

The importance of being NICE

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In the run-up to the UK parliamentary elections in 2015, the *Lancet* called on all political parties to abandon 'tired and politically reflexive solutions [for the National Health Service (NHS)] that betray the intellectual underinvestment in health by recent parliaments'.^{1,20} We could not agree more with the journal's verdict about the current state of health policy in the UK. Recent developments like the Cancer Drugs Fund (CDF)² amount to a dangerous move away from policy that is based on robust evidence and sound ethical principles, and writ large pose a real threat to the future of the NHS.

The CDF has evolved considerably since its inception in 2011, due to increasing budgetary problems and criticism by academics as well as public controversy.^{3–5} Conceived as a temporary solution for granting NHS patients rapid access to innovative cancer treatments, the CDF has been prone to 'quick fixes.' It introduced cost-effectiveness as a funding criterion in early 2015, but its methods and procedures for evaluating cost-effectiveness are haphazard and decoupled from those used elsewhere in the NHS. These developments, together with the CDF's ballooning budget, question the fairness of the NHS to all patients.

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 public

unable to recognise 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.²¹ 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.⁶

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 through the NHS 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 recognised social or ethical values – such as extending the end of life, addressing the needs of disabled people, relieving stigma, or reducing health inequalities (Table 1).^{7–9} Thus, NICE's methodology defaults to prioritising the value of cost-effectiveness but recognises that other values can overturn this default and 'trump' the value of cost-effectiveness.

So understood, NICE's method is eminently reasonable.⁶ 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

Table 1. NICE's methodology for evaluating health interventions: values that can or cannot trump the value of cost-effectiveness.

Recognised values or criteria	Excluded values or criteria
<ul style="list-style-type: none"> • Innovation not adequately captured in the measurement of health gain • Special consideration of the needs of disabled people • Special consideration of the relief of stigma • Special consideration of life-extending treatment at the end of life* • Reducing health inequalities 	<ul style="list-style-type: none"> • Individual choice or individuals' values, cultural attitudes and religious views (if they support interventions that are not clinically effective and / or cost-effective) • Treating rare diseases or conditions as special • 'Rule of rescue' • Personal responsibility for health (unless it is a proxy for clinical effectiveness) • Race / ethnicity (unless they are a proxy for clinical effectiveness) • Age as a proxy for social worth[†] • Sex / gender and sexual orientation (unless they are a proxy for clinical effectiveness) • Socioeconomic status and social roles

Based on NICE's *Social Value Judgments* and *Guide to the Methods of Technology Appraisal*.^{7,9} Other social values that have been invoked in actual NICE appraisals are not represented.

*End-of-life criteria: (1) patients with life expectancy of <24 months; (2) intervention offers life extension of >3 months compared to existing alternatives; and (3) intervention is licensed for small patient populations (total <7000 patients).

[†]Age may be invoked if it is (1) a good indicator of patients' health status and / or the likelihood of adverse effects and / or treatment response, and there is (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 (a) restores full or near full health in patients who would otherwise die or have a very severely impaired life and (b) the resulting health benefits are long-term (>30 years, i.e. typically applying to younger patients).

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 – that is, an ethical framework for evaluating the acceptability of investing in some health technologies over others. NICE's methodology provides just that.

NICE's methodology prioritises the value of cost-effectiveness and thereby helps to ensure that the available resources for health and healthcare 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 recognised social and ethical values warrant funding technologies above the general cost-effectiveness threshold – or, put differently, whether values other than cost-effectiveness justify the opportunity costs of financing costly interventions. This recognises that patients can have claims to the available resources for health and healthcare over and above cost-effectiveness, such as claims of justice or compassion.

