

The Regulation and Quality Improvement Authority

**National Institute for Health and Care
Excellence (NICE) Guidance:**

**Baseline Review of the Implementation
Process in Health and Social Care (HSC)
Organisations**

July 2013

The Regulation and Quality Improvement Authority

The Regulation and Quality Improvement Authority (RQIA) is the independent body responsible for regulating and inspecting the quality and availability of health and social care (HSC) services in Northern Ireland.

RQIA provides independent assurance about the safety, quality and availability of health and social care services in Northern Ireland.

Review reports are submitted to the Minister for Health, Social Services and Public Safety. Review reports are open documents, accessible to the public and available on the RQIA website.

More details of our role and function can be accessed at our web site www.rqia.org.uk.

Executive Summary

National Institute for Health and Care Excellence (NICE) Guidance: Baseline Review of the Implementation Process in Health and Social Care (HSC) Organisations

On 1 July 2006 the Department of Health Social Services and Public Safety (DHSSPS) established formal links with NICE whereby guidance published by the Institute from that date is locally reviewed for applicability to Northern Ireland and, where appropriate, endorsed for implementation in HSC organisations.

In September 2011 the Chief Medical Officer (CMO) issued Circular HSC (SQSD) 04/11, to inform the HSC sector of a new process for endorsement, implementation, monitoring and assurance of NICE guidance in Northern Ireland. This Circular established new arrangements for RQIA to provide assurance in relation to the implementation of NICE clinical guidelines. This review was carried out to provide a baseline profile of the current arrangements in place to support implementation of all types of NICE guidance currently used in NI. RQIA was advised, during the course of this review, that the process for dissemination of clinical guidelines is being revised.

All Health and Social Care (HSC) organisations demonstrated high level support for the implementation of NICE guidance and have put systems in place to take forward the implementation of Circular HSC (SQSD) 04/11.

A NICE Implementation Facilitator has been appointed for Northern Ireland to support the implementation of NICE guidance.

The Health and Social Care Board (HSC Board) co-ordinate a range of activities to support the implementation, monitoring and assurance of NICE guidance. The planned arrangements are that approved NICE guidance is received by the HSC Board which produces a draft service notification for approval by DHSSPS within 15 weeks. Following approval of service notifications by DHSSPS, they are issued by the HSC Board to trusts within 10 days.

During the course of the review, RQIA was informed that the HSC Board dissemination process for clinical guidelines had been temporarily suspended while discussions were taking place between DHSSPS and the HSC Board about changes to the arrangements. This was the cause of some confusion among trusts as to the status of recent guidelines which had been approved by DHSSPS, but not disseminated by the HSC Board. The HSC Board was advised by DHSSPS, in a letter dated 1 March 2013, to reinstate the existing process until such times as a revised process could be agreed.

All Health and Social Care Trusts (trusts) have policies in place for the dissemination, implementation, monitoring and assurance of clinical standards and guidelines.

In all trusts, on receipt of NICE guidance, it is disseminated from the Chief Executive's office to the Standards and Guidelines Manager or equivalent and logged on to a Standards and Guidelines database. It is then circulated by email to a number of

individuals or groups who consider the relevance of each guideline. Each trust nominates a lead director who has the responsibility to manage the implementation process through operational line management structures. None of the HSC organisations have a dedicated NICE manager/lead.

All HSC organisations felt that the volume, content and range of guidance being issued is challenging. There is an identified need for more support to manage the processes for implementation. In general there is strong support from clinicians for the implementation of NICE guidance.

Formal monitoring of implementation by the HSC Board has not yet commenced. As an interim arrangement, HSC Board utilises bi-monthly meetings with each of the five trusts to seek assurances or to identify risks. Updates on implementation and compliance with standards are produced and tabled at relevant governance meetings. Final assurance statements are approved by the trust Senior Management Team and Trust Board prior to submission to HSC Board.

The RQIA review team found that there are no arrangements in place (with the exception of the HSC Board and PHA) for horizon scanning to be carried out routinely for advance notice of upcoming guidance. Organisations generally wait until the guidance is issued and then consider the implementation process. HSC Board and the Public Health Agency (PHA) routinely make use of NICE tools which are designed to support implementation. However RQIA found that the awareness among provider organisations of the types of support tools available was generally low. There were examples of use of some NICE tools; however this is not routine practice.

Organisations expressed a desire to make better use of available NICE support tools to implement guidance. The NICE Implementation Facilitator for Northern Ireland will have a key role in supporting HSC organisations to develop their internal processes for the implementation of NICE guidance.

In March 2013 a stakeholder summit event provided an opportunity for a range of key staff from across Health and Social Care to discuss the initial findings of the review and consider how implementation processes could be enhanced.

This report sets out 12 recommendations to enhance the arrangements for implementation of NICE clinical guidelines. In the future as part of its on-going review programme RQIA will carry out reviews of the implementation of a number of specific guidelines to provide assurance of the implementation process.

We thank all those individuals, organisations and staff who facilitated this review through the provision of information, participation in interviews or attending the summit event.

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Appendix 1: Organisations represented at the RQIA Summit Event

Appendix 2: DHSSPS Circular HSC (SQSD) 04/11

1. Introduction

1.1 Context

In September 2011, the Chief Medical Officer (CMO) issued Circular HSC (SQSD) 04/11, to inform Health and Social Care (HSC) organisations of a new process for endorsement, implementation, monitoring and assurance of NICE guidance in Northern Ireland.

The new arrangements, effective from 28 September 2011, applied to all HSC organisations, including Family Practitioners. All clinical guidelines and technology appraisals published by NICE from that date were to be considered under the new process and timescales. It was the responsibility of HSC organisations, under the statutory duty of quality as specified in Article 34 of the HPSS (Quality, Improvement and Regulation) (Northern Ireland) Order 2003, to put in place the necessary systems, as part of their clinical and social care governance arrangements, for implementing NICE guidance.

This Circular stated that RQIA would inspect and report on the implementation of one to two clinical guidelines each year. To inform this on-going process, RQIA determined that an initial baseline assessment of the implementation of NICE guidance in HSC organisations should be undertaken. This review has been carried out as part of the RQIA review programme for 2012-2015.¹

Circular HSC (SQSD) 04/11 details the responsibility for organisations in relation to the endorsement, implementation, monitoring and assurance of NICE guidance. This describes the current arrangements which have been put in place to implement the Circular. The findings of the review are presented for organisations using the themes identified in the NICE Into Practice Guide.²

- Policies and Procedures in place for handling of NICE guidance
- Receipt and Consideration of Applicability
- Dissemination
- Implementation
- Monitoring and Review
- Horizon Scanning

The organisations considered include:

- The Health and Social Care Board (HSC Board)
- Public Health Agency (PHA),
- 6 Health and Social Care Trusts

¹ RQIA Three Year Review Programme 2012-15

http://www.rqia.org.uk/cms_resources/RQIA%203%20Year%20Review%20Programme%202012-15_Web.pdf

² NICE Into Practice Guide

<http://publications.nice.org.uk/using-nice-guidance-and-quality-standards-to-improve-practice-pg1/introduction>

- Belfast Health and Social Care Trust
 - Northern Health and Social Care Trust
 - Southern Health and Social Care Trust
 - South Eastern Health and Social Care Trust
 - Western Health and Social Care Trust
 - Northern Ireland Ambulance Service Health and Social Care Trust
- The Northern Ireland Blood transfusion Service

The findings from this baseline assessment will be used to inform future reviews which will consider implementation of specific areas of NICE guidance.

1.2 Terms of Reference

- I. To produce a baseline report of the processes currently in place within HSC organisations for the consideration and/or implementation of NICE guidelines specifically in relation to:
 - Technology Appraisals
 - Clinical Guidelines
 - Public Health Guidance
 - Interventional Procedures
- II. Consider the processes in place for the receipt and consideration of applicability, dissemination, implementation, monitoring and review of each aspect of NICE guidance
- III. To seek the views of HSC organisations on steps which may improve or enhance the receipt and consideration of applicability, dissemination, implementation, monitoring and review of NICE guidance within Northern Ireland.
- IV. To make recommendations for improvement if required

1.3 Methodology

The methodology adopted for this review was designed to gather information on the processes currently in place within HSC organisations for the receipt, consideration of applicability, dissemination, implementation, monitoring and review of NICE guidance, through direct engagement with staff that hold responsibility in this area.

RQIA worked in partnership with the NICE Implementation Facilitator for Northern Ireland who provided external expert advice and input to this project. The role of the NICE Implementation Facilitator is to engage with organisations and networks to encourage, inform and facilitate their implementation activities. The facilitator seeks to gather examples of good practice to share with other organisations and to receive feedback to underpin all aspects of NICE's work. The facilitator also promotes the wide range of support tools that NICE provides to help put guidance into practice.

The methodology used included the following steps.

1. An initial information gathering exercise was undertaken to establish the processes currently in place within HSC organisations across Northern Ireland. Lines of enquiry were then developed to explore these processes in more depth with each organisation in order to obtain a clear picture of the processes involved.
2. A series of semi-structured interviews were held with key staff involved with the implementation of NICE guidance within individual organisations. The aim of this informal engagement process was to allow two-way discussion to establish the strengths and weaknesses of the current arrangements.

This stage of the review was facilitated by:

Lesley Edgar, NICE implementation Facilitator, Northern Ireland
Helen Hamilton, Project Manager, RQIA

3. The initial findings from the interviews were collated and the results used to inform a summit event in March 2013. At this event, the initial findings were presented and discussed. Possible approaches to enhance the arrangements were then considered. This summit event included representation from across the HSC. A full list of organisations represented is included at Appendix 1.

2. National Institute for Health and Care Excellence

2.1 National Institute for Health and Care Excellence (NICE)

The National Institute for Health and Care Excellence (NICE) was set up in 1999 to reduce variation in the availability and quality of NHS treatments and care. Evidence-based guidance and other products developed by NICE help resolve uncertainty about which medicines, treatments, procedures and devices represent the best quality care and which offer the best value for money for the NHS.

NICE also produces public health guidance recommending best ways to encourage healthy living, promote wellbeing and prevent disease. The public health guidance is for local authorities, the NHS and all those with a remit for improving people's health in the public, private, community and voluntary sectors.

