# Nasty or Nice? A Perspective on the Use of Health Technology Assessment in the United Kingdom

# Michael Drummond, PhD,<sup>1</sup> Corinna Sorenson, MPH, MHSA<sup>2</sup>

<sup>1</sup>Centre for Health Economics, University of York, York, UK; <sup>2</sup>LSE Health and Social Care, London School of Economics, London, UK

Keywords: health technology assessment, HTA, National Institute for Clinical Excellence, NICE, United Kingdom.

# Introduction

Health technology assessment (HTA) has a long history in the United Kingdom. The first study undertaken to inform a central policy decision was the economic evaluation of screening for tuberculosis using mass miniature radiography [1]. Another well-known study was the evaluation of the heart transplant program, commissioned by the Department (i.e., Ministry) of Health (DH) to decide whether to expand heart transplant facilities [2].

Health technology assessment expanded rapidly in the 1990s, following the decision to spend up to 1.5% of the National Health Service (NHS) budget on research and development (R&D). The HTA program, which commenced in 1993, became one of the largest R&D programs and this led to the establishment of the National Coordinating Centre for Health Technology Assessment (NCCHTA) in June 1996. The Centre commissions and coordinates a wide-ranging program of primary and secondary research in HTA.

However, the international profile of HTA in the United Kingdom greatly increased with the establishment of the National Institute for Clinical Excellence (NICE) in 1999, renamed the National Institute for Health and Clinical Excellence in 2005. Here the difference was that not only were HTAs to be conducted, but the results would be used in developing guidance for the NHS on the use of health technologies. Such has been the impact of NICE, both in the UK and beyond, that the Institute's activities have become synonymous with the conduct of HTA in the United Kingdom. Therefore, this article will focus mainly on the activities of NICE, given in Section I, discussing NICE's major achievements given in Section II, major issues unresolved given in Section III, and lessons for other jurisdictions given in Section IV.

# SECTION I: NICE'S ACTIVITIES IN HTA

In broad terms, NICE serves as an "arms-length" organization that provides national guidance on the promotion of good health and the prevention and treatment of ill health. NICE's remit is to consider both clinical *and* cost-effectiveness in developing its guidance. When it was established and during the bulk of its existence, NICE has produced three types of guidance: technology appraisals, clinical guidelines, and interventional procedures. However, as a result of the DH's 2004 ongoing review of its various arms-length bodies, NICE also assumed the responsibili-

Address correspondence to: Michael Drummond, Centre for Health Economics, University of York, Heslington, York, UK YO1O 5DD. E-mail: md18@york.ac.uk

10.1111/j.1524-4733.2009.00552.x

ties of the Health Development Agency in mid-2005, which provided the Institute with authority to develop guidance on public health interventions or programs.

Overall, NICE guidance is advisory and much is left to local discretion, in terms of its adoption and implementation. However, as of January 2005, technology appraisals were supported by mandate, in that the NHS in England and Wales are now legally obligated to provide funding for medicines and treatments recommended by NICE. Specifically, if NICE guidance supports that a particular technology be made available by the NHS to a certain patient group(s), then associated health-care organizations are obligated to implement such recommendations within 3 months from the date the guidance is issued [3]. The mandate is a result, in part, of the well-publicized "postcode lottery" debates around disparate funding of treatments from location.

Although all aspects of NICE's work involves an element of HTA, it is the technology appraisal program—coordinated by NICE's Centre for Health Technology Evaluation—which has attracted the most interest and debate. The Centre develops guidance on the use of new and existing medicines, treatments, and procedures within the NHS. As a result of a public consultation process in mid-2006, NICE was given responsibility for the initial stages of the topic selection process on behalf of the DH. Specifically, the stated criteria include [4]:

- 1. Burden of disease (population affected, morbidity, mortality).
- 2. Resource impact (cost impact on the NHS or the public sector).
- 3. Clinical and policy importance (whether the topic falls within a government priority area).
- 4. Presence of inappropriate variation in practice.
- 5. Potential factors affecting the timeliness for the guidance to be produced (degree of urgency, relevancy of guideline at the expected date of delivery).
- 6. Likelihood of guidance having an impact on public health and quality of life, reduction in health inequalities, or the delivery of quality programs or interventions.

