

‘PUBLIC REASONING AND HEALTH CARE PRIORITY SETTING: THE CASE OF NICE’

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ABSTRACT

Health systems that aim to secure universal patient access through a scheme of pre-payments - whether through taxes, social insurance or a combination of the two - need to make decisions on the scope of coverage that they guarantee, such tasks often falling to a priority-setting agency. This article analyses the process of public reasoning at one such agency in particular - the UK’s National Institute for Health and Care Excellence (NICE) – and considers the reasonableness of its priority-setting processes. We find that while NICE’s processes may not necessarily be the ideal priority-setting procedure, nor the only reasonable approach to priority-setting dilemmas, the general framework of NICE’s approach to evaluating health technologies and setting priorities for health care coverage is a reasonable one. As such, NICE’s decision-making method offers an exemplar for other health care systems facing similar coverage dilemmas.

1. INTRODUCTION

Health systems that provide for universal patient access through a scheme of pre-payments - whether through taxes, social insurance or a combination of the two - need to make decisions on the scope of coverage that they secure. It is increasingly recognized that

the best way to do this is to set priorities among competing claims for coverage in an explicit, transparent and fair manner based on cost-effectiveness and other considerations. A recent WHO report recommended that national health care systems set up institutions to make reasonable and accountable decisions on the path to universal health coverage (WHO 2014). In a growing number of countries, governments have already established expert bodies to this effect (e.g. The Canadian Agency for Drugs and Technologies in Health (CADTH), Haute Autorité de Santé (HAS) in France, Health Intervention and Technology Assessment Program (HITAP) in Thailand, Health Insurance Review and Assessment Services (HIRA) in South Korea, Pharmaceutical Benefit Advisory Committee (PBAC) in Australia) (Glassman and Chalkidou 2012). Moreover, even in countries that explicitly reject considering cost-effectiveness in coverage decisions, this stance is now being questioned. For example, one of the most influential medical societies in the U.S., the American Heart Association, recently announced that they would begin to use cost data to rate the value of treatments in their clinical practice guidelines and performance standards (Cardiosource Website 2014; Anderson et al 2014), arguably because system-wide solutions for determining the scope of coverage are lacking (New York Times Website 2014).

Decisions on the scope of coverage are inherently controversial, implying, as they do, that some patients will receive neither comprehensive health care nor complete protection from the financial consequences of ill-health, even when there is a clinically effective therapy to which they might otherwise have access. Controversial decisions of this sort call for legitimisation, i.e. a public justification for a given treatment's inclusion and exclusion from the relevant scheme. Priority-setting agencies play a key role in providing such a justification and, by reaching decisions through legitimate processes, may help to narrow disagreement about what ought to be done.

In this paper, we analyse the process of public reasoning of one priority setting agency in particular, the UK's National Institute for Health and Care Excellence (NICE). We offer this case study for a number of reasons. First, since its establishment in 1999, NICE has secured a high reputation for its work among informed observers in the UK and abroad (Culyer 2006; Hill et al 2003). Although sometimes criticised, its processes of decision-making are widely respected, not least for their rigorous approach to the assessment of value for money in health care. Indeed, NICE International, the institutes' global arm, plays an active role in advising other countries interested in setting up bodies for making explicit coverage decisions (NICE Website 2014a).

Second, NICE has also been praised for its recognition of various procedural and substantive ethical values in its decision-making processes. For example, in respect to the former, in their influential discussion of the idea of deliberative democracy, Gutmann and Thompson (2004) cite NICE as operating an exemplary decision-making process. In respect to the latter, NICE has also been praised for recognising a wide range of what it terms 'social values', like fairness, non-discrimination and responsiveness to need as necessary components of legitimate decision-making (Littlejohns and Rawlins 2009; NICE 2005; NICE 2008).

Third, in its fifteen years of existence, NICE has completed a large volume of work and, correspondingly, been the focus of a large amount of external commentary. Between

2000 and February 2014, NICE published 306 technology appraisals ranging across interventions for conditions as diverse as cancer, multiple sclerosis, depression and anxiety. It has thus built up a considerable body of ‘case law’ alongside the formal statements of its decision protocols, much of which has prompted political mobilisation by patient groups, vocal opposition by industry, hostile coverage in the press, and controversy among parliamentarians, political activists and academics, especially when NICE decision has been negative and NHS coverage for an intervention has not been recommended. NICE’s body of work and the debate it has engendered therefore offers a rich resource for commentary and analysis.

Focusing on NICE, then, in this article we aim to evaluate its approach to priority-setting. Specifically, we consider the extent to which NICE’s approach to evaluating health technologies is *reasonable*. In doing so, we offer something of a departure from the standard measure against which most priority setting bodies are evaluated. That is, following the enormous success of Daniels and Sabin’s *Accountability for Reasonableness* (AfR) framework (Daniels and Sabin, 2008), the justifiability of priority setting mechanisms is often now taken to consist in their *procedural* virtues; that is, the extent to which they are *accountable* for their reasonableness (or lack of it). In this analysis, by contrast, we evaluate the *substantial values* of NICE’s methods against Daniels’ more limited sense of *reasonableness* (itself largely inherited by Rawls), wherein reasonableness is said to abide in the extent to which decision-makers’ appeal to reasons, including values and principles, ‘that are accepted as relevant by people who are trying to find ways of cooperating with each other on mutually acceptable terms’ (Daniels, 2008, 124). Such an evaluation may complement an evaluation of NICE’s procedural virtues against AfR – in particular by giving an account of how far NICE’s reasoning can be considered to meet the AfR’s ‘relevancy’ condition – yet, significantly it can also exist independently of it (a body such as NICE may be reasonable without being accountable by Daniels and Sabin’s definition).

