

From the Chief Medical Officer
Dr Michael McBride

Circular HSC (SQSD) 04/11

Subject: NICE Technology Appraisals and Clinical Guidelines – New Process for Endorsement, Implementation, Monitoring and Assurance in Northern Ireland

For action by:

Chief Executive of HSC Board – **for distribution to:**
Director of Performance Management & Service Improvement
Director of Commissioning
Assistant Directors of Commissioning
Head of Pharmacy and Medicines Management
Family Practitioner Services Leads – for cascade to all Family Practitioner groups

Chief Executive of Public Health Agency – **for distribution to:**
Director of Public Health
Director of Nursing

Chief Executives of HSC Trusts – **for distribution to:**
Medical Directors – for cascade to relevant staff
Directors of Nursing – for cascade to relevant staff
Heads of Pharmaceutical Services – for cascade to relevant staff
Directors of Acute Services – for cascade to relevant staff
HSC Clinical and Social Governance Leads

Chief Executives of HSC Special Agencies and NDPBs
Chief Executive, Regulation & Quality Improvement Authority
Chairs of GAIN Committees

For Information to:

Chair of HSC Board
Chair of Public Health Agency
Chairs of HSC Trusts
Chief Executive Patient and Client Council
Chief Executive/Postgraduate Dean, NIMDTA
Chief Executive, NICPLD
Chief Executive, NIPEC
Chair, RMSG

Summary of Contents:

The purpose of this circular is to explain the new arrangements for the endorsement, implementation, monitoring and assurance of NICE technology appraisals and clinical guidelines in NI

Enquiries:

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Related documents:

Superseded documents

HSS (PPMD) 01/06

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Action

Implementation:

Effective from Wednesday 28th September 2011

Additional copies:

Available to download from
<http://www.dhsspsni.gov.uk/index/phealth/sqs/sqsd-guidance.htm>

Dear Colleagues

**NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE (NICE)
TECHNOLOGY APPRAISALS AND CLINICAL GUIDELINES – THE NEW PROCESS FOR
ENDORSEMENT, IMPLEMENTATION, MONITORING AND ASSURANCE IN NORTHERN
IRELAND**

Introduction

1. The Department of Health, Social Services and Public Safety (DHSSPS) has reviewed the process for endorsing and securing implementation of NICE Technology Appraisals and Clinical Guidelines in Northern Ireland. Thanks to HSC colleagues who contributed to the process at all the various stages.
2. The purpose of this circular is to inform the HSC sector of the arrangements for this new process and to explain exactly what is required of them. The new arrangements will be effective from **Wednesday 28th September 2011** and will apply to all HSC organisations, including Family Practitioners. All Clinical Guidelines and Technology Appraisals published by the Institute from this date will be considered under the new process and timescales. It will be the responsibility of HSC organisations, under the statutory duty of quality as specified in Article 34 of the HPSS (Quality, Improvement and Regulation) (NI) Order 2003, to put in place the necessary systems, as part of their clinical and social care governance arrangements, for implementing NICE guidance.

Background

3. NICE is the independent organisation tasked with producing national guidance on the promotion of good health and the prevention and treatment of ill health. The Institute was established in 1999 as a Special Health Authority with the remit to promote clinical excellence and the effective use of resources for people using the NHS in England and Wales, therefore the guidance does not automatically apply in NI. The Institute publishes guidance in various categories and this circular focuses on:

