Doncaster and Bassetlaw Teaching Hospitals
NHS Foundation Trust

***Please Note: This policy is currently under review and is still fit for purpose.***

# NICE Guidance

## An Organisation-wide Document for the Review, Dissemination, Implementation and Monitoring of NICE Guidance

**This procedural document supersedes: CORP/COMM 10 v.4 – NICE Guidance**

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The Trust discourages the retention of hard copies of policies and can only guarantee that the policy on the Trust website is the most up-to-date version. **If, for exceptional reasons, you need to print a policy off, it is only valid for 24 hours.**

| | |
|---|---|
| Author/reviewer: (this version) | Chas Harrison – Clinical Audit Manager<br>Yvonne Hall – Cancer Data Manager |
| Date written/revised: | May 2017 |
| Approved by: | Policy Approval and Compliance Group<br>Sub group - Audit and Effectiveness Forum |
| Date of approval: | 7 June 2017 |
| Date issued: | 25 July 2017 |
| Next review date: | May 2020 – **extended to December 2022** |
| Target audience: | Trust Wide |

# Amendment Form

Please record brief details of the changes made alongside the next version number. If the procedural document has been reviewed **without change**, this information will still need to be recorded although the version number will remain the same.

| Version | Date | Brief Summary of Changes | Author |
|---|---|---|---|
| Version 5 | 25 July 2017 | • Moderate changes made throughout | C Harrison<br>Y Hall |
| Version 4 | August 2012 | • Moderate changes made throughout<br>• Revision of the policy following NHSLA assessment.<br>• Includes General Manager role in duties and responsibilities<br>• Incorporates a monitoring table within the monitoring section of the policy. | C Harrison<br>R J Cuschieri<br>D Swift<br>T Evans-Philips |
| Version 3 | December 2011 | • Title change<br>• Major changes made throughout, **please read in full.**<br>• Previous document CORP/COMM 10 v.2 now split into 3 documents:<br>- CORP/COMM 10 v.3 – NICE Guidance,<br>- CORP/COMM 20 v.1 – National Confidential Enquiries and<br>- CORP/COMM 21 v.1 – Central Alert System | C Harrison,<br>T Evans-Phillips<br>R J Cuschieri |

# Contents

## 1. INTRODUCTION

**National Institute for Health and Clinical Excellence (NICE):** An independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health www.nice.org.uk

- This policy has been developed to ensure that the Trust has in place a systematic approach for the review, dissemination, implementation and monitoring of Guidance issued by the National Institute for Health and Clinical Excellence (NICE). Implementation of NICE Guidance is considered a core objective of the organisation and supports the standards set by the Care Quality Commission (CQC) and Clinical Negligence Scheme for Trusts (CNST).

- Clinicians can recommend treatment or care which differs from that recommended by NICE. Decisions to depart from NICE Guidance should be made in consultation with the patient and/or guardian/carer and the discussion, which should include reasons for the proposed deviation, documented in the medical records. Where care which deviates from NICE Guidance is likely to be offered to several patients, the reasons for so doing should be explained in a patient information leaflet.

- The legal status of NICE Guidance is unclear but the importance of awareness of NICE Guidance and the recording of reasons for departure from NICE Guidance are summed up in a statement by the Medical Defence Union (MDU): "Ignorance of NICE Guidance is a poor defence, but a reasoned and reasonable decision to reject the Guidance in an individual case, together with a good record, made at the time, may be acceptable."

## 2. PURPOSE

This policy provides a framework for the review, dissemination, implementation and monitoring arrangements as well as the exception reporting process, which effectively informs senior management of the Trust's position as to the compliance on all Guidance.

The policy describes the process in place to manage NICE Guidance and ensure there are clear procedures in place to inform and support all those involved in the process, and that the process for managing the risks associated with the dissemination, implementation and monitoring of compliance with the NICE Guidance is managed effectively.

The minimum standards are (2012/13):

a) Duties – both strategic and operational roles.
b) How the organisation identifies which NICE guidelines are relevant to its services.
c) How a Gap Analysis is conducted to identify shortfalls.
d) How Action Plans are created to address any shortfalls, including recording decisions not to implement NICE Guidelines.
e) How the organisation monitors compliance with all of the above.

The Trust has to demonstrate that it is monitoring compliance with the minimum requirements. Where monitoring has identified deficiencies there must be evidence that recommendations and action plans have been developed and changes implemented accordingly.

