

# ORIGINAL ARTICLES

## NICE Guidance in the Scottish Context

H Kohli<sup>1</sup>, A Tannahill<sup>2</sup>

<sup>1</sup>Medical Advisor, NHS Quality Improvement Scotland, Delta House, 50 West Nile Street, Glasgow G1 2NP

<sup>2</sup>Head of Evidence for Action and Consultant in Public Health Medicine, NHS Health Scotland, Clifton House, Clifton Place, Glasgow G3 7LS

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### Correspondence to

Dr Harpreet Kohli, Medical Advisor, NHS Quality Improvement Scotland, Delta House, 50 West Nile Street, Glasgow G1 2NP  
Tel: 0141 225 6988 Fax: 0141221 3262 Email: harpreet.kohli@nhs.net

### Abstract

The UK landscape of guidance for clinical practice and public health has become increasingly complicated in recent times, and it is easy to feel confused as to what is available for what purposes, what applies where, and who does what. Within this overall picture, there is potential for uncertainty as to the applicability, or otherwise, in Scotland of guidance produced by the National Institute for Health and Clinical Excellence (NICE) in England, including NICE technology appraisals, clinical guidelines, interventional procedures guidance, and public health programme and intervention guidance. This paper is offered as a map to help health professionals and others to find their way through the Scottish landscape, with particular reference to NICE's outputs and the respective roles of NHS Quality Improvement Scotland (NHS QIS) and NHS Health Scotland (HS).

pioneering influence internationally; and by the more recent development of rapid assessment of all newly licensed medicines by the Scottish Medicines Consortium (SMC).<sup>8</sup> Further scope for confusion has arisen from the extension of NICE's remit to producing public health guidance (on promoting good health and preventing ill-health).

Ever since NICE started publishing its guidance, the question has been asked: 'Does the guidance apply in Scotland?' The answer depends on the type of guidance concerned. This paper seeks to clarify the situation, and its authorship reflects the evidence and knowledge translation roles of NHS QIS and NHS Health Scotland (Health Scotland, or HS) in relation to health care and health improvement respectively.

### NHS QIS and Health Scotland

NHS QIS was established in January 2003, to achieve better integration and coordination of work on clinical effectiveness and quality improvement in Scotland. Since its inception, one of NHS QIS's roles has been to work with NICE and act as the link to Scotland for relevant outputs. The publication *NHS QIS and NICE Advice - Definitions and Status*<sup>9</sup> describes various forms of guidance and advice used by NHS Scotland.

NHS Health Scotland (Health Scotland - HS) was established in April 2003 as Scotland's national agency for improving health, through a bringing together of the Health Education Board for Scotland and the Public Health Institute of Scotland. One of its roles is to promote and support evidence-informed action to improve health and reduce health inequalities in Scotland. As part of that, HS produces commentaries on published NICE public health guidance to help organisations, professionals and others make use of it in a Scottish context.

### Areas Covered by NICE Guidance and Related Outputs

NICE publishes guidance and related outputs in a number of areas:

- **Health technologies**
  - Technology appraisals - guidance on the use of new and existing medicines and treatments within the NHS in England and Wales.
  - Interventional procedures - guidance on whether interventional procedures used for diagnosis or treatment

### Introduction

The National Institute for Clinical Excellence (NICE) was established for England and Wales in 1999. In April 2005 the organisation became the National Institute for Health and Clinical Excellence (still known as NICE) when it took over the functions of the Health Development Agency to create a single body responsible for providing guidance on the promotion of good health and the prevention and treatment of ill-health.

There are three main reasons why NICE guidance commands attention in the Scottish context. First, there is the international standing and quality of NICE's output.<sup>1,2</sup> Second, the output is substantial and represents a considerable investment of time, expertise, infrastructure and money.<sup>3,4</sup> Third, the facts that NICE guidance is prominent in the public domain and can be the subject of much comment and debate (as seen in the case of the recent appraisal on drugs for Alzheimer's disease)<sup>5,6,7</sup> can lead to uncertainty among health professionals, the media and the public about applicability in Scotland. Complexity is added by the existence in Scotland of clinical guidelines from the Scottish Intercollegiate Guideline Network (SIGN - now part of NHS Quality Improvement Scotland - NHS QIS), which was established before NICE was created and which have been of

are safe enough and work well enough for routine use in England, Wales, Northern Ireland and Scotland.