Independent Committees

Every piece of NICE guidance and every NICE quality standard is developed by an independent committee of experts including clinicians, patients, carers and health economists. All NICE guidance is considered and approved by the NICE guidance Executive, a committee made up of NICE Executive Directors, Guidance Centre Directors and the Communications Director, prior to publication. The Citizens Council, comprising 30 members of the public, provides NICE with advice that reflects the public's perspective on what are often challenging social and moral issues raised by NICE guidance.

2.2 Functions of NICE

NICE is there to help those working in the NHS, local authorities and the wider community deliver high-quality healthcare.



More detailed information on the functions of NICE can be obtained from the website at <http://www.nice.org.uk/>³

Looking to the future

Prior to 1 April 2013, NICE was a Special Health Authority funded by the Department of Health in England. The Health and Social Care Act 2012⁴ set out plans for NICE to become a Non Departmental Public Body from 1 April 2013 and for its remit to expand to include the publication of guidance, advice and quality standards for the social care sector.

2.3 Types of NICE guidance

The Institute publishes guidance in various categories:



- technology appraisals
- clinical guidelines
- public health guidance
- interventional procedures
- medical technologies (not considered for inclusion in this baseline report)
- diagnostics (not considered for inclusion in this baseline report)

Technology Appraisals

Technology appraisals are recommendations on the use of new and existing medicines and treatments within the NHS, such as:

- medicines
- medical devices (for example, hearing aids or inhalers)
- diagnostic techniques (tests used to identify diseases)
- surgical procedures (such as repairing hernias)
- health promotion activities (for example, ways of helping people with diabetes manage their condition).

NICE recommendations are based on a review of clinical and economic evidence:

- clinical evidence measures how well the medicine or treatment works.
- economic evidence measures how well the medicine or treatment works in relation to how much it costs the NHS; does it represent value for money?

Clinical Guidelines

Clinical guidelines are recommendations by NICE on the appropriate treatment and care of people with specific diseases and conditions within the NHS. They are

³ <http://www.nice.org.uk/>

⁴ <http://www.publications.parliament.uk/pa/bills/lbill/2010-2012/0119/2012119.pdf>

based on the best available evidence. While clinical guidelines help health professionals in their work, they do not replace their knowledge and skills.

Public Health Guidance

Public health guidance makes recommendations for populations and individuals on activities, policies and strategies that can help prevent disease or improve health. The guidance may focus on a particular topic (such as smoking), a particular population (such as schoolchildren) or a particular setting (such as the workplace).

NICE public health guidance is aimed at public health professionals and practitioners and others with a direct or indirect role in public health within the NHS, local authorities and the wider public, voluntary, community and private sectors.

Interventional Procedures Guidance

An interventional procedure is a procedure used for diagnosis or for treatment that involves:

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

NICE interventional procedures guidance covers:

- the safety of the procedure
- whether it works well enough for routine use
- whether special arrangements are needed for patient consent.

Medical Technologies Evaluation Programme

The Medical Technologies Evaluation Programme (MTEP) selects and evaluates new or innovative medical technologies (including devices and diagnostics). MTEP helps the NHS adopt efficient and cost effective medical devices and diagnostics more rapidly and consistently.

The types of products which might be evaluated are medical devices that deliver treatment such as those implanted during surgical procedures; technologies that give greater independence to patients; and diagnostic devices or tests used to detect or monitor medical conditions.

Diagnostics Assessment Programme

As part of NICE's work on evaluating medical technologies, the Diagnostics Assessment Programme (DAP) focuses on the evaluation of innovative medical diagnostic technologies in order to ensure that the NHS is able to adopt clinically and cost effective technologies rapidly and consistently.

Diagnostics includes all types of measurements and tests that are used to evaluate a patient's condition, such as physiological measurements, laboratory tests and pathology tests, imaging tests, and endoscopy.

NICE Quality Standards

NICE Quality Standards are a concise set of statements designed to drive and measure priority quality improvements within a particular area of care.

NICE Quality Standards are derived from the best available evidence such as NICE guidance and other evidence sources accredited by NICE. They are developed independently by NICE, in collaboration with NHS and social care professionals, their partners and service users. Evidence relating to effectiveness and cost effectiveness, people's experience of using services, safety issues, equality and cost impact are considered during the development process.

NICE Quality Standards enable:

- health and social care professionals and public health professionals to make decisions about care based on the latest evidence and best practice.
- people receiving health and social care services, their families and carers and the public to find information about the quality of services and care they should expect from their health and social care provider.
- service providers to quickly and easily examine the performance of their organisation and assess improvement in standards of care they provide.
- commissioners to be confident that the services they are purchasing are high quality and cost effective and focussed on driving up quality.

2.4 NICE Into Practice Guide: Using NICE guidance and quality standards to improve practice⁵

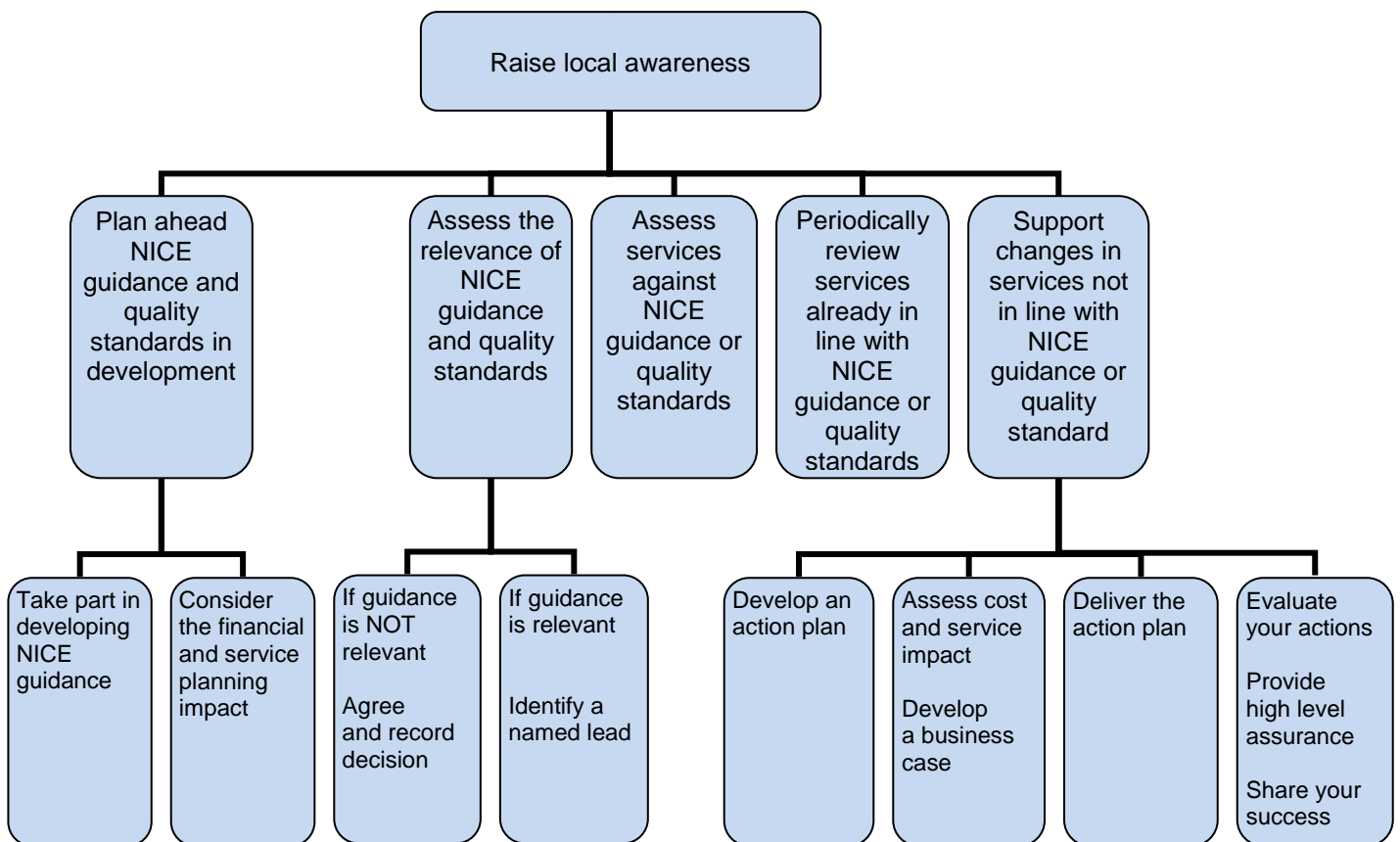
This guide aims to help and support HSC provider organisations to implement NICE guidance and use NICE quality standards to achieve improved quality of care in local settings. It aims to support health and social care professionals and managers in providing care of the highest quality and the best value for money. The guide suggests what an organisation can put in place, and what staff can do to use NICE evidence-based guidance and quality standards to improve practice. The NICE Into Practice Guide covers the following aspects:

What organisations need to have in place:

- high level support and leadership
- a nominated lead
- a multidisciplinary forum
- a local policy

⁵ <http://www.nice.org.uk/usingguidance/implementationtools/howtoguide/howtoguides.jsp>

What organisations need to do as set out in the NICE Into Practice Guide:



This review has used the themes identified in the NICE Into Practice Guide to inform the areas of consideration during discussion with organisations on the implementation arrangements in Northern Ireland.

3. NICE guidance in Northern Ireland

3.1 Background

On 1 July 2006, DHSSPS established formal links with NICE. All guidance published by the Institute from that date is reviewed for applicability to Northern Ireland and, where appropriate, endorsed for implementation in HSC organisations. This arrangement has ensured that Northern Ireland has access to up-to-date, independent, professional, evidence based guidance on the use of healthcare interventions.

In 2006 DHSSPS stated that, under the new arrangements, NICE Technology Appraisal guidance endorsed by the DHSSPS as applicable for Northern Ireland, was to be treated as essential within the published Quality Standards for Health and Social Care (March 2006)⁶. Endorsed NICE Clinical Guidelines were to be regarded as standards that HSC was expected to achieve over time.

In September 2011, the CMO issued Circular HSC (SQSD) 04/11⁷, to inform the HSC sector of new arrangements for the implementation process.