Our argument proceeds as follows: in Section Two we set out the nature of NICE’s process. Here we argue that while NICE has been exemplary in publicising its methods, confusion about the detail of that method remains. In particular, NICE’s use of evidence on a given technology’s cost-effectiveness is often wrongly described as part of an implicit or explicit attempt to maximize the sum-total of Quality-Adjusted Life-Years (QALYs) gained within the NHS. Instead, we show that NICE’s use of cost-effectiveness data is best understood as dictated by a satisficing strategy, wherein NICE assumes a presumption not to fund interventions the cost-effectiveness of which (compared to an existing treatment) is below a minimum threshold. We also stress that in both theory and practice, NICE takes this presumption to be rebuttable: that is, it can be overturned by considerations drawn from public social or ethical values. In Section Three, we then set out the notion of ‘reasonableness’ against which we aim to evaluate NICE, its relevancy as a standard of evaluation in this domain and why, at a basic level, it would be unreasonable for such systems *not* to have at least some body that sets priorities for healthcare coverage based on publicly justifiable principles. In Section Four, we then show that, as well as it being generally reasonable that some body is instructed to set priorities for healthcare coverage, NICE’s method of prioritising treatments for coverage – its rebuttable presumption to fund

interventions below a given threshold of cost effectiveness – is also reasonable. While this argument shows that NICE’s *general* framework for prioritisation decisions is reasonable, its *particular* application of that framework may be more open to question. In particular, in the last section, we question its choice of cost-effectiveness threshold and the rationale for that choice, its process of choosing certain social or ethical values as grounds for departing from that threshold, and its adjustment of its threshold in light of those social and ethical values.

2. NICE’S APPROACH TO PRIORITY-SETTING: THE PRESUMPTION OF COST-EFFECTIVENESS

NICE is responsible for a variety of functions within the English National Health Service clustered around the production of guidance. These include clinical guidelines which advise on the appropriate treatment and care of patients with specific diseases and conditions; guidance on interventional procedures, which detail the safety and efficacy of any surgery, test or treatment that involves entering the body; and guidance on public health activities, i.e. those that to promote a healthy lifestyle and prevent ill health (for example, giving advice to encourage exercise or providing support to encourage mothers to breastfeed). The core elements of NICE’s work, however, are its technology assessments, that is, its guidance to NHS purchasers on whether a given intervention (typically pharmaceuticals, devices, diagnostics, surgical and other procedures and health promotion tools) constitutes a ‘good buy’. In theory, if not in practice, these technology appraisals have the potential to have a profound impact on the range of services and treatments the NHS provides. If an intervention passes NICE’s evaluation process, then it is recommended for use within the National Health Service and those commissioning services have an obligation to make them accessible to the populations whom they serve (the NHS Constitution giving patients have the right to services and treatments recommended by NICE) (Department of Health 2013). If the intervention is not recommended, NHS purchasers are still free to fund that intervention if they so wish but not obligated to do so.

In the first instance, NICE’s appraisal agenda is set by the Department of Health. However, it also has a significant autonomy in deciding exactly how the issues for any one appraisal are determined and it operates with expert panels for appraisals that it constitutes and convenes. Key stages of the evaluation process are as follows:

- 1) An initial choice of which technologies are submitted for appraisal. Potential topics come from the National Institute for Health Research (NIHR) Horizon Scanning Centre, individual healthcare professionals, NHS commissioners, and the Department of Health’s policy teams. Ministers at the Department of Health make the final decision about which topics are referred to NICE for appraisal.
- 2) A ‘scoping’ process, wherein the Institute determines the appropriateness of the proposed remit and defines the specific questions that each technology appraisal will address.
- 3) An ‘assessment’ process, wherein an independent academic group is tasked with a systematic evaluation of the relevant evidence available on a technology (including

evidence pertinent to its cost-effectiveness) either from published data or the submission of a report from Industry.

- 4) An ‘appraisal’ process, wherein an Appraisal Committee considers evidence contained in the reports and analyses produced in the assessment phase and additional information supplied by consultees, commentators, clinical specialists, patient experts and commissioning experts.
- 5) A regular review of values for use in the appraisal of new technologies by a ‘Citizen’s Council’. This council, set up in 2002, consists of 30 members of the public (aiming to reflect the demographic characteristics of the UK), and considers some of the social and ethical values mentioned in *Social Value Judgments* (e.g. age, rule of rescue, ultra orphan drugs) (NICE Website 2014b). The Council has published 16 reports to date, some of which address additional social and ethical values that are recognized or rejected as constraints on cost-effectiveness (NICE Website 2014c).

