The National Institute for Health and Clinical Excellence (NICE) was established as a part of the British National Health Service in 1999 to set standards for the adoption of new health care technologies and the management of specific conditions. In doing so it was required explicitly to take into account both clinical effectiveness and cost-effectiveness. This article describes how NICE has responded to the challenge and considers whether its experience of balancing quality, innovation, and value for money holds policy lessons for the United States.

**Quality, Innovation, and Value for Money**

NICE and the British National Health Service

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The interplay among quality of care, technological innovation, and cost control creates a policy challenge for all health care systems. Improvements in the quality of care can reduce health care costs; for example, better management of chronic conditions may lessen the chance of hospitalization, and new drugs and medical devices might improve the quality and efficiency of care. Often, however, innovation comes with a significant additional cost. Even the most affluent health care systems must consider the benefits of medical innovation compared with other efforts to improve the quality of care. This article describes how this policy challenge is being addressed in Britain through the activities of the National Institute for Health and Clinical Excellence (NICE).

NICE was established in 1999 to provide health care professionals in England and Wales with advice on securing the highest attainable standards of care for National Health Service (NHS) patients. The institute has a broad mandate to set standards for the use of new technologies and procedures within the NHS and to produce guidance for clinical and public cost. NICE therefore sits at the controversial intersection of quality, innovation, access, and cost. The characteristics of the British and US health care systems make direct extrapolation inappropriate, but, as the United States seeks to address the long-term challenges facing its health care system, there may be useful policy lessons to be learned from the structure, methods, and experience of NICE.

**NICE Guidance**

The institute has 4 distinct programs producing various forms of what are collectively known as “NICE guidance”:

1. Appraisals of individual or classes of health technologies (eg, pharmaceuticals, devices, procedures, diagnostic methods), taking account of both their clinical effectiveness and cost-effectiveness; (2) development of clinical guidelines, involving considerations of both clinical effectiveness and cost-effectiveness, for management of individual conditions or symptoms; (3) guidance on the safety and efficacy of interventional procedures (both diagnostic and therapeutic). This program is analogous to the functions of a national drug regulatory authority and does not evaluate cost-effectiveness; and (4) a new (since April 2005) program of public health guidance including advice on the clinical effectiveness and cost-effectiveness of single interventions (eg, needle exchange for reducing the prevalence of blood-borne infections in intravenous drug users) and broader public health approaches for communities (eg, combinations of educational, regulatory, and zoning changes to reduce childhood injuries).

Details about the processes used in the development of these various forms of NICE guidance can be found elsewhere, but they all have common features. First, they are based on a method that includes a full systematic review of the topic and a rigorous approach to economic modeling of cost-effectiveness. Second, all NICE guidance is developed by various independent advisory bodies whose members are drawn from clinicians, professional groups, researchers, and individuals with experience in patient advocacy. Third, stakeholders (including relevant professional and patient organizations as well as manufacturers) are involved at all stages: they have full access to the supporting systematic reviews and are encouraged to comment on draft forms of guidance.

See also p 2630.
However, decisions about the content of NICE guidance, are the responsibility of the institute's independent advisory bodies, and although health ministers have reserve powers to advise the NHS to ignore NICE guidance, they have never done so or threatened to do so. Finally, the institute attempts to ensure that its processes are as transparent as possible. NICE's work programs are publicized well in advance, and the data from which its conclusions are drawn are in the public domain with the exception of the details of studies that manufacturers insist remain “commercial in confidence.”

Economic Evaluation. Of all the elements of NICE guidance, the most distinctive, from a US perspective, is its use of economic evaluation to help judge the value of technologies that provide additional benefit but at an increased cost. The key measure used by NICE to assess the marginal value of a technology for different patient groups is the additional cost per quality-adjusted life-year (QALY) gained. If appropriate data on quality of life are unavailable, cost-effectiveness is estimated using alternatives such as cost per life-year gained.