The new arrangements, effective from 28 September 2011, apply to all HSC organisations, including Family Practitioners. All Clinical Guidelines and Technology Appraisals published by the Institute from this date are now considered under the new process and timescales. It is the responsibility of HSC organisations, under the statutory duty of quality as specified in Article 34 of the HPSS (Quality, Improvement and Regulation) (Northern Ireland) Order 2003, to put in place the necessary systems to implement NICE guidance. These should be set up incorporated within the clinical and social care governance arrangements for the organisations.

The new system provides 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 is considered by the DHSSPS to check for legal, policy and financial consequences related to its implementation in Northern Ireland. DHSSPS does not reassess the clinical and cost effectiveness evidence used by NICE in formulating its advice.

Following consideration by DHSSPS 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 in Northern Ireland. 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.

⁶ http://www.dhsspsni.gov.uk/gpi_quality_standards_for_health_social_care.pdf

⁷ http://www.dhsspsni.gov.uk/circular_hsc_sqsd_04_11_nice_guidelines_8211_new_process.pdf

3.2 The DHSSPS Circular HSC (SQSD) 04/11

The DHSSPS Circular HSC (SQSD) 04/11 outlines the roles and responsibilities of HSC organisations in respect of endorsed NICE guidance. A full copy of this Circular is referenced at Appendix 2.

Commissioning

Following approval by the Chief Medical Officer (CMO) the DHSSPS issues endorsed NICE guidance to the HSC Board requesting that the Board prepares:

- 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.

Both types of response are known as “service notifications”.

Once each service notification is agreed it will represent the formal Departmental policy position on implementation. The DHSSPS will confirm that position to the HSC Board.

Implementation

On receipt of the service notification from the HSC Board the trusts disseminate it to relevant professional and managerial leads and identify a named officer to lead implementation.

Monitoring and Assurance

The HSC Board is responsible for monitoring implementation of NICE guidance within the HSC. The DHSSPS requires the HSC Board to formally report annually on the progress made in commissioning services in accordance with NICE guidance. Should DHSSPS, the HSC Board or PHA identify any concerns about the implementation of NICE guidance, then the issue will be added to the agenda of the accountability meeting with the appropriate organisation.

For Technology Appraisals, trusts will be asked to confirm after 3 months that:

- targeted dissemination took place;
- the clinical/management change leader has been agreed;
- an implementation plan is in place.

For Clinical Guidelines, the HSC 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.

The circular stated that the HSC Board and trusts are required to confirm in a mid-year Assurance Statement and a Statement on Internal Control that effective arrangements are in place to ensure the timely and effective implementation of agreed NICE guidance and to highlight by exception any material areas where this has not been possible.

4. Findings

4.1 The Health and Social Care Board and the Public Health Agency

Policies and Procedures in place for Handling of NICE guidance

The culture of both the HSC Board and the PHA is to support the implementation of evidence based practice. The HSC Board and PHA advised that they implement NICE guidance in line with the Departmental Circular HSC (SQSD) 04/11.

Implementation of NICE guidance is a process, co-ordinated on behalf of both organisations via the HSC Board's Commissioning Directorate. The Director of Commissioning has the responsibility for implementation of NICE guidance.

A NICE Business Support Officer was appointed in January 2013. This role encompasses a range of operational activities to support the implementation, monitoring and assurance of NICE guidance, endorsed as applicable in Northern Ireland.

A "service notification" sets out for providers the HSC Board's/PHA's expectations for implementation. The "service notification" process is taken forward through a number of Commissioning Service Teams. Each Commissioning Service Team;

- is multidisciplinary in its composition and includes staff from both the HSC Board and PHA;
- includes input from local commissioning, primary care, pharmacy, finance, and information;
- is expected to source additional clinical input to the production of service notifications where required; and
- is responsible for defining a service model or specification for the service area for which it is responsible, which is both needs-led and evidence-based and which is developed with appropriate input from local commissioners, service providers and service users.

Service specifications are live documents, which are reviewed on an ongoing basis as the needs of the population and the evidence base evolves. The service model or specification sets out the commissioning intention in relation to that service area, ensuring that, as funding is made available, it is aligned to and supports the service developments required to implement the service model.

Receipt and Consideration of Applicability

When an approved piece of NICE guidance is received by the HSC Board it is allocated to the most appropriate Commissioning Service Team. If the piece of guidance holds relevance across a number of commissioning teams, the lead team is determined through discussion with the chairs. The lead team is responsible for cross working with other commissioning teams as required. The commissioning

team is required to produce a draft service notification within 15 weeks for approval by the DHSSPS.

Dissemination by HSCB and PHA

Once a service notification is approved by the DHSSPS it is disseminated internally within the HSCB/PHA by the Commissioning Directorate to the Director of Finance, Head of Pharmacy (HSC Board), Local Commissioning Groups (LCGs) and the Executive Medical Director/Director of Public Health (PHA). The Executive Medical Director/Director of Public Health (PHA) then disseminates within PHA through the normal line management cascade.

Following approval by DHSSPS, service notifications are issued to trusts within 10 days. Currently the HSC Board sends service notifications to HSC trusts via the offices of the Chief Executives. The HSC Board advised that service notifications are not routinely disseminated to primary care at present or to other organisations apart from HSC trusts

The commissioning teams examine all NICE guidance received and they prioritise what can be taken forward within financial constraints.

The HSCB and PHA consider that the volume, content and range of guidance being issued is challenging to process. The arrangements in relation to NICE technology appraisals are considered to work well. However, HSCB/PHA staff advised RQIA that the arrangements in relation to clinical guidelines should be reviewed.

The review team was advised by the HSC Board and PHA that the current process for the implementation of NICE Clinical Guidelines was suspended pending review by the HSC Board and the DHSSPS. After a temporary pause the process was reinstated on 1 March 2013. Trusts were not aware of this suspension and this had led to some confusion as to which Clinical Guidelines had been endorsed for application.

The HSC Board and PHA suggested that once a NICE Clinical Guideline is agreed it should be sent out directly from the DHSSPS to the entire service (provider and commissioner). If there is a commissioner element which needs to be addressed this will be considered as part of the ongoing commissioning cycle. At the time of this review the DHSSPS had not agreed this proposed approach.

In the interim, the review team was advised that there are plans to make all service notifications available on the HSC Board website from April 2013 which aspires to improve openness and transparency to the public. This will also enable trusts to confirm the status of each guideline and check related caveats.

The HSC Board suggested that, in future, NICE Quality Standards may be usefully disseminated within Northern Ireland and would provide opportunities for commissioners and providers to enhance quality improvement processes. It should be noted however that these are designed for England and their priorities may not always match Northern Ireland.

There is currently no dedicated funding stream within the HSC Board for the implementation of NICE Clinical Guidelines. The material issues are taken forward through the commissioning process but it is in competition with many other priorities, which sometimes have to take precedence.

Monitoring and Review

In January 2013 the HSC Board commenced a process through which director level bi-monthly meetings with each trust are used to seek assurance that NICE Technology Appraisals and Clinical Guidelines are being progressed in accordance with commissioner expectation. Reporting is by exception, there is no requirement for trusts to submit formal monitoring reports regarding the status of implementation of each piece of NICE guidance.

The HSC Board is satisfied that the monitoring of the implementation of NICE Technology Appraisals is achievable and relatively straightforward.

For NICE Clinical Guidance the HSC Board seeks information from trusts in relation to material patient safety and clinical risk issues. This dialogue allows any specific issues regarding implementation to be raised. The HSC Board does not want to over-bureaucratise the assurance process and expects trusts to be open and transparent in these meetings so that any resulting 'red' issues can be discussed; and if necessary added to the risk register.

While there are no timescales for reporting back on NICE Clinical Guidelines at present, the HSC Board advised that consideration of timescales will come into the new process which is to be discussed and agreed with the DHSSPS.

The HSC Board considers that trusts should be routinely utilising NICE clinical audit tools for NICE Technology Appraisals and NICE Clinical Guidelines.

4.2 Health and Social Care Trusts

Policies and Procedures in place for Handling of NICE guidance

Whilst NIAS is also a HSC Trust it will be dealt with separately at section 4.3 below.

In each trust there is high level support for the implementation of NICE guidance, quality improvement and evidence based practice. Each trust has established multidisciplinary approaches to the implementation of evidence based practice.

All trusts have organisational policies in place for the dissemination, implementation, monitoring and assurance of clinical standards and guidelines. The implementation of NICE guidelines is either described in a specific policy, or is integrated within a wider policy.

Trust processes are described in policy documents which are in some cases supported by algorithms/flowcharts. The policies are set within the trusts' governance assurance/accountability framework.

None of the trusts have a dedicated manager/lead specifically for implementation of NICE guidance. However, all trusts have named individuals who co-ordinate the implementation of the organisational policy usually with the support of a core group which facilitate the triage and dissemination of guidance.

- In the Belfast Trust the Chair of Standards and Guidelines Committee is the identified lead, supported by the Senior Manager for Standards, Quality & Audit, the Co-Director for Risk & Governance and the Standards & Guidelines Manager.
- In the Northern Trust the identified lead is the Assistant Trust Clinical and Social Care Governance Manager.
- In the Southern Trust the identified lead is the Patient Safety and Quality Manager, Acute Services.
- In the South Eastern Trust the identified lead is the Associate Medical Director, the Assistant Director for Safe and Effective Care supported by the Safe and Effective Care Manager.
- In the Western Trust the identified lead is the Assistant Governance Manager.

Some of the core groups have administrative support while others do not have this resource. Where available, this support assists with the dissemination and follow up of NICE guidance and the preparation of assurance and monitoring reports. This work is generally carried out in tandem with other responsibilities, including co-ordination of the clinical policy approval and the issue, monitoring and review of DHSSPS Circulars and PHA Safety Alerts.

Receipt and Consideration of Applicability

Trusts reported some confusion about the dissemination process from the HSC Board. They would welcome the identification of an agreed contact at HSCB/PHA for guidance in relation to each service notification.

Currently each trust receives NICE guidance from the HSC Board through the trust Chief Executive's office. It is then forwarded as per internal arrangements. This can be either via the Medical Director or the trust Standards and Guidelines Departments, which have delegated responsibility for dissemination, to relevant named clinical or management leads.

Each trust has a multidisciplinary committee where a review of the particular relevance of the NICE guideline to the organisation is considered. These committees vary in structure and membership. The role of these multidisciplinary committees varies, but one aspect is to oversee the dissemination and implementation of NICE guidance. In each trust the role of the multidisciplinary committee is broader than the implementation of NICE guidance.