In the context of these procedures, NICE uses a decision protocol prioritising cost-effectiveness data. NICE’s assessment of cost-effectiveness contains the following elements (NICE 2013):

- 1) Evaluation of effectiveness: NICE seeks to identify the benefits arising from a health care intervention. The benefit is defined as the average improvement in the health status of individuals receiving the intervention over and above any other gain they might receive. The key measure of this benefit is the gain in QALYs that a typical individual derives from an intervention. Health benefit is therefore measured by reference to both an extension of life and an improvement in the quality of life.
- 2) Evaluation of cost: In the case of technology appraisals, costs are total NHS and personal social service costs. For medicines and devices, costs are given by the published list price. In recent years there has been some modification of this arrangement in the case of “patient access schemes” (which is to say, innovative pricing agreements designed to improve cost effectiveness and facilitate patient access to specific drugs or other technologies) negotiated between Industry and the Department of Health. However, such schemes are usually initiated when draft guidance from NICE suggests that the intervention is not cost-effective.
- 3) Evaluation of cost-effectiveness: NICE evaluates an intervention by reference to its ‘incremental cost-effectiveness ratio’ (ICER). NICE defines the ICER as ‘the ratio of the difference in the mean costs of an intervention compared to the next best alternative (which could be no action or treatment) to the differences in the mean health outcomes’ (NICE 2008). Although NICE has explicitly denied having a maximum value of an ICER above which it does not recommend an intervention (NICE 2002), based on its decisions to date, commentators have surmised that its normal threshold cost per QALY gained (i.e. prior to any other consideration) is between £20,000 and £30,000 (Towse 2002).

It is sometimes asserted that NICE’s use of cost-effectiveness data in evaluating health care technologies is best interpreted as part of an implicit or explicit attempt to

maximize QALY gain within the NHS. For example, Shah *et al.* suggest that ‘The use of cost effectiveness analysis in NICE's technology appraisals reflects an underlying ‘non-welfarist’ or ‘extra welfarist’ normative position that the principal aim of the NHS is to maximise QALYs’ (Shah et al 2012, p. 158; Schlander 2008; Neuman and Greenberg 2009). Similarly, Alan Williams (2004, 6) argued that technology assessments were ‘driven by the objective of maximising population health subject to a budget constraint’. Indeed, such an interpretation is even suggested by NICE itself. For example, in its document on *Social Value Judgements*, NICE states that it incorporates a maximizing approach into its work, as an expression of one principle of justice in the distribution of health care resources (NICE 2008).

However, there are reasons for resisting such an interpretation. First, if NICE *were* attempting to follow a maximizing approach, one would normally expect it to make some sort of effort to identify and prioritise those interventions that offer the least cost per QALY gain out of all those interventions that might be funded. Such an endeavour might typically involve drawing up a league table of all relevant interventions setting them in some order of priority, much like the first stage of the Oregon health care plan, in which a league table was drawn up with the intention of discontinuing funding below a limit of cost-effectiveness (Tengs et al 1996). Indeed, Alan Williams, (2004, 16-18) an influential figure in the establishment of NICE, once suggested that this is precisely what NICE should do, arguing that it needed to develop ‘a comprehensive cost-effectiveness audit of all the main clinical activities of the NHS’ (which he thought would number around 300 interventions accounting for 90% of the main clinical work), with the aim of checking which ones met the threshold. However, what NICE actually does is assess technologies one by one, making piecemeal judgements about whether a particular intervention meets its threshold degree of cost effectiveness, irrespective of whether that intervention offers the least cost per QALY gain of all those interventions that might be funded. Such an approach does not equate to a maximizing strategy. To offer an analogy, according to Disney World's height restrictions, to ride *Big Thunder Mountain Railroad* passengers must be at least 40 inches tall, but this does not mean the height of passengers will be ‘maximised’, given the pool of prospective riders, for in order to that, Disney World would need to rank all prospective riders by their height, prioritising the tallest first. Instead, entrants are required to meet a specified minimum.

Another reason for resisting the ‘maximizing’ gloss on its use of cost-effectiveness data is that NICE only judges the cost-effectiveness of those interventions it assesses ‘compared to the next best alternative (which could be no action or treatment)’ (NICE 2008). In other words, a new treatment will be funded if the health gain that it provides *relative* to the existing standard treatment comes in at below the threshold cost. Again, this fails to equate to a maximising strategy, for where the existing standard treatment is of low-cost effectiveness, the new treatment may be incrementally cost-effective, even it would be of low cost-effectiveness in absolute terms.

It might be argued that, while each choice NICE makes may not be *optimally* maximizing (given its failure to engage in a synoptic approach), the cumulative effect of its piecemeal decisions over time will lead to a defined set of interventions with the highest value, measured by aggregate health gain for a given budget. However, for this to be true, the target of its evaluations – that is, costs and benefits of the services and treatments under

scrutiny – would need to remain constant over the course of the decision-making process and, needless to say, this is simply not reflective of the context in which NICE’s evaluations are made. In reality, each assessment requires substantial information gathering and processing and during that time new medical treatments are developed; the benefits package being, in this sense, a moving target. Thus, as students of public policy have recognised since the pioneering work of Simon on bounded rationality, as well as Braybrooke and Lindblom on incrementalism in policy making, a synoptic view of policy agendas is rendered practically impossible simply by virtue of the demands of information collection and processing (Simon 1976; Simon 1983; Braybrooke and Lindblom, 1963). Rather than taking NICE to be operating a kind of non-optimum maximizing strategy, then, it is clearer to think of NICE’s process in terms of what Simon called ‘satisficing’, or ‘satisfying of the minimum’ (cf. Lord, Laking, and Fischer 2004), in this case, ensuring that each recommended technology fulfils a minimum cost-effectiveness threshold.

Having established data on how far a given intervention satisfies its cost-effectiveness threshold, NICE next recognizes a further set of ‘social values’ as considerations that may justify recommending a technology whose ICER puts it over that threshold (Devlin and Parker 2004; Rawlins and Dillon 2005; Culyer 2006; Rawlins, Barnett and Stevens 2010). As NICE states in Principle 3 of its *Social Value Judgments*: ‘Decisions about whether to recommend interventions should not be based on evidence of their relative costs and benefits alone. NICE must consider other factors when developing its guidance, including the need to distribute health resources in the fairest way within society as a whole’ (NICE 2008).