The key objectives are:

- Support the delivery of higher quality of care by aiding the Trust in systematically working towards the implementation of all NICE Guidance.
- Identify the overall responsibilities for implementation, which includes dissemination, assurance and monitoring arrangements.
- Ensure that recommendations are only introduced into practice after due consideration of all the relevant issues relating to appropriate training, business planning, capital and revenue investment and safety.
- Provide a fully transparent structure, including the ready availability of the appropriate evidence of compliance.

## 3. DUTIES AND RESPONSIBILITIES

All healthcare professionals are expected to be aware of NICE Guidance relevant to their area of clinical practice and to take it fully into account.

### 3.1 Board of Directors

The Board of Directors delegates responsibility to the Medical Director for the review, dissemination, implementation and monitoring of NICE Guidance. The Medical Director provides an Annual Report to the Board of Directors.

### 3.2 Medical Director / Deputy Medical Director

The Medical Director delegates the responsibility for the process of review, dissemination, implementation and monitoring of NICE Guidance effectively to the Deputy Medical Director – Clinical Standards who is the chair of the Audit and Effectiveness Forum.

### 3.3 Clinical Audit Manager

The Clinical Audit Manager is the delegated lead for the process of review, dissemination, implementation and monitoring of NICE Guidance.

Role of the Clinical Audit Manager:

- View the NICE website each month, download any new NICE Guidance and maintain a central NICE database.

- Consult the Audit and Effectiveness Forum to ascertain which Care Group Governance Lead is responsible for individual NICE Guidance.

- Disseminate NICE Guidance to relevant Governance Leads, within the same month the Guidance is issued, requesting the Guideline be reviewed and the position of the Care Group identified, within 21 days of dissemination of Guidance.

- Where Guidelines are relevant and the Trust is partially or non-compliant the Clinical Audit Manager will co-ordinate completion and monitoring of Gap Analysis and Action Plans. Any breaches in time scales will be reported to the Audit and Effectiveness Forum for action as necessary.

- Report to the Audit and Effectiveness Forum on a monthly basis by way of a written report.

### 3.4 Care Group Governance Lead

The Care Group Governance Lead ensures that there is a full discussion of the NICE Guidance and the decision for compliance or non-compliance is recorded in the minutes of the Specialty Clinical Governance Group. NICE Guidance should be a standard item on the agenda for every Clinical Governance Group meeting. The Clinical Governance Group will undertake a Gap Analysis and Action Plan to implement such Guidance where it has not already been implemented and ensure it is included in the minutes of the Clinical Governance Group meeting. The Gap Analysis should then be taken to the Clinical Management Team to raise awareness with the Care Group Director. Where the Guidance has already been implemented, the Care Group Governance Team should review the implementation and commission the Governance Lead to undertake an audit of such implementation.

### 3.5 Individual Clinicians

Individual Trust clinicians are responsible for ensuring that they:

- Are aware of NICE Guidance which is relevant to their area of work.

- Read and comply with disseminated NICE Guidance including supporting the review, implementation and monitoring phases of the policy.

- Attend any training that is organised by the specialty to ensure familiarity and compliance with NICE Guidance relevant to their role.

- Raise any queries about implementation with the lead clinician and/or Care Group Governance Lead.

### 3.6 Clinical Governance Standards and Quality Committee (CGSQC)

This committee receives assurance that the process for monitoring the implementation of NICE Guidance is undertaken by the Audit and Effectiveness Forum. The CGSQC will:

- Receive a 6 monthly report from the Audit and Effectiveness Forum.
- Receive, from the Care Groups, any issues of non-compliance with NICE Guidelines due to organisational/practice/financial constraint and report to the Board of Directors. This will appear on the Care Group Risk Register and may be escalated to the Corporate Risk Register. *Escalation to Corporate Risk Register does not imply relinquishing of ownership by the Care Group.*

### 3.7 Audit and Effectiveness Forum

This committee is responsible for the organisational dissemination and monitoring of implementation of NICE Guidance. It will:

- Agree appropriate Care Group Governance Lead for each specific NICE Guideline.
- Advise appropriate Care Group Governance Lead of each specific NICE Guideline appropriate to their Care Group.
- Monitor responses received regarding implementation, or not, of NICE Guidance

The Deputy Medical Director – Clinical Standards, as Chair of the Audit and Effectiveness Forum, will present a report on compliance with NICE Guidance to the CGSQC on a six monthly basis

## 4. PROCESS FOR IDENTIFYING RELEVANT DOCUMENTS

A flowchart for the NICE Guideline process is shown at Appendix 1.