- In the Belfast Trust, the Standards and Guidelines Committee tracks the receipt and implementation of NICE guidance.
- In the Northern Trust, the Policy, Standards and Guidelines Committee oversees the dissemination and implementation of NICE guidance.
- In the Southern Trust, the Standards and Guidelines Prioritisation and Risk Review Group ensures the implementation process from NICE is in place.
- In the South Eastern Trust, the NICE guidelines management system is led by the Associate Medical Director who works closely with the Safe and Effective Care Manager to oversee the implementation of the standards across the multidisciplinary team.
- In the Western Trust, a Standards Triage Group was established in August 2012. This group liaises with relevant professional staff.

The membership of trust multidisciplinary committees varies, however the committees are usually chaired by a senior doctor or nurse. Some committees have representation from each trust directorate. The frequency of meetings varies from 2 to 8 weeks.

- In the Belfast Trust, the Standards and Guidelines Committee meet every 6 – 8 weeks. This is a multi-disciplinary committee with representation from each directorate, pharmacy and quality and nursing governance.
- In the Northern Trust, the Policy, Standards and Guidelines Committee meet every 6 weeks. All Executive Directors and operational directorates are represented on the committee along with pharmacy representation and various staff members from the governance department.
- In the Southern Trust, the Standards and Guidelines Prioritisation and Risk Review Group meet every 2 weeks. This is a multi-disciplinary committee with representation from each directorate, pharmacy, quality and governance. The group is co-chaired by the Assistant Director of Clinical and Social Care Governance and the Medical Director.
- In the South Eastern Trust, the Clinical and Social Care Guidelines Monitoring Group meets twice yearly and has multidisciplinary representation. The Associate Medical Director, the Assistant Director of Safe and Effective Care, the Head of Pharmacy and Safe and Effective Care Manager hold established fortnightly meetings with operational service areas which facilitate detailed discussion on the compliance against standards, risk management and escalation where relevant.
- In the Western Trust, the Standards Triage Group meets every 2 weeks. Current membership includes an Associate Medical Director, Head of Clinical

Quality and Safety and representatives from governance. Nursing and pharmacy input is sought as and when required.

An example of the remit of a trust Standards and Guidelines Group includes the following functions:

- Log all NICE guidelines on to the trust standards and guidelines database.
- Ensure all NICE guidelines are prioritised in line with other competing governance requirements.
- Ensure expert clinical opinion is sought regarding the implementation of NICE guidelines.
- Consider prioritisation of NICE guidelines within the context of risk management (i.e. lessons learnt from complaints, serious adverse incidents, litigation).
- Using the approved risk assessment form, determine the risk associated with non-compliance with NICE guidelines.
- Identification of the lead director for implementation and, where the NICE guideline applies to more than one directorate, seek agreement between directors as to who will lead on implementation.
- Propose a 'change leader' for consideration by the appropriate director.
- Outline the monitoring arrangements for NICE guidelines to ensure that the action plan/progress reports are submitted to the lead director and Senior Management Team for approval before submitting assurances to the HSC Board.
- Ensure that processes are in place for escalating concerns regarding the trusts ability to achieve full compliance with the NICE guideline.
- Ongoing monitoring of the trusts' accountability report for standards and guidelines in order to ensure that progress is monitored, and challenges or barriers to gaining full compliance are escalated to the relevant Director/Senior Management Team.

If a guideline is not relevant to the HSC trust, this conclusion is recorded on the trust's standards and guidelines database. If the NICE guideline is not considered relevant to the organisation, such as when the trust does not provide the service, the guidance is recorded as closed on the database.

Generally there were no arrangements for the review of decisions about 'not-applicable' guidelines. The exception is in the event of further service development when, if relevant, the guidance may then be reconsidered. If a trust cannot comply with guidance, as the result of resource issues, then the non-compliance may be recorded on the risk register.

Dissemination

In all trusts, NICE guidance is disseminated from the Chief Executive's office to the Standards and Guidelines Manager or equivalent, and copied to other named individuals. The guidance is logged on to the standards and guidelines database and is then emailed to a number of individuals or groups. If the guidance is drug related the guidance is also emailed to the trust Head of Pharmacy and Medicines Management.

- In the Belfast Trust NICE guidance is disseminated from the Chief Executive's office to the Standards and Guidelines Manager, and copied to the Co-Director for Risk and Governance, Senior Manager, Safety and Quality Assurance and the Joint Chair of the Standards and Guidelines Committee. Individual service directors are primarily responsible for the implementation of NICE guidance.
- In the Northern Trust guidance is sent to the relevant operational director who has primary responsibility for implementation.
- In the Southern Trust guidance is reviewed by the Trust Standards and Guidelines Review Group which identifies a lead director. The lead director is then responsible for ensuring the appropriate identification of 'change leaders'.
- In the South Eastern Trust NICE guidelines are sent to the Triage Team, and disseminated to the relevant nominated contact in the directorate who disseminates to the Director, an operational lead and a professional manager. All three nominees are responsible for implementation.
- In the Western Trust NICE guidance is forwarded to the Medical Director/Director of Social Work/other relevant director. The Medical Director then directs all guidance to the Standards Triage Group which identifies a responsible director, operational manager and professional responsible for the implementation of the guideline.

There is no dedicated multi-professional group in place to support implementation of NICE guidance in any trust. Following consideration of the relevance of each guideline, each trust nominates a lead director. This delegation to a lead director is usually undertaken by a smaller core group, by the trust Medical Director or by the chair of a wider multidisciplinary group, e.g. Standards and Guidelines Committee.

Nominations for committees and implementation groups are identified from within the operational directorates. This provides assurance that clinical and management ownership is embedded into everyday working practices rather than sitting outside operational structures. The skills and knowledge of nominees are considered as part of this selection process to implementation groups.

It is the responsibility of the lead director to manage the implementation process through operational line management structures. Where guidance is relevant to more than one directorate all relevant directors are asked to liaise to identify which will take the lead in co-ordinating implementation. It is the role of the lead director to disseminate information to relevant staff/managers within their directorate and identify a lead management/change leader.

Onward Circulation

At an operational level, NICE guidance is sent to relevant clinical teams. If the guidance is fairly specific to certain localised teams, it is then their responsibility to disseminate the guidance to all staff within that team. To ensure the guidance reaches all relevant staff, including junior doctors, the lead director will usually nominate someone to act as a champion and disseminate the guidance to healthcare and management staff. In many cases, clinicians are already aware of the content of the guidance as it may already have been received from other sources.

It is the role of individual ward managers to make sure their staff are aware of relevant NICE guidance which they should be considering in their individual areas.

Generally there are no arrangements to record that individual members of staff have received and viewed the guidance.

In all trusts it is a governance function to ensure that staff are accessing and following best practice guidance. Some guidance with wider applicability, that would be relevant to large groups of staff, can be disseminated via other mechanisms such as; the use of trust intranets, consultants' e-newsletters or via trust newsletters; all of which have a wide circulation base. In all trusts, awareness of NICE guidance, and how to access it, is raised at staff induction and reinforced at manager's induction.

The review team noted that in the South Eastern Trust a monthly 'all users' email is issued when policies are updated and these are then discussed at governance and staff meetings. Rather than disseminate NICE guidelines as they are published, a decision was taken to issue one single alert bulletin every month drawing attention to all policies that have come out or been updated in that month. Where there is a safety issue an patient safety alert is initiated immediately.

Implementation

While NICE Clinical Guidelines are not mandatory they are managed through the same process as other guidelines within trusts. Individual directors are primarily responsible for the implementation of NICE guidance. The lead director is responsible for ensuring the appropriate identification of 'change leaders', and that operational line management and governance structures are in place to monitor progress and compliance.

It is common practice in trusts for lead directors to be asked to respond with an indication of the actions required for implementation with timescales and responsibilities. Assurance and implementation plans are usually required to be returned no later than three months following receipt of the guidance by the directorate.

- In the Belfast Trust, guidance is circulated via an email which will indicate the immediate action to be taken and the date feedback is due (six weeks). The completed form is returned to the Standards and Guidelines Manager and compliance is recorded on the standards and guidelines database. An update on progress on implementation and compliance with all standards is produced by the Standards and Guidelines Department and is then tabled at the relevant lead directors' governance meetings.
- In the Northern Trust, when a copy of a guideline is circulated, it is indicated that feedback should be sent to the Standards and Guidelines Manager within six weeks. Feedback is provided using the assurance plan and an implementation plan which are issued along with the guideline when initially circulated. When feedback is received it is logged onto the standards and guidelines database. Six monthly progress reports are prepared and submitted for consideration to the Policy, Standards and Guidelines Committee, Governance Management Board and Governance Committee.
- In the Southern Trust, a change lead is appointed to lead a working group which undertakes a standardised baseline assessment which assesses the organisation's current status against the guideline. A red/amber/green coding system is in place to define compliance. A time limited action plan is

subsequently drawn up by the change lead. A working group under the direction of the change lead will take the actions forward. Updates on implementation and compliance with all standards are produced by the Patient Safety and Quality Manager and tabled at the relevant lead directors' governance meetings. This is recorded on the standards and guidelines register.

- In the South Eastern Trust, NICE guidance is circulated along with an indication of the action required and a request for assurance of appropriate action, with timescales and responsibilities. Leads with responsibility for the implementation of guidelines meet fortnightly with operational service areas to facilitate detailed discussion on compliance against standards, risk management and escalation where relevant. The system also enables each directorate service area to meet the triage group every two months, to discuss the level of compliance with NICE guidelines and areas of risk where non-compliant. The current governance arrangements facilitate the dissemination, implementation and the monitoring of compliance, tracking is via the Clinical and Social Care database and Datix.
- In the Western Trust, NICE guidance is circulated along with an indication of timescales for action and adherence. A Standards, Circulars and Guidelines summary dashboard is shared on a quarterly basis at service directorate governance meetings. The dashboard details title of guidance, date issued, total number of recommendations, current status, lead professional and date last update provided. Implementation of guidance is monitored by the Quality and Standards Sub-Committee with exception reports provided to the Trust's Governance Committee. The Assistant Governance Manager ensures that all actions identified by the Standards Triage Group are taken forward and that the database is updated accordingly.