NICE often commissions an independent academic center or centers, called technology assessment groups, to prepare assessment reports for consideration by the technology appraisal committee (TAC). The TAC is an independent entity with membership drawn from the NHS, patient organizations, academia, and industry, and is the primary decision-making body in the production of guidance on new health technologies. Members are typically appointed for a 3-year term, and allocated to one of three branches within the committee. Although the TAC represents the views of its varied membership, its advice is intended to be separate from any vested interests. In addition to the aforementioned, the Centre confers with various "consultee organizations," ranging from national patient groups, health professional bodies, and manufacturers of the technology in review. Such entities are able to submit evidence during the evaluation process, comment on the appraisal documents, and can appeal against the TAC's final recommendations. Moreover, the Centre relies on "commentator organizations," which are represented by manufacturers of comparator products, NHS Quality Improvement Scotland, and research groups working in the relevant topic area. These bodies can comment on evidence and other documents used or produced by the appraisal process, but cannot submit evidence.

NICE's standard approach to technology appraisal, now called multiple technology appraisals (MTAs), takes 54 weeks from initiation of the process to issuing of guidance. Key features of the process are scoping of the topic, which now includes a scoping workshop involving the manufacturers and other key consultees, a company submission, and an independent technology assessment report (TAR) by one of the assessment groups mentioned earlier. The TAR normally includes a systematic review of the clinical literature and an economic model, and can be quite extensive, especially because more than one technology is being assessed. The report and any other relevant evidence are then considered by the technology appraisal committee and an appraisal consultation document (ACD) is issued. Consultees are then given an opportunity to comment before the final appraisal determination (FAD) is issued, following a second discussion by the appraisal committee. Consultees then have the opportunity to appeal, in which case an appeal hearing takes place. If no appeal is launched, the guidance is issued to the NHS within 6 weeks.

In addition to the aforementioned appraisal procedure, NICE developed a single-technology appraisal (STA) process in 2005 for the review of single technologies for a sole indication. This was introduced in response to criticisms surrounding the length of time taken by the MTA process. The STA process is similar to that of the full MTA appraisal process, as previously described. However, in terms of the former, only evidence submitted by the manufacturer is formally considered in the independent review. Moreover, formal consultation procedures take place only if the appraisal committee's preliminary recommendations are substantially more restrictive than the terms of the licensed indication of the product in appraisal [5]. The timelines for the STA process also differ. Specifically, STAs require less time to produce the guidance, approximately 39 weeks from initiation of the appraisal to publication [5]. However, the timeline for STAs is not substantially compressed and with any delays in the appraisal or appeals, it could approach the duration required for an MTA. To date, the STA process has been applied only to drugs, mainly cancer drugs, but is increasingly being employed in other disease areas.

NICE's new STA process is similar to the one that has been in operation in Scotland for several years. Here, if a company wishes guidance on the use of its drug to be issued, it submits a dossier to the Scottish Medicines Consortium (SMC). The dossier is then evaluated by the Consortium's assessors and guidance issued. There has been some interest in comparing and contrasting the costs and outcomes (in terms of decisions) of the English and Scottish approaches [6].

# SECTION II: MAIN ACHIEVEMENTS OF NICE

#### Methodological Rigor

Most commentators agree that the approach to HTA followed by NICE is fairly rigorous. First, both company submissions and the

TARs conducted by the independent assessment groups are expected to conform to a clear set of methodological guidelines set forth by NICE [7]. The guidelines embody the "reference case" principle [8], whereby any analytic approach is permissible, as long as one of the analyses performed corresponds to the reference case. The reference case encourages consistency and compatibility of the studies submitted to NICE.

NICE's methodological guidelines embody most of the features found in other international guidelines, such as those existing in Australia and Canada [9,10]. The most contentious aspects of the current guidelines are the following.

