

**GOOD PRACTICE GUIDANCE ON MANAGING THE INTRODUCTION OF
NEW HEALTHCARE INTERVENTIONS AND LINKS TO NICE TECHNOLOGY
APPRAISAL GUIDANCE.**

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GOOD PRACTICE GUIDANCE ON MANAGING THE INTRODUCTION OF NEW HEALTHCARE INTERVENTIONS AND LINKS TO NICE TECHNOLOGY APPRAISAL GUIDANCE.

Introduction

This good practice guidance responds to a number of requests, received by the Department of Health, to update guidance originally issued in 1999 (HSC 1999/176) and to further clarify guidance on Directions to Primary Care Trusts and NHS Trusts concerning the funding of Technology Appraisal Guidance issued by the National Institute for Health & Clinical Excellence (“the funding Directions”).¹

Background

The National Institute for Health & Clinical Excellence (NICE) is a Special Health Authority which was set up in April 1999 to give advice to the NHS on best clinical practice including the clinical and cost effectiveness of drugs and other treatments.

Purpose of the Guidance

The purpose of this guidance is twofold:

(i) to reiterate the guidance originally published in Health Service Circular 1999/176 and explain in more detail what that guidance means for the NHS. This updated guidance also provides more information on sources of evidence that NHS organisations may wish to refer to in making decisions about the introduction of new interventions if NICE guidance is not yet available.

(ii) to further clarify guidance on the obligations of Primary Care Trusts and NHS Trusts under the funding Directions that apply to NICE Technology Appraisals.

¹ See Directions to Primary Care Trusts and NHS trusts in England concerning Arrangements for the Funding of Technology Appraisal Guidance from the National Institute for Clinical Excellence (NICE) dated 1st July 2003. The funding Directions were amended by Directions dated 24 September 2003, 13 February 2004, 30 September 2004, 30 August 2005 and 1 April 2006.

Part 1) Managing the Introduction of New Healthcare Products in the absence of NICE guidance.

Background

Original Guidance

The wording of the original guidance published in HSC 1999/176 is as follows:

“If a new intervention is not referred to NICE, this does not imply any judgement on whether the intervention(s) in question are clinically or cost effective. NHS bodies should continue to use existing arrangements to access the publicly available evidence and to determine local policies for the managed entry of the new intervention. The same principle should apply if an intervention has been referred to NICE but guidance is not yet available at the point at which the new intervention is first introduced. In the case of new pharmaceuticals, the *New Drugs in development* bulletin published by the National Prescribing Centre and Drug Information Pharmacists Group may be a helpful source of information.”

Reiterating the Message of HSC 1999/176

It is not acceptable to cite a lack of NICE guidance as a reason for not providing a treatment. A key role of the NHS is to make decisions about the use of new interventions and this has always been the case, long before NICE was established.

NICE underpins the decision making processes of the NHS in reaching a decision as to what new interventions are the most appropriate to use and under what circumstances. Guidance from NICE exists to provide advice to NHS clinicians, commissioners and patients as to those treatments that are clinically and cost effective. Clinicians are not obliged to follow NICE guidance in every case if they feel that alternative courses of treatment are more appropriate for an individual patient, though they will need to be able to account through clinical governance arrangements for decisions to depart from NICE guidance.

NICE does not exist to “kite mark” all the interventions which are introduced for use in the NHS and decisions are taken by Ministers against published criteria as to which products NICE should be asked to assess. Not all new interventions will be referred to NICE for appraisal and for those interventions that are referred to NICE there may be a time lag whilst NICE guidance is being developed, though the new NICE Single Technology Appraisal process should help to minimise this lag. Therefore, the NHS will have to continue to make informed decisions about the use of these interventions under either circumstance.

Sources of Available Evidence

There are a number of valuable sources of information available to the NHS, which can help in making decisions about the use of new interventions where NICE guidance is not available. Most of these sources are available online and include summaries of the available evidence on the safety and effectiveness of new treatments.