Trusts did describe some difficulties when implementing NICE guidance. It was reported that the management of standards and guidelines continues to be challenging, due to the volume, complexity and interconnection between a number of standards and guidelines. Challenges include:

- lack of availability of people to provide facilitation and support to 'change leaders';
- lack of availability of finance to enable implementation to take place;
- size and complexity of health and social care services;
- competing priorities for funding and implementation processes;

Trusts reported that guidelines which are unable to be immediately implemented remain on a list until the relevant director provides an update on progress, or if they still require resources to be implemented.

Whilst trusts acknowledged that NICE Clinical Guidelines need to be implemented, they indicated that the majority of the work required is at directorate level and relevant staff juggle this demand with other pressures. Trusts reported that the overall volume of work is ever increasing for front line staff who need more help and support to manage the processes for implementation.

Trusts advised that they are unclear as to the status and assurance arrangements required for NICE guidance issued before Northern Ireland entered into a partnership arrangement with NICE in 2006. Some of this guidance is used to inform local clinical policies, although it is not formally endorsed for application here. As the evidence base is continually evolving, it was suggested that a definitive list is

maintained, as to which guidance is required to be implemented, and where guidance requires assurance of implementation.

Monitoring and Review

All trusts record receipt and monitor implementation of NICE guidance on a database. This tends to be Microsoft Excel or Access based, but Datix is sometimes used. Several trusts would like to procure a system which has been specifically designed to monitor implementation of NICE guidance. However, options examined to date do not provide the full range of functions required, such as tracking the individual work streams.

Those organisations which use Datix would like to develop the clinical guidelines module to be able to produce reports around non-compliance and those which are a risk for the trust. At present the systems allow the monitoring of guidance implementation using a red/amber/green colour coding system. All dates for response to the HSC Board are recorded on the standards and guidelines database.

Trusts reported that they track implementation via self-assessment of compliance of guidelines when they are first launched. Each clinical area is encouraged to assess their level of safety and quality and to develop their own areas for improvement.

Regular meetings with service areas, triage teams and directorate governance meetings (dependent on the trust) enable specific focus on compliance with guidelines and new circular management. Operational areas take the required actions to implement standards or identify areas where non-compliance is evident. Where this is in relation to specific guidance they will consider action to address, including escalation if appropriate. The current governance arrangements in place facilitate the dissemination, implementation and the monitoring of compliance.

Line management and governance structures also provide mechanisms for lead directors and change leaders to escalate any barriers, challenges and risks in implementation to the Senior Management Team and Trust Board. All trusts advised the review team that there is a section on the reporting template, for each directorate, to report any emerging risks which require to be brought to the Trust Board.

Trusts felt that there is no clear procedure to escalate the financial requirements for implementation of guidelines. Trusts can submit business cases for additional funding however there is no collective process across organisations to develop these. Trusts would welcome consideration to be given to a joint approach to address this issue.

Assurance to the HSC Board

Each trust has arrangements in place to provide assurance to the HSC Board when required in relation to implementation:

- In the Belfast Trust, final assurance statements are approved by the Senior Management Team and Trust Board prior to submission to the HSC Board. A

six monthly accountability report is submitted by the organisation to the HSC Board and it forms part of the trust accountability review with DHSSPS.

- In the Northern Trust, six monthly updates are sought to monitor progress made regarding implementation and to identify any issues impacting on implementation. This information is shared at 6 monthly accountability review meetings internally, and with the HSC Board and the DHSSPS.
- In the Southern Trust, final assurance statements are approved by the Senior Management Team and Trust Board prior to submission to the HSC Board. A six monthly accountability report is submitted by the organisation to the HSC Board and it forms part of the accountability review with DHSSPS.
- In the South Eastern Trust the performance management operating cycle (under the Safety, Quality and Experience agenda) and accountability reviews: (twice yearly) facilitate the reporting of compliance with all DHSSPS guidelines including NICE.
- In the Western Trust a summary update of the Standards, Circulars & Guidelines dashboard is brought to each Quality & Standards Sub-Committee Meeting and directorate governance meetings. It is also available for mid-year accountability meetings with the HSC Board.

Audit of NICE guidelines

Trusts provided details of a number of audits designed to assess the effectiveness of their arrangements for implementation of NICE guidelines:

- The Belfast Trust has requested that Internal Audit reviews dissemination of NICE Technology Appraisals as part of the 2012/13 audit plan. The report will be submitted to Assurance and Audit Committees of the Trust Board.
- The Northern Trust is currently engaged in a stocktake of all NICE Clinical Guidelines endorsed by the DHSSPS as applicable to HSC organisations, and issued between 1 April 2007 and 27 September 2011.
- The Southern Trust considers the evaluation of the implementation of NICE guidance within their audit prioritisation processes.
- The South Eastern Trust tracks the implementation status of NICE Clinical Guidelines using a database and via service area reports which are monitored at each service area meeting. Existing governance arrangements facilitate the monitoring of compliance.
- The Western Trust seeks updates from the lead professional/director to provide assurance on the implementation of NICE guidance. Unless an audit is specifically requested, to date evaluation has been the responsibility of individual professionals. If audit is mentioned in any of the guidelines it is noted by the Assistant Governance Manager and a new process has been set up to add these to a list of priority audits.

Audit departments are encouraging service teams to consider priority areas for audit. Trusts indicated that prioritisation of audit activity is based on key organisational priorities. A structured audit programme is in place which incorporates standards and guidelines, including NICE guidance. Trusts reported that they try to encourage re-audit on at least an annual basis but this doesn't always happen as services do not always have the capacity to do these

Trusts do use NICE audit tools in assessing application of NICE guidance when this has been specifically requested by the HSC Board at the time of dissemination of the guidance.

Some trusts reported that they share good practice from audit, both within their own organisations and wider. All audit managers meet with the Guidelines and Audit Implementation Network (GAIN) and this is an opportunity for networking and to share learning and experience.

Horizon Scanning

At present trusts do not use NICE tools (such as the NICE forward planner) to proactively plan ahead for the release of future guidance.

NICE Technology Appraisals can have significant financial impact and this can be accommodated within the commissioning plan, which includes a costing element. If significant additional finance is identified, trusts can prepare and submit a business case for consideration by the HSC Board as commissioner.

For Technology Appraisals trusts stated that the supporting documentation provided by the HSC Board when guidance is issued, is helpful, as it outlines where implementation can occur within existing resources or whether additional resources might be required. Expenditure is monitored by trust Pharmacy directorates and involves liaison with directors and outside organisations as necessary.

From discussion with trusts, there are generally not processes in place to actively scan for future release of guidance. The NICE website does give an indication of which guidelines will be issued. However costing templates are not available from NICE until the guidance is published, therefore the financial implications may not be clear, which limits the potential for future financial planning. Trusts would welcome consideration of how to improve arrangements for forward planning.

4.3 NI Ambulance Service Health and Social Care Trust

Policies and Procedures in place for Handling of NICE guidance

In NIAS there is high level support for the implementation of NICE guidance, quality improvement and evidence based practice. However, the organisation does not have a formalised policy for the implementation of NICE guidance.

NIAS does not have a dedicated NICE manager/lead. There is a named individual who co-ordinates the organisational policy. These individuals deal with relevant NICE guidelines and all other standards and guidelines received by the organisation in tandem with other responsibilities.

Receipt and Consideration of Applicability

Previously NICE guidance has been received from DHSSPS but the process ceased when responsibility for dissemination transferred to the HSC Board.

NIAS indicated that it would be helpful to be included in the dissemination of NICE guidance in order to consider relevant applicability, as some of the guidance may have a relevant focus. The review team has been advised that dissemination of service notifications will be reviewed by the HSC Board/PHA so that Commissioning Service Teams are asked to consider which relevant organisations the service notification needs to be shared with.

NIAS does have a small management team which includes the Medical Director, the Assistant Medical Director and the Risk Manager who meet weekly and look at all guidance and alerts, for example, coroners' reports. This is not dedicated specifically to NICE guidance. When NICE guidelines are received by NIAS, they are reviewed for their applicability and relevance to NIAS and any relevant action determined. Applicability decisions are made jointly by this group, seeking specialist medical advice if required. Input from relevant Royal Colleges will be sought if required.

NIAS uses nationally agreed Clinical Practice Guidelines which are produced by the Joint Royal Colleges Ambulance Liaison Committee (JRCALC). The NIAS Medical Director is a member of this committee and NIAS contributed significantly to the newly updated JRCALC guidelines (2013). These guidelines incorporate the relevant NICE guidelines. An application for them to be accredited by NICE Evidence has recently been submitted.

At induction, NIAS staff are made aware of the JRCALC National Clinical Practice Guidelines and advised where they can access any NICE guidance which would be of relevance to them.

Dissemination

In NIAS, dissemination of relevant guidelines will take place usually via the Regional Ambulance Training Centre which also co-ordinates the development of any associated training programmes. If guidance received is considered relevant to the NIAS, the guidance is passed to the Clinical Training Manager for dissemination through the Regional Ambulance Training Centre and the NIAS Clinical Training

Team, consisting of Regional and Divisional Training Officers and Clinical Support Officers, at local operational level.

Implementation

While there is no dedicated single lead for the implementation of NICE guidance in NIAS, when guidance is received and requires implementation, a baseline assessment is carried out and an action plan is developed. NIAS is not resourced specifically for the implementation of NICE guidance and, where necessary, this would be absorbed within the training budget and within the roles of existing staff.

There is a named lead in the NIAS clinical training team who is responsible for taking forward actions in respect of NICE guidance where it is necessary to do so in collaboration with the Trust's medical director. The guidance is then disseminated down through the clinical training team including a tier of Clinical Support Officers. NIAS also undertakes annual refresher training which will include significant new guidelines and changes in practice as necessary and appropriate. The training team review the guidelines and highlight the differences in the guidelines from previous versions and indicate changes that need to be highlighted using a Red/Amber/Green system. If a significant change in practice is required, this change will be addressed either during the refresher training or directly through the Clinical Support Officers who will communicate with staff as necessary.

If a NICE Technology Appraisal is relevant to NIAS the organisation would look at its current practice, assess actions required and any cost implication and refer this to the HSC Board, if required. If guidance is considered not relevant to NIAS, this is recorded and kept on file. To provide assurance that things are actioned as required, NIAS provides reports for the NIAS Trust Board through the Clinical Assurance Committee.

