity in 2013/14 was intended to move commissioning away from disjointed and inconsistent provision towards a service able to address the obesity crisis [1, 2]. In 2013/14 an NHS England (then the NHS Commissioning Board) and Public Health England working group defined the four tier system of weight loss interventions that currently operates in England, outlining who should hold the commissioning responsibility for each tier [1, 2]. Prior to that, the commissioning of weight management programmes (‘tier 3’) was limited, and bariatric surgery (‘tier 4’) primarily funded on a case by case basis [3]. At the working group’s recommendation the commission of tier 3 services was allocated to Clinical Commissioning Groups (CCGs) (with tiers 1 and 2 residing with Local Authorities as the local government organisation responsible for a broader range of public service provision, including public health provision, rather than the CCGs whose primary aim is NHS provision). Tier 4 commissioning was to be transferred from the NHS Commissioning Board to CCGs in 2016 [4] with the expectation that this would be once tier 3 services were commissioned and operating effectively, but in many cases this did not occur until 2017 with limited requirement for tier 3 provision in place.

However, the shift in policy has arguably had limited impact, with rates of morbid obesity [5] and type two diabetes [6] continuing to increase in the UK. Furthermore, rates of surgery have stayed stagnant or decreased in recent years [7], with CCGs being accused of unfairly restricting surgery [8-10], and have struggled with the commissioning of effective tier 3 programmes [11], despite extensive commissioning guidance [4].

In this paper we explore the role of asymmetric perspectives between the CCG and the evidence generated to inform the clinical and cost-effective commissioning of tier 3 and 4 services from an economic evaluation viewpoint. We consider a number of factors that have contributed to the uninformative nature of much of the available economic evidence, primarily resulting from failures on the part of those generating evidence to make recommendations that reflect the realities faced by local commissioners. These issues are likely to occur throughout healthcare decision making when evidence generation and guidance is national but the commissioning and decision making local. All challenges were identified with the support of the co-author (LH) from the Vale of York CCG who have been seeking to commission a tier 3 and 4 pathway.

1. **What does the current evidence say on the cost-effectiveness of tier 3 and 4?**

The original NHS Commissioning Board report in 2013 provided the basis for the categorisation of weight loss services into the tiered system, defining tier 3 as ‘a primary/community care based multi-disciplinary team (MDT) to provide an intensive level of input to patients’, and tier 4 as ‘specialised complex obesity services (including bariatric surgery)’ p7 [1]. The report briefly considered the evidence around the cost-effectiveness of the different service options, providing reference to some studies on tier 4 services, however, at that time nothing was published that was deemed relevant to tier 3 service provision.

Since the initiation of the tiered service in 2013/14 there have been a number of publications regarding the effectiveness and cost-effectiveness of tier 3 and 4 services, the majority of which arrive at the same conclusion, that there is little known about the cost-effectiveness of tier 3 services but that tier 4 is likely to be cost-effective under conventional evaluative methodology. The significant statement in the Commissioning Board report [1] that the costs of tier 4 are recouped in the short to medium term has, however, been discredited, as discussed below.

Both NICE clinical guidance documents produced in that time [18, 19], briefly considered the published evidence, concluding that tier 3 is an effective service for those who have failed to adequately manage their weight through tier 2 services, and tier 4 cost-effective for those with BMI≥40 or ≥35 with significant weight related co-morbidities and for whom all other non-surgical interventions have failed to achieve or maintain weight loss.

More widely, many studies of bariatric surgery have been published, of note Gulliford et al. [16] conducted a large cohort study and cost-effectiveness analysis of bariatric surgery, where all bariatric surgery patients were assumed to also receive tier 3. They found bariatric surgery to be more expensive over the life of the patients, but cost-effective, with an incremental cost-effectiveness ratio (ICER) of £7,129 per quality adjusted life year (QALY), well below conventionally applied thresholds. They further found that there was no group of patients where providing tier 4 resulted in cost-savings to the NHS.

