NICEly Done!

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Perhaps you missed the page 1 story in The Wall Street Journal or the nearly simultaneous article in the Journal of the American Medical Association. I was amazed and pleased by the level of attention given to NICE—the National Institute for Health and Clinical Excellence in the United Kingdom (U.K.).

For P&T readers who are not familiar with NICE, allow me to briefly trace its history, mission, and vision and to comment on its potential future applicability for P&T committees in the U.S.

NICE was established in 1999 (as the National Institute for Clinical Excellence) to provide health care professionals in England and Wales with advice on securing the highest attainable standards of care for patients within the National Health Service (NHS). On April 1, 2005, NICE merged with the Health Development Agency.

Pearson and Rawlins described NICE as being “at the controversial intersection of quality, innovation, access and cost.”

NICE 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 health. According to its Web site (www.nice.org.uk), four distinct programs comprise various forms of what are collectively known as “NICE guidance.” The four programs include:

- an appraisal of individual or classes of health technologies.
- development of clinical guidelines involving considerations of both clinical effectiveness and cost effectiveness.
- guidance on the safety and efficacy of interventional procedures.
- public health guidance, such as advice on the clinical effectiveness and cost effectiveness of a single intervention (e.g., needle exchange for reducing the prevalence of blood-borne infections in intravenous drug users).

A key characteristic of NICE is its emphasis on the economic evaluation of new technologies, including drugs. The key measure used by NICE to assess the marginal value of a new technology for different patient groups is the additional cost per quality-adjusted life-year (QALY). Although NICE does not set a specific per-QALY threshold above which a technology is rejected, this type of analysis is clearly essential to its final evaluation of new products.

Another distinguishing characteristic of NICE is its overarching political structure, as stated in The Wall Street Journal article:

... 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.

Simply, NICE is independent in all respects, akin to the Federal Reserve in the U.S.

Two key questions remain in my mind: Has NICE worked? Can we possibly import it here?

The literature is ambiguous regarding the overall effectiveness of NICE itself. Surely, NICE has been able to limit runaway pharmaceutical-based inflation in the U.K., and has created a central government model for a rational approach to drug purchasing that is currently the envy of the world. Paradoxically, NICE has been criticized as 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 treatment to all British citizens. If criticism from the left and right is indicative of success, then NICE is doing a splendid job indeed!

The question of importing the NICE model, however, remains controversial. In my view, it seems silly to pass a potential budget-busting piece of legislation such as the Medicare Modernization Act (MMA) without some kind of centralized approach to the evaluation of new technology. Pearson and Rawlins report that the NICE Web site receives more than one million hits each month from the U.S. alone, which suggests that there is tremendous interest in importing the program. Clearly, aspects of the evidence-based work completed by NICE would be applicable to virtually every P&T committee in the U.S. Even though we might not be able to import the entire model, we certainly can take advantage of the publicly available results of its deliberations.

Sometimes I think Americans tend to take a parochial view of our world. We can learn much from our neighbors in Europe and Australia about a government-sponsored, independent assessment of new technologies, especially pharmaceuticals. My hat is off to our British colleagues for a job NICEly done. I hope that many of our own citizens will embrace aspects of NICE’s innovative work in our field.

As usual, I am interested in your views. I can be reached at my e-mail address, david.nash@jefferson.edu.

REFERENCES