Actions against NICE guidelines are standing items on the NIAS Governance Committee. An electronic database is maintained by the Risk Manager. If implementing best practice is delayed for any reason, it is recorded in the action plan. It may also be recorded as a risk which would be included in a report to the NIAS Trust Board.

NIAS did describe the volume of guidance as being work intensive for a small team and in many instances the impact is also considered at national and regional level.

Monitoring and Review

NIAS advised the review team that clinical performance indicators have been developed for a number of clinical conditions and performance is reported through the NIAS clinical audit process to the Assurance Committee as a standing agenda item. Other elements, such as hand hygiene and other clinical interventions, are monitored and audited directly through clinical support officers and training officers.

NIAS has a small information department which undertakes all reporting activity as well as undertaking clinical audit. All information in an ambulance is recorded manually, therefore all audit is paper based and as such is labour intensive.

Horizon Scanning

NIAS participates in the development of national guidelines along with other national ambulance groups that consider equipment, infection prevention & control, and the development of UK ambulance training programmes.

NIAS stated that due to the volume of guidance there is a time constraint which makes horizon scanning more difficult and they have limited capacity in terms of resources. NIAS does check the NICE website for relevant guidance particularly when investing in new equipment.

4.4 NI Blood Transfusion Service

Policies and Procedures in place for Handling of NICE guidance

In the NIBTS there is high level support for the implementation of NICE guidance, quality improvement and evidence based practice. However, the organisation does not have a formalised policy for the implementation of NICE guidance.

NIBTS does not have a dedicated NICE manager/lead. There is also a named individual who co-ordinates organisational policy. These individuals deal with relevant NICE guidelines and all other standards and guidelines received by the organisation, in tandem with other responsibilities.

Receipt and Consideration of Applicability

Previously NICE guidance was received from DHSSPS, for information and relevant consideration but this process ceased when the responsibility for dissemination transferred to the HSC Board.

NIBTS indicated that it would be helpful to be included in the dissemination in order to consider applicability, as some of the guidance may have a relevant focus. The review team has been advised that dissemination of service notifications will be reviewed by the HSC Board/PHA so that Commissioning Service Teams are asked to consider which relevant organisations the service notification needs to be shared with.

Dissemination

In NIBTS, dissemination and local awareness is dependent on the particular piece of guidance, although this would often include discussion with staff within the Belfast HSC Trust such as the Director of the Haemophilia Centre at Belfast City Hospital. When there is a requirement for particular action this is taken through the same change control process as other guidelines and would be disseminated to staff via email, staff newsletter or via an electronic system which can be used to disseminate and record receipt of information.

Implementation

A limited amount of NICE guidance is directly relevant to NIBTS. They are not however isolated from wider consideration of NICE guidance, for example at trust Hospital Transfusion Committee, Regional Transfusion Committee and Northern Ireland Consultant Haematologist Forum. These fora provide an opportunity to discuss NICE guidance and to consider the possible implication of NICE guidance to the NIBTS and to the wider HSC family.

NIBTS stated that implementation of NICE guidance would only be problematic for the organisation when a piece of guidance had the potential to conflict with any regulatory requirement of the service.

Monitoring and Review

NIBTS stated that review and audit is part of the organisation's internal monitoring processes. Clinical audits are undertaken via the Northern Ireland Transfusion Committee. Audits have been undertaken in relation to anti-D and platelets and this audit did consider relevant NICE guidance in this area.

When there are any areas of non-compliance, in respect of regulatory standards, the NIBTS raises a non-conformance on an electronic database. If changes are required as a result of the issuance of new guidance, the required changes in procedures are proposed and approved. This is all co-ordinated via the database system. Where any change is implemented this is subject to a post implementation review. This process is compatible with the monitoring and review of NICE guidance.

Horizon Scanning

NIBTS stated that in advance of this baseline review, the Medical Director did visit the NICE website to review which guidance was applicable to the organisation but stated that they would not have routinely checked the website by way of horizon scanning.

4.5 Utilising NICE Support

NICE Support Tools

The review team found that the HSC Board and PHA routinely make use of NICE support tools including the costing template, commissioning guide and NICE pathways. The HSC Board also advises and signposts trusts to resources including patient information templates and audit tools.

There is an HSC Board expectation that trusts use NICE audit tools. The feedback received from trusts is that they wouldn't routinely use the tools unless guided to do so.

Trusts do not routinely ask directors/teams to report back on any specific NICE tools used as part of the implementation of NICE guidance. Nevertheless there was evidence to indicate that, in some trusts, costing tools are used. Some trusts have used a limited number of support tools such as slides for use in teaching programmes.

The Southern Trust stated that it does consider the use of NICE tools to support implementation of NICE guidance, for example NICE baseline audit assessment tools. The South Eastern Trust has referred to the audit and self-assessment tools to guide implementation of NICE guidelines.

Generally, organisations expressed their views that NICE implementation tools are not readily accessible. They considered that the NICE website is difficult to navigate and it was suggested that a section of the website, specifically for Northern Ireland, might be helpful. To facilitate access, one trust has signposted the NICE Website through a link on the trust's Safe and Effective Care Website. Others are considering similar linkages.

Overall the awareness of the types of NICE support tools available was generally found to be low. However, as they look to the future, trusts are considering how best to use NICE implementation tools, even if they are not currently doing so.

Most provider organisations expressed limited awareness of NICE quality standards and how they could be used to support quality improvement. Trusts indicated that they would be keen to have more information on NICE Quality Standards as they may prove useful in the implementation process and in monitoring quality improvement. The review team was advised that some directorates within trusts are already aware of NICE Quality Standards and use a significant number of them, in their own improvement work.

Guideline Development

The review team asked organisations if they had ever participated in NICE guideline development. The HSC Board advised that it has never been involved in a stakeholder exercise but would like to be involved in the future. Some trusts were aware that some specialties/staff have participated in guideline development groups, but that this was on an individual rather than an organisational basis.

It was reported that some clinicians do comment on NICE guidance development however this is usually through their own professional organisations. Organisations were supportive of the process to register as stakeholders, feeling it would help clinicians see guideline development as a two-way process which they have an opportunity to feed into.

NIAS, which currently participates in the development of the National Clinical Practice Guidelines, indicated that they would be keen to work with NICE in the future, particularly if NICE is planning the development of a set of ambulance specific guidelines.

Most organisations were unaware of the process for registering to receive NICE News and NICE e-Alerts which would allow them to keep abreast of possible consultations, which would give advance notice of guidance in development. The NICE Implementation Facilitator for Northern Ireland is to liaise in the future with all organisations to advise them how to register.

In discussions, trusts could see the benefit of a NICE manager in organisations who would be involved in:

- registering the organisation as a stakeholder,
- drafting of response to guidelines' consultations,
- working with directorates to ensure the response to the guideline,
- the response and the implementation,
- the audit and monitoring process, and
- reporting any gaps in implementation through the risk register.

Public Health Guidance

NICE Public Health guidance is not formally endorsed for application in Northern Ireland at present. Individual clinicians and teams in their pursuit of delivering high quality care and best practice may choose to consider relevant NICE Public Health guidance which is available on the NICE website. There is evidence that some teams have considered such guidance as various items have been referenced within trust clinical policies.

While there is no organisational/corporate consideration or co-ordination of usage, trusts told the review team that they take account of any NICE Public Health guidance which is referenced within DHSSPS regional strategies and other guidance. Service areas are expected to follow best practice in service provision and therefore give consideration to NICE Public Health guidance where appropriate.

When received, NICE Public Health guidance is passed to the directorate leads but many aspects are considered not to be relevant to trusts. However, in some specific areas such as Health Improvement Departments, trust staff will link with the PHA to take relevant areas forward using public health guidance.

Interventional Procedures

All but one trust was aware of the DHSSPS procedure in relation to interventional procedures; however, there has been minimal need to access the policy to refer new procedures to NICE for review.

Training

It was suggested that it would be useful if NICE could provide appropriate training packages, including competency frameworks, when guidance is issued. This approach would be useful in managing the training needs of staff moving from one organisation to another and would also provide an assurance to trusts that a consistent regional approach to training was in place.

Role of the NICE Facilitator for Northern Ireland

All HSC organisations welcomed the appointment of the NICE Implementation Facilitator for Northern Ireland and expressed significant interest in how they could utilise the assistance offered in the future.

It was reported that staff are sometimes confused as to how they should be implementing guidance and there is a perceived lack of regional direction to guide them. Trusts requested that NICE share information around implementation systems used by trusts in other parts of the UK in order to learn from their experiences.

It was felt that perhaps the appointment of the NICE Implementation Facilitator for Northern Ireland may lead to the establishment of a regional network/group to look specifically at implementation and share experiences and successes.

4.6 The RQIA Summit Event and proposed refinements to the process of dissemination and implementation

As part of the review methodology, RQIA hosted a stakeholder summit event in March 2013. This event provided an opportunity for a range of key staff from across Health and Social Care to discuss the initial findings of the review, to evaluate the current processes in place and to identify steps that may improve or enhance the receipt, consideration of applicability, dissemination, implementation, monitoring and review of NICE guidance within Northern Ireland.

The review team presented the initial findings from their earlier work to the group and it was agreed that the issues identified represented a fair reflection of the current processes in place and some of the difficulties faced.

The current process, as described in Circular HSC (SQSD) 04/11, came into effect on 28 September 2011. Trusts felt that this had provided greater clarity about the implementation process and they are aware that they should not implement any guidance until it is formally issued as a service notification from the HSC Board.

However, throughout the course of the review, it has become clear that since the Circular was issued, experience in working with the process has led to the identification of a number of areas for potential improvement.

Views and suggestions made by Summit participants

Initial comments made at the summit event suggested that trusts would welcome an indication of what the DHSSPS plans for the year ahead, in terms of guidance to be issued.

Trusts also raised the issue of the latency between NICE guidance being issued nationally and the regional endorsement of guidance in Northern Ireland. It was suggested that perhaps this process could be shortened in the future. They would value getting the notification from the Department at the endorsement stage. The trusts suggested that the development of an interagency timeline would be useful to track progress of each NICE guideline. It was felt that consideration should be given to posting of this information on a centralised website as this would aid planning processes.