*Perspective on costs*. Costs are limited, in the primary analysis, to NHS and personal social services costs only. This is embodied in the remit given to NICE by the DH, which is to advise on the best use of the NHS budget. However, in the case of the appraisal of public health programs, the perspective has been broadened to consider costs falling on other public sector budgets. This leads to the rather perverse situation that a (public health) appraisal of an educational program to reduce substance abuse could consider the potential reductions in criminal justice costs, whereas the (technology) appraisal of a drug maintenance program for heroin addicts could not.

QALYs as the measure of health gain. NICE insists on the presentation of QALYs and then uses these in the calculation of an incremental cost-effectiveness ratio. This has been criticized on two grounds: first, that there are methodological problems with QALYs; and second, that the QALY does not fully capture the social value of health-care interventions (this is discussed further in the following discussion).

*Subgroup analysis*. NICE is often keen to analyze costs and effects by patient sub-group, even if the original clinical studies were not powered to assess such differences. This is in conflict with the principles of clinical trial design, but NICE argues that as long as the uncertainty around such estimates is adequately characterized, it is better to have these analyses than not. It is certainly true that much of NICE's guidance restricts the use of health technologies only to those subgroups of the patient population for whom this is cost-effective, rather than rejecting the technology altogether.

*Probabilistic Sensitivity Analyses (PSA).* Although everyone agrees that parameter uncertainty needs to be addressed in economic evaluations, there has been criticism of NICE's insistence on PSA. The main concerns are that the multivariate uncertainties are not readily specified and that there could be restrictions on the use of some types of models because of the computational difficulties of conducting PSAs. NICE's view is that PSA is the best approach to characterizing parameter uncertainty and that practical problems should not compromise this principle. However, the Institute has accepted studies that do not have a full PSA.

The second way that NICE has promoted methodological rigor is through its commissioning of independent analyses by the independent assessment groups. For a full MTA, the studies incorporate both a full systematic review and a *de novo* economic model. All of the TARs are subject to peer-review and are published (excluding any data that are commercial-in-confidence) in the NCCHTA's publication, *Health Technology Assessment* (see: http://www.hta.ac.uk/project/htapubs.asp).

However, NICE has run into criticisms over the length of time these more detailed assessments take. There is also conflicting evidence on whether the additional methodological rigor is justified, in terms of better decision-making [6,11]. Certainly, one result of this relatively resource-intensive approach is that NICE has undertaken fewer technology appraisals than it otherwise might have done [12]. NICE's response to these criticisms has been to establish the STA program as mentioned earlier.

#### Transparency

From the outset, NICE has sought to be transparent in its processes and procedures. As mentioned earlier, all the evidence gathered by the assessment groups are published, with the exception of those data that are deemed commercial-in-confidence (e.g., unpublished clinical trial data). Also, in producing its guidance, NICE gives details of the appraisal committee's appraisal of the evidence and the reasons for the guidance given. Both the ACD and Final Appraisal Determination are posted on the Institute's website.

Nevertheless, in the recent review of NICE by the Health Select Committee (of Parliament), several commentators felt that transparency could be further increased [13]. First, it was felt that NICE should open up the technology appraisal committee hearings to the public, at least for the part of the meeting where the evidence was being discussed (this is currently in review). Second, it was felt that NICE should make executable versions of the assessment group models available to manufacturers. This was one of the issues successfully contested in the judicial review of NICE's reappraisal of drugs for Alzheimer's disease.

#### Stakeholder Involvement

NICE has encouraged extensive stakeholder involvement in all areas of its work, including HTAs. In the case of technology appraisals, stakeholder involvement begins at the scoping stage, where key stakeholders are invited to a scoping workshop. This defines the precise question(s) to be posed in the appraisal, including the clinical alternatives to be compared. These can include alternative treatment strategies, whereby particular drugs enter at various points in the sequence, as well as simple headto-head comparisons of two or more drugs.