- *Technology Appraisals* where NICE determines whether or not a drug, medical device or surgical procedure should be funded by the NHS, based on its cost-effectiveness; and
 - *Clinical Guidelines* on the management of specific diseases and groups of patients.
4. NICE also publishes *Public Health Guidance* and *Interventional Procedures Guidance*. Public Health Guidance covers the promotion of good health and the prevention of ill health. The Department will be reviewing the process for endorsing Public Health Guidance in Northern Ireland and a separate circular setting out the arrangements will be issued accordingly. England, Wales, Scotland and Northern Ireland are full participants in the Interventional Procedures Programme which assesses the safety and efficacy of new interventional procedures. The arrangements and requirements for the Interventional Procedures Programme are addressed in a separate circular.
 5. The Department established formal links with NICE on 1 July 2006 whereby all guidance published by the Institute from that date would be locally reviewed for applicability to Northern Ireland and, where appropriate, endorsed for implementation in Health and Social Care (HSC). This link has ensured that Northern Ireland has access to up-to-date, independent, professional, evidence-based guidance on the value of health care interventions. The original procedures for locally reviewing applicability of NICE guidance to NI are set out in circular HSS(PPMD) 01/06 which can be accessed via the Department's website at: <http://www.dhsspsni.gov.uk/index/phealth/sqs/sqsd-guidance/sqsd-guidance-nice-guidance.htm>.

New NICE Process

Departmental review of NICE guidance for applicability to Northern Ireland

6. The new system will provide a single process for endorsing NICE guidance with variations as necessary to take account of the differences between Technology Appraisals and Clinical Guidelines. NICE guidance will be proofed by the Department to check for legal, policy and financial consequences related to its

implementation in NI on receipt of the final version of the Clinical Guidelines and near-final versions of the Technology Appraisals (Final Appraisal Determinations (FADs)). This is not a reassessment of the clinical and cost evidence used by NICE in forming its advice. As a result, the guidance may be endorsed with a caveat to advise local healthcare professionals of any equivalent legislation/policy or any specific instructions/requirements. For example, the majority of NICE clinical guidelines refer to the Department of Health document on consent which does not apply here therefore healthcare professionals are advised to follow the DHSSPS equivalent guidance on consent. In a small number of cases the guidance or a section of it will not be applicable in Northern Ireland for legal/policy reasons.

7. It is essential to consider affordability issues in NI therefore the Department will continue to use the NICE costing templates, where available, to produce costing estimates for implementing each piece of guidance. Where the Department is aware of higher incidence of a disease/condition in NI, adjustments can be made to the cost e.g. the higher prevalence of multiple sclerosis. In the case of certain cancer drugs where services are better developed in NI costs can be lower than the costing template estimate, but in other less well developed areas the costs could be significantly greater.
8. The guidance and any legal/policy caveats and costing information will be referred to the Chief Medical Officer (CMO) for approval. Following this approval, the Department will issue the endorsed guidance to the HSC Board requesting that the Board prepare a **Commissioning Plan** in respect of Technology Appraisals or a **Board Response** in respect of Clinical Guidelines in the context of currently available resources and other HSC service priorities.

Equality Screening

9. In compliance with Section 75 of the Northern Ireland Act 1998, and in keeping with commitments given in its Equality Scheme, in 2006 the Department wrote to a number of groups representing Section 75 dimensions, inviting them to comment on the equality implications of guidance being developed by NICE. Equality considerations will continue to be an important element in the new process therefore as part of checking the guidance for any legal and policy

impediments, the Department will continue to issue all NICE Clinical Guidelines and Technology Appraisals to all organisations who agree to participate.

Timescale for endorsement of NICE guidance in Northern Ireland

10. On the fourth Wednesday of each month, NICE publishes its final Guidelines and Appraisals, and any costing templates or statements. The Institute publishes the FAD approximately 6 weeks prior to the final Technology Appraisal which allows the Department to locally review the guidance at a much earlier stage than the Clinical Guidelines. However, the costing information for Appraisals is not available until the final Technology Appraisal has been published therefore financial proofing can only begin at this point. The local DHSSPS review of NICE Technology Appraisals is expected to be complete within 4 weeks of the final publication by NICE and the majority of Clinical Guidelines are expected to be reviewed within 8 weeks of publication by NICE. As soon as the local DHSSPS review is complete, endorsement decisions will be published on the Department's website under 3 categories:

- NICE guidance endorsed as applicable to NI;
- NICE guidance endorsed, or partially endorsed, as applicable to NI, including caveats (for example, to set out equivalent NI legislation or additional local advice);
- NICE guidance not endorsed as applicable to NI, for which explanations will be provided.