An important note on terminology here: the suggested distinction here between NICE’s assessment of cost-effectiveness and its use of ‘social values’ as grounds upon which decisions may depart from a strict adherence to that assessment can be misleading, for, of course, NICE’s use of cost-effectiveness data and the metrics upon which it is based are themselves imbued with social value judgments; for example, one might think here of Dan Brock’s seminal work on the value judgments implicit in the use of the QALY (Brock 2004). Principle 3 of NICE’s *Social Value Judgments* is typical of this confusion, since it appears to draw a contrast between decisions based on evidence of a technologies ‘relative costs and benefits’ and decisions based on an understanding of how health resources can be distributed ‘fairly’. However, in order to ensure readability across NICE documents and subsequent commentary, we maintain this somewhat artificial divide over the course of this paper.

NICE adopts a two level process for assigning weight to ‘social value judgments’ in its decision-making process. At one level, departure from an ICER of over £20,000 per QALY gained is considered acceptable on the basis of five considerations (described in its *Guide to the Methods of Technology Appraisal* as ‘modifiers’): i) the degree of certainty around the ICER; ii) whether there are strong reasons to doubt whether the assessment of the change in health-related quality of life has been captured adequately; iii) the innovative nature of the technology; iv) whether the technology meets the criteria for special consideration as a ‘life-extending treatment at the end of life’; v) aspects that relate to non-health objectives of the NHS (NICE 2013).

In a recent consultation document, NICE has outlined plans to expand this list to include two further modifiers: vi) ‘burden of illness’, (defined as the proportional loss or shortfall of QALYs occurring as a consequence of having a disease or condition, when

compared with the QALYs that people would expect to have over the rest of their lives without the condition from the point at which the new treatment is to be used), which will replace special consideration to ‘end of life’; and vii) ‘wider societal impact’, (defined as the absolute loss of QALYs a person suffers as a result of living with the disease or condition, measured by subtracting the total QALYs expected as a consequence of having the condition from the total QALYs expected for people with the same age and gender distribution without the condition) (NICE 2014). However, at the moment such changes remain only proposals.

Together, NICE takes modifiers i) – v) possibly to warrant a departure from the ICER of £20,000 cost per QALY, where Appraisal Committees need to make an increasingly stronger case for recommending the intervention with reference to the factors considered above as the ICER climbs over £20,000 (NICE 2013). Although NICE has never issued specific instruction to Appraisal Committees with regard to the upper limit of the additional weight they should attach to the health benefits achieved by technologies in light of such considerations, in practice in the fifteen years the Technology Appraisal Programme has been running, the cumulative weight in circumstances where all modifiers apply has not exceeded 2.5 from a starting point of £20,000 per QALY (NICE 2014).

As well as those values specified as grounds for weighting QALYs, NICE also uses a set of further social and ethical values outlined in its key document *Social Value Judgements*. Some of these are follow from NICE’s institutional context. For example, under UK law, NICE has an obligation to avoid discrimination, so that factors like race or ethnicity, age, sex or gender, and sexual orientation are only to be considered as relevant if clear evidence shows them to be proxies for clinical effectiveness (NICE 2008). However, NICE also includes other values taken to be widely held in UK society, including special consideration of the needs of disabled people, special consideration of the relief of stigma, reducing health inequalities (especially by benefiting the most disadvantaged), amongst others (NICE 2008).

While recognising these values, however, NICE either ignores others, or explicitly rejects them (e.g., individual choice or preferences, rule of rescue, treating rare conditions as special, age as a proxy for social worth, personal responsibility for health, socio-economic status) (NICE 2008). Precisely where and how those values that NICE includes within its decision-making process enter into its evaluation of a given technology’s merits is not always clear. However, the influence of such values in justifying departures from a strict accounting of a given technology’s cost-effectiveness is clear enough. For example, Devlin and Parker (2004) show that cost effectiveness, uncertainty and the burden of disease together explain NICE decisions better than cost effectiveness alone. Moreover, Table 1 gives examples where NICE has explicitly recognised certain values as influencing evaluations of particular technologies.

[Table 1 about here.]

Overall, then, how are we best to conceptualise NICE’s process? We propose that NICE’s method is best thought of as setting a rebuttable presumption or default to prioritize the social value of cost effectiveness that can be modulated by other social or ethical values, such as reducing health inequalities. It is this method, then, that we look to evaluate in the next few sections.

3. REASONABLENESS, ITS RELEVANCY WITH RESPECT TO PRIORITY SETTING AGENCIES AND THEIR NECESSITY

Our aim in this essay is to evaluate the extent to which NICE's method might be considered reasonable. The concept of reasonableness we draw on here is largely inherited from the philosophical literature, in particular Daniels's description of reasonableness in resource allocation, as requiring 'appeals to reasons, including values and principles that *are accepted as relevant* by people who are trying to find ways of cooperating with each other on mutually acceptable terms' (2008, 124), and Rawls' conception of reasonableness as a willingness to propose fair terms of cooperation and abide by them (provided that others do) (1993, 48-54).

