

The legal implications of NICE guidance

Currently NICE produces guidance in three main areas of health:

- **technology appraisals** - which focus on the use of new and existing medicines and treatments within the NHS in England and Wales;
- **clinical guidelines** - which set out the appropriate treatment and care of people with specific diseases and conditions within the NHS in England and Wales; and
- **interventional procedures** – which consider whether procedures that are used for diagnosis or treatment are safe enough and work well enough for routine use. This programme has been recently extended to cover Scotland as well as England and Wales.

Whilst health professionals are expected to take all NICE guidance into account, the implications of NICE guidance for clinical governance and practice vary depending on the type of guidance.

Funding technology appraisal guidance

The Secretary of State has directed that the NHS is required to provide funding and resources for medicines and treatments recommended by NICE through its technology appraisals work programme. It normally has three months from the date of publication of each technology appraisal guidance to provide funding and resources.

Where it is not possible to acquire the technology or where, perhaps because insufficient trained staff are available, the intervention cannot be applied within the three month period, it can be extended. Extensions are granted by the Secretary of State, on advice from NICE.

The three month funding Direction has been waived or extended for about ten percent of the technology appraisals issued to date. They include surgery to aid weight reduction for people with morbid obesity, home compared with hospital haemodialysis for patients with end-stage renal failure, patient-education models for diabetes, continuous subcutaneous insulin infusion for diabetes (insulin pumps) and photodynamic therapy for age-related macular degeneration.

To view the full Directions on funding NICE technology appraisal guidance, you can click on the link to the left of this page.

Similar directions have been issued to the NHS in Wales.

NICE does not have a role in enforcing these funding directions.

Funding clinical guidelines and interventional procedures guidance

The clinical guidelines and interventional procedures work programmes are not subject to a mandatory requirement regarding funding, although if it

appears that there may be issues around funding or resourcing of a guideline then the health departments in England and Wales can issue advice to the NHS on this at the same time as the guideline itself is published. For example, the Secretary of State for Health in England issued advice in February 2004 to the NHS regarding the implementation of recommendations on IVF contained in the NICE guideline on fertility.

Interventional procedures – balancing safety with innovation

The aim of NICE's interventional procedures programme is to protect the safety of patients and to support health professionals, healthcare organisations and the NHS as a whole in the process of introducing procedures. Many of the procedures that NICE looks at are new, but it also looks at more established procedures if there is uncertainty about their safety or the way they work – for example, NICE has issued interim guidance on diathermy in tonsillectomy. The Programme also fosters innovation by facilitating data collection and analysis, conducting rapid reviews and providing advice on the safety and efficacy of new procedures.

The health departments in England, Wales and Scotland have issued advice to their respective health services explaining what should be considered a new procedure and what process the NHS should follow if a clinician wishes to perform a new procedure. In England, for example, the Health Services Circular explains that medical practitioners planning to undertake new interventional procedures (except in emergencies or when the procedure is being used only within a protocol approved by a Research Ethics Committee) must seek approval from their NHS Trust's Clinical Governance Committee before doing so.

The HSC states that:

- Any (fully trained) doctor considering use in the NHS of a new interventional procedure which he/she has not used before, or only used outside the NHS, should seek the prior approval of their NHS Trust's Clinical Governance Committee. If the procedure is the subject of NICE guidance, the committee should consider whether the proposed use of the procedure complies with the guidance before approving it.
- If no NICE guidance on the procedure is available, the Committee should only approve its use if:
 - The doctor has met externally set standards of training.
 - All patients offered the procedure are made aware of the special status of the procedure and the lack of experience of its use. This should be done as part of the consent process and should be clearly recorded.
 - The Committee is satisfied that the proposed arrangements for clinical audit are sound and will capture data on clinical outcomes that will be used to review continued use of the procedure.

- The Committee should also take account of the Clinical Negligence Scheme for Trusts standard 5.2.6.

The Welsh Assembly Government and the Scottish Executive have issued similar circulars to the NHS in Wales and Scotland which can be found online at <http://howis.wales.nhs.uk/doclib/whc-2003-058-e.pdf> and http://www.show.scot.nhs.uk/sehd/mels/hdl2004_04.pdf respectively.

