**Academy of Medical Sciences response to the House of Commons Health Committee Inquiry in to the National Institute for Health and Clinical Excellence (NICE)**

## 1. Introduction

The Academy of Medical Sciences welcomes the opportunity to respond to the above consultation. This response was prepared following consultation with a number of Academy Fellows[1] and will focus on the following issues:

- Why NICE's decisions are increasingly being challenged and public confidence in the Institute
- NICE's evaluation process and whether any groups are disadvantaged by the process
- The speed of publishing guidance
- Comparison with the work of the Scottish Intercollegiate Guidelines Network (SIGN)
- The implementation of NICE guidance
- Improvements in gathering evidence
- Areas of guidance

2. The Academy fully supports the role of NICE in providing guidance for the promotion of good health and the prevention and treatment of ill health. We consider that NICE is based on a sound principle, since it is crucial that an effective body is available to consider the efficacy and cost of innovations in healthcare. It should be recognised that this is a challenging role, and that it is almost inevitable that some of the decisions taken by NICE will be controversial. Nevertheless, NHS funds are limited and it is essential that the balance between the cost and benefit of new treatments be scrutinised carefully.

## 3. Challenge of NICE guidance and public confidence in the Institute

Recent responses to NICE guidance for expensive new drugs such as Herceptin[2] and Aricept[3] indicate the growing public disquiet regarding decisions made by NICE. The perception by patients that they are being denied effective treatments is clearly an emotive issue and extensive press coverage of specific decisions further influences public confidence in the Institute. Patient advocacy groups are a growing feature of democratic health care systems. Thus, provided that such groups fairly represent the interests of patients and are not unduly influenced by commercial lobbyists, they should have an opportunity to put forward their views for a considerate hearing. However, whilst these views should be taken in to account, a consistent approach based on the best available evidence should be maintained by NICE, combined with a fair appeal process. Greater public engagement during NICE appraisals may be necessary to improve understanding of the evidence-based process, restore confidence in the Institute and reduce future protests over the availability of new drugs.

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[1] See Annex.

[2] Herceptin is a monoclonal antibody treatment that targets HER2+ breast cancer cells. HER2+ cells are present in approximately 15-25% of breast cancer patients.

[3] Aricept is an acetylcholinesterase inhibitor, which is approved for use in people with mild to moderate Alzheimer's disease. There has been anger over NICE's decision not to license the drug for use in early and late stage patients.

**4. NICE's evaluation process and whether any particular groups are disadvantaged by the process**

The Academy highlights that it is essential that the basic assumptions and models used during NICE's evaluation process are transparent and open to external scrutiny. We also consider it important that during evaluations of cost-effectiveness, NICE takes the overall burden of disease into account, to include societal costs to patient carers, unemployment costs or the expenditure of social services, for example. Quality of life assessments should also factor in the effect on carers or family members of those with a severe illness and relative enhancements in quality of life. The comparative benefit of a modest extension of life for an individual for whom the overall life expectancy is short is quite different from a modest extension of life for an individual for whom life expectancy is much longer. Such distinctions are important considerations during the evaluation process.

5. A further consideration is that a minority of patients may respond well to a medicine that is seen to offer unacceptably low efficacy for the majority. It would be useful if the sponsors of such medicines and independent patient advocacy groups could help to develop the means of identifying the patients most likely to respond to a treatment and to provide evidence of efficacy to NICE.

**6. The speed of publishing guidance**

Any delay in assessment is undesirable and the referral of some drugs for licensing in the USA before Europe may contribute to the perception that the UK process is slower than necessary. Final decisions may occur between 18 months and 5 years after a new drug is licensed, a delay often referred to as 'NICE blight'.[4] In order to reduce the delay between a drug being licensed and its referral for appraisal by NICE, we consider that potential drugs should be referred to NICE as they are identified, rather than via 'waves' of recommendation from the Department of Health. This would reduce the time period required for the treatment to be approved.

7. Furthermore, whilst it is apparent that a detailed assessment of evidence is a necessary and time-intensive process, there is a clear need for a faster appraisal system. We welcome the introduction of the Single Technology Assessment (STA) process to 'fast-track' the publication of guidance for certain new medicines referred to NICE.[5] Indeed, this model is based largely on the process used by the Scottish Medicines Consortium (SMC), the introduction of which greatly reduced the occurrence of problematic delays in decision-making. However, it is not yet clear whether the STA model adopted by NICE will deliver the early decisions necessary and we are concerned that the appraisal of other useful drugs may be subject to delay whilst resources are focused on drugs in the STA process. This issue is especially problematic since doctors may prescribe treatments before they have been approved by NICE when Primary Care Trusts (PCTs) are not required to fund them. Inevitably, this leads to variable availability, public disagreements and confusion amongst patients, indirectly affecting confidence in NICE.

8. The scenario would be improved by the provision of NICE guidance at an early stage following referral of new medicines and the formulation of an agreed programme of ongoing (and rigorous) evaluation thereafter. All drugs could effectively be evaluated using the STA while still being subject to rigorous and specific 'hurdles' before they are finally approved. Suitable evidence is not

[4] As referred to in BMJ news (*BMJ* 2002; 324:191, *BMJ* 2000; 321:980)

[5] http://www.dh.gov.uk/en/Publicationsandstatistics/Pressreleases/DH_4122650

always available at the time of drug licensing for NICE to be able to carry out a full appraisal and data regarding efficacy of any drug (or the safety of drug combinations) accumulate over time. Indeed, advances in therapeutics may progress in small increments and successive steps taken over time may transform the efficacy and acceptability of a given treatment for a serious disease. The early uptake system would regulate and reward such advances according to the scale of improvement, rather than delaying progress by maintaining an 'all or nothing' approach. Furthermore, it would facilitate appraisals of multiple technologies for any one disease following their introduction. This would enable a comprehensive review of treatment options and comparative benefit at a stage when clinical and cost-efficacy may be more evident.

9. Whilst appraisal decisions would still be subject to appeal, an early evaluation process might also reduce the delay in approving treatments by avoiding a lengthy appeal process. In the current system, an inclusive and transparent appeal process is crucial. However, early uptake of drugs may avoid appeals of NICE's decisions by encouraging ongoing evaluation. The early adoption method has the added benefit of rewarding innovation and translational research by incentivising drug development whilst ensuring that only drugs that offer clear benefit to health are approved. The NHS Connecting for Health programme would have an important role to play in enabling and supporting such evaluations. It is therefore important that the requirements of NICE are considered in the development of Connecting for Health.

10. The Academy notes that although a faster appraisal system could accelerate the uptake of new treatments, care will need to be taken if, during the subsequent evaluation, drugs that are beneficial for some patients are deemed not be cost-effective and are withdrawn. In the absence of an alternative treatment, this might lead to further pressure on NICE from pressure groups, the public and via the appeal system.

11. We emphasise that improvements in the speed of publishing guidance are dependent upon resources. It is vital that NICE is supported by sufficient resources from the Department of Health to carry out all necessary evaluations swiftly and to ensure that new guidance is implemented rapidly into clinical practice.

**12. Comparison with SIGN**

NICE clinical guidelines may have an advantage over SIGN guidelines in that they include an assessment of both clinical and cost effectiveness, as well as identifying treatments that provide good value for money. For example, the NICE clinical guidelines on hypertension, prepared with the British Hypertension Society, give a clear view on the clinical and cost effectiveness of different treatments and the order in which they should be introduced for the best value for money.[6]

13. In contrast, the extent of the delays in publishing NICE guidance is far greater compared to guidance from the Scottish Medicines Consortium (SMC). Decisions on new drugs taken by NICE may be finalised anywhere between 18 months and 5 years after decisions made by the SMC for similar drugs. The introduction of the STA, largely modelled on the SMC approach, may reduce such delay. Ongoing evaluations of the new system utilised by NICE will be important in providing further information.

[6] http://guidance.nice.org.uk/CG34/guidance/pdf/English

**14. The implementation of NICE guidance**

The Academy supports the introduction of a programme to support and evaluate the implementation of NICE guidance. Such measures ensure that guidance is disseminated and evaluated and that the appropriate tools are provided for successful implementation. Reports on the uptake of guidance provided by the 'Evaluation and Review of NICE Implementation Evidence' (ERNIE) database are a useful resource, which can inform the development of improved implementation strategies. Regular audits of implementation and compliance with guidance are essential to fully understand the effectiveness of both clinical guidelines and technology appraisal and how these have influenced NHS activity in England and Wales. Furthermore, evaluation of evidence regarding nationwide implementation may improve the consistency of provision between PCTs.

15. We recommend close communication between NICE and PCTs so that Trusts are financially prepared for the provision of new treatments. Information needs to be readily accessible for healthcare professionals so that doctors are aware of the complete range of treatments that may be prescribed and funded by the PCT. Advance preparation of all PCTs would reduce inconsistencies between those that provide a treatment and those that do not. The NICE costing template, forward planner and horizon scanning information should also be broadly disseminated and advertised to encourage timely implementation.

**16. Improvements in gathering of evidence**

The Academy considers that investment in clinical trial capacity in the NHS is highly desirable so that a greater number of large drug trials are carried out in the UK. The possibility that clinical trials of relevance to the NHS could be carried out using the research capacity and infrastructure provided by the UK clinical research network (UKCRN) should be explored. This would enable medicines to be available as part of a clinical drug trial at no additional drug cost and would ensure the collation of information of direct relevance to the NHS. Indeed, specific end points and outcomes required for NICE approval could be defined before commencement of the trial.

17. We also note the recommendations detailed in the Cooksey Review of Health Research Funding[7] for an expansion of the Health Technology Assessment (HTA) programme. As above, this would improve clinical trial infrastructure and may facilitate a greater level of research and/or assessment of technologies for use in NICE appraisals.

18. We are concerned by potential conflicts of interest of experts. Clearly, it is essential that experts provide evidence during the appraisal of novel drugs. However, for the process to remain transparent, all potential conflicts of interest should be declared when evidence is provided for the Institute. This would reduce the risk that a perceived conflict of interest could damage the Institute's standing.

**19. Areas of guidance**

In light of the recommendations made in the report *'Pandemic Influenza: Science to Policy'* published by the Academy of Medical Sciences and Royal Society (2006), we consider that NICE guidance on antiviral drugs likely to be used during an influenza pandemic should be updated as soon as possible. It

[7] A Review of UK Health Research Funding, Sir David Cooksey, December 2006

is crucial that appropriate appraisal of such drugs is carried out in advance as part of the Government's pandemic preparedness strategy.

20. The Academy further considers that NICE could play a role in the appraisal of complementary and alternative medicines (CAM). Studies show that up to 50% of General Practitioners provide some access to CAM[8] and it is important that patients are assured of the safety and efficacy of such treatments. Moreover, CAM treatments or interventions provided by the NHS should be evaluated using robust scientific evidence prior to use in routine practice and consistent nationwide provision ensured.

[8] Thomas KJ, Coleman P, Nicholl JP (2003). Trends in access to complementary or alternative medicines via primary care in England: 1995-2001 results from a follow-up national survey. Family Practice 20(5): 575-7

Annex

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