One important feature of this concept is that it allows for an allocation of resources that is reasonable and yet at the same time is based on a set of reasons about which reasonable people might disagree. A disagreement is reasonable when it is possible for reasonable and well-informed individuals to continue to disagree about the topic despite all the evidence and arguments that can be brought to bear on both sides. For example, Rawls argues that reasonable disagreements occur because of a variety of epistemic factors that make achieving unanimity unlikely, including i) 'The evidence - empirical and scientific - bearing on a case may be conflicting and complex, and hard to assess and evaluate'; ii) 'Even where we may agree fully about the kinds of considerations that are relevant, we may disagree about their weight, and so arrive at different judgements.'; iii) Our moral concepts are 'vague and subject to hard cases', and so we need to employ interpretive skills to apply moral concepts. Different people may reasonably disagree about interpretations in such cases'; iv) 'The way we assess evidence and weigh moral and political values is shaped... by our total experience, our whole course of life up to now; and our total experiences surely differ'; v) 'Often there are different kinds of normative considerations of different force on both sides of a question and it is difficult to make an overall assessment' (2001, 35-6).

Overall, then, the actions of a decision-making body might be said to be *reasonable* to the extent that they appeal to reasons accepted as relevant by people who are trying to find ways of cooperating with each other on mutually acceptable terms; *unreasonable* to the extent that they *do not* appeal to reasons accepted as relevant *etc.*; and that they might *still* be considered reasonable *even if* they ultimately rest on matters about which reasonable people might disagree.

Why think that whether an institution such as NICE meets the criterion of reasonableness is important? That is, why think that it matters, ethically speaking, whether NICE is reasonable or not? In our view, the moral significance of how far NICE is able to meet this standard arises from the institutional context in which NICE operates, that is, the effort on the part of the UK government – and in this case, their agent, the NHS – to secure universal access to medical care.

As is the case in the overwhelming majority of modern health care systems in high income countries - and increasingly in middle income countries – in order to secure universal access to medical care the UK operates a system of 'shared savings' (White 1995) by which

the financial risks associated with health care costs are spread widely among those living in the country through systems of pre-payment. Two features of this model are relevant here: first, in tax-funded systems, like those of the UK, spending on health care is in direct competition with spending for other politically determined goals, for example education, transport or security. Second, the fixed budgets of these systems are insufficient to cover all conceivable and technically possible medical needs. To begin with, new therapies can be expensive per unit cost. For example, Novo Seven, a recombinant therapy for haemophilia resistant to first line treatment, costs €6,000 per dose, with doses needing to be administered every two hours until bleeding stops, a protocol that in one German case led to total costs of over €2m for one patient (Social Values Project Website 2014a). Moreover, even where unit costs are low, the widespread use of interventions that by themselves are relatively modest in cost can lead to considerable expenditure. For example, the National Health Service in the UK spent £321.7m on atorvastatin in 2009 (The Health and Social Care Information Centre 2010), though its unit costs in 2005 ranged from £0.35 to £0.64 to per patient per day (NICE 2006).

By virtue of the economic constraints in which it occurs, then, health care expenditure within a system of shared savings might be seen to automatically invoke the ethics of opportunity costs. Given that money spent on one set of interventions will inevitably displace resources devoted to other interventions, public authorities need to evaluate the opportunity costs involved in funding one set of health care intervention over others. Unless a positive decision to spend on one form of treatment is set against the forgone opportunity of the same resources going to other forms of treatment, there is a risk of unfairness in the allocation. In particular, those most able to articulate their case may well be disproportionately favoured at the expense of those less articulate.

For this reason, any body tasked with making decisions as to how resources are allocated such as NICE might be thought to be under a general duty to act *reasonably*. That is, at a minimum, a rationale must be provided that makes clear how the social values and the processes involved in such priority setting decisions are acceptable to those seeking fair terms of cooperation. This requirement might be thought of as both a moral requirement and an obligation arising from the social contract upon which many publicly-funded health care systems are built.

Drawing on the discussion of reasonableness earlier, we might also make three important points about the allocation of healthcare resources. First, a scheme of shared savings in health can be reasonable even when it entails that some interventions will not be funded. Perhaps the least contentious case of a reasonable refusal to fund a particular treatment would be when funding it would displace a greater number of more effective treatments – as when a therapy is of high cost but only marginal effectiveness. Second, there can be *reasonable disagreement* about the social values and processes to be used in prioritising healthcare. Third, we might also say that any attempt to contain costs for healthcare treatments by setting explicit priorities will require a body that is similar to NICE. Such bodies may invoke different values but in all cases there will need to be explicit appeal to publicly-held social values, to justifiable processes, and there will need to be a body to make the choices. Institutions like NICE, therefore, meet a general criterion of reasonableness, in that they should be considered reasonable by fair-minded people who are

trying to find ways of cooperating with each other on mutually acceptable terms, or who are willing to propose fair terms of cooperation and abide by them provided that others do. In this sense, they reflect a duty of reciprocity among the beneficiaries of a scheme of shared savings: those who benefit from scheme of mutual advantage have an obligation to restrain their demands where this is required for the viability of that scheme.

Given this, it is not surprising to find that many countries now have institutions like NICE that conduct various forms of health technology assessment and health care priority-setting. Rather, perhaps what is more surprising is that certain countries have been known to deny the need for such bodies altogether. Indeed, it is a natural outcome of the analysis thus far that while there might be room for reasonable disagreement about some of the particular social values and the processes that NICE uses – indeed they might be unreasonable altogether – it does not look like there is much room for reasonable disagreement that a system of shared savings in health will require *some* kind of priority setting body for healthcare, indeed to argue the opposite seems *unreasonable*. The only alternatives to authorising a body to set priorities would appear to be unconstrained expansion of the healthcare budget (something that neither governments nor citizens in systems of shared savings should allow), or forms of implicit rationing (which would fail to meet requirements of transparency and consistency). Neither approach is reasonable. Society is best served if it has institutions and agencies in which the terms of the social contract for shared health care savings can be clarified and openly debated.