NICE Guidance is issued on the 4th Wednesday of each month. The Clinical Audit Manager collates the NICE Guidance by downloading from the NICE website.

The list of newly issued NICE Guidance is put on the agenda of the next available Audit and Effectiveness Forum. This meeting will advise the Clinical Audit Manager:

- if the Guidance is relevant to our Trust
- which Care Group Governance Lead the Guidelines should be sent to.

A document used for this process is attached at Appendix 2.

## 5. PROCESS FOR DISSEMINATING NICE GUIDANCE

- The NICE Guidelines are distributed to the relevant Care Group Governance Lead requesting an initial response on relevance within 21 days and a full response, if necessary, within 3 months. The response will include, if the Guidance is relevant or not, if an audit is to be undertaken and any other evidence of compliance using the form at Appendix 3. The Clinical Governance Lead will ensure it is an agenda item and is discussed and included in the minutes of the Specialty Clinical Governance Group meeting.

- A summary of responses is presented to the next available Audit and Effectiveness Forum for information and necessary action. A document used for this process is attached at Appendix 4.

- Any NICE Guideline not responded to in a timely manner will be escalated to the Medical Director.

## 6. PROCESS FOR CONDUCTING AN ORGANISATIONAL GAP ANALYSIS FOR NON COMPLIANCE AND ACTION PLANNING

When reviewing any new Guidance and it has been identified that it is relevant and the Trust is non-compliant, it is essential to identify the gap between recommended practice and current practice (Gap Analysis).

The nominated lead(s) are responsible for undertaking the Gap Analysis using the template at Appendix 5.

This assessment of the NICE Guidance in relation to non-compliance should identify all the factors involved in any change, (staffing, training, equipment, financial resources and implications for other services). This allows better identification of the practical actions needed to implement the change and the groups of professionals who are key to bridging these gaps.

The wide ranging nature of the Gap Analysis means that it should be undertaken by an appropriate group within the specialty affected: Care Group Governance Group, Clinical Management Team etc. These arrangements are for the speciality to decide but must include management presence for incorporation into routine business planning processes where appropriate.

Where gaps are identified, an Action Plan should also be submitted to the Clinical Audit Manager and the Audit and Effectiveness Forum with the Gap Analysis within 3 months of dissemination. Where the implementation of NICE Guidance is dependent on incorporating developments into the service planning process, this should be clearly indicated in the Action Plan, with indicative timescales.

The Gap Analysis, along with any Action Plans, periods and review dates, will be submitted to the Audit and Effectiveness Forum. This will be registered and monitored by the Quality and Effectiveness Department.

## 7. TIMESCALES FOR IMPLEMENATION

The impact of the Guideline and the planning of the implementation of the Guideline should start immediately, with implementation itself taking place over a longer but clearly defined timeline.

The speciality will set the timescales within the Action Plan, taking into account the NICE and DoH requirements and will be monitored at each Audit and Effectiveness Forum meeting.

When an Action Plan has been achieved, a formal audit should be undertaken within one year, to provide sufficient assurance of compliance. These audits should be first priority in the Care Group's Annual Audit Plan, and junior doctors in the Care Group should be encouraged to undertake them, using the NICE published criteria.

## 8. PROCESS FOR DOCUMENTING ANY DECISION NOT TO IMPLEMENT NICE RECOMMENDATIONS

In the event of a decision being made not to implement specific NICE Guidelines, the relevant Care Group will inform the Audit and Effectiveness Forum. The Clinical Governance Standards and Quality Committee will be made aware of this by receipt of Audit and Effectiveness Forum minutes.

The relevant Care Group will risk assess and escalate to the Care Group Risk Register explaining why the decision not to implement was taken and this will be noted at Clinical Governance Standards and Quality Committee.

## 9. TRAINING & SUPPORT

All new Care Group Governance Leads are offered the opportunity of meeting with the Chair of Audit and Effectiveness Forum and the Clinical Audit Manager to discuss roles and responsibilities. Ongoing support for the Care Group Governance Leads/Specialty Governance Leads is always available from the above named personnel and the Quality and Effectiveness Department.