Then, manufacturers have the opportunity to submit data and analyses on their product to the assessment group for consideration, and also have the opportunity to comment on the group's report prior to the appraisal committee meeting. All stakeholders, including manufacturers, professional groups, patient organizations, and the NHS, have the opportunity to comment on the ACD and FAD. Finally, if they are not happy with the FAD, key stakeholders have the opportunity to appeal. Around 30% of NICE's decisions have been subject to appeal, a proportion that has remained constant over the years. However, there are early signs that the proportion of decisions subject to appeal may be higher with STAs.

As was the case with transparency issues (discussed earlier) some commentators feel that NICE could do even more to involve stakeholders. Manufacturers believe that there would be much to be gained from early involvement, even before their product is selected for appraisal. In particular, they would like to have the opportunity to discuss with NICE its likely requirements prior to making large investments in economic data gathering. Manufacturers would also welcome the opportunity to submit oral evidence to the appraisal committee, or to correct misconceptions. they argue that this would reduce the number of appeals.

The other area where stakeholder involvement could be increased is with respect to patient participation. Although every NICE committee has a patient representative, these individuals sometimes find it hard to make an effective contribution, given the technical nature of the process. It is hard to assess the extent of this problem and it is likely that patient participation in NICE's decision-making processes is highly variable.

# SECTION III: MAJOR UNRESOLVED ISSUES

As might be expected, the advent of NICE has led to considerable discussion and debate in the UK around issues relating to the allocation of healthcare resources. Of course, many of these issues existed previously, albeit under the surface. However, the advent of NICE has made them more explicit.

# Independence of HTA

Although NICE is classed as an "arms-length" organization, there are accusations that the Institute is essentially following a government, or payer's, agenda. Indeed, to a large extent this is true, because NICE's remit is to ensure that the use of NHS resources is consistent with the principles of clinical and costeffectiveness. Therefore, on occasions it is bound to issue negative guidance if a given technology, or its use in certain indications, does not meet the criteria.

Whether this constitutes more rationing of care than would have occurred in the absence of NICE is open to debate. Because the determination of the NHS budget is made by the DH largely independent of NICE, it is likely that NICE has led to different rationing, as opposed to more rationing.

Although NICE views the DH as its major stakeholder, there are very few examples of government actions that impinge on NICE's work. Following NICE's decision not to issue positive guidance on the use of beta interferon for multiple sclerosis, the Department, perhaps fearing a negative political backlash, brokered a risk-sharing scheme with the manufacturers. This allowed certain categories of patients to obtain, or to continue with, therapy, at the same time limiting the financial risk to the NHS. More specifically, within the scheme, the government will be entitled to a refund of part of the expenditure on beta interferon, if the long-term benefits from treatment are not as favorable as the manufacturers claim.

Although government interference in NICE's affairs has been minimal, the perception of lack of independence remains, as evidenced by some of the comments made to the Health Select Committee [13]. Therefore, NICE continues to seek to counter this by engaging with all its stakeholders and by ensuring wide representations by patients and health professionals on its advisory committees. However, recently the Office of Fair Trading argued that the Pharmaceutical Price Regulation Scheme (the main financial agreement between government and the pharmaceutical industry) should be abandoned in favour of "value-based pricing" [14–16]. If this concept were to be embraced by government, there may be a role for NICE in the process. If this change did take place, NICE would be perceived (unambiguously) as being the government's price negotiator for drugs.

#### Topic Selection and Priority Setting

Although NICE has taken over the role of topic selection from the Department of Health, problems still remain. Several commentators make the comparison with Scotland, where the SMC considers every new drug in every licensed indication. This means that the coverage of guidance by the SMC is much broader than that of NICE, which prioritizes fewer topics. Some argue that NICE would have more impact if it offered less depth and more breadth [12]. Others argue that the rigorous assessments undertaken by NICE are its major strength [17].