It is difficult to deny, then, that it is reasonable to have a body that performs healthcare prioritisation in a system of shared savings. But it does not yet follow from this that the particular values and processes through which NICE has attempted to deal with these problems are reasonable. It is to this matter that we turn in the next two sections.

4. THE REASONABLENESS OF NICE'S APPROACH

As seen in Section Two, NICE uses cost effectiveness as a filter: a cost per QALY of *less* than the threshold amount will nearly always be sufficient to guarantee that the medical technology is approved. Above the threshold, a technology will be approved if there are social values that give sufficient reason to overturn the default assumption. There are two fundamental ways, then, in which the reasonableness of NICE's methods need to be justified: a) the reasonableness of having a cost effectiveness threshold that functions as a default; and b) the reasonableness of departing from that default on the basis of a given set of social values. We turn to related matters, such as the justifiability of NICE's actual choice of cost effectiveness threshold, in Section 5.

a. The Reasonableness of NICE's Use of a Cost Effectiveness Threshold as a Default

The main justification for NICE's focus on cost-effectiveness again derives from the ethics of opportunity costs. Section Three explained how attention to opportunity costs is required in order to protect a system of shared savings - given that money spent on one set of interventions inevitably displaces resources devoted to other interventions, public authorities

need to evaluate the opportunity costs involved in funding one set of health care intervention over other. Within such protocol, NICE's attention to cost-effectiveness is rendered as an implicit value-judgment on the acceptability of certain displacements over others: that is, to be considered acceptable, those technologies that displace existing services must be able to secure a certain level of health benefit, relative to those services it displaces. The recognition of this logic is explicitly recognised by NICE when it states that those 'developing clinical guidelines, technology appraisals or public health guidance must take into account the relative costs and benefits of interventions (their "cost-effectiveness") when deciding whether or not to recommend them' (NICE 2008). Such logic might also be seen to follow Dworkin (2000, 315), who once argued that it would be a 'disservice to justice' for some citizens to expect others to contribute to cost-ineffective care, that is to say care that only marginally extends life of relatively poor quality.

Again, there may be disagreement about whether NICE's privileging of certain treatments on the basis of their ability to secure a certain level of health benefit over those that do not is the most important concern in questions of health care justice. However, to the extent that such disagreement exists, it looks like *reasonable disagreement* in the sense we have described: that is, a disagreement that persists even amongst reasonable and well informed individuals despite all the evidence and arguments that can be brought to bear on both sides. In this sense, then, while commentators might question whether NICE's use of a cost effectiveness threshold as a default represents the optimum strategy in priority setting dilemmas, they would be hard pressed to argue that such a strategy is unreasonable.

As an important side point, it should also be pointed out that NICE's use of a cost-effectiveness threshold as a default might easily be justified on more instrumental grounds. For example, giving a strong emphasis to cost-effectiveness is an effective policy tool to guide innovation in health care as well as pricing of new interventions. By specifying a cost-effectiveness threshold that health care interventions must meet, NICE communicates clearly to innovators what level of clinical effectiveness interventions should generally achieve, and how they should be priced, in order to qualify for reimbursement through the shared system of savings.

b. The Reasonableness of Departing from the Default on the Basis of a Given Set of Social Values.

As set out in Section Two, although NICE's method gives primacy to cost-effectiveness, it does not make decisions solely on whether a given intervention passes its threshold, rather it recognizes that other social or ethical values act as constraints on prioritizing cost effectiveness, and that these values can justify exceeding the general cost per QALY threshold. Again, this is eminently reasonable.

If NICE's focus on cost-effectiveness reflects a shared interest in the prudent use of resources, it is important that that interest is also framed by sensitivity to other claims that individuals have as a matter of justice to the benefits of those shared savings. Some of these claims may be served by a wider effort to ensure cost-effectiveness. However, some will not and, as is recognised by a wide variety of both consequentialist and non-consequentialist ethical theories, such values ought to constrain our judgements on what constitutes a just distribution of resources overall. That NICE only sets a *default or rebuttable presumption* to

prioritize the social value of cost-effectiveness rather than making its decisions in light of cost effectiveness data alone, then, is justified by a minimally pluralistic account of justice, even though reasonable people might disagree about the particular constraints that NICE recognizes and the relative importance it attributes to providing value for money.

5. AREAS FOR IMPROVEMENT

We have argued that the general structure of NICE's method – its setting of a presumption to prioritize cost-effectiveness rebuttable in light of certain social values - is reasonable. But to say that this general structure is reasonable is not to say that it, or the particular way in which NICE's applies it, cannot be improved. In the following, we outline three areas in which NICE's application of its method looks questionable. We also argue that each of these might be seen as a problem of *procedure* – of NICE failing to make its reasoning transparent – rather than of *substance* – of NICE committing an error, or making arbitrary decisions. However, bereft of proper explanation, NICE remains open to the charge that its actions are, in some respects at least, unreasonable.

a. The Cost-Effectiveness Threshold.

The reasonableness of NICE's cost effectiveness threshold depends on not just on the fact that it sets a cost effectiveness threshold but on the level at which that threshold is set and the rationale for this level.