Whether to recommend the use of a technology for certain patients and indications depends in part on the point at which the incremental cost per QALY is judged to no longer be cost-effective. Recognizing this central feature of economic evaluation, NICE has carefully described its approach and expects its advisory bodies to use estimates of cost-effectiveness to inform, but not determine, their decisions. In other words, NICE does not have a specific cost per QALY threshold above which a technology is rejected. Although research is continuing in this area, there is currently no empirical basis for assigning a specific cost per QALY threshold within the NHS; even if there were an empirical guide, an explicit threshold would suggest that health utility as measured by QALYs has absolute priority over other objectives, including various forms of equity. Nevertheless, NICE has arrived operationally at a band of approximately $30 600 to $45 900 per QALY (based on purchasing power parity of US $1=£0.65) as the threshold above which it would be increasingly likely to reject a technology on grounds of cost-ineffectiveness. For example, the institute has approved the use of etanercept and infliximab, both with incremental cost-effectiveness ratios of $47 430 per QALY, in the treatment of rheumatoid arthritis, but it has rejected anakinra, with an incremental ratio of $102 510 per QALY. Adopting this range of $30 600 to $45 900 per QALY as a benchmark for cost-effectiveness maintains consistency across the many different types of health care technologies that NICE appraises and, at the same time, provides NICE's advisory bodies with latitude to consider the degree of uncertainty surrounding the estimate, the particular features of the condition, the innovative nature of the technology, and, where appropriate, the wider societal costs and benefits.

It is important to note that NICE does not take the budget impact of a new technology into account. For example, although a new drug might have a favorable cost-effectiveness ratio of $30 000 per QALY, the overall impact might be too great for the NHS budget if very large numbers of patients were to be eligible for treatment. Affordability is not the responsibility of NICE; the government remains accountable for the overall NHS budget and must therefore judge a particular intervention unaffordable for the NHS even though NICE might have judged it cost-effective. Such a situation has not yet arisen.

Implementation. Not all of NICE's guidance is mandatory for the NHS. For technology appraisals, however, every local health care body within the NHS is legally required to provide funding from its overall government allocation within 3 months to support care for all patients who meet NICE-approved indications for treatment. This has raised concerns that local health care organizations will be forced to displace other, allegedly more cost-effective interventions. Without a mandatory feature, however, it is likely that expensive new technologies would remain subject to continued postcode prescribing. From a policy perspective, the mandatory funding of NICE technology appraisals also serves the important purpose of fostering innovation. If NICE guidance is acted on consistently, manufacturers producing novel cost-effective technologies have an explicit mechanism to gain funding for their products, and patients have security of access to new technologies wherever they live in the United Kingdom.

Political Support and Structure
The creation of NICE required the fusion of 2 significant but different political forces. First, with an active press highlighting individual patient cases, the British public discovered in the 1990s that their ability to receive a new medicine could be determined by which street they lived on. The phenomenon was dubbed “postcode prescribing” and was a result of divergent funding decisions made by local health care authorities. The prospect of a new body, committed to ensuring that new treatments were available equally to all, was a potent political icon, and one that provided the public face that generated much of NICE’s early support.

Second, there was mounting concern across all levels of government about the financial sustainability of the NHS. Despite the stereotype of the British public as being aware of, and accepting, limits to health care funding, no government wanted to acknowledge explicit rationing within the NHS. Nevertheless, there was a broad acceptance within governmental and academic circles that the unbridled adoption of new technologies would create ever greater pressures on the NHS budget. What was needed was an organization that was independent and objective yet rooted in the NHS and that could make defensible decisions to help the health service allocate its re-

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souces more effectively. In its founding legal instruments, NICE was therefore established with a special status as one of several “arms-length bodies” within the NHS.10

The directors of the institute’s governing board are appointed by an independent appointments commission, and these directors, in turn, have the discretion to select the executives who run the institute’s day-to-day operations. Importantly, while the institute’s funding still comes solely from government, its work agenda is independent of direct political control. The political insulation provided by this structure has been critical to NICE’s independence and durability and has allowed the institute to fulfill its charge: to consider cost-effectiveness as well as clinical effectiveness and to “perform such functions in connection with the promotion of clinical excellence and the effective use of available resources in the health service as the Secretary of State may direct.”10

From its inception, therefore, NICE has wielded a joint mandate to ensure equal access to new technologies while saying no when the cost does not represent acceptable value for money. Framed in this way, the institute’s broad mission has allowed it to function as a ship flying under several flags and enabled it to draw on support from different stakeholders at different times. Over the 6 years of its existence, NICE has won bipartisan political support, a substantial growth in its funding from the government, and a wider range of responsibilities.