The evidence sources listed below are not being suggested as substitutes for NICE guidance when it becomes available, rather they can help local NHS organisations make more informed decisions on the managed introduction of new healthcare interventions.

This list will be reviewed on a yearly basis. Any updates issued after the review will reflect changes to websites, names and products of the evidence sources listed, as well as additions and deletions when appropriate.

If you have any queries about the list, please contact the Department of Health's NICE Liaison Team by phone on: 0113 2545965
or e-mail: refreshguidancehealthtech@dh.gsi.gov.uk

List of Resources

Centre for Evidence-based Purchasing (CEP)

<http://www.pasa.nhs.uk/evaluation/>

The role of the Centre for Evidence-based Purchasing is to underpin NHS purchasing decisions by providing objective evidence to support the uptake of useful, safe, innovative products and related procedures in health and social care.

The CEP provides a range of publications that are available on the NHS PASA website. There is also a facility for individuals to make proposals of technologies, product(s) or related procedures that they would like the centre to consider as part of its work programme.

The website also maintains details of any forthcoming presentations or meetings that the centre will be running.

The London Cancer New Drugs Group

The London Cancer New Drugs Group is a sub-committee of the London Cancer Networks Steering Group. Members are nominated by and represent the five cancer networks in London. The group has delegated responsibility to develop recommendations for the managed entry of new treatments in cancer across London. The decisions of the New Drugs Group can be found on the National Electronic Library for Medicines website at:

<http://www.druginfozone.nhs.uk/search/product.aspx?id=98>

The guidance is to help Primary Care Trusts (PCTs) reach decisions on the use of new cancer drugs until such time as NICE guidance becomes available.

London New Drugs Group

<http://www.londonpharmacy.nhs.uk/lndg/>

The LNDG aims to assist healthcare professionals in managing the entry of new drugs in a cost-effective and equitable manner, by providing advice based on independent, evaluated information, in a timely manner. The area covered by the LNDG now includes the London Region, Bedfordshire, East Anglia, Essex and Hertfordshire.

The LNDG consists of a range of healthcare professionals who volunteer their services. In April 2002, the NHS was re-organised into larger regions, consisting of PCTs. The membership has recently undergone a review to include representatives of PCTs, as well as Public Health and NHS Trusts.

The LNDG's website is aimed at healthcare professionals who require a detailed summary of the clinical trial information and discussion points or recommendations for use as well as the cost implications of new drugs. LNDG documents are produced for use within the NHS and must not be reproduced for commercial purposes. Any technology appraisal produced by NICE automatically supersedes a LNDG review written on that subject.

National Horizon Scanning Centre

<http://pcpoh.bham.ac.uk/publichealth/horizon>

The National Horizon Scanning Centre (NHSC) aims to provide advance notice to the Department of Health in England and national policy-making bodies in the NHS of selected key new and emerging health technologies (including changing applications and uses of existing technologies) that might require urgent evaluation, consideration of clinical and cost impact or modification of clinical guidance.

The scope of the NHSC's activity includes health technologies in the broadest sense and includes pharmaceuticals, devices, diagnostic tests and procedures, surgical and other interventions, rehabilitation, and public health activities.

The NHSC writes briefings about potentially significant developments up to two years before their launch on the NHS. The NHSC maintains copies of all the technology briefings it has produced to date (from January 2000) on its website.

National Prescribing Centre

www.npc.co.uk
www.npc.nhs.uk

The National Prescribing Centre (NPC) is a health service organisation, formed in April 1996 by the Department of Health. Its aim is to 'promote and support high quality, cost-effective prescribing and medicines management across the NHS, to help improve patient care and service delivery'. The NPC New Medicines Scheme provides a useful range of evaluated information, both pre-and post-market launch, on new medicines.

