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EDITORIALS

Cost effective but unaffordable: an emerging challenge for health systems

New "budget impact test" is an unpopular and flawed attempt to solve a fundamentally political problem

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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 tackle this problem by delaying the introduction of interventions with a "high budget impact."[1] The change may deliver short term savings but is flawed.

What prompted the new policy? In 2015 NICE recommended the use of several new drugs for hepatitis C.[2] Although they were judged clinically useful and cost effective, NHS England considered them unaffordable, with annual costs of between £700m and £1bn, and delayed adoption.[3,4]

From 1 April 2017, the current requirement to fund NICE recommended technologies within 90 days will not apply for those with annual costs that exceed £20m (€23m; $24m).[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 some new technologies will be substantially slowed.

Views expressed during the consultation on this policy were far from supportive. Respondents recognised the pressures on the NHS, but less than a third believed that a budget impact threshold should be introduced, and only 23% agreed with delayed implementation for technologies exceeding the threshold. When the views of NHS commissioning bodies were excluded, figures for support fell substantially.[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. Judgments sometimes reflect broader social and ethical values, but cost effectiveness is normally the main consideration.[5]

The budget impact test means that technologies costing the NHS more than an additional £20m 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 infliximab, currently recommended 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 4000 eligible patients with Crohn's disease. Under the new approach use for Crohn's disease would probably fail the budget impact test, delaying introduction; use for ulcerative colitis 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 patients as individuals.[8,9] The new test requires NICE to treat patients in one group less favourably than those in another solely because there are more in the first group than the second. It is numerical discrimination. And if large numbers 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

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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 in our view.[1] The recent consultation did not ask for other options. Had it done so, several could have been canvassed. NICE's methods assume that the NHS will pay for new cost effective interventions through disinvestment, removing existing treatments 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 to politicians or 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. This would allow for a nuanced, case-by-case deliberative response and bring affordability into the existing opportunity cost framework.[5]

All these options raise important ethical and political challenges. But they should be considered before NICE commits to an inequitable approach that 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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