

# The Importance of Being NICE

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## **Abstract**

Recent policy developments in the U.K. health system such as the Cancer Drugs Fund constitute a dangerous move away from evidence-based and ethically sound policy-making, towards populist approaches that could ultimately damage public health. We argue that key players in the NHS such as National Institute of Health and Care Excellence (NICE) need to demonstrate leadership by reaffirming the underlying principles of the NHS and clearly communicating how the values and principles underpinning their methods are a pre-requisite for an efficient fair and sustainable NHS.

(85 words)

In a recent editorial, the *Lancet* argues that health deserves a “central role in the (UK) election campaign” and warns that the electorate “will not be satisfied with tired and politically reflexive solutions that betray the intellectual underinvestment in health by recent parliaments”.<sup>1</sup> We could not agree more. Recent developments like the Cancer Drugs Fund (CDF)<sup>2</sup> amount to a dangerous move away from health policy that is based on robust evidence and sound ethical principles, and writ-large pose a real threat to the future of the National Health Service (NHS).

Policies like the CDF have emerged mostly due to political expediency and are now advocated by both main parties. However, key players within the NHS could be considered partly responsible because they have failed to adequately communicate their worth to the wider public. The National Institute of Health and Care Excellence (NICE) is one such case. Although aspects of NICE’s work can and should be improved, we argue that the Institute’s overall approach to evaluating new health technologies for use within the NHS is ethically sound. Yet NICE has struggled to communicate its values and procedures to the wider public, and it has thereby left the electorate unable to recognize when the health service is being used as a political battleground. We therefore urge NICE to use its central position within the NHS and in the public eye to inform the ensuing health debate by clarifying its values, as well as asserting their essential role for preserving a sustainable and fair NHS.

### **The reasonableness of NICE**

A key function of NICE is to evaluate whether new health technologies offer “value for money” within the NHS. The Institute has developed its methods for making these

evaluations for more than 15 years. Today, NICE’s methodology is best described as “filtering” new technologies based on their cost-effectiveness.<sup>3</sup> NICE uses Quality-adjusted Life Years (QALYs) as a measure to judge the effectiveness of new technologies. It then evaluates how their cost-effectiveness compares to the cost-effectiveness of existing interventions, and generally recommends funding new technologies that do not add costs beyond £20,000–30,000 per QALY gained. Costlier technologies may still be funded, but this must be justified based on recognized social or ethical values—such as extending the end of life, addressing the needs of disabled people, relieving stigma, or reducing health inequalities (table).<sup>4,5</sup> Thus, NICE’s methodology defaults to prioritizing the value of cost-effectiveness, but recognises that other values can overturn this default and “trump” the value of cost-effectiveness.

**Table. NICE’s methodology for evaluating health interventions: values that can or cannot trump the value of cost-effectiveness.** Based on NICE’s *Social Value Judgments and Guide to the Methods of Technology Appraisal*.<sup>4,6</sup> Other social values that have been invoked in actual NICE appraisals are not represented.

Recognized values or criteria	Excluded values or criteria
<ul style="list-style-type: none"> <li>• Innovation not adequately captured in the measurement of health gain</li> <li>• Special consideration of the needs of disabled people</li> <li>• Special consideration of the relief of stigma</li> <li>• Special consideration of life-extending treatment at the end of life*</li> </ul>	<ul style="list-style-type: none"> <li>• Individual choice or individuals’ values, cultural attitudes and religious views (if they support interventions that are not clinically effective and / or cost-effective)</li> <li>• Treating rare diseases or conditions as special</li> <li>• “Rule of rescue”</li> </ul>

<ul style="list-style-type: none"> <li>• Reducing health inequalities</li> </ul>	<ul style="list-style-type: none"> <li>• Personal responsibility for health (unless a proxy for clinical effectiveness)</li> <li>• Race / ethnicity (unless a proxy for clinical effectiveness)</li> <li>• Age as a proxy for social worth<sup>%</sup></li> <li>• Sex / gender and sexual orientation (unless a proxy for clinical effectiveness)</li> <li>• Socio-economic status and social roles</li> </ul>
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\* End-of-life criteria: 1) patients with life expectancy of <24 months, 2) intervention offers life extension of >3 months compared to existing alternatives, 3) intervention is licensed for small patient populations (total <7000 patients)

<sup>%</sup> Age may be invoked if 1) a good indicator of patients' health status and / or likelihood of adverse effects and / or treatment response and 2) no practical way of identifying patients other than by age. Furthermore, a lower discount rate for costs and benefits may be applied if a treatment 1) restores full or near full health in patients who would otherwise die or have a very severely impaired life and 2) the resulting health benefits are long-term (>30 years, i.e. typically applying to younger patients).

So understood, NICE's method is eminently reasonable.<sup>3</sup> Funded by general taxation, the NHS operates with a fixed budget that is insufficient to cover all conceivable and technically possible health needs. This implies that money spent on one set of interventions will inevitably displace resources devoted to other interventions. In a situation like this, there is a genuine risk of unfairness because the demands of the most vocal can easily drive out the claims of the needy. Allocating the NHS budget therefore requires an *ethics of opportunity costs*—and NICE's methodology provides just that.