As set out in Section Two, despite NICE's explicit assertions to the contrary, analysis of its decisions seems to imply that it currently operates a threshold of around £20,000 to £30,000 per QALY gained. Although NICE also remains silent on the rationale for this threshold (which it hasn't explicitly claimed exists), other sources make clear that it is taken to be the mean cost of producing a QALY elsewhere in the healthcare system (Claxton and Culyer 2007). If £20,000 to £30,000 is the mean cost of producing a QALY within the NHS, then this threshold looks reasonable: within a fixed budget system, funding a new treatment will have the implication that some activities currently being undertaken will have to be foregone. If a new treatment is funded that costs more per QALY than the threshold, then funding the new treatment will displace activities that would have created more QALYs. So, unless there are reasons for thinking that the treatment should be funded despite its displacing a greater health benefit elsewhere (and if so, they should be captured by the social value judgments), it should not be funded.

However, NICE's use of the £20,000 - £30,000 threshold looks questionable on a number of points. First, we might be generally suspicious of the thought that the threshold marks the mean cost of producing a QALY within the NHS, simply on the basis that it does not appear to have been altered in NICE's lifetime. Even assuming that the threshold was set at the right level when NICE began, then, it would be very surprising if it were still at the right level. Second, recent research has suggested that there is good reason to doubt whether £20,000 - £30,000 is the mean cost of producing a QALY within the NHS. Claxton et al. (2013), for example, make a persuasive case that the cost to QALY in the wider NHS being £12,936 per QALY gained, meaning NICE's existing threshold is too high and that

recommended interventions are displacing those purchasing greater numbers of QALYs at equal or lower cost.

b. NICE's Choice of Social or Ethical Values

NICE's choice of certain social or ethical values as considerations with the power to overturn its cost-effectiveness threshold might be thought of as a paradigmatic case of a set of judgments about which people might reasonably disagree. Paraphrasing Rawls's thought quoted earlier, here it seems we might reasonably question NICE's choice of certain values as either relevant or irrelevant, its formulation of those values and the relative weight it assigns to included values within its decision making process, both in respect to its more general priority of cost-effectiveness and in relation to one another.

However, even if we recognise the *outcome* of these kinds of decisions as inherently contentious, to be considered reasonable the *way* in which NICE chooses which values to include and exclude still needs to abide by requirements of good public reasoning; that is, they still need to be made on the basis of a set of reasons and, in Daniels' phrase, those values and principles '*accepted as relevant*' by people who are trying to find ways of cooperating with each other on mutually acceptable terms (2008, 124). The way in which NICE seems to choose which social and ethical values have the potential to overturn its cost-effectiveness threshold, however, remains confused and confusing. In *Social Value Judgements*, for example, NICE sets out a range of reasons for rejecting a range of different social or ethical values but such rationales lack consistency and clarity: the 'rule of rescue' is rejected on normative grounds (the need to balance the needs of individual patients with the needs of present and future users of the NHS); 'age as a proxy for social worth' and 'personal responsibility' are rejected because the Citizen's Council said so; 'rare conditions' are excluded because they fall outside NICE's remit (other NHS institutions manage the availability of 'ultra-orphan drugs'). On occasion, values are also rejected without explanation: for example, no explicit reason is given for why 'socio-economic status' should not be considered, though it is explicitly ruled out.

To better defend the reasonableness of its choices, NICE needs a clear process for deciding on which social and ethical values can overturn its cost effectiveness threshold and which are deemed irrelevant. Most notably, it needs to find a way of arbitrating between the different demands of ethical considerations (e.g. its considerations of normative arguments in the case of its exclusion of 'the rule of rescue'), procedural dictates (e.g. its focus on the outcome of Citizen Council meetings in its exclusion of 'personal responsibility') and institutional directives (e.g. its considerations of NICE's remit in its exclusion of 'rare conditions').

c. How NICE Uses Social and Ethical Values in its Decision Making Process

As described in Section Two, NICE operates a two-fold process in bringing social and ethical values (other than cost-effectiveness) into play in appraising technologies for funding on the NHS: an initial stage where departure from an ICER of over £20,000 per QALY gained can be justified by appeal to matters of certainty, doubts about assessments of change in health-related quality of life, innovation, end of life considerations and aspects that relate to non-health objectives of the NHS; and another stage wherein a number of further ethical

values including special consideration of the needs of disabled people, relief of stigma, health inequalities and NICE's obligations under UK law are brought to bear on decisions over whether or not a technology ought to be recommended for use on the NHS. In marked contrast to the extensive detail NICE enters into in describing its method for assessing cost effectiveness, however, neither of these processes for taking other social and ethical values into account are particularly clear.

Although NICE's *Guide to the methods of technology appraisal* explains that Appraisal Committees can use 'modifiers' to weight health benefits achieved by technologies and, in this sense, bring them into play in their 'judgment' of a technology's overall cost-effectiveness, no explicit instruction is given either to how this weighting should be done or what would be a maximal weight for individual considerations or all in tandem (although, as mentioned earlier, precedence seems to discourage a maximum cumulative weight of over 2.5 from a starting point of £20,000 per QALY) (NICE 2013).

NICE's process of applying those social and ethical values outlined in its *Social Value Judgements* is, if anything, less clear. *Social Value Judgements* itself explains that these values should be used by NICE and its Appraisal Committees 'in designing the processes it uses to develop its guidance (recommendations), and in developing individual pieces of guidance'. However, at no point does the document explain how such Committees are supposed to employ the principles it outlines; for example, whether they are supposed to consider the impact of each and every value in each technology appraisal, how the different demands of each value are supposed to be balanced against one another, how they are supposed to relate to 'modifiers' such as certainty and innovation, and so on. At one point, *Social Value Judgements* does instruct Committees to include a statement of 'broad compliance' with the principles it outlines, and justify any departure from the principles it includes'. However, this instruction only tells Committees that they must not act against the social and ethical values detailed in the document, not how to bring such principles to bear on the judgments they are making.