The "On the Horizon" portfolio and "Planning Ahead for New Medicines" resource provides key senior decision-makers in the NHS with advance information. These sensitise the NHS to significant new medicines, and facilitate local planning, commissioning and a more effective managed introduction. "On the Horizon" information is published approximately six months pre-launch for medicines either not currently covered in the NICE programme or, where covered, the NICE appraisal is not expected for at least four to six months post launch. This information is produced in collaboration with Wessex Regional Medicines Information Centre. NPC information is updated at product launch, where significant additional information has emerged since the first publication and if no NICE guidance is planned near that time.

The NPC also publishes the MeReC Publication portfolio, which provides concise, evidence-based information on marketed medicines and prescribing-related issues. These publications are distributed to health care professionals working in primary care organisations and hospital trusts providing prescribing support and medicines management services. However, managers and those working in other sectors of the NHS will also find them a useful resource. MeReC publications are funded by the National Institute for Health & Clinical Excellence.

All the above publications are accessible via the NPC's websites at www.npc.co.uk and www.npc.nhs.uk. Users can register for an e-mail alert to notify them when new information is published. (The New Medicines Scheme pre-launch information is available on NHSnet only.)

Scottish Medicines Consortium

www.scottishmedicines.org.uk

The Scottish Medicines Consortium (SMC) provides advice to NHS Boards and their Area Drug and Therapeutics Committees (ADTCs) across Scotland about the status of all newly licensed medicines, all new formulations of existing medicines and new indications for established products (licensed from January 2002). This advice is made available as soon as practical after the launch of the product involved. The remit of SMC excludes the assessment of vaccines, branded generics, non-prescription-only medicines (POMs), blood products, plasma substitutes and diagnostic drugs. The review of device-containing medicines will be confined to those licensed as medicines by the MHRA/EMA.

While the guidance contained within the SMC's advice is aimed at NHS Scotland, the analysis of the evidence considered by the Consortium is a useful source of information to all local NHS managers when making decisions on the introduction of new medicines. The SMC's advice is available on its website and the site also has a list of forthcoming assessments. The website offers a subscription service to inform individuals when new guidance is published.

Note that NICE Multiple Technology Appraisal (MTA) guidance always supersedes SMC advice.

United Kingdom Medicines Information Group

www.ukmi.nhs.uk

UK Medicines Information is an NHS pharmacy based service. Its aim is to support the safe, effective and efficient use of medicines by the provision of evidence-based information and advice on the therapeutic use of medicines.

The service has two broad functions:

- to support medicines management within NHS organisations
- to support the pharmaceutical care of individual patients

The UKMI service is provided by a network of:

- 260 local medicines information centres based in the pharmacy departments of most hospital trusts
- 16 regional centres
- 2 national centres (Northern Ireland and Wales).

These centres work closely together to provide a 'virtual' national service. The centres are staffed by pharmacists with clinical expertise, and particular skills in locating, assessing and interpreting information about medicines. Details of the individual centres are available in the UKMI address book (www.ukmi.nhs.uk).

The **Prescribing Outlook Series** is also published on the UKMI website. This series is intended to assist NHS budget holders and those involved in prescribing planning assess the potential impact of new drugs and national guidance on the local health economy. It is available in three parts:

Prescribing Outlook A includes information on drugs with launches planned over the next 12 to 18 months and on marketed drugs with new major indications. It contains brief clinical and therapeutic data plus information on predicted launch date, potential target population and estimated impact on service delivery and cost. *Prescribing Outlook A* is produced in collaboration with the National Prescribing Centre (NPC) and the National Horizon Scanning Centre.

Prescribing Outlook B contains information on existing and forthcoming NICE guidance, NSFs, the GMS contract and other national targets that may have budgetary implications over the next 12 to 18 months. It is intended to facilitate the implementation of national targets and guidelines and to calculate the cost of such implementation.

Prescribing Outlook C is an excel spreadsheet based on the content of *Prescribing Outlook A* and *B*. It allows crude calculations of potential costs of prescribing changes for a local population.