### Timeliness

An issue partly linked to that of priority setting and methodological rigor is that of timeliness. The concern has been raised that a period of 54 weeks (minimum) to conduct assessments is much too long. As mentioned previously, STAs were introduced to deal with this issue. However, STAs only reduce the core assessment time from 54 to 39 weeks and there are worrying signs that, with a higher proportion of appraisals going to appeal, the average time to issue guidance may be increased.

These concerns are compounded by the fact that, once a technology is selected for appraisal by NICE, the NHS is less likely to introduce it, pending NICE's decision. The extent of so-called "NICE blight" has not been formally studied, but does exist. Of course, the technology manufacturers feel (in the case of drugs) that all licensed products should be used until NICE issues guidance to the contrary. On the other hand, the NHS is cautious about introducing new technologies, which will be hard to remove or restrict if they are subsequently shown to be poor value for money.

NICE already makes recommendations for future research when issuing its guidance, but these are only rarely binding on the manufacturer [18]. However, the extension of these arrangements, within the umbrella of a policy of conditional reimbursement, is widely regarded by all parties as a promising way forward. One manufacturer of a cancer drug recently offered the NHS a "credit note" arrangement based on patient outcomes, in order to secure a positive recommendation by NICE.

# QALYs and Social Values

From the outset, NICE has been quite clear that the measure of health benefit to use in technology appraisals is the qualityadjusted life-year (QALY). The theoretical and methodological weaknesses of the QALY approach have been well-discussed elsewhere [19] and will not be reiterated here. However, in the discussions of NICE's decisions, an additional issue has arisen, namely, does the QALY capture all the elements of social value relevant to decisions about the allocation of health-care resources?

NICE uses QALYs in a "standard" fashion in its technology appraisals; namely a QALY is considered of equal value no matter who receives it. However, some argue that society, if consulted, would not apply this principle. For example, some research studies indicate that members of the public may value a QALY given to someone in a very poor health state higher than one given to someone in good health. NICE has attempted to explore these issues through its Citizens' Council, a small group of individuals chosen to reflect the views of the general population [20]. As one might expect, the situation is not clear, although there was a suggestion that seriousness of the patient's condition is a factor that people feel should be taken into account.

## The Cost-Effectiveness Threshold

The use, or nonuse, by NICE of a threshold has been a continuing topic for debate, because it would be clear evidence that NICE rations care. Three criticisms have been raised: 1) there should not be a threshold; 2) the threshold has been set at the wrong level, or is arbitrary; and 3) different thresholds should apply, depending on the nature of the treatments or patient populations being studied.

Of course, the first criticism is rather meaningless in that whenever decisions are made whether or not to reimburse a particular technology some assessment of value for money is being made. Perhaps a more relevant question is whether the cost-effectiveness threshold (or thresholds) should be explicitly stated. In its early days, NICE denied that it was applying a threshold. However, as the information on the decisions made by NICE accumulated, it was possible to infer what the threshold might be [21].

Subsequently, the director and deputy director of NICE discussed the issues surrounding the use of cost-effectiveness thresholds and stated that NICE applied a threshold range, namely, interventions with an incremental cost per QALY ratio of less than  $\pounds 20\ 000$  have a high probability of being funded, those with a ratio exceeding  $\pounds 30\ 000$  have a low probability of being funded [22,23]. Rawlins and Culyer also discuss possible situations where the upper bound of  $\pounds 30\ 000$  might be exceeded, for example on grounds of equity.

The main arguments for an explicit threshold are that it is transparent and may encourage more consistency in decisionmaking. Also, as happened with NICE, a threshold would be inferred even if it were not explicitly stated. The main arguments against an explicit threshold are that it tells us little about the likely opportunity cost of adopting a new technology [24] and that it provides guidance to technology manufacturers on the maximum amount they can charge. However, even if there were evidence that manufacturers' estimates of the incremental cost per QALY of their products were clustering around £29 000, it would be important to know whether this was the result of raising or lowering price expectations.