More recently Avenell et al. [17] conducted a mixed method analysis of bariatric surgery and lifestyle interventions for those with BMI≥35kg/m2. The authors found that general weight management programmes, including tier 3 type services, were cost-effective compared to usual care (£1,541/QALY), and that bariatric surgery was also cost-effective over a 30 year time horizon (£10,126/QALY). Similarly to Gulliford, they found no evidence for long-term cost saving of bariatric surgery, however, they did not conduct sub-group analysis.

Specific to tier 3, both Brown [20] and Alkharaiji [21] conducted systematic reviews, finding that there was reasonable evidence that tier 3 type services result in clinically meaningful weight loss. However, the follow up period of the majority of studies was very short, with almost all being under one year, making any conclusions about the long term impact and cost-effectiveness highly uncertain.

1. **Why has the published evidence failed to translate to commissioning?**

As the commissioners and budget holders of approximately two-thirds of the NHS budget, it is vitally important that CCGs are implementing the best available evidence, which in turn must reflect their needs and commissioning reality. While it is challenging to quantify their compliance with the evidence base, previous authors have argued that there has been limited commissioning of tier 3 services in line with national guidance [22], and that this was due to structural barriers including a lack of trained staff, financial barriers to new service development, and workload constraints. Others have argued that the tiering system itself is at fault [23]. While these factors are likely to play a role in the tribulations of the services, we consider the challenge to be even more fundamental, that much of the evidence generated extoling the cost-effectiveness of tier 3 and 4 services is largely inappropriate for commissioning CCGs. In this section we explore how fundamental differences in the perspective faced by the local commissioners from the national frameworks, applied to conduct cost-effectiveness analysis in the UK, have contributed to this poor level of relevance.

In any evaluation of an intervention, such as the tier 3 and 4 pathways, perspective plays a key role. If treatment strategies are to be considered and compared in terms of their associated costs and outcomes, the question of whose costs and outcomes are considered relevant, and how to measure them, must be addressed [24]. For the evaluation and commissioning of health policy to be efficient, the perspectives of the evaluators and commissioners must be aligned. Failure to do so risks inconsistent conclusions, where clinical guidance does not align with commissioning reality, and therefore inefficient outcomes for patients.

The perspective used by NICE in their considerations of cost-effectiveness are well publicised [25], and have become the default for many NHS based economic evaluations [24], including those referenced in the previous section. Broadly consisting of the estimation of lifetime costs to the NHS and Personal Social Services and health outcomes of patients (measured as QALYs), both discounted at a rate of 3.5% per year to weigh current against future outcomes. Costs and outcomes which fall outside of this perspective are not included in the headline estimation of cost-effectiveness. Any gains in health which result in an additional total cost to the NHS are considered against a cost-effectiveness decision rule ‘threshold’, whereby gains which cost less than £20,000 per additional QALY gained are considered cost-effective.

However, the NICE perspective is based on a national decision maker deliberating on marginal changes to a large budget, who is able to offset long term population health gains against upfront costs, and to whom the implications of failing to balance finances are very different than a local decision maker, such as CCGs. Furthermore, while the cost-effectiveness analysis is meant as an element in deliberations, it plays arguably the major role in NICE recommendations. In contrast, local decision makers are faced with short term financial constraints, a diverse decision making set of criteria, and very real repercussions should investment decisions prove inappropriate.

We consider there to be four areas where the NICE perspective fails to reflect the challenges faced by CCGs, and have contributed to the reduced relevance of the published literature to them as commissioners, we explore each in turn below.

* 1. The cost-effectiveness threshold

The simplification of economic evaluations to a binary statement about expected cost-effectiveness relative to the threshold is potentially misleading for local decision makers for two reasons. Firstly, recent research suggests that the range used by NICE, of £20,000 to £30,000/QALY, is a significant overestimate of the true marginal productivity of the NHS, indicating a figure closer to £13,000/QALY [26]. Claxton et al. also argued that the true value is likely to vary significantly at a local level and that the implications of overestimating the threshold are much worse than underestimating it.

