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EDITORIAL

Politicised Changes to the NICE Threshold Risk Making Cost-Effectiveness Analysis Performative, Not Informative

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1 Introduction

In health systems operating with finite resources, cost-effectiveness analyses are essential for informing healthcare funding decisions. Adopting a new intervention necessarily means diverting resources from other uses, implying an opportunity cost in the form of healthcare activities that could otherwise have generated health benefits. A fundamental purpose of a cost-effectiveness analysis is therefore to determine whether the health gains generated by a new intervention exceed these health opportunity costs. This principle is widely recognised across health systems and is explicitly articulated in the social value framework of the National Institute for Health and Care Excellence (NICE) in the UK; for example, the NICE Manual establishes that *"decisions about a new technology must consider implications for healthcare programmes for other patient groups that may be displaced by the adoption of the new technology*" [1].

To enable this evaluation, health economists estimate the incremental costs and health effects—typically expressed in quality-adjusted life-years (QALYs)—to derive an incremental cost-effectiveness ratio (ICER) for each health technology being evaluated. This ICER must then be compared against the health opportunity cost of adopting the new technology.

2 Current National Institute for Health and Care Excellence (NICE) Threshold

Consistent with this framework, NICE states that "*the appropriate maximum acceptable ICER to be considered is that of the opportunity cost of programmes displaced by new, more costly technologies*" [1]. However, NICE's long-standing £20,000–£30,000 per QALY threshold range was not derived from empirical evidence on health opportunity costs, in part because such evidence was not available at the time of its foundation. Instead, it emerged from deliberative judgement during the early institutionalisation of health technology assessment in the UK [2].

While the £20,000–£30,000 per QALY range has remained formally unchanged, its application has not been uniform. In practice, NICE has accepted higher thresholds in specific circumstances, most notably through the end-of-life criteria and for highly specialised technologies, until these approaches were replaced in 2022 by the introduction of severity modifiers [3]. These departures have been explicitly justified as exceptions based on value adjustments and, particularly for the severity modifiers, followed extensive methodological review and deliberative public engagement.

By contrast, recent debates have increasingly focused on whether the threshold range should be raised or lowered. Arguments in favour of increasing the threshold often appeal to inflationary adjustment [4]. However, a cost-effectiveness threshold grounded in opportunity cost is neither a price

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index nor a willingness-to-pay parameter, but an estimate of the marginal productivity of the healthcare system. Applying inflation adjustments to update such estimates relies on a strong ceteris paribus assumption that the composition of healthcare goods and services reallocated at the margin to pay for a new intervention remains the same as when the threshold was first determined. Moreover, it assumes that the healthcare needs of the population from whom those resources are reallocated remains the same. Such assumptions are unlikely to hold, particularly in the context of increasing under-funding [5]. More fundamentally, the central issue is not whether marginal productivity should be updated through an inflation adjustment, but whether the NICE baseline threshold values were ever grounded in the marginal productivity of the National Health Service (NHS).

In line with the above, arguments for lowering the threshold are based on growing empirical evidence on NHS opportunity costs. Existing estimates place the marginal cost of generating a QALY in the NHS at approximately £13,000 per QALY [6]. Such empirical estimates have converged remarkably across methodologies and data sources. Using programme budgeting data, disease-specific mortality outcomes and incorporating morbidity effects, studies consistently estimate the marginal cost of a QALY in the NHS to lie well below the lower bound of the current NICE threshold range [7–9].

3 Decision to Change the NICE Threshold

Despite this evidence, the UK Government has now confirmed an increase in the NICE threshold—from £20,000–£30,000 to £25,000–£35,000 per QALY [10]. Crucially, this change has not been justified by empirical evidence, nor by any articulated belief that the opportunity cost faced by the NHS has increased. Instead, according to public reporting and parliamentary statements, the change followed intense pressure from the US Government during negotiations related to investment in pharmaceutical innovation and threats of retaliatory trade measures, combined with explicit warnings from major pharmaceutical companies regarding disinvestment or relocation away from the UK [11, 12].

Proponents of the policy shift have argued that it could deliver wider economic benefits for the UK, including strengthening the life sciences sector and supporting investment in pharmaceutical innovation [10, 13]. Yet such claims remain largely unsubstantiated and have been characterised as a false promise [14]. Moreover, recent reporting has further suggested that the Government's arrangements to avert pharmaceutical tariffs rest on limited headline commitments rather than binding agreements [15].