In order to apply an explicit threshold, the decision-maker needs to know what the right level would be. NICE has never claimed to know the answer to this question. Some of those close to NICE have described the Institute's decision-making process as a deliberative one which, in essence, is searching for a threshold [23]. Some research in the UK is beginning to tackle the issue of the threshold level. In one study, Martin et al. [25] have attempted to estimate the threshold level implied by decisions currently being made within the NHS. Their conclusion is that NICE's threshold range is, if anything, a little on the high side. Another major research effort has been launched to determine the feasibility of estimating a monetary value of a QALY from a societal perspective [26].

The third concern is that the cost-effectiveness threshold, if one can be determined, may differ depending on the treatments being evaluated, or the patient populations being studied. In part, this links back to the discussion earlier; if the QALY does not fully capture all the relevant elements of social value, it may not make sense to apply a single threshold. This issue has been raised in the context of drugs for rare diseases (i.e., orphan drugs). Even if these treatments do not appear very cost-effective (i.e., have a very high cost-effectiveness ratio), society may still prefer to make them available, because many of the diseases treated with orphan drugs are life-threatening or because it would be unfair for someone not to be offered treatment just because their disease is rare [27]. On the other hand, it has been pointed out that valuing rarity per se may not make sense, in that resources could be denied to patients suffering from more common diseases, some of which could be equally serious [28].

Further research is needed on whether QALYs should be weighted other than equally and whether society values attributes of health care that cannot easily be incorporated in the QALY framework. It is possible that factors such as the severity of the patient's condition, or the availability of alternative treatments, could be relevant, but there is little evidence that these feature in NICE's decision-making. However, in one working article, NICE did suggest that, pending further research, a higher cost-effectiveness threshold ,around 10 times the existing threshold,may have to be applied in the case of ultra-orphan drugs (i.e., those drugs for conditions with a prevalence of less than 1 in 50,000) [29]. More recently, NICE has initiated a consultation on whether there should be a higher threshold in the evaluation of treatments given in the last months of life, such as drugs for metastatic cancer.

#### Implementation of NICE Guidance

Several studies have shown that the implementation of NICE guidance is uneven across the NHS [30,31]. This is despite the fact that guidance resulting from technology appraisals is mandatory on the NHS and should be implemented within three months. This is particularly worrying because NICE was set up to reduce geographical variations in the adoption of new technologies (so-called "postcode rationing").

Several factors are considered to affect whether NICE guidance is implemented or not. This include local political considerations, lack of (health care) provider support, lack of knowledge and understanding of the assessment process, media and patient group pressure, lack of a broad systems approach to implementation, minimal reinforcement of compliance or accountability, and poor financial planning. Specifically, the Audit Commission [31] found inappropriate use of allocated funding, lack of horizon scanning for future NICE guidance, and poor planning. The organizations reviewed perceived that NICE guidance was unaffordable, but where robust implementation systems were in place, funding was not found to be the biggest barrier.

One issue, relating to the lack of understanding of guidance, is that the majority of NICE guidance on the use of technologies is not a straight "yes" or "no." Rather, NICE will often advise that a technology can be used, but only for certain subgroups of patients, defined (for example) by their level of baseline risk, or stage of disease. Depending on how clearly the patient subgroups can be defined, such guidance may be harder to implement or to monitor.

In the recent review of NICE by the Health Select Committee, several stakeholders argued that a more stringent monitoring process should be implemented, with financial sanctions for NHS organizations failing to implement guidance. Problems over lack of implementation are likely to remain. One of the difficulties is that the UK NHS operates with global budgets for service provision and predominantly salaries for medical practitioners. Therefore, it is more difficult to use financial incentives (e.g., fees for particular procedures) to either encourage or discourage the adoption of particular health technologies.

# SECTION IV: LESSONS FOR OTHER JURISDICTIONS

Because NICE is one of the more sophisticated and most studied HTA entities, it is worth reflecting on whether there are any lessons for other jurisdictions using, or contemplating using, HTA. In general, one should be cautious about making such inferences, because all HTA entities are creations of the healthcare systems in which they are based and their current structure, organization, and processes may also be a result of previous history with HTA in the jurisdiction concerned.