In order to assist provider organisations manage the workload of NICE and other guidelines and safety alerts, it was suggested that the DHSSPS or HSC Board could stratify NICE guidance with all of the other guidance to provide an overall picture of what is being issued and when. Again, this would assist planning processes. In order to achieve this, it was suggested that the HSC Board and PHA develop a process to ensure standards and guidelines are circulated in manageable numbers to ensure the opportunity to properly embed information and key recommendations, and monitor and review the outcomes.

The different clinical arrangements in Northern Ireland can sometimes conflict with NICE guidance. For example some NICE guidance has referenced age 16 in relation to paediatric clinical management and this guidance does not align with the process in place in Northern Ireland where children as young as 13 years can be in the care of a physician. This is not always established when the DHSSPS

undertakes its initial review before approving new guidance for use in Northern Ireland. Trusts felt that it would be helpful if specific requirements for Northern Ireland were clarified before new guidance is issued. It should be noted that Departmental policy is that someone remains a child until the age of 16. There is consequently an operational issue of how paediatric guidance is applied to those under 16 years of age in adult wards.

There was also support for a centralised approach to the development of an action plan to implement clinical guidelines so that responses could be made on behalf of the region rather than individual trust responses. This would also assist trusts in making a collaborative response when there are resource issues, to make sure all issues are addressed in a single business case. Currently the Trust Policy Collaborative group gives the opportunity for trusts to work together on issues such as this. However the establishment of a network, to enhance and promote collaborative working in relation to the implementation of NICE guidance, may provide a valuable forum to facilitate this.

At present, bi-monthly assurance is provided to the HSC Board via the Trust Directors meeting. Trusts would welcome the development of an agreed template, to provide information about NICE guidance, for these meetings. This should include both positive statements as to where the guidance has been implemented as well as any areas where implementation has not yet been completed.

Trusts suggested that guideline dissemination, and return reporting, should be centralised, as currently trusts are required to provide feedback updates to different people on different guidelines.

Overall there was broad support for the proposed changes to the process which were outlined by DHSSPS and attendees agreed to study the proposals in more depth and to return any comments/suggestions to the DHSSPS.

Proposed refinements to the process

At the summit event the DHSSPS presented HSCB proposed refinements to certain parts of the process, as set out in the Circular. The suggested changes would not alter the policy aim, but rather seek to ensure a more streamlined and robust process, as well as improved assurance mechanisms, to ensure that the population of Northern Ireland continue to receive timely access to best practice and evidence based care.

Under the proposed changes, the HSC Board would continue to issue service notifications for Technology Appraisals, although these would no longer be submitted to the DHSSPS for approval and can be circulated 15 weeks after endorsement. Trusts/providers will then have a 3 month period to plan for implementation. It is expected that, in most cases, Technology Appraisals should be fully implemented within 6 months of issuing.

The proposed revised arrangements, which had not been agreed by the date of the summit, would mean that DHSSPS will issue endorsed NICE Clinical Guidelines directly to the HSC by Circular. Service notifications for Clinical Guidelines would no longer be issued by the HSC Board. On receipt of the Circular, each trust should provide targeted dissemination, agree a clinical/management lead to take

forward implementation and ensure the development of the implementation plan. In order to assess what change is required, the trust would need to look at the gap between the current system and that set out in the best practice guidance. NICE baseline assessment tools may be of assistance with this. This implementation planning should be completed within 3 to 6 months. It is expected that, in most cases, NICE Clinical Guidelines should be fully implemented within 3 years of issue.

HSC organisations would need to continue to provide assurance to their boards on the implementation of NICE guidance. Assurance would be sought at the mid and end of year accountability meetings between the DHSSPS and the HSC Board/trusts. A range of assurance mechanisms should be put in place, including

- individual clinician – through annual appraisal and revalidation
- internal audits by clinical and social care teams
- clinical network audits

This revised process was presented in order to ascertain provider views and given the comments particularly around the value of positive assurance and the role of the HSC Board/PHA and Trust collaborative further consideration was needed.

Attendees agreed to study the HSC Board proposals in more depth and to return any comments/suggestions to the DHSSPS.

5. Conclusions

On 1 July 2006, DHSSPS established formal links with NICE whereby all guidance published by the Institute from that date is locally reviewed for applicability to Northern Ireland and, where appropriate, endorsed for implementation in HSC organisations. 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.

In September 2011, the CMO issued Circular HSC (SQSD) 04/11. The purpose of the Circular was to inform the HSC sector of new processes for endorsement, implementation, monitoring and assurance of NICE guidance in Northern Ireland. Although NICE guidance is not mandatory in Northern Ireland, under the new arrangements, NICE Technology Appraisal guidance endorsed by the DHSSPS as applicable for Northern Ireland is now treated as essential. Endorsed NICE clinical guidelines are regarded as standards that HSC is expected to achieve over time.

This review was carried out to complete a baseline assessment of the arrangements in place to implement NICE guidance in Northern Ireland. This will inform future RQIA reviews which will consider the implementation of specific areas of NICE guidance.

A NICE Implementation Facilitator has been appointed for Northern Ireland to support the implementation of NICE guidance

RQIA has concluded that all Health and Social Care organisations subject to this review demonstrated high level support for the implementation of NICE guidance. Systems have been put in place to take forward the implementation of Circular HSC (SQSD) 04/11.

Policies & Procedures in place for handling of NICE guidance

In the HSC Board and the PHA, implementation of NICE guidance is co-ordinated on behalf of both organisations via the HSC Board's Commissioning Directorate through a range of activities to support the implementation, monitoring and assurance of NICE guidance.

Each HSC trust has a procedure in place for the dissemination, implementation, monitoring and assurance of clinical standards and guidelines. NIAS and NIBTS do not have written policies for the implementation of NICE guidance, although both organisations use relevant guidance as part of their commitment to implementing evidence based practice.

Trusts do not have dedicated NICE managers or leads. However, within each organisation, there is a named individual who co-ordinates the organisational processes for implementation, either individually, but more commonly through a small core group/triage group. These individuals take forward NICE and other standards and guidelines received by the organisation.

Their responsibilities usually include dissemination and follow up of NICE guidance and preparation of assurance and monitoring reports. Their other duties may

include co-ordination of the clinical policy approval process and the issue, monitoring and review of DHSSPS Circulars and PHA Safety Alerts.

The benefit of a single dedicated lead for NICE implementation in organisations has been demonstrated from the experience of using the model in England. The identified lead ensures that the day-to-day aspects of implementation are coordinated effectively. This includes:

- disseminating guidance to key groups and arranging educational events
- horizon scanning for NICE guidance
- coordinating financial plans
- ensuring effective processes for monitoring and feedback
- production of regular board reports.

It is recommended that all HSC organisations should consider having an identified lead to manage the distribution and implementation of NICE guidance. For larger organisations, the potential benefits of having a dedicated lead for this function should be considered.

Receipt and Dissemination of NICE guidance by HSC Board and PHA

Approved NICE guidance received by the HSC Board, is allocated to a lead Commissioning Service Team which is responsible for collaborative working with other service teams as required. The lead service team produces a draft service notification for approval by the DHSSPS within 15 weeks. Following approval of the service notification by the DHSSPS, the service notification is issued to trusts within 10 days.

Under current arrangements the HSC Board issues service notifications to trusts. They are not routinely disseminated to primary care providers or independent sector providers or to the voluntary sector.

These arrangements are taking place in relation to NICE Technology Appraisals. However, RQIA was advised that the HSC Board process in relation to NICE Clinical Guidelines had been suspended pending review by the HSC Board and the DHSSPS. The process set out in the circular was reinstated from 1 March 2013. Trusts were not generally aware that this had happened, which had led to a confusion as to the status of some guidance. Some were recorded as endorsed on the DHSSPS website but had not been issued by the HSC Board to the service because of their suspension.

During the RQIA summit event, possible new arrangements for dissemination of NICE Clinical Guidelines were described by DHSSPS through which Clinical Guidelines would be issued directly to organisations from DHSSPS while Technology Appraisals would continue to be issued as service notifications by the HSC Board. This proposal has not been formally agreed.

RQIA considers that the proposed new dissemination arrangements would clarify and simplify the process and makes the following recommendations in this regard:

The HSC Board should establish a central on-line information point where the status of all NICE guidance is recorded for Northern Ireland.

The HSC Board dissemination arrangements for all NICE guidelines should be reviewed to ensure that all organisations receive the guidance which is relevant to their functions. This should include consideration of dissemination to primary care, independent sector organisations and the voluntary sector.

The proposal to amend the dissemination process in the light of experience demonstrates the value of keeping new systems under review at appropriate intervals.

It is recommended that the revised dissemination arrangements, once agreed, should be reviewed after a year of operation to ensure that they are working effectively.

All organisations felt that the volume, content and range of guidance being issued is challenging. The review team was advised that there are plans to make all service notifications available on the HSC Board website from April 2013, which will also enable trusts to confirm the status of each guideline. This in turn should aid trust planning processes.

Dissemination of guidance within HSC provider organisations

The current process specifies that each trust receives the NICE guidance from the HSC Board to the trust Chief Executive's office, where it is then forwarded through trust-specific internal arrangements.

In all trusts, NICE guidance is disseminated through the Chief Executive's office to the Standards and Guidelines Manager or equivalent. Guidance received is logged on to a standards and guidelines database and is then circulated by email to a number of relevant individuals or groups.

Each trust has a multidisciplinary committee where a review of relevance of a NICE guideline to the organisation is considered. These committees have other roles which are not specific to the implementation of NICE guidance.

If a guideline is not considered relevant to the trust, this would be recorded as such and closed on the trust database. If the trust determines that the guideline is relevant but it cannot comply with the guidance, for example, as the result of resource issues, then the non-compliance is considered as a potential risk and should be recorded on the risk register.

Historically in both NIAS and NIBTS, NICE guidance was received for information but since the arrangements set up in 2011, neither organisation routinely receives service notifications from the HSC Board. These organisations were interested in receiving NICE guidance for consideration of applicability, as some of the guidance

would be relevant to them. When NIAS and NIBTS receive guidance documents, they have appropriate mechanisms in place to process and disseminate these.