- **Clinical practice** - clinical guidelines on the appropriate treatment and care of people with specific diseases and conditions within the NHS in England, Wales and Northern Ireland.
- **Cancer services** - a set of service guidance on the main cancers that was produced to support the cancer plan in England - eg in 2006, NICE developed guidance on the healthcare that should be provided for people with brain tumours and other central nervous system tumours. There are no current plans to update the set.
- **Commissioning guides** - these provide support for the local implementation of NICE clinical guidelines through commissioning, and are underpinned by the clinical guidelines.
- **Optimal practice** - NICE issues recommendation reminders to the NHS in England and Wales to help reduce ineffective practice, eg in relation to the effective use of asthma inhaler devices for children under five, and preoperative tests. These are designed to be used in conjunction with the NICE guidance in which the recommendations appear.
- **Patient safety solutions** - This is a pilot project arising from the review of patient safety commissioned by the Chief Medical Officer for England. NICE and the National Patient Safety Agency (NPSA) were asked to develop and evaluate the production of a technical solution to address patient safety problems, which will form guidance for the NHS in England. Safety guidance is expected to be issued to the NHS in England in early 2008. The pilot will involve assessing the evidence on clinical and cost-effectiveness and producing recommendations. The topics under assessment for the pilot project are:

- systems-based and information technology- based interventions in medicines reconciliation; and
- the prevention of ventilator-associated pneumonia (VAP).

• **Public health** - NICE produces two types of guidance on the promotion of good health and the prevention of ill-health, for those working in the NHS, local authorities and the wider public and voluntary sector, in England:

- public health intervention guidance (interventions being defined as involving single measures, eg GP advice to patients to be more active), and
- public health programme guidance (on broader activities, eg strategies for smoking cessation).

• **Implementation** - NICE provides people responsible for implementing NICE guidance with generic and specific implementation tools:

- generic implementation tools (eg "How to" guide to implementation, horizon scanning, audit advice) support the implementation of all types of NICE guidance
- guidance-specific implementation tools (eg costing tools, implementation advice, audit tools, interventional procedures arrangements) relate to a specific piece of NICE guidance.

### NICE Guidance and Related Outputs and Scotland

Table I summarises how NICE guidance and related outputs relate to, or are dealt with in, Scotland. It should be noted that NICE publications that are not formally applicable in Scotland may, nevertheless, be used by health professionals as sources

of evidence when considering particular clinical topics or issues.

**Table I. NICE Guidance and Related Outputs, and Applicability in Scotland**

Type of NICE output	Formally applicable in Scotland?
Technology appraisals	Yes – after validation by NHS QIS
– multiple technology appraisals (MTAs)	No – SMC remains the source of advice on new medicines
Technology appraisals	Yes – guidance distributed directly to NHSScotland from NICE
– single technology appraisals (STAs)	No – but HS produces commentaries to facilitate use in the Scottish context
Interventional procedure guidance	No – but HS produces commentaries to facilitate use in the Scottish context
Public health programme guidance	No – SIGN remains the source of clinical guidelines for Scotland
Public health intervention guidance	No
Clinical guidelines	No
Cancer service guidance	No
Implementation tools	No
Commissioning guides to support clinical service redesign	No
Optimal practice review: recommendation reminders	No
Patient safety solutions	No

The relevant Scottish processes for dealing with the first five types of NICE guidance shown in Table I are described in the final three sections of this paper.

### NHS QIS Involvement in NICE Appraisals

In 2001, one of NHS QIS's predecessor organisations, the Health Technology Board for Scotland, was asked by the then Scottish Executive Health Department (SEHD) to develop a process for validating NICE appraisals for Scotland. This was done as a response to questions about the status of NICE appraisals in Scotland from clinicians, managers, patients, public and politicians in Scotland.

In 2006, NICE introduced its single technology appraisal process (STAs). It has been agreed that SMC will remain the source of advice for all new medicines for NHSScotland and NICE STAs have no status in Scotland. Consequently, NHS QIS processes only NICE multiple technology appraisals (MTAs), validating these for NHSScotland as appropriate.

Since 2001, the processing of NICE appraisals has been streamlined. The current process is available at: <http://www.nhshealthquality.org/nhsqis/files/NICE%20Guidance%20process%20.pdf> (Accessed 22 November 2007).

Up to and including October 2007, 130 NICE appraisals had been published. Of these 13 were STAs and therefore excluded; 94 MTAs have been processed by NHS QIS. There are 60 NICE appraisals in their work programme of which 34 are MTAs. The system of involvement of a small number of experts in Scotland has allowed NHS QIS to make decisions about the validity of NICE appraisals for Scotland. Consequently it issues emails to NHS Board Chief Executives on the same day as NICE publishes its appraisals (usually on the fourth Wednesday of each month).