Nevertheless there are probably lessons to be learned from NICE's assessment activities. Given the political nature of healthcare decision-making, the methodological rigor of the assessments has been important, since these are often challenged. Therefore, any jurisdiction thinking of establishing a body like NICE should consider carefully how such rigor can be maintained, by establishing comprehensive and clear guidelines for conducting studies and by nurturing local skills in clinical and economic evaluation in the jurisdiction concerned. Certainly NICE developed such skills in its associated academic units, by putting in place long-term contracts for undertaking independent technology assessments. Although, paradoxically, this is now somewhat diluted by the increased emphasis on STAs.

The use of independent evaluation groups was part of a broader strategy of encouraging transparency in NICE's activities. This strategy has worked well for NICE and jurisdictions thinking of establishing similar bodies should consider how transparent their activities can be made.

Linked to the notion of transparency, NICE has always followed a policy of encouraging stakeholder involvement in scoping appraisals and in commenting on draft reports. Although stakeholders still request even greater involvement, this policy has clearly been a success, as compared with what is observed in many other jurisdictions. NICE's experience is that stakeholder involvement can be time-consuming and may also increase the total time required undertaking assessments. However, it may pay off in the long run, if assessments are improved in quality and more often accepted.

In contrast to the assessment procedures, it is probably harder to draw many general lessons from NICE's activities in decisionmaking (or appraisal). For example, whereas general recommendations based on a single incremental cost-effectiveness ratio, and the use of a threshold or acceptable range of cost-effectiveness, may make sense in an integrated, single-payer system like the UK NHS, they may not make sense in more decentralized systems. Therefore, one would need to think carefully about the role of a central HTA entity in a country where the responsibility for providing health care is regionalized, or where there is a wide range of public and private payers.

In such jurisdictions, perhaps the role of any central HTA entity should be restricted to the production of high quality assessments, which can subsequently be used by different decision-makers. Then local decisions may differ, depending on the resources available. If technology assessments are to be used in this way they need to be adaptable to local needs. For example, the economic model underpinning the assessment could be made available so that it can be populated with local data. In countries like the Unite States, where there are many private insurers, extra thought needs to be given to how transparency in decisionmaking can be maintained, in a situation where insurers are in competition with one another.

### Conclusions

NICE has been widely debated and often criticized since its inception in 1999. However, it can claim several major achievements and still represents one of the more sophisticated attempts to integrate HTA into the decision-making process. So is NICE being nasty? Certainly, patients are being denied access to therapy that they otherwise might have received. However, short of making all effective therapy available, some mechanism needs to be put in place to decide on health-care priorities. In the UK, the approach followed by NICE has proved workable. Nevertheless, many important issues remain unresolved and NICE definitely remain a "work in progress."

Source of financial support: ISPOR provided a modest honorarium.

Michael Drummond is chair of one of NICE's Guideline Review Panels. Corinna Sorenson has no conflicts to declare.

#### References

1 Pole JD. Mass radiography: a cost/benefit appraisal. Oxford: Problems and Progress in Medical Care—Essays on Current Research, Nuffield Provincial Hospitals Trust, 1971.