## 10. MONITORING COMPLIANCE WITH THE PROCEDURAL DOCUMENT

| Criteria | Who | How | Frequency | Review / Where |
|---|---|---|---|---|
| All NICE Guidelines are being reviewed. | Clinical Audit Manager | Check NICE website with Guidelines entered on NICE database and listed for QEF | 6 monthly | Audit and Effectiveness Forum |
| All NICE Guidelines are disseminated within the same month they are issued | Clinical Audit Manager | Check date of issue against date of dissemination | 6 monthly | Audit and Effectiveness Forum |
| Non-compliant Guidelines have a Gap Analysis. | Clinical Audit Manager | Check all non-compliant Guidelines against Gap Analysis Register. | 6 monthly | Audit and Effectiveness Forum |
| Gap Analysis and Action Plans are completed to agreed timescales. | Clinical Audit Manager | Check Gap Analysis Register | 6 monthly | Audit and Effectiveness Forum |
| All outstanding issues are reported to Audit and Effectiveness Forum | Clinical Audit Manager | Check Gap Analysis Register with QEF minutes and agendas | 6 monthly | Audit and Effectiveness Forum |
| All NICE Guidelines to be audited as instructed by Clinical Governance Group are included in Annual Audit Forward Plan. | Clinical Audit Manager | Check Clinical Governance minutes against Annual Audit Forward Plan | Annually | Audit and Effectiveness Forum |

## 11. DEFINITIONS

This section includes a list of the documents issued by the **National Institute for Health and Clinical Excellence (NICE)**

- **Technology Appraisals (TA)**
- **Interventional Procedure Guidelines (IPG)**
- **Clinical Guidelines (CG)**
- **Public Health Guidance (PHG)**
- **Nice Guidelines (NG)**
- **Diagnostic Guidance (DG)**
- **Medical Technology Appraisals (MTA)**

All references in this policy to NICE Guidance will include all the above documents

## 12. EQUALITY IMPACT ASSESSMENT

The Trust aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are disadvantaged over others. Our objectives and responsibilities relating to equality and diversity are outlined within our equality schemes. When considering the needs and assessing the impact of a procedural document any discriminatory factors must be identified.

An Equality Impact Assessment (EIA) has been conducted on this procedural document in line with the principles of the Equality Analysis Policy (CORP/EMP 27) and the Fair Treatment For All Policy (CORP/EMP 4). (see Appendix 6).

## 13. ASSOCIATED TRUST PROCEDURAL DOCUMENTS

CORP/RISK 19 - Clinical Audit Strategy and Policy
CORP/EMP 4 - Fair Treatment for All
CORP/EMP 27 - Equality Analysis Policy

## 14. REFERENCES

Darzi, Professor the Lord. (2008). *High Quality Care For All: NHS Next Stage Review Final Report*. London: Department of Health. Available at: www.dh.gov.uk

Department of Health. (2003). *Health Service Circular 2003/011. The interventional procedures programme: working with the National Institute for Clinical Excellence to promote safe clinical innovation*. Department of Health. Available at: www.dh.gov.uk

Department of Health. (2005). *Chief Medical Officer Annual Report. Learning how to Learn: Compliance with Patient Safety Alerts in the NHS*. London: Department of Health. Available at: www.dh.gov.uk

Department of Health. (2006 [2004]). *Standards for Better Health*. London: Department of Health. Available at: www.dh.gov.uk

National Institute for Health and Clinical Excellence (NICE). (2004). *Legal Context of NICE guidance*. NICE. Available at: www.nice.org.uk

National Institute for Health and Clinical Excellence (NICE). (2005). *How to put NICE guidance into practice: A guide to implementation for organisations*. London: NICE. Available at: www.nice.org.uk