Commissioning NICE guidance

11. On receipt of the DHSSPS-endorsed guidance, the HSC Board will firstly confirm to the Department that the endorsement notification has been received and then consider how best to commission services in line with the NICE Guidance. This will require two different approaches to reflect the different nature of Technology Appraisals and Clinical Guidelines in the context of currently available resources and other HSC service priorities:

- ***Technology Appraisals***

For each Technology Appraisal, the HSC Board will submit a **Commissioning Plan** to the Department within no more than 15 weeks from the date of confirmed receipt of notification of endorsement. The Department will then either approve the commissioning plan for that Technology Appraisal or if necessary, will refer it back to the HSC Board for further consideration.

- ***Clinical Guidelines***

NICE Clinical Guidelines, endorsed under the new process, will continue to be regarded as standards that the HSC is expected to achieve over time. It is recognised that Clinical Guidelines, unlike Technology Appraisals, can cover broad aspects of clinical practice and service delivery and, as such, can often be complex. Therefore implementation may involve initial planning with incremental delivery over a number of years. Immediate commissioning of services per se may not actually be realisable or practical, but preliminary steps to identify current practice and benchmarking prior to a commissioning decision may be necessary. Consequently, the HSC Board, in taking account of endorsed NICE Clinical Guidelines may need to plan strategically for necessary change in practice and service delivery over significant periods of time. For each Clinical Guideline endorsed by the Department, the HSC Board will submit a **Board Response** to the Department within no more than 15 weeks from the date of confirmed receipt of notification of endorsement. The Board Response will confirm arrangements for taking forward implementation of the Clinical Guideline over time as part of ongoing commissioning processes. The Department will then either approve the Board Response for that Clinical Guideline or, if necessary, refer it back to the HSC Board for further consideration.

Once each NICE guidance Commissioning Plan or Board Response is agreed, it will represent the formal Departmental policy position on implementation. The Department will confirm that position to the HSC Board.

At this stage, in relation to Technology Appraisals, the HSC Board will issue a NICE Guidance circular to HSC Trusts and other relevant providers setting out the expectations for implementation. In relation to Clinical Guidelines, the Board will write to Trusts advising of the agreed arrangements for the Clinical Guideline to be taken forward. This correspondence to Trusts will include cost estimates and any caveats provided by the Department's initial local review and will be copied to relevant stakeholders, including the Department.

Implementation

12. On receipt of the HSC Board circular for a Technology Appraisal the HSC Trusts or other provider organisations should disseminate it to relevant professional and managerial leads and identify a named officer to lead implementation. The arrangements for assuring the commissioner regarding implementation will be set out in the circular. As noted above, in relation to Clinical Guidelines, the Board will write to Trusts advising of how these are to be taken forward. This will vary according to the nature of the Clinical Guideline.
13. Where a patient has been receiving treatment with a drug which NICE has appraised and not recommended, the patient should have the option of continuing their therapy until they and their clinicians consider it appropriate to stop. Clinical judgement will continue to have precedence for individual patients to allow for people with complex underlying conditions. Nevertheless, in the great majority of cases, the NICE Technology Appraisals are expected to be implemented. All HSC bodies including Family Practitioners should ensure that drugs not recommended by NICE are not used to start treating a new patient.
14. The Department will check that Patient Access Schemes apply in NI. It is important for HSC Trusts to claim all reimbursements where any funding agreements or Patient Access Schemes have been agreed with the manufacturer. Such agreements generally relate to the pharmaceutical industry and have been put in place to allow a drug to pass the NICE test for cost-

effectiveness. The schemes tend to be different, for example, relating to the cost of treatment after the first phase is complete or the first treatment cycle could be free. Trusts need to be able to provide evidence to the manufacturer to demonstrate that they have complied with the protocol. The tracking of these is not easy, but if refunds are not claimed then the drug should not be used since it is not cost-effective without reimbursement.

15. There are many financial risks that are important for Trusts to manage and NICE guidance can often be associated with new costs. Where the guidance recommends multiple drugs for treating a specific condition, clinicians should follow the NICE recommendations in terms of the order of treatments and not move immediately to the most expensive treatment unless it is clinically required. NICE guidance also makes recommendations on disinvestment in certain drugs or treatment as well, resulting in savings. It is vital therefore that the Trusts achieve these savings to avoid unnecessary cost pressures.

