

Cost-effective but ‘unaffordable’: an emerging challenge for health systems

NICE’s and NHS England’s new “budget impact test” is an unpopular and flawed attempt to solve a fundamentally political problem

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Abstract

Policy-makers worldwide are struggling to ensure patient access to cost-effective but expensive new health technologies. The National Institute for Health and Care Excellence (NICE) and NHS England are seeking to address this challenge by introducing a 'budget impact test' for cost-effective technologies, bringing considerations of affordability into individual NICE appraisals for the first time. This editorial highlights the ethical dilemmas involved and suggests a range of alternatives to be explored instead.

With hospital wards overflowing and trusts in deficit, the introduction of cost-effective but expensive new technologies places increasing strain on NHS finances. The National Institute for Health and Care Excellence (NICE) and NHS England plan to address this issue by delaying the take-up of interventions with a 'high budget impact'.¹ The change may deliver short-term savings. Yet it is flawed.

How did the change come about? In 2015 NICE recommended the use of several new hepatitis C drugs.² Judged clinically- and cost-effective, they were nevertheless expensive. NHS England considered them unaffordable, with annual costs of between £700 million and £1 billion, and delayed adoption.³⁻⁴

The new 'budget impact test' seeks to resolve such problems by linking health technology assessment and cost control. From April 1 2017, the current requirement to fund NICE recommended technologies within 90 days will not apply above an annual 'budget impact threshold' of £20 million.¹ Instead, NHS England will be granted up to three years – longer in exceptional circumstances – to conduct commercial negotiations.¹ As a result, patient access to many new technologies will be dramatically slowed.

The proposal went out for consultation last December, and responses were far from supportive. Respondents recognized the pressures on the NHS, but less than a third believed that a budget impact threshold should be introduced, and only 23% agreed that technologies exceeding the threshold should be subject to delayed implementation. Excluding the views of NHS commissioning bodies, both figures fall by half.¹

The policy brings ‘affordability’ into NICE’s remit in an unprecedented way. To date, NICE has based its recommendations on an ethics of opportunity costs.⁵ New technologies are judged principally on their incremental cost-effectiveness ratio, a measure of their cost-effectiveness compared with existing interventions. Judgements sometimes reflect broader social and ethical values, for example special concern for end-of-life treatments. But, normally, cost-effectiveness is the key consideration.⁵ The budget impact test means that technologies costing the NHS more than an additional £20 million a year will be ‘slow-tracked’, regardless of their cost-effectiveness or other social or ethical values.

This risks undermining the existing opportunity costs framework. Consider the case of infliximab, currently recommended as a cost-effective treatment for both acute exacerbations of ulcerative colitis and severe active Crohn’s disease.⁶⁻⁷ Its list price is the same across indications, but the total cost of treating the handful of eligible patients with ulcerative colitis is far lower than that of treating the 4,000 eligible patients with Crohn’s disease. Under the new approach the latter would likely fail the budget impact test, delaying introduction. The former would not.

Budget impact is essentially the price per patient multiplied by the number of patients treated. Yet the prevalence of someone's condition should not determine their access to treatment. The principle of equity means that like cases should be treated as like; the NHS Constitution requires the NHS to respond to the clinical needs of individuals *as individuals*.⁸⁻⁹ The new test requires NICE to treat individual patients in one group less favourably than those in another solely because more patients are in the first group than the second. It is numerical discrimination. And if a large number of patients experience delays, the policy threatens widespread harms.

Affordability is driven by public expenditure, a fundamentally political matter. NICE and NHS England should be commended for seeking to square the circle on affordability when the current government's response is inadequate. Perhaps the policy aims to pressurise industry to lower its prices when volumes are high. But this is to use large patient groups as a bargaining chip.

NICE's justification for pursuing its approach – that “no alternative solutions” have been put forward – is invalid.¹ The recent consultation did not ask for alternative options. Had it done so, several could have been canvassed. NICE's methodology assumes that the NHS will pay for new cost-effective interventions through disinvestment, removing existing interventions that are relatively cost-ineffective. This rarely happens.¹⁰⁻¹¹ A systematic and transparent programme of disinvestment, though difficult, could increase the resources available to fund new technologies. An increase in the NHS budget would of course help too. But even without that, NICE's cost-effectiveness threshold could be updated for *all* technologies, so treating patients equitably.¹² More widespread use of risk-sharing on costs might also help to reduce total budget impact. Or, most controversially, the 90-day funding requirement for

NICE-approved technologies could be removed entirely and the power to make decisions about affordability given back either to politicians or to NHS England.

Even if it is no longer feasible politically for NICE to ignore overall affordability in individual technology appraisals, budget impact could be a ‘special consideration’ modifying the cost-effectiveness calculation alongside other social or ethical values, allowing for a nuanced, case-by-case deliberative response. This would bring affordability into the existing opportunity cost framework.⁵

These alternatives raise significant ethical and political challenges. But they should be considered before NICE commits to an inequitable approach which few support. The recent consultation should have marked the start, not the end, of a more substantial debate about the role of affordability in the NHS. It is not too late to correct this mistake.

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Competing Interests

All authors have read and understood BMJ policy on declaration of interests and declare the following interests: as declared individually on the online BMJ declaration of interests form (<http://goo.gl/forms/Lk7hqTkABD>).

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