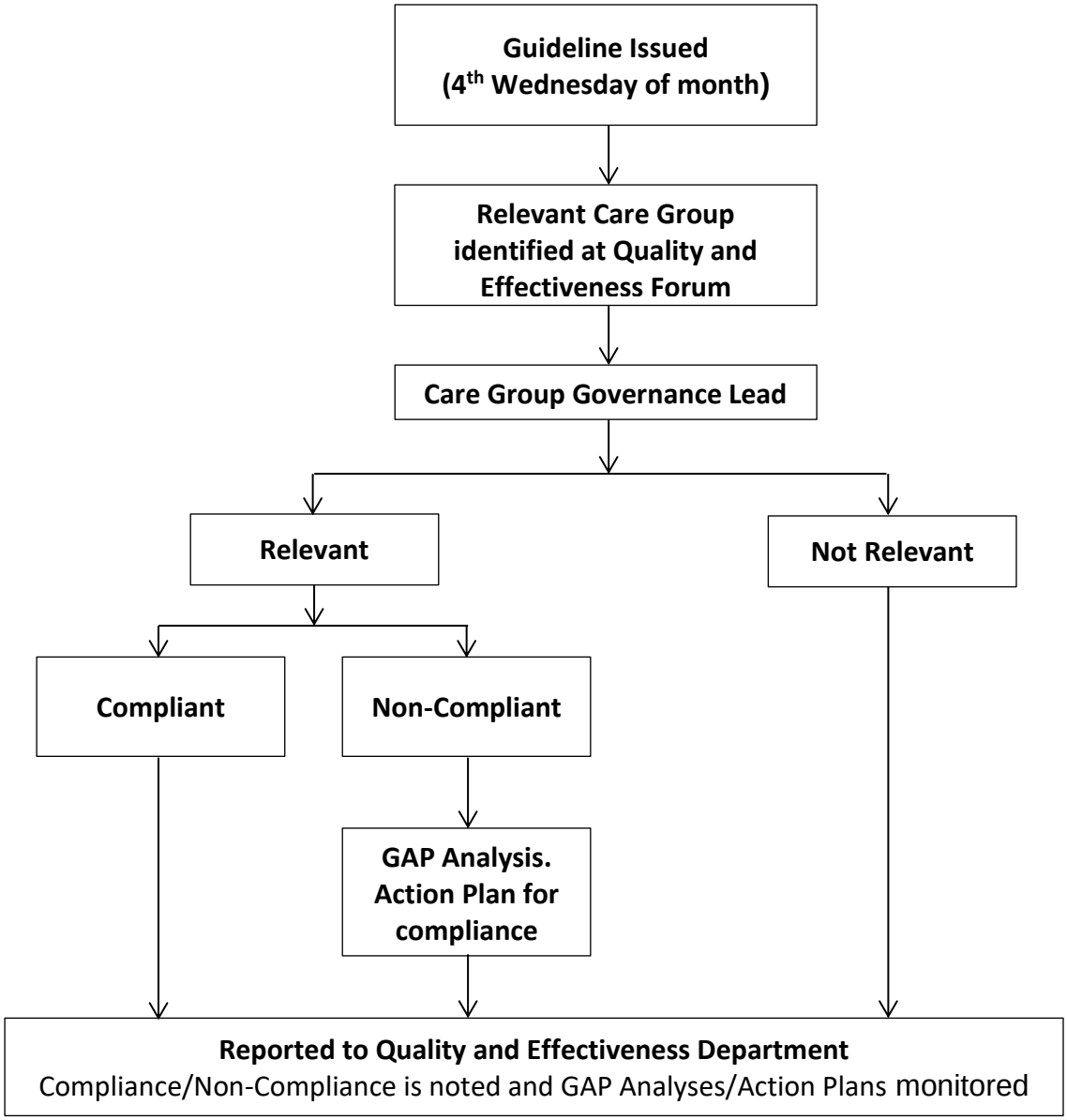
National Institute for Health and Clinical Excellence (NICE). (2007). *How to change practice*. London: NICE. Available at: www.nice.org.uk

National Institute for Health and Clinical Excellence (NICE). (2008). *Our guidance sets the standard for good healthcare*. NICE. Available at: www.nice.org.uk

National Institute for Health and Clinical Excellence (NICE). (2008). *Vital Signs Mapping*. NICE. Available at: www.nice.org.uk

## APPENDIX 1 – FLOWCHART FOR NICE GUIDELINE PROCESS

### Flowchart for NICE Guideline Process




**Evidence:**

- Policy
- Audit
- IPOC/Clinical Documentation
- Posters
- Prescribing Data
- Staffing changes
- Patient information
- Minutes of meeting

# APPENDIX 2 – NICE GUIDANCE TEMPLATE

**New NICE Guidance**

| NICE No. | Title | Date guidance released by NICE | To be dispatched to: | Additional Comments |
|---|---|---|---|---|
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# APPENDIX 3 – NICE GUIDANCE RESPONSE FORM

NHS
Doncaster and Bassetlaw Teaching Hospitals
NHS Foundation Trust

National Institute for Health and Care Excellence

**Guidance Response Form**

To:

Month Guideline Published:

| Publication Details | |
|---|---|
| | |

**Section 1: Initial response**

I have sought the views of my colleagues on this publication and our response is given below:

1. ☐ Guidance is not relevant, and the reasons for this are: .....