The Government has also justified the change in the threshold on the grounds that it would facilitate faster access to innovative technologies, with NICE arguing that three to five additional medicines per year would be recommended under the new range [16]. Yet no assessment has been made of the corresponding health losses that will accrue from the additional displacement of cost-effective NHS services, nor of the price effects of raising the threshold, which will allow technologies that would have been supplied at lower prices to be priced up to the higher threshold [17].

4 Implications of Changing the NICE Threshold: Population Health

Previous estimates suggest that, even under current NICE thresholds, drugs funded in the UK between 2000 and 2020 were associated with net health losses of approximately 1.25 million QALYs [18]. New estimates have now shown that the UK-US deal, which also affects the rebate scheme provided under the Voluntary Scheme for Branded Medicines Pricing, Access and Growth (VPAG), would have substantial consequences for population health. Under a conservative scenario in which spending on new medicines in England imposes an additional £1 billion annual cost on the NHS, estimates suggest that the resulting displacement of NHS activity could lead to around 4500 additional deaths and a loss of nearly 120,000 QALYs per year [19].

These losses are diffuse, invisible and politically silent, but no less real. Every pound allocated to new health technologies is a pound not available to reduce delays in current cancer screening, to expand mental health services, improve primary care access or relieve waiting times for elective surgery. Moreover, displaced health is also likely to increase social care needs and the demand for support services provided by already financially constrained local authorities [20]. This risks exacerbating the existing gap between demand and supply in adult social care, with adverse consequences beyond the healthcare sector.

5 Implications of Changing the NICE Threshold: Purpose of Cost-Effectiveness Analyses

Seen in this light, the proposed change in the NICE threshold represents far more than a numerical adjustment. It marks a fundamental shift in how a health technology assessment is understood and operationalised. If the new values are implemented, it will be essential for NICE to acknowledge this openly in their Methods Guide and Principles. Rather than emerging from NICE's established methodological deliberations or new empirical evidence, these thresholds stem from a Government decision aimed at incentivising pharmaceutical investment and innovation, even at the expense of population

health outcomes. This alone marks a profound departure from the institutional independence that has long been regarded as one of NICE's defining strengths. Interestingly, innovation modifiers were themselves subject to a rigorous assessment by NICE, which concluded that they lacked moral and empirical justification and that the value of innovation was better captured through estimated therapeutic benefit [21].

Once the threshold values are explicitly no longer anchored to health opportunity costs, a more fundamental question arises about the purpose of NICE's continued use of a cost-effectiveness analysis. Why should analysts devote substantial time and effort to rigorously estimating incremental costs and health effects if those estimates are ultimately assessed against values derived not from evidence, but from geopolitical negotiation and industrial bargaining? In such circumstances, a cost-effectiveness analysis risks becoming performative rather than informative. The danger is not merely technical, but institutional: a gradual erosion of the coherence and credibility that has underpinned NICE's authority, with potential international spillovers if this shift sets a precedent.

The UK may be first in line, but similar political and industrial pressures are likely to be exerted on many other countries, whether or not they have an explicit cost-effectiveness threshold. As in the UK, in other countries there is evidence that applied thresholds are higher than would be the case if the threshold reflected opportunity costs [22]. Further rises would exacerbate the expected net health losses incurred by these populations.

6 Recommendations

If the primary purpose of the NHS is to improve population health, the only analytically valid reference value for NICE's threshold is one that reflects health opportunity costs. Concepts such as net health benefit and value of information require formal consideration of the health displaced elsewhere in the system, and cannot be coherently estimated using arbitrary thresholds that do not represent opportunity costs.

Comparing ICERs against such an arbitrary policy threshold should not be the role of health economists when they are tasked with assessing cost effectiveness. Instead, economic evaluations should use the best available empirical estimates of health opportunity costs.

7 Conclusions

In summary, while the UK government has committed in its recent US trade agreement to increasing NICE's cost-effectiveness threshold—with negative impacts for the health of the population—the potential economic benefits of this agreement remain highly uncertain. By arbitrarily increasing NICE's threshold, without regard for the potentially serious negative impact on the health of the UK population, the government is forcing NICE to move further away from its foundational social values. Unless these concerns are addressed, the UK's long-established model of evidence-based priority setting may cease to function, becoming instead an instrument of industrial policy implemented at the expense of NHS patients.

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Declarations

Conflict of Interest Laura Vallejo-Torres, Laura C. Edney, Oscar Espinosa, Jonathan Karnon, Francesco Longo, Mike Paulden, Daniel Howdon and David J. Vanness have no conflicts of interest that are directly relevant to the content of this article.

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