Monitoring and Assurance

16. It is important that effective arrangements are in place for the implementation of NICE guidance. As part of reviewing the current process, the Department has developed a new system for monitoring and assuring implementation. The details of this are explained below.
17. The HSC Board will be responsible for monitoring implementation of NICE guidance within the HSC. In relation to Technology Appraisals, the Board will seek assurances from Trusts and Family Practitioner Services in relation to their implementation in accordance with agreed timescales as set out in the HSC Board Circular. Trusts will be asked to confirm after 3 months that: targeted dissemination took place; the clinical/management change leader has been agreed; and that an implementation plan is in place. After the specified implementation period, the Trust should confirm to the HSC Board that the guidance is fully implemented, consistent with the requirements of the relevant Board Circular. The Board will also establish appropriate arrangements for ensuring implementation by Family Practitioner Services, using existing governance arrangements.

18. In relation to Clinical Guidelines, the Board and Trusts will demonstrate active consideration of endorsed Guidelines, aimed at securing full implementation over time, within the annual Commissioning Plan and, as appropriate, Trust Delivery Plans.
19. The Board and Trusts will be required to confirm in the mid-year Assurance Statement and the Statement on Internal Control that effective arrangements are in place to ensure the timely and effective implementation of agreed NICE guidance, highlighting by exception any material areas where this has not been possible.
20. When the HSC Board reports to the Department that a Technology Appraisal is being implemented by Trusts according to plan, then it can be selected for review. To provide further assurance regarding implementation, the Guidelines and Audit Implementation Network (GAIN) will extend its support of regional audits to cover some clinically based NICE guidance and will look at a sample of the technology appraisals each year.
21. The Regulation and Quality Improvement Authority (RQIA) inspections against the 'Quality Standards for Health and Social Care' will include, at a high level, the implementation process for NICE guidance by both commissioners and HSC Trusts. In addition, RQIA will lead on assessing the implementation of Clinical Guidelines, as they are complex, often cover a range of services for a broad condition or type of patient, and are less suitable for clinical audit. The Department, in consultation with RQIA, will use set criteria to select a small number of guidelines on which RQIA will be asked to assess the extent of implementation of the guidance on publication. Then after an appropriate period when implementation has been reported through the monitoring system RQIA will inspect and report on 1-2 clinical guidelines each year.
22. The Department will require the HSC Board to formally report annually on the progress made generally in commissioning services in accordance with NICE guidance endorsed by the Department.
23. Should the Department, the HSC Board, the Public Health Agency, RQIA or GAIN identify any concerns about the implementation of NICE guidance, then

the issue will be added to the agenda of the next 6-monthly Accountability meeting with the appropriate organisation.

NICE Consultations and Stakeholder Registration

24. NICE undertakes extensive literature reviews to ensure the robustness of its guidance. In areas where Northern Ireland is at the cutting edge and particularly where services cross health and social care, it is important that we contribute to NICE research at the scoping stage. It is also crucial to comment at the consultation stage as there is no opportunity to influence the guidance once it is published. I would therefore strongly encourage all HSC Trusts to register as stakeholders with NICE so that they can submit any expert comments they may have. The Trusts and healthcare professionals should register to receive the Institute's e-newsletter to be kept informed of all NICE activities and guidance in development.
25. The success of the new process depends on everyone playing their part and in particular on good communication and effective clinical leadership. To ensure that endorsed medicines are affordable it is vital that NICE protocols for multiple technologies are fully implemented and that potential savings are achieved in areas that NICE have identified for disinvestment. Through working together co-operatively and making the most of evidence based best practice, we can achieve the best outcomes for the people of Northern Ireland.

Enquiries

26. Any queries relating to this circular should be directed to Standards and Guidelines Quality Unit, D1.4, Castle Buildings, Stormont, Belfast, BT4 3SQ, or e-mail: SGU-NICEGuidance@dhsspsni.gov.uk



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