- 2 Buxton M, Acheson R, Caine N, et al. Costs and Benefits of the Heart Transplant Programme at Harefield and Papworth Hospitals. London: Her Majesty's Stationery Office, 1985.
- 3 Mason A, Smith PC. Health Basket Project Benefit Report: England. Dublin: European Health Management Association, 2005.
- 4 National Institute for Health and Clinical Excellence (NICE). Department of Health Selection Criteria. London: NICE, 2006a.
- 5 National Institute for Health and Clinical Excellence (NICE). Guide to the Single Technology Assessment (STA) Process. London: NICE, 2006b.
- 6 Cairns J. Providing guidance to the NHS: the Scottish Medicines Consortium and the National Institute for Clinical Excellence compared. Health Policy 2006;76:134–43.
- 7 National Institute for Clinical Excellence (NICE). A Guide to the Methods of Technology Appraisal. London: NICE, 2008.
- 8 Gold M, Siegel J, Russell LB, Weinstein M. Cost-effectiveness in Health and Medicine. New York: Oxford University Press, 1996.
- 9 Commonwealth of Australia. Guidelines for preparing submissions to the PBAC (Version 4.0). Canberra: Australian Government Department of Health and Ageing, 2006.
- 10 Canadian Agency for Drugs and Technologies in Health (CADTH). Guidelines for the Economic Evaluation of Health Technologies: Canada. Ottawa: CADTH, 2006.
- 11 Barbieri M, Hawkins N, Sculpher M. Who does the numbers? The role of independent technology assessment to inform health systems' decision making about the funding of health technologies. Paper presented at the Health Economists' Study Group Meeting, Birmingham, 2007.
- 12 Buxton M. Economic evaluation and decision making in the UK. Pharmacoeconomics 2006;24:1133–42.
- 13 House of Commons Health Committee. National Institute for Health and Clinical Excellence. First Report of Session 2007– 2008, vol. 1. HC 27-1. London: The Stationery Office, 2008.
- 14 Office of Fair Trading: The Pharmaceutical Price Regulation Scheme: An OFT Market Study. London: OFT, 2007.
- 15 Claxton K. OFT, VBP; QED? Health Econ 2007;16:545-58.
- 16 Towse A. If it ain't broke, don't price fix it: the OFT and the PPRS. Health Econ 2007;16:653–5.
- 17 Barbieri M, Hawkins N, Sculpher MJ. Who does the numbers? The role of third-party technology assessments to inform health

systems' decision-making about the funding of health technologies. Value Health 2009;12:193–201.

- 18 Mason A, Drummond MF, Towse A. Economic Post-Launch Studies: Matching the Desirable with the Feasible. London: Office of Health Economics, 2006.
- 19 Drummond MF, Sculpher MJ, Torrance GW, et al. Methods for the Economic Evaluation of Health Care Programmes. Oxford: Oxford University Press, 2005.
- 20 National Institute for Health and Clinical Excellence (NICE). Social Value Judgements. London: NICE, 2005.
- 21 Devlin N, Parkin D. Does NICE have a cost-effectiveness threshold and what other factors influence its decisions? A binary choice analysis. Health Econ 2004;13:437–52.
- 22 Rawlins MD, Culyer AJ. National Institute of Clinical Excellence and its value judgments. BMJ 2004;329:224–7.
- 23 Culyer AJ, McCabe C, Briggs A, et al. Searching for a threshold, not setting one: the role of the National Institute for Health and Clinical Excellence. J Health Polit Policy Law 2007;12:56–8.
- 24 Birch S, Gafni A. Information created to evade reality (ICER): things we should not look to for answers. Pharmacoeconomics 2006;24:1121–31.
- 25 Martin S, Rice N, Smith PC. The Link Between Health Care Spending and Health Outcomes: Evidence from English Programme Budgeting Data. York: CHE Research Paper 24, Centre for Health Economics, University of York, 2007.
- 26 Donaldson C, Mason H, Shackley P. Contingent valuation in health care. In: Jones A, ed. Elgar Companion to Health Economics. Cheltenham: Edward Elgar Publishing, 2006.
- 27 Drummond MF, Wilson D, Kanavos P, et al. Assessing the economic challenges posed by orphan drugs. Int J Technol Assess Health Care 23:36–42.
- 28 McCabe C, Claxton K, Tsuchiya A. Orphan drugs and the NHS: should we value rarity? BMJ 2005;331:1016–19.
- 29 Nation Institute for Health and Clinical Excellence (NICE). Appraising Orphan Drugs. London: NICE, 2006.
- 30 Sheldon TA, Cullum N, Dawson D, et al. What's the evidence that NICE guidance has been implemented? Results from a national evaluation using time series analysis, audit of patients' notes and interviews. BMJ 2004;329:999. doi:10.1136/bmj. 329.7473.999.
- 31 Audit Commission. Managing the Financial Implications of NICE Guidance. London: Audit Commission, 2005.