At this point, of course, it may be argued that no-one has yet constructed an algorithmic method to balance various values against one another and that, as such, to criticise NICE for failing to succeed on this score is to hold them to an unachievable ideal. However, although it is true that such a method is lacking, various proxies are available, not least balancing through deliberation. Indeed, it may be that this *is* the method that NICE uses. Yet, if it does, then it really needs to say so. For without such an explanation, NICE's use of social and ethical values as considerations that can overturn its general primacy to cost-effectiveness seems reasonable, can look deficient, even arbitrary. Again, this seems to leave NICE open to the accusation that its methods are, in their particulars if not generalities, unreasonable.

d. A Substantive Issue or a Process Issue?

Following from the last point, it could be argued that all the criticisms levelled at NICE above are open to an important counter-argument: namely, that such criticisms mistake a process problem for a substantive problem. On this line of argument, then, it is not that NICE's methods, either in their setting of the threshold, choosing of social and ethical values, or taking those social and ethical values into account in their decisions, are themselves

deficient, rather it is just that NICE has failed to adequately explain and articulate its various ways of working and rationales for the decisions it makes.

Given we are commenting on NICE's processes from the outside, this possibility must be recognised. However, even if NICE's failure is only a failure to adequately communicate its processes, that is still a significant criticism of its ways of working. As commented in the introduction to this essay, priority-setting bodies such as NICE may be evaluated not just on the principles they bring to bear in their decision-making processes (as we have done in this article), but on the character of their processes. In the latter category, the most influential model of good practice here is Daniels' Accountability for Reasonableness (AFR), which claims that, to be considered fair, regardless of what substantive principles they use in their decision-making processes, priority setting bodies such as NICE need to meet four conditions: that decisions regarding coverage for new technologies and their rationales must be publicly accessible; that these rationales must rest on evidence, reasons, and principles that all fair-minded parties (managers, clinicians, patients, and consumers in general) can agree are relevant; that there is a mechanism for challenge and dispute resolution regarding limit-setting decisions; and that there is either voluntary or public regulation of the process to ensure that the first three conditions are met (Daniels and Sabin 2008; Daniels 2008). Generally speaking, NICE fares well when measured against Daniels' four conditions of a fair decision-making procedure. Indeed, NICE has added several important procedural requirements missing from the original AFR framework (e.g. stakeholder involvement through its use of Citizens Councils for revising its processes and, in particular, social value judgements). However, if NICE has failed to adequately communicate its processes around setting the threshold, choosing social values, or using social values to justify departures from the threshold, it has also failed to abide by best practice described by AFR, namely by failing to make the rationales for its decisions publicly available.

6. CONCLUSION

NICE's approach to priority setting provides a standard framework in which the worth of different interventions can be discussed. What NICE's process offers is a priority setting process which privileges cost effectiveness but considers it defeasible. It operates, then, by a presumptive standard decision framework, or default approach, that clarifies issues and enables citizens and their representatives to see what complexities emerge. In this, we consider NICE's approach eminently reasonable, even if it is an approach that can meet with reasonable disagreement.

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Table 1: The Use of Social Values to Overturn Pure Cost-Effectiveness

Technology Appraised	Description	Initial assessment of ICER	Additional values considered	Accepted or Rejected
Sunitinib (Social Values Project Website 2014b)	Treatment for renal cell carcinoma	Between £49,300 and £54,366 per QALY gained	End-of-Life as a special case; Innovation	<i>Accepted</i> - if a patient has an ECOG performance status of 0 or 1 and there are no further treatment options recommended by NICE after first-line sunitinib treatment
Trastuzumab plus cisplatin and capecitabine or 5-fluorouracil (Social Values Project Website 2014c)	Treatment for advanced and metastatic cancer.	For the whole population covered by the marketing authorisation - between £63,100 and £71,500 per QALY gained. For IHC3-positive subgroup - between £45,000 and £50,000 per QALY gained.	End-of-Life as a special case	<i>Rejected</i> for the whole population covered by the marketing authorisation. <i>Accepted</i> for HER2-positive, gastric cancer who have not received prior treatment for their metastatic disease and whose tumours are IHC3 positive
Lapatinib (Social Values Project Website 2014d)	Treatment for advanced or metastatic breast cancer	For lapatinib plus capecitabine compared with vinorelbine monotherapy - £79,000 per QALY gained. For lapatinib plus capecitabine in comparison with trastuzumab monotherapy - £24,000 per QALY gained, (but this did not take into account the comparison of trastuzumab with capecitabine, for which the ICER was approximately £109,000 per QALY. For lapatinib plus capecitabine in comparison with all comparators - £61,000 per QALY gained.	End-of-Life as a special case; that the treatment is administered orally (Patient Choice).	<i>Rejected</i>
Lucentis (Social Values Project Website 2014e)	A treatment for Age-Related Macular Degeneration (AMD)	In cases where there were classic lesions - £15,638 per QALY gained when compared with the current practice of Photodynamic Therapy; £11,412 per QALY gained when compared with the best supportive care for non-classic lesions; £25,098 per QALY gained when compared with best supportive care for classic lesions.	Dread; 'That Something Ought to be Done'.	<i>Approved</i> for treatment of the first eye that came to clinical attention with AMD.