.....

2. ☐ Guidance is relevant, the Trust/Specialty* of ..... is fully compliant and it is demonstrable.

3. ☐ Guidance is relevant, the Trust/Specialty* of ..... is not fully compliant and I will conduct and submit a gap analysis within 3 months of the above date.

4. ☐ Other:

.....

.....

**Delete as applicable*

**Section 2: Audit (Please contact the Quality and Effectiveness Department if applicable)**

☐ The specialty intends to carry out an audit on the topic
☐ An audit is currently being carried out
☐ An audit has been carried out
☐ Not applicable due to low numbers of patients
☐ Other: .....

**Section 3: Clinical documentation / Trust Policy**

☐ Clinical documentation is to be amended as a result of the implementation of this guideline
☐ Clinical documentation already contains relevant guidance
☐ The specialty intends to incorporate this guidance into departmental/Trust policy
☐ Departmental/Trust policy already contains the relevant guidance

Signature: ..... Print Name: .....

Designation: ..... Date: .....

**Please return to Yvonne Hall, Quality and Effectiveness Department, C Block, DRI or email Yvonne.hall@dbh.nhs.uk**

Quality and Effectiveness Department, C Block, DRI.

# APPENDIX 4 – NICE GUIDANCE MONITORING FORM

NICE Guidance - Update

NICE Guidance

| NICE No. | Title | Response |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

# APPENDIX 5 – GAP ANALYSIS

NHS
Doncaster and Bassetlaw Teaching Hospitals
NHS Foundation Trust

## Gap analysis for implementation of NICE guidance:

*To be completed once the decision is made that NICE Guideline is **Relevant** and the Trust is **Non-compliant**.*
*To be submitted by Clinical Director following consultation with Clinical Governance Lead and Clinical Audit Lead.*

**NICE Guideline: CG:**_____ **Title:** _____

| *NICE Guideline section* | *Reason for non-compliance* | *What is the GAP Shortfall* | *Who is to action* | *By when* |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |

Submitted by: Signature: _____ Print name: _____ Date: _____ / _____ / _____

# APPENDIX 6 – EQUALITY IMPACT ASSESSMENT - PART 1 INITIAL SCREENING

| Service/Function/Policy/Project/ Strategy | Care Group/Executive Directorate and Department | Assessor (s) | New or Existing Service or Policy? | Date of Assessment |
|---|---|---|---|---|
| Nursing, Midwifery & Quality | Quality and Effectiveness | Chas Harrison | Existing | 19/05/2017 |

**1) Who is responsible for this policy?** Name of Care Group/Directorate: Quality and Effectiveness

**2) Describe the purpose of the service / function / policy / project/ strategy?** Procedures for review of NICE Guidance

**3) Are there any associated objectives?**

**4) What factors contribute or detract from achieving intended outcomes?** Lack of communication from clinicians

**5) Does the policy have an impact in terms of age, race, disability, gender, gender reassignment, sexual orientation, marriage/civil partnership, maternity/pregnancy and religion/belief?** No

- **If yes, please describe current or planned activities to address the impact** [e.g. Monitoring, consultation]

**6) Is there any scope for new measures which would promote equality?** No

**7) Are any of the following groups adversely affected by the policy?**

| Protected Characteristics | Affected? | Impact |
|---|---|---|
| a) Age | No | |
| b) Disability | No | |
| c) Gender | No | |
| d) Gender Reassignment | No | |
| e) Marriage/Civil Partnership | No | |
| f) Maternity/Pregnancy | No | |
| g) Race | No | |
| h) Religion/Belief | No | |
| i) Sexual Orientation | No | |

**8) Provide the Equality Rating of the service / function /policy / project / strategy – tick (✓) outcome box**

| Outcome 1 ✓ | Outcome 2 | Outcome 3 | Outcome 4 |
|---|---|---|---|

**If you have rated the policy as having an outcome of 2, 3 or 4, it is necessary to carry out a detailed assessment and complete a* **Detailed Equality Analysis form in Appendix 4**

**Date for next review: May 2020**

**Checked by: Chas Harrison** **Date: 22/05/2017**