


TRUST POLICY AND PROCEDURE FOR THE MANAGEMENT OF NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE (NICE) GUIDANCE

Reference Number POL-	Version: 7		Status: Draft		Author: June Bettson - Green Job Title: Medical Directors Office Manager
Version Amendment History /	Version	Date	Author	Reason	
	1	January 2008	Pam Twine	New Policy	
	2	March 2010	Pam Twine	Monitoring section changed to revised format	
	3	February 2013	Pam Twine	Policy Reviewed –Amendment History	
	4	July 2013	Pam Twine	Changes following Internal Audit review	
	5	January 2018	Lorna Priestman	New Policy details added	
	6	November 2019	Lara Raworth	Review / amendment to reflect new processes and harmonisation of sovereign organisation policies	
	7	October 2022	June Bettson-Green	Changed following Internal Audit review	
Intended Recipients: All staff members involved in patient care in University Hospital Derby and Burton NHS Foundation Trust. Target audience: