

Specialised Healthcare Alliances' submission to the Health Select Committees inquiry into the work of the National Institute for Health and Clinical Excellence

The Specialised Healthcare Alliance is a broad coalition of 41 patient groups supported by eight corporate members¹. It has been set up to campaign on behalf of people with conditions which require specialised medical care. These conditions tend to be rarer and both complex and expensive to treat. Examples are numerous but include certain cancers, cystic fibrosis, haemophilia, HIV and neurological conditions. Accidents or complications of more common conditions such as diabetes can also trigger the need for specialised services. Cumulatively, the number of patients affected by such conditions number many tens of thousands.

We welcome this opportunity to submit evidence to the Health Select Committee's inquiry into aspects of the work of the National Institute for Health and Clinical Excellence.

1. Executive Summary

- 1.1 The Specialised Healthcare Alliance considers NICE to have a critical role in ensuring that treatment delivered by the NHS is equitable, cost effective and to a uniformly high standard.**
- 1.2 The existence in NICE of an independent national forum where decisions about cost effectiveness and prioritisation can be made in a consistent and fair manner is particularly important for patients with specialised medical conditions.**
- 1.3 The Alliance believes the Institute's evaluation system should be more transparent. Reform of the process may allow for a fairer consideration of some treatments. In the case of orphan or ultra-orphan treatments social value judgments are likely to be necessary which should rest with parliament.**
- 1.4 The Specialised Healthcare Alliance welcomes the recent moves by NICE to ensure lifesaving drugs can be assessed more quickly and supports this process being extended to other technologies.**
- 1.5 Unless greater consideration is given to how and when tariffs reflect NICE guidance, patients could face greater delays in accessing recommended treatments.**
- 1.6 The Alliance believes that much greater priority should be attached to ensuring the implementation of NICE guidance. If NICE were to assume responsibility for this it would need additional resources.**

¹ A full list of members is available on our website at www.shca.info

2. Public confidence in the Institute

- 2.1 The Specialised Healthcare Alliance believes that NICE has an important role to play in ensuring that patients receive equitable and fair treatment and that decisions about whether medicines are cost effective are made in a robust manner free from political influence.
- 2.2 The existence of a body such as NICE is particularly important for patients who have specialised medical conditions which may be expensive to treat. Devolution within the NHS means that local priorities increasingly drive allocation of resources. Whilst this development has many benefits it can unfairly disadvantage patients with specialised conditions who will inevitably be smaller in number and may therefore have less of a voice locally. NICE provides an important national forum where decisions about which drugs are cost effective can be considered with input from a range of stakeholders.
- 2.3 The members of the Specialised Healthcare Alliance and the patients they represent do not consider that public confidence in NICE has suffered substantially. In some respects current concern about the role of NICE appear to have arisen as a result of the Institute's success. NICE guidance is for the most part highly respected and significantly influences clinical and purchasing behaviour within the NHS.
- 2.4 However, the Alliance does believe that a number of factors would support public confidence in the Institute. In particular, promoting greater understanding of the role of NICE, greater transparency in terms of topic selection², changes to the evaluation process and above all a greater focus within the NHS on the implementation of guidance would benefit the Institute's public standing (see sections 3 and 5)

3. NICE's evaluation process, and whether any particular groups are disadvantaged by the process

- 3.1 The Specialised Healthcare Alliance recognises that NICE's evaluation process is rigorous and has gained international respect. However, the Alliance is concerned that the current process may disadvantage certain groups.
- 3.2 The Alliance understands that NICE does not publicly admit to any formal cost-effectiveness threshold, but many observers believe it is around £30,000 per quality of life-year (QUALY) gained. Whether or not this is the case, a number of orphan or ultra-orphan drugs are unlikely to receive NICE approval if the same cost effectiveness threshold applies as for other treatments. This could mean that patients suffering from rare and in some cases extremely serious health conditions are denied treatment on the NHS. It might also deter innovation which ultimately benefits the wider population eg as new indications are discovered and developed.
- 3.3 The Specialised Healthcare Alliance is aware the NICE has considered this issue in some detail and welcomed the contribution that a Citizen's Council made to the debate in a report issued in November 2004. However, we believe that such social value judgements eventually rest with those who are democratically accountable and that the government, informed by NICE and initiatives such as the Citizen's Council. The Alliance strongly believes that the standard and availability of such treatments is fundamental to a properly functioning National Health Service.