Clinicians who wish to undertake a procedure during the period between the notification of a procedure to NICE and the issuing of guidance on its use should inform the chief executive of their Trust or hospital of their intention – whether they need the agreement of the Trust is for local determination. They should also appropriately inform patients/carers of the status of the procedure and the uncertainty around its safety and efficacy. This should be done as part of the consent process and should be clearly recorded. Patients need to understand that the procedure's safety and efficacy is uncertain, and to be informed about the anticipated benefits and possible adverse effects of this treatment and alternatives, including no treatment.

The English HSC makes it clear that the Healthcare Commission will assess how well clinical governance is working in Trusts by establishing, amongst other things, how Trusts' Clinical Governance Committees introduce new interventional procedures. You can view the Health Service Circular on interventional procedures by clicking on the link at the left of this page.

Implications for clinical practice

Once NICE guidance is published, health professionals are expected to take it fully into account when exercising their clinical judgment. However, NICE guidance does not override the individual responsibility of health professionals to make appropriate decisions according to the circumstances of the individual patient in consultation with the patient and/or their guardian/carer.

In particular, guidance that does not recommend a treatment or procedure, or that recommends its use only in defined circumstances, is not the same as a ban on that treatment or procedure being provided by the NHS. If, having considered the guidance, a health professional considers that the treatment or procedure would be the appropriate option in a given case, there is no legal bar on the professional recommending the treatment or on the NHS funding it.

For example, if an individual patient is known or is likely to suffer a serious adverse reaction to a recommended drug it would be appropriate for their health professional to prescribe an alternative. Any health professional who is considering departing from NICE guidance may wish to discuss the issue fully with the patient and/or their guardian or carers and should keep a record of his/her reasons for taking such a decision in the patient's notes.

NICE guidance and legal cases

So what happens if there is a conflict between the patient and clinician as to whether to follow guidance? And what is the status of NICE guidance in legal

cases? There has not yet, to the Institute's knowledge, been a legal case where the decision of a clinician not to follow NICE guidance has been tested either in court or in front of the General Medical Council. NICE is often asked for its opinion on this and the Institute has discussed the issue with the Medical Defence Union (MDU).

The MDU advise their members that health professionals have a legal, contractual and ethical duty to act in the best interests of the patient. The MDU acknowledge that NICE guidance carries great weight as it is arrived at by considering the best available evidence and expert professional advice. They acknowledge the importance for health professionals to be aware of NICE guidance and to follow it if, in their clinical judgement, to do so would be in the patient's best interest.

As a core principle, the MDU believe that "It is unlikely that the General Medical Council would make an adverse finding against a doctor if his or her actions are supported by a responsible body of colleagues."¹ (the 'Bolam principle'). As NICE guidance is based on a robust assessment of the clinical evidence and/or reflects a consensus of current medical opinion, one would expect that a health professional who acts in accordance with NICE guidance would be able to count on that fact to help with his or her defence.

Whilst a health professional who *follows* NICE guidance might be able to count on that fact to help their defence, it does not necessarily follow however, that health professionals who *deviate* from NICE guidance are negligent. Whilst there is always likely to be a "responsible body" of health professionals supporting the recommendations made in NICE guidance, there may be other health professionals who subscribe to a different view. As the MDU say "Courts rely on expert evidence, not guidelines, to determine what is reasonable practice. Experts guide the courts as to whether there is a responsible body of opinion which would have adopted the same course of action as the doctor concerned, regardless of whether or not the doctor followed guidelines."

The MDU conclude "Ignorance of NICE guidance is a poor defence, but a reasoned and reasonable decision to reject the guidance in an individual case, together with a good record, made at the time, may be acceptable."

The Institute's purpose is to help reduce uncertainty for health professionals and their patients. NICE guidance sits alongside the knowledge and skills of experienced health professionals. It is not the intention of NICE guidance to replace the clinician's knowledge and skill, rather to support it.

¹ Dr Paul Colbrook, medico-legal adviser at the MDU, Doctor magazine special report, March 2002.