One example is NICE's recognised value of giving special consideration to life-extending treatment at the end of life.⁹ Funding costly end-of-life technologies can be justified based on the ethical and social importance of being compassionate towards the dying, including providing them with more time for ordering their affairs. Thus, like the CDF, NICE is poised to recommend spending more on novel cancer treatments at the end of life. Yet NICE's methodology does not treat cancer differently than other end-of-life conditions, and it uses the same general cost-effectiveness threshold for all NHS services – whether at the end of life or not. While the CDF can be excused of unreasonable 'cancer exceptionalism', NICE applies a reasonable framework for the ethics of opportunity costs in order to preserve sustainable and fair services for all NHS patients.

The need for better communication

Although 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.⁹ The *Social Value Judgments* document – largely unknown beyond specialist confines – promises to set out NICE's key principles, but does not deliver in this respect.⁷ 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 and a half of its existence – which is 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 maximise QALY gain within the NHS.^{10–12} Of course, for some economists, this is a virtue because they see a maximising approach as a way of using available resources to best effect.^{10,12} However, NICE's methodology is clearly not one of simple maximisation. If the Institute was trying to maximise 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 because NICE endorses a satisficing approach rather than maximising one, meaning that it merely 'filters' novel technologies based on their cost-effectiveness rather than identifying the most cost-effective interventions. In addition, NICE 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 maximising 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 public 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. The recent triennial review of NICE equally finds communication an area for improvement for the Institute, stating that 'NICE goes to a great deal of effort to communicate and engage across the health and care sector but this is not always regarded as successful and it was felt improvement was needed.'²²

The need for further refinement

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 healthcare 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? Is NICE's existing list of recognised and excluded values other than cost-effectiveness justified? Should the Institute recognise additional social and ethical values? How should competing values be balanced? And should NICE's remit be extended in order to better control healthcare costs, for example by giving it the power to negotiate prices with the private sector or consider the total cost impact of funding a technology?

While we cannot discuss these questions in detail here, two are particularly timely to address. First, recent evidence suggests that NICE's cost-effectiveness threshold may need to be revisited. The threshold should reflect the mean cost of producing a QALY elsewhere in the NHS, so as to ensure that NICE's approval of novel technologies is not overly costly relative to the interventions they displace.¹³ However, recent research indicates that the NHS spends on average £12,936 per QALY gained, not £20,000–30,000 as the current threshold suggests.¹⁴ Moreover, data show that NICE's appraisals have been based on a higher threshold than £20,000–30,000 per QALY.¹⁵ If this research is substantiated, NICE may need to lower and better monitor its cost-effectiveness threshold so that it can adequately fulfil its mission of evaluating a novel technology's opportunity costs.

Second, NICE's remit is expanding to social care, and this has spurred discussion about whether its methodology should reflect the 'wider societal impact' of funding novel health technologies. For example, an effective treatment for Alzheimer's disease would not only benefit patients, but also their carers. The UK government recently launched a public consultation on widening the concept of 'value' in the drug appraisal process along these lines, yet NICE rejected the government's proposals on grounds that it would be inconsistent with legislation on age discrimination.^{16,17} Although this decision settled the issue for the moment, it is bound to resurface and raise complex questions about the ethics of evaluating new technologies based on their impact beyond the individual patient.

By refining its present values and methods, NICE would be able to respond better to its current critics

while also providing a structure for constructive debate about critical future questions.

The future of NICE

We have argued that NICE's overall methodology is eminently reasonable and requires, above all, better explanation and defence against countervailing political or financial interests. Ironically, the solution is already in NICE's hands in its current revision of the *Social Value Judgements* (SVJ) document.¹⁸ 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, publicise SVJ widely and hold firmly to its tenets in discussions with patients, clinicians, policy-makers and the private sector.

This has implications beyond NICE's approach to its technology appraisal programme. For example, NHS England recently decided to suspend its contract with NICE to produce evidence-based guidance on safe staffing levels, suggesting that the eagerness for robust policy may be on the wane.¹⁹ It will be even more important for NICE to affirm its principles as its role in social care becomes more active.

We recognise that acting on these recommendations 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.

Declarations

Competing interests: PL 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. AR, JW, BR, KK and AW 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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