² The SHCA responded to the DH consultation on NICE topic selection and believes the changes instituted as a result of this process should be evaluated in due course. A copy of the SHCA submission is available upon request.

- 3.4 In addition, the Alliance believes consideration should be given to reforming the evaluation process to allow for consideration of broader economic costs when assessing the cost-effectiveness of particular treatments. The SHCA is concerned that in the current financial climate, with a tendency to silo budgeting, decisions about whether to fund treatment are often made without weighing the wider cost implications, such as palliative care, social service costs and lost productivity. NICE is well placed to broaden understanding of costs and benefits and these considerations should be reflected in its evaluation process.
- 3.5 Above all, the Alliance considers that NICE should be more transparent about the appraisal process. Lack of clarity and openness about how decisions are taken about clinical effectiveness and cost-effectiveness and the weight that the Institute gives to different kinds of evidence may erode the credibility and authority of NICE.

4. The speed of publishing guidance

- 4.1 The Specialised Healthcare Alliance is aware that striking a balance between maintaining the integrity of the NICE process and the speed with which it can complete appraisals is difficult. The new "single technology appraisal" process has been developed as a means of more rapid assessment of treatments.
- 4.2 It was initially to be applied to lifesaving drugs that have already been licensed and to new lifesaving medicines close to the time that they first become available. The Specialised Healthcare Alliance considers that this process should be open to all technologies where patients and other stakeholders believe a more rapid appraisal process would be beneficial.
- 4.3 This is particularly important given the development of payment by results which may add a further delay exacerbating the process commonly known as "NICE blight" where PCTs refuse to fund new technologies until a NICE assessment is completed. It is not known how often tariffs will be reviewed in the future, but even if revisions occur annually there is likely to be a considerable delay between NICE guidance and the reflection of the cost of the technology in the tariff price. Under payment by results a "pass through payment" can be negotiated between a Trust and PCT to cover the cost of new treatments, but these are subject to local negotiation and are unlikely to be applied fairly or consistently.
- 4.4 The Alliance believes that the resources open to NICE should be substantially increased to enable it to assess more technologies and to produce guidance more quickly where there is a need. Furthermore the Alliance would like to see greater collaboration between NICE and the PBR team to ensure that tariff prices reflect NICE guidance as soon as possible.
- 4.5 In the medium term, it would seem likely and desirable that the single technology appraisal should become the standard approach. Care will need to be taken to ensure that assessment of existing classes of therapy, which may provide the most cost-effective treatment options, does not get left in a slow lane.

5. The implementation of NICE guidance, both technology appraisals and clinical guidelines (which guidance is acted on, which is not and the reasons for this)

- 5.1 The Specialised Healthcare Alliance is greatly concerned by the continuing problems regarding the implementation of NICE guidance. The SHCA recognises that the NHS necessarily operates within cash limits and that difficult decisions regarding priorities need to be made by commissioners and other staff on a daily basis. However, NICE was established in part with the aim of ensuring the process of prioritisation was consistent, well-

founded and fair. We therefore believe that much greater emphasis should be given to ensuring NICE guidance is implemented.

- 5.2 The Alliance is aware the NICE has no formal powers or remit with regard to implementation of its guidance. Despite this, it has recently developed new commissioning tools and databases to aid implementation in addition to establishing local representatives to explain guidance. These initiatives are welcome as is the growing emphasis on withdrawing investment from outmoded, cost ineffective technologies.
- 5.3 Implementation of NICE guidance forms part of the Healthcare Commission's assessment process. However, this process is largely based on self-assessment and is constrained by the fact that it only formally assesses PCTs and other Trusts. This presently means that Specialised Commissioning Groups, which will be responsible from 1 April 2007 for commissioning of many of the areas covered by NICE guidance, may not be assessed. The Alliance is greatly disappointed by this and urging the Commission to assess Specialised Commissioning Groups as a function of its assessment of their constituent PCTs.
- 5.4 Meanwhile, the Alliance considers that NICE's remit should be extended to include responsibility for promoting and monitoring implementation of its guidance. If this is to be successful it will be necessary to allocate sufficient additional resources to NICE for it to carry out its role successfully.