Furthermore, it has been argued that comparing the ICER to a fixed threshold is insufficient to determine cost-effectiveness, as consideration must also be made of the affordability of the intervention [27, 28]. This is especially evident for interventions with significant short term budget impacts, such as the use of sofosbuvir to treat hepatitis-C [29, 30] which was estimated to cost up to £70,000 for each of the 160,000 sufferers in England [31]. Clearly this also applies to bariatric surgery, with an estimated 1.38 million adults [5] fulfilling NICE’s BMI≥40 criteria and the cost of bariatric surgery roughly £9,000 per person in the first year [16]. A crude interpretation of the published research suggests that the large impact of such an intervention can be accounted for by reducing the threshold against which the ICER is compared, in certain cases below £12,000/QALY [27].

* 1. The impact of exceeding budgets and decision uncertainty

At a national level, the implications of exceeding a budget and of uncertainty in the impact of a new service on this budget are undeniably different than at a local level. Taken as a simple comparison between a NICE decision and a commissioning CCG there are few negative implications to NICE (or a publishing author) should a guidance recommendation turn out to be incorrect at a later date, as they are arm’s length from commissioning decisions and funding, and subject to only minimal retrospective assessment.

In contrast, a CCG commissioning an intervention which results in an unexpected budgetary overspend face potentially serious implications such as financial special measures. Not only does a potential overspend deter the commissioning of interventions with high upfront costs, but it also discourages investment in interventions associated with an uncertain cost impact as the implications of success and failure of the intervention are not symmetric. This implies that a CCG may be less likely to take on an investment where there is uncertainty regarding its cost-effectiveness, despite a favourable point estimate.

Both of these issues are evident in tier 3 and 4 commissioning, where not only are the additional costs front heavy, with weight loss programmes and surgery implying a short term cost but aiming to reduce long term expenditure, but there remains a dearth of evidence on the long term resource use implications of either, making the expected results highly uncertain.

* 1. The valuation of future costs and benefits

Under the NICE framework of evaluation a lifetime perspective is recommended [25], with both costs and outcomes discounted at a rate of 3.5% per year. The appropriate discount rate has been argued to depend on several factors, including: the opportunity cost of expenditure today, time preference, catastrophic risk, consumption growth, and the tradability of money and health [32].

Given the high upfront cost of many obesity interventions but health gains in the long term, the discount rate applied has a significant role. While there is published literature exploring the merits of discounting and the most suitable value to apply [32, 33], there has been little consideration of the relevance of the NICE discounting approach to local decision makers. A different rate may be appropriate for local decision makers as they are likely to be faced by different decision criteria than a national decision maker across the factors that impact the appropriate discount rate. For example, the opportunity cost of budget expenditure may differ as they may not have the same access to investment portfolios as national budget holders, budgetary and policy cycles may play a larger role, and they have more restricted budgetary independence. Furthermore, due to their proximity to patients there may be an argument for their decisions to more closely reflect individual time preferences, known to differ from the societal time preferences that are used to inform the NICE approach [33].

Currently, it is not possible to estimate the direction of the difference in the discount rate between national and local decision makers, as factors such as the availability of investment options may reduce the appropriate rate, while the short term nature of budget cycles may increase it. Other factors, such as the reflection of individual time preferences and budgetary dependence, may imply that the assumption of exponential discounting that NICE typically applies is not appropriate, and that other approaches, such as hyperbolic or stepped discounting, are more so.

* 1. Scope of costs included

Finally, it is important to consider the relevance of the costs included in the analyses. Under NICE’s framework all costs to the NHS and Personal Social Services are considered relevant, with all other costs falling on public health budgets, patients, or their carers, not included. However, the budgetary reality faced by CCGs as the commissioners of tier 3 and 4 services are potentially more complex. In addition to the discussion above about the nature of their budgetary independence, local decision makers’ budgetary responsibility often differs from the NICE framework.

Two examples demonstrate this, firstly, it is only until recently that CCGs and NHS Trusts (the providers of services such as secondary and mental health) have started to agree aligned incentive contracts (AICs), largely as a means of progressing towards integrated care services [34]. Without AICs, Trusts have been primarily concerned with maximising hospital income rather than system wide budgets, implying that the impact of Trust interventions on primary care budgets may not carry much weight.