Implementation arrangements in HSC provider organisations

Within HSC trusts, individual directors are primarily responsible for the implementation of NICE guidance. The lead director is responsible for ensuring the appropriate identification of 'change leaders', and, through the operational line management and governance structures, trusts have mechanisms in place to monitor progress and compliance.

Line management and governance structures also provide mechanisms for lead directors and change leaders to escalate any obstacles or challenges in implementation to the trust Senior Management Team and Trust Board. If there is a resource issue around the implementation of NICE guidance, trusts highlight this to the HSC Board. The issue remains on a list of guidance deemed unable to be implemented, until the resource issue is resolved.

Trusts advised that, in view of the volume of guidance being issued, including those from sources other than NICE, there is an identified need for more help and support internally to manage the processes for implementation. Despite these challenges, trusts advised that generally, there was support from clinicians in respect of implementing NICE guidance.

The process to endorse NICE guidance became operational in 2006. Some NICE guidance which pre-dated the start of the process has not yet been endorsed for use in Northern Ireland. One example of this is the NICE guidance on the use of long-acting reversible contraception. In most cases guidance issued before 2006 has been updated and replaced, or is in the process of being updated. Therefore the updated guidance has been endorsed, or will be once published. The remaining clinical guidelines are reviewed by NICE every 3 years and require no update at present. These are referred to by the DHSSPS as being on the static list.

It is recommended that the static list of guidance issued prior to 2006, and which has not yet been reviewed for endorsement in Northern Ireland, should be prioritised at the earliest opportunity.

Monitoring and Review

Formal monitoring of implementation by the HSC Board has not yet commenced. As an interim arrangement, HSC Board utilises bi-monthly meetings with each of the five trusts to seek assurances or to identify risks. Updates on implementation and compliance with standards are produced and tabled at relevant governance meetings. Final assurance statements are approved by the trusts Senior Management Teams and Trust Board prior to submission to HSC Board.

For NICE Clinical Guidelines, the HSC Board seeks information from trusts in relation to material patient safety and clinical risk issues and there is an expectation that any specific issues regarding implementation are raised. It has been suggested that an agreed template should be developed, to provide information about NICE guidance, for these meetings. This should include both positive

statements as to where the guidance has been implemented as well as any areas where implementation has not yet been completed.

It is recommended that a template should be developed, to provide information about NICE guidance, for bi-monthly Trust Directors meetings. This template should include both positive statements as to where the guidance has been implemented as well as any areas where implementation has not yet been completed.

Trusts record the receipt of NICE guidance on a database system. This allows for the monitoring of guidance implementation using a red/amber/green colour coding system. Regular meetings are held which enable a specific focus on compliance and new circular management. Organisational governance arrangements facilitate the dissemination, implementation and the monitoring of compliance.

Trusts provided examples where certain aspects of NICE guidance have been subject to audit but advised that the volume of guidance received means that it is not possible to subject all areas to clinical audit.

Trusts are investigating the potential of information systems to record the stage of implementation of specific pieces of NICE guidance however at present there is no specific information management system which meets all requirements or all the functions required.

RQIA considers that it would be desirable if all trusts were using the same system and that a regional project should be established to take this forward.

It is recommended that a regional project is established to agree the specification of an information management system for the implementation of NICE guidance.

There have been joint approaches between trusts in some areas through the work of the Trust Collaborative Group. RQIA has concluded that the establishment of a network of trust implementation leads would be useful to share good practice in relation to implementation processes for NICE guidance

It is recommended that a network is established which would include NICE implementation leads from both commissioning and providing organisations, to discuss common issues and share good practice in the implementation of NICE guidance.

All trusts have risk management systems in place. RQIA found that processes are not fully developed for linking risks associated with the implementation of NICE guidance to risk registers. There was a lack of clarity around which risks needed to be recorded on the risk register.

It is recommended that all organisations review their arrangements for linking risks, associated with the implementation process for NICE guidance, to the process of updating risk registers.

Trusts track the implementation of NICE guidance via self-assessment of compliance and individual clinical areas are encouraged to assess their level of safety and quality. Clinical areas are asked to develop their own actions for improvement based on this and regular meetings are held to discuss monitoring and review arrangements and compliance with NICE guidance.

NIAS advised that performance against clinical performance indicators, developed for a number of clinical conditions, is reported through the NIAS clinical audit process to their Assurance Committee as a standing agenda item.

NIBTS stated that review and audit is part of the organisation's internal monitoring processes. Clinical audits are undertaken via the Northern Ireland Transfusion Committee. Previous audits have considered relevant NICE guidance.

Horizon Scanning

RQIA found that there are no arrangements in place for organisations (with the exception of the HSC Board and PHA) to proactively plan ahead for the issue of upcoming guidance by NICE. NICE do have a Forward Planner which sets out which pieces of guidance are due for release.

The current arrangements for dissemination of NICE guidance have sometimes led to the situation where a significant number of pieces of guidance have been issued in a short period of time; this can create difficulties for organisations.

The implementation model from NICE is generally to issue guidance on a monthly basis on the same day of the month. This facilitates planning arrangements for organisations in this regard. However, NICE also sometimes publish guidance at other times in the month which, in order to meet the 4 or 8 week endorsement targets or the 15 week Service Notification target, it must be released at a different point in the month than the rest of the guidance.

It is recommended that, under the new arrangements for dissemination of endorsed guidance for Northern Ireland a planned system is considered for release of guidance on a monthly basis where possible.

Use of NICE support tools and involvement in NICE processes

The HSC Board and PHA routinely make use of NICE tools, including the costing template, commissioning guide and NICE pathways. The HSC Board signposts trusts to other resources which are available to them including patient information templates and audit tools.

While there is an HSC Board expectation that trusts use the NICE implementation audit tools, RQIA found that the awareness of the types of support tools available was generally low. The review team found that tools were being used in some organisations for specific purposes but that this is not routine practice.

HSC organisations advised that they would be interested in making more use of the suite of tools provided by NICE to support implementation.

It is recommended that all HSC organisations review their use of NICE implementation tools.

All HSC organisations welcomed the appointment of the NICE Implementation Facilitator for Northern Ireland and expressed significant interest in how they could utilise the assistance offered in the future.

It is recommended that all HSC organisations should collaborate with the NICE Implementation Facilitator for Northern Ireland to raise awareness within organisations, of NICE implementation support tools and how HSC organisations could utilise them to support quality improvement.

The NICE Implementation Facilitator for Northern Ireland will have a key role in supporting HSC organisations to develop their internal processes for the implementation of NICE guidance, this will include:

- promotion of the use of NICE tools
- awareness raising in relation to the NICE Quality Standards and the caveats relating to their use in Northern Ireland.
- understanding of how NICE can be used to support quality improvement
- liaison with organisations to advise them how to register for NICE updates
- liaison with organisations to encourage participation in guideline development
- information sharing on best practice/initiatives
- participation in any regional network/group set up to look specifically at implementation, to share experiences and successes.

RQIA found a lack of awareness of the potential opportunities available to participate in NICE guideline development. Some individual clinicians had participated in guideline development groups. All of the HSC organisations were supportive of the process to register as stakeholders and felt it would help clinicians see guideline development as a two-way process.

Opportunities to be involved in NICE guideline development are outlined in the online publication, NICE News. It is recommended that all HSC organisations register for NICE News and consider future participation as stakeholders in the development of NICE guidance.

Most HSC organisations were unaware of the process for registering for NICE News which would allow them to keep abreast of possible consultations which would give advance notice of guidance in development.

6. Recommendations

Recommendation 1: All Health and Social Care organisations should consider having identified lead to manage the distribution and implementation of NICE guidance. For larger organisations, the potential benefits of having a dedicated lead for this function should be considered.

Recommendation 2: The HSC Board should establish a central on-line information point where the status of all NICE guidance is recorded for Northern Ireland.

Recommendation 3: The HSC Board dissemination arrangements for all NICE guidelines should be reviewed to ensure that all organisations receive the guidance which is relevant to their functions. This should include consideration of dissemination to primary care, independent sector organisations and the voluntary sector.

Recommendation 4: The revised dissemination arrangements for NICE guidance, once agreed, should be reviewed after a year of operation to ensure that they are working effectively.

Recommendation 5: The static list of guidance issued prior to 2006, and which has not yet been reviewed for endorsement in Northern Ireland, should be prioritised at the earliest opportunity.

Recommendation 6: A template should be developed, to provide information about NICE guidance, for bi-monthly Trust Directors meetings. This template should include both positive statements as to where the guidance has been implemented as well as any areas where implementation has not yet been completed.

Recommendation 7: A regional project should be established to agree the specification of an information management system for the implementation of NICE guidance.

Recommendation 8: A network should be established which would include NICE implementation leads from both commissioning and providing organisations, to discuss common issues and share good practice in the implementation of NICE guidance.

Recommendation 9: All organisations should review their arrangements for linking risks, associated with the implementation process for NICE guidance, to the process of updating risk registers.

Recommendation 10: Under the new arrangements for dissemination of endorsed guidance for Northern Ireland a planned system should be considered for release of guidance on a monthly basis where possible.

Recommendation 11: All HSC organisations should review their use of NICE implementation tools.

Recommendation 12: All HSC organisations should collaborate with the NICE Implementation Facilitator for Northern Ireland to raise awareness within

organisations, of NICE implementation support tools and how HSC organisations could utilise them to support quality improvement.

Appendix 1: Organisations represented at the RQIA Summit Event

Department of Health, Social Services and Public Safety

Health and Social Care Board

Public Health Agency

Belfast Health and Social Care Trust

Northern Health and Social Care Trust

Southern Health and Social Care Trust

South Eastern Health and Social Care Trust

Western Health and Social Care Trust

Northern Ireland Ambulance Service Health and Social Care Trust

Northern Ireland Blood Transfusion Service

National Institute for Health and Care Excellence

Regulation and Quality Improvement Authority

Appendix 2

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

Circular Reference: HSC (SQSD) 04/11

Date of Issue: 26 September 2011

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:

Any enquiries about the content of this Circular should be addressed to:
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Stormont Estate
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BT4 3SQ

SGU-NICEGuidance@dhsspsni.gov.uk

Related documents:

Superseded documents

HSS (PPMD) 01/06

Status of Contents:

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>

Working for a Healthier People

Chief Medical Officer Group



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:

Working for a Healthier People

- *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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