NICE's methodology prioritizes the value of cost-effectiveness and thereby helps to ensure that the available resources for health and health care are used prudently. Moreover, it sets a general cost-effectiveness threshold for all services within the NHS. This does not only provide a rough and ready test of whether financing care for one group of patients is likely to lead to care for other patients being denied or delayed. It also embodies the idea that, *prima facie*, all patients have an equal claim to the available resources. Finally, the Institute's methodology offers a framework for judging whether other recognized social and ethical values warrant funding technologies above the general cost-effectiveness threshold—or, put differently, whether other values justify the opportunity costs of financing costly interventions. This recognizes that patients can have justice claims to the available resources for health and health care over and above cost-effectiveness.

### **The need for better communication**

While it is relatively straightforward to reconstruct and defend NICE's methodology along the above lines, the Institute itself has failed to clearly communicate all the values that it serves. Its *Guide to the Methods of Technology Appraisal* focuses primarily on the criteria and procedures for evaluating evidence.<sup>6</sup> The *Social Value Judgements* document—largely unknown beyond specialist confines—promises to set out NICE's key principles, but does not deliver in this respect.<sup>4</sup> It embraces a mixture of ethical theories and principles, legal obligations, recommendations from NICE's Citizen's Council, procedural ideals, institutional directives, and specific decision criteria and values. What is lacking is the overarching framework to unify these considerations.

After more than a decade of its existence—a very long time in today’s NHS—there is still confusion and unhelpful controversy around NICE’s fundamental values. For example, some commentators often gloss the Institute’s methodology as simply an explicit or implicit attempt to maximize QALY gain within the NHS.<sup>7,8,9</sup> For some economists, this is a virtue because they see a maximizing approach as a way of using available resources to best effect.<sup>7,9</sup> However, NICE’s methodology is clearly not one of simple maximization. If the Institute was trying to maximize benefit within the NHS, it would rank-order all interventions by their cost-effectiveness and recommend spending money only on items high up the list. The reality is very different, both because NICE endorses a satisficing approach rather than maximizing one, and because it recognises a range of other values that can trump the value of cost-effectiveness. These distinctions are important. For if NICE *did* adopt a simple maximizing approach, then it would be open to numerous criticisms—for example, that its methodology systematically sacrifices important needs of small groups for the greater good. NICE’s failure to clarify its values thus leads to inaccurate glosses and controversy that is both polarising and unnecessary.

Furthermore, given the Institute’s failure to adequately communicate its values, the electorate lacks a clear framework by which to evaluate recent policies like the CDF. If NICE conveyed its methodology and the underlying rationale more clearly, more people would be asking more questions about the opportunity costs of funding cancer drugs that have not (yet) been recommended by NICE; what—if anything—might justify special health expenditures for cancer; why legislators assumed that NICE’s methodology did not account for the value we attach to cancer drugs, or could not be

modified in this respect; and so on. In other words, more clarity about NICE's values and methods should help to press greater public accountability by politicians and legislators.

Finally, NICE's ambiguity about its methodology means that stakeholders and the wider public lack a clear framework for discussing how we should build on the Institute's work in the pursuit of a just allocation of limited health care resources. Although we have argued that NICE's overall methodology is reasonable, many details require further discussion. In particular, is the cost-effectiveness threshold of £20,000–30,000 per QALY set at the right level? Are all of the social and ethical values other than cost-effectiveness justified? Should NICE recognize additional values? How should competing values be balanced? By clarifying its present values and methods for evaluating new technologies, NICE would be able to respond better to critics from new quarters<sup>10, 11</sup> while also providing a structure for constructive debate.

### **The future of NICE**

We have argued that NICE's overall methodology is eminently reasonable and requires, above all, better explanation. Ironically, the solution is already in NICE's hands in its current revision of the *Social Value Judgements* (SVJ) document.<sup>12</sup> NICE should seize the opportunity of re-drafting SVJ to elevate this document to the Institute's principal statement of its overarching philosophy and values. NICE should also aim to clarify its values and publicise SVJ widely. Next, the SVJ document should be used to guide discussions both about NICE's current methods and how



these methods should be applied to its expanding remit for social care. We recognize that these discussions will be challenging. However, we firmly believe that a clear framework of values is essential for guiding NICE as well as the wider public—both in the present and into the future.

## **Conclusion**

The future of the NHS depends on making decisions based on robust evidence and sound ethical principles, but recent developments like the CDF suggest that support of these ideas is waning among politicians and legislators. We have argued that key NHS players are partly at fault because they have failed to clearly emphasise the values that must guide a fair and sustainable health service. NICE is a case point, in that it is not the Institute's values and methods, but their presentation that is the problem.

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### **Contributors and Sources**

All authors contributed equally to the conception and writing of this paper and have approved the final version. Annette Rid is the guarantor of the article.

### **Declaration of Interest**

Peter Littlejohns is a medical doctor who was the founding Clinical and Public Health Director of the National Institute of Health and Care Excellence (NICE) from 1999 to 2011. In this role, he designed the process and methods for the development of NICE guidelines and was the executive director responsible for the Citizens Council and the R&D programme. All author authors report that they have no financial and personal relationships with other people or organisations that could inappropriately influence (bias) their work.

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