It should be emphasised that NHS QIS does not re-assess the evidence used by NICE. Rather, its remit (as determined by Scottish Government Health Department) has been to look at contextual differences for Scotland based on four criteria:

- principles and values of NHSScotland;
- epidemiology (frequency, distribution and stage at presentation);
- structure and provision of services in Scotland;

- other implications for NHSScotland, eg rural issues, predicted uptake, existing advice from SMC.

### **NICE Interventional Procedures Programme (IPP)**

NICE makes recommendations about whether interventional procedures used for diagnosis or treatment are safe enough and work well enough for routine use. An interventional procedure is a procedure used for diagnosis or treatment that involves any of the following:

- making a cut or a hole to gain access to the inside of a patient's body - eg when carrying out an operation or inserting a tube into a blood vessel;
- gaining access to a body cavity (eg the digestive system, lungs, womb or bladder) without cutting into the body - for instance, examining or carrying out treatment on the inside of the stomach using an instrument inserted via the mouth;
- using electromagnetic radiation (which includes X-rays, lasers, gamma-rays and ultraviolet light) - for example, using a laser to treat eye problems.

Most of the procedures NICE looks at are new. Exceptionally, NICE may be asked to issue urgent guidance where new evidence raises questions about the safety or efficacy of an established procedure. Where guidance is needed urgently, NICE may issue "interim guidance". When NICE issues interim guidance, it will usually go on to issue final guidance at a later date following a fuller review of the evidence.

In January 2004, Scotland became a full participant in the Interventional Procedures Programme (IPP),<sup>10</sup> and Scotland is included in the circulation of IPP guidance directly from NICE. NHS Boards and their operating divisions should check whether NICE has issued guidance before carrying out a new procedure. If NICE has not issued guidance, approval should be sought through their Board's clinical governance arrangements, and patients must be informed, and consent given, before the procedure concerned is used on them.

It is obligatory for NHSScotland to follow NICE IPP guidance if these procedures are provided by NHS Boards. Up to and including October 2007, 235 NICE interventional procedures guidance had been published.

### **NICE Public Health Guidance**

NICE has been publishing guidance on the promotion of good health and the prevention of ill-health since March 2006. Up to and including October 2007, one piece of public health programme guidance had been issued, and eight more were planned or in development; five pieces of public health intervention guidance had been published, with nine more planned or in development. Each piece of guidance is arrived at after consideration of available evidence, and sets out recommendations for action that are intended to be taken into account as applicable (in England) when carrying out professional, managerial or voluntary duties. The guidance also includes recommendations for research, designed to fill identified evidence gaps.

Unless otherwise decided (eg on the basis of the remit and priorities of HS and other agencies, or any relevant developments in Scotland), HS produces a commentary on each piece of NICE public health guidance. As well as dealing with NICE's public health guidance, HS produced a commentary on the public health aspects of the NICE clinical

guideline on the prevention, identification, assessment and management of overweight and obesity. That guideline had separate public health and clinical recommendations for historical reasons (it was instigated jointly by NICE and the HDA before the latter was absorbed into the expanded NICE).

The HS commentaries are intended to help organisations, professionals and others in Scotland to make use of NICE public health guidance, with due regard to Scottish circumstances. They do not in themselves constitute formal guidance or guidelines. It is stressed in each case that their scope and contents are limited by those of the NICE guidance on which they are based, and that they should be seen not as full action plans or constituting the full basis for a health improvement strategy on the subject area concerned but rather as evidence-informed contributions to such an action plans or strategies.

Each HS commentary is produced in collaboration with an appropriately constituted specialist reference group, with members drawn from within and beyond HS, working with the relevant short-life reference group, and a named sign-off officer. Following examination of the scope, study selection criteria and study appraisal methods described in the NICE guidance in question, the cited evidence and recommendations for action and for research are considered, taking account of Scottish context in terms of policy, infrastructure, practice and developments. In the resulting HS commentary, a given NICE recommendation may be supported in full, or supported with minor amendment or addition of Scottish contextual points; or an alternative HS conclusion may be offered. Full text and summary versions of the commentaries are produced. The target date for completion and dissemination of these is four months after the publication of the NICE guidance concerned.

The finalised commentaries are sent to NHS Board Directors of Public Health (DsPH), with a request for local distribution within and beyond the NHS, to Scottish Government officials, and to partner evidence agencies including NHS QIS, SIGN and NICE. In the interests of promoting awareness and facilitating forward planning, HS produces and issues a schedule of published and planned NICE public health guidance and HS commentaries, reviewed monthly and updated as necessary.

### **Conclusion**

It is hoped that this paper will prove to a useful practical reference resource for health professionals and others in furthering evidence-informed practice and policy in Scotland. The authors will welcome any feedback in that regard.

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