Secondly, public health interventions such and the National Health Checks are commissioned by Local Authorities, not CCGs. As the potential future cost savings associated with such public health interventions fall on CCG budgets through healthcare resource use, and not Local Authority budgets, there is only limited incentive for commissions of such services to fully implement the interventions [35]. The budgetary challenges make the assumption that all NHS and PSS costs are relevant, and no others, potentially misrepresentative of the true local decision maker’s perspective.

1. **Discussion**

The tiered approach to weight loss care in the NHS was designed to provide an effective and cost-effective framework in keeping with the shift to decentralised commissioning that resulted from the 2012 Health and Social Care Act. However, there has been limited commissioning of tier 3 and 4 services by CCGs and significant variation in what is offered [9-11, 20, 22]. This is in spite of repeated economic evaluations demonstrating that, using the NICE framework for cost-effectiveness, bariatric surgery is cost-effective in almost all obese patient groups [16, 17], and tier 3 services appear likely to be similarly cost-effective [20, 21].

We believe that one of the key reasons for the failure of the policy to be routinely commissioned is the incompatibility of the available evidence to the commissioning CCGs, however, there are many other factors at play, including continued risks of weight stigma impacting care provision [36]. In this manuscript we have argued that the failure of the existing evidence demonstrating the cost-effectiveness of the services to reflect a local decision maker perspective has been a key barrier to its uptake. We have highlighted how failure in the national guidance and published research to appropriately consider the relevance of factors such as the cost-effectiveness threshold and the impact of uncertainty and large budgetary changes, has contributed to the evidence relating to the cost-effectiveness of the interventions being inapplicable to CCGs. However, if cost-effectiveness evaluations were to become completely responsive to local conditions there would be the risk of developing a ‘postcode lottery’ of service provision which national decision makers such as NICE are designed to alleviate.

We recognise, however, that the challenges of knowledge translation between national and local perspectives are neither restricted to economic evaluation nor weight management services. Previous research has identified the need for research, in general, to better reflect the true nature of decision making [12-14], and the health and economic value of implementing national decisions at a local level [15], however, the relevance of the core principles underpinning the determination of cost-effectiveness have been largely overlooked.

While the challenges of translating the broader national and international evidence base to local decision makers have been well explored in the literature [12-14], this debate has overlooked the impact of the asymmetries present on the core principles of economic evaluation and the question of cost-effectiveness. While many of the same factors are at play as in the wider topic of knowledge transfer, it is our opinion that the additional knowledge gap present in the interpretation of economic evaluation literature has compounded the impact of this asymmetry.

1. **Conclusion**

As in many developed nations the UK has spent over a decade trying to address the increasing rate of obesity in an attempt to curtail the significant long term health implications associated with excess weight. Political desires to decentralise commissioning and clarify treatment pathways led to the recommendation of a locally commissioned tiered weight loss pathway, allowing the progression of patients through levels of increasing intensity of care, informed by the best evidence on effectiveness and cost-effectiveness published at the time. However, the available guidance has failed to reflect the fundamental fact that the conventional approach to defining the most cost-effective pathway at a national level does not necessarily translate to local decision makers such as the CCGs. As a result, policies that are deemed to be cost-effective have come up against repeated reluctance from local commissioners, resulting in accusations of CCGs failing their responsibility to patients. In this manuscript we have highlighted several reasons why this situation has occurred, and how the current divide between evidence generation and commissioning in areas such as this are to blame.

It is important that both research and national guidance considering the cost-effectiveness of any intervention considers the appropriateness of the economic evaluation framework to the setting in which it is applied, not just in weight loss but all interventions. The routine use of the NICE framework risks recommendations being inappropriate to the respective commissioners, and the funding of policies which are cost-effective from a national perspective, but not at a local level under the current decentralised system. However, there currently exists no equivalent framework directly structured around local decision makers’ perspectives, with CCGs and Local Authorities primarily informed by national guidance published by NICE. Whether commissioning responsibilities and budgetary controls should be reorganised such that the perspectives of the two groups align, or economic evaluations should be conducted to reflect the realities faced by the relevant commissioner requires further debate and research.

**Compliance with Ethical Standards**

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**Author Contributions**

SH, LB and GR conceived the idea for the manuscript, LH provided input regarding the accuracy of the descriptions of the CCG and other local decision maker processes. All authors read and approved the final manuscript.

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