**Criticisms of NICE**

Not surprising for an organization at the fulcrum of decisions that can have far-reaching implications for patients, clinicians, and manufacturers, NICE and its guidance have received much attention in the United Kingdom, and not all of it has been favorable. Some of these criticisms focus on practical aspects of NICE’s function, but others highlight unsolved tensions between innovation and limited resources, efficiency and equity, and centralized and local decision making that, despite NICE, continue to confound decision makers in the NHS and to roil the British media and public.

Some critics have pointed out that NICE’s approach to using cost-effectiveness, although touted as a mechanism for making difficult decisions to limit the approval of new technologies, has in fact led to the approval for funding, at least for some indications, of most new drugs and devices. NICE has thus been called a “golden goose” for the pharmaceutical industry and has been blamed for NHS inflation and the creation of a constant stream of new budgetary requirements for local health care authorities struggling to support local spending priorities of higher value.5,11,12

NICE in fact has operated during the halcyon days of an unprecedented period of sustained growth in the overall NHS budget, a rate of growth (7.3% annually since 2000) that cannot continue indefinitely.13 When budgets cease to grow, a new day will dawn for NICE and the NHS as they manage the delicate balance between cost-effective new technologies and local health authority budgets. Critics foreseeing this funding squeeze often suggest that NICE should become engaged more directly in the true trade-off budgetary decisions within the NHS. This could occur by adjusting its cost-effectiveness threshold downward to reflect the preferences of local authorities, by shifting its work program to identify a greater number of “obsolete” technologies whose funding should be eliminated, or by having a yearly fixed budget itself, out of which all funding for new innovations would have to come.11

From the other end of the spectrum, drug and device manufacturers have a mixed view of NICE. Some are eager to have their products appraised by NICE to gain rapid entry into the UK market. Others claim publicly that economic modeling based on QALYs is unreliable and inappropriate to use as the standard for early evaluations of many new products.14 Many of those opposed to NICE’s approach probably have the chief concern that a negative appraisal would have adverse consequences on global sales. Manufacturers of all views, however, continue to appeal many of NICE’s decisions when the guidance is viewed as too restrictive or when the guidance declines to promote one product over another in appraisals of several drugs in the same class.

Manufacturers and others have also faulted NICE because evidence continues to document that local health authorities have failed to consistently implement its positive guidance for funding of new innovations.15-17 According to these critics, NICE and the NHS have not done enough to eliminate postcode prescribing and ensure support for the funding of medical innovations across the NHS.

NICE therefore finds itself not uncommonly facing criticism that it is being too lax in its appraisals at the same time that it is fending off appeals from manufacturers and defending itself in the national press against charges that it is denying “lifesaving” treatments to ill British citizens. NICE guidance has indeed approved new technologies whose funding, if fully implemented, would cost approximately $1.3 billion per year, but the same decisions usually have included denials for some indications on the basis of cost-ineffectiveness.18 If one measure of the appropriate calibration of policy in the midst of inherent political and ethical tensions is the presence of sharp criticism from both sides of an issue, NICE can usually be found to “enjoy” this measure of success.

The extent to which NICE has met its objectives of improving the standard of care and the effective use of resources within the NHS is still a matter of opinion. NICE is but one piece of several NHS initiatives to set standards at the national level, and the institute’s functions do not include all of the levers for improving quality and value in a health care system. Implementing NICE’s guidance consistently is also an ongoing and difficult chal-
The use and cost of devices such as implantable cardiac defibrillators is also rapidly increasing. However, caution may be the most obvious lesson to be drawn from the checkered history of technology assessment efforts at the federal level in the United States. Beginning with the Office of Technology Assessment, founded in 1972, and continuing through many other offices, councils, centers, and agencies, efforts to establish a publicly funded but politically insulated entity to conduct technology appraisals have each succumbed in turn to pressure from manufacturers and the medical profession. The most recent incarnation, the Medicare Coverage Advisory Committee (MCAC), was chartered in 1998 to “advise CMS [the Centers for Medicare and Medicaid Services] . . . on whether specific items and services are reasonable and necessary under Medicare law.” But as has been noted by several commentators and participants, while the MCAC yields a sophisticated approach for evaluating clinical effectiveness, it has been given no mandate to consider costs or value in making its coverage recommendations. Although the Medicare statute is silent on the role of cost-effectiveness into decision making, it has been given no mandate to consider costs or value in making its coverage recommendations. Although the Medicare statute is silent on the role of cost-effectiveness into decision making, it has been given no mandate to consider costs or value in making its coverage recommendations.