The National Electronic Library for Medicines (www.nelm.nhs.uk) website provides a gateway to many sources of information produced by medicines information services. This information includes

- news and current awareness
- evaluated information to support the planning for, and implementation of new medicines
- product updates and alerts
- quick evidence based answers to commonly asked medicines related questions
- evidence based resources including critical appraisal of key published papers
- list of published national therapeutic guidelines and the bodies which have published them.

Pharmaceutical Companies

Information on new medicines can also be obtained directly from pharmaceutical manufacturers. In particular, Drug and Medical Information Departments can be contacted to obtain information on both current drugs and on future pipeline drugs to support the NHS in forward budgetary planning.

Reflecting the Guidance in Standards for Better Health

Standards for Better Health represents the Government's response to the consultation on the health care standards, which was launched in February 2004, and puts quality at the forefront of the agenda for the NHS and for private and voluntary providers of NHS care. The standards describe the level of quality that health care organisations, including NHS Foundation Trusts, and private and voluntary providers of NHS care, will be expected to meet in terms of safety; clinical and cost effectiveness; governance; patient focus; accessible and responsive care; care environment and amenities; and public health.

The guidance on "**Managing the Introduction of New Healthcare Interventions in the Absence of NICE Technology Appraisal Guidance**" is reflected in the core standards.

"C5: Health care organisations ensure that they conform to NICE technology appraisals and, where it is available, take into account nationally agreed guidance when planning and delivering treatment and care;"

Part 2) Directions on the Implementation of NICE Guidance

Background to the Funding Direction

On 5 December 2001 the Government announced that it would meet its manifesto commitment to ensure that patients receive drugs and treatments recommended by NICE on the NHS if deemed appropriate by their clinicians. Subject to certain exceptions, Directions that came into force on 1st January 2002 require Primary Care Trusts and NHS Trusts to make funds available to ensure that a health care intervention² recommended by NICE is available to NHS patients within three months of NICE issuing new Technology Appraisal Guidance.³ These Directions are referred to as the “Funding Directions” in this Good Practice Guidance.

The Funding Direction

The Directions provide PCTs with a period of three months within which to make a health care intervention available to NHS patients in recognition of the fact that it can take some time to put the necessary funding arrangements in place.

Each PCT should use its best endeavours to ensure that any new treatments recommended by NICE are available as soon as possible after NICE issues Technology Appraisal Guidance. If it is possible for a PCT to make the necessary arrangements without utilising the full three month period stipulated in the Directions, it should do so.

Information published by NICE can assist PCTs to begin making those arrangements in advance of NICE issuing new Technology Appraisal Guidance. For example, NICE provides information about the likely publication dates for all new Technology Appraisal Guidance and Final Appraisal Determinations (FADs) usually give a good indication as to the direction of travel and intended nature of final guidance.

NICE also publishes a regularly updated horizon scanning forward planner document on its website which provides information about all upcoming appraisals and their timings to assist the NHS with forward budgetary and capacity planning (at <http://www.nice.org.uk/page.aspx?o=ForwardPlanner>).

² Which includes a medicine, medical device, diagnostic technique, surgical procedure and other therapeutic intervention.

³ See Directions to Health Authorities, Primary Care Trusts and NHS trusts in England dated 11th December 2001 (“the 2001 Directions”). The 2001 Directions have been replaced by Directions to Primary Care Trusts and NHS trusts in England concerning Arrangements for the Funding of Technology Appraisal Guidance from the National Institute for Clinical Excellence (NICE) dated 1 July 2003 (as amended by Directions dated 24 September 2003, 13 February 2004, 30 September 2004, 30 August 2005 and 1 April 2006).

Implementation of the Single Technology Appraisals (STA) Process

Single Technology Appraisals (STAs) are developed via a much more rapid process than Multiple Technology Appraisals (MTA), but are also covered by the 3 month funding direction.