The dismal story of NICE-like organizations at the federal level in the United States, and the general failure across public and private sectors to incorporate notions of cost-effectiveness in evaluations of new drugs and devices, casts a stark shadow across any consideration of the positive lessons that NICE might hold for US policy. Yet the convergence of the huge financial commitment of the Medicare drug benefit, the torrent of effective yet expensive new medical devices, and fiscal pressures across the entire federal budget at a time when a single party controls all the branches of government may crystalize political will to consider the value of what Medicare pays for. In that light, what are the distinctive policy lessons that NICE holds for the United States? Why might it be that in a single month, NICE’s Web site receives more than 1 million hits from the United States?

First, NICE was able to neutralize much of the early concern about its role by taking great efforts to produce guidance of the highest possible quality and ethical legitimacy. The rigor and independence of NICE’s scientific review process brings an objectivity to NICE guidance that is widely respected. Through scrupulous adherence to its principles of stakeholder involvement and procedural transparency, the positive effects of scientific rigor and independence are strengthened and help to underscore the legitimacy of all of NICE’s guidance.

An important point for the United States is that NICE has also demonstrated that cost-effectiveness analysis can work at the core of a national guidance program, and the institute has made strong claims for its ethical and practical benefits. A key to this success lies in the balance between NICE’s use of cost-effectiveness to set limits and the institute’s explicit role in facilitating the funding of innovative new technologies. Manufacturers have benefited not only from the funding mandate that comes with NICE approval but also from clarification of the rules of the game. Manufacturers now know what data they will need from clinical trials to provide acceptable evidence of the clinical effectiveness and cost-effectiveness of their products; they can therefore see and engage in a clear process.

NICE’s arm’s-length structure within the NHS and use of independent advisory groups also holds important policy lessons related to its success. Much like the US Federal Reserve Board, NICE is able to operate with a sense of security from any direct political influence. This independence was recently tested when NICE produced draft guidance proposing the elimination of funding for drug therapies for Alzheimer disease because of cost-ineffectiveness. Public pressure mounted against this draft decision, with the media trumpeting...
NICE’s “attack” on the elderly. The issue reached the floor of the House of Commons, where the prime minister reasserted that NICE was an independent body whose judgments should be respected and not open to political pressure. He faced no opposition to this statement. A broad mandate and structural independence are both necessary to build this kind of durable support. Options for an analogous structure in the United States would inevitably be vigorously debated but could be based on 1 of the 2 following possibilities: bolstering the independence and scope of the MCAC inside CMS or inviting an independent organization, such as the Institute of Medicine, to form a NICE-like body. Political independence would be maximized with the second of these alternatives and may therefore be the preferred option. With either approach, however, the resources of the Agency for Healthcare Research and Quality could be effectively used to provide the necessary technical expertise.

It is possible to consider whether the United States’ current fragmented approach to coverage decisions for new technologies provides a positive diversity and whether, through multiple natural experiments and incremental challenges by myriad formulary committees and coverage groups, a decentralized market-oriented approach adds richness, greater learning potential, and value in contrast with a monolithic, centralized process. We believe this holds no merit. It is unlikely that the US public would like to experiment with “postcode prescribing.” Private health plan medical directors want a more centralized process to produce a unified medical policy. And if the policy intent is to grapple seriously with the tensions among quality, innovation, and value in a federally funded program such as Medicare, then a centralized, rigorous, and transparent process presents itself as the only real option for ensuring an ethically legitimate structure worthy of political support.

Conclusion
It is easy to discount lessons for the United States from the creation and experience of NICE by focusing on the many differences between the US and British health care systems. Yet both nations face the same essential challenge: how to improve quality, foster innovation, and ensure value for the money spent on health care. While no policy intervention is easily transplanted from one setting to another, it is not unreasonable to suspect that NICE holds lessons that the United States might find useful as it seeks to develop its own answers to this ongoing challenge.

Financial Disclosure: Dr Rawlins has been chairman of NICE since its inception in 1999. Dr Pearson reported no financial disclosures.

Funding/Support: Dr Pearson was supported during his time at NICE by an Atlantic Fellowship in Public Policy from the British Foreign and Commonwealth Office.

Role of the Sponsor: The sponsor had no involvement in the conception, preparation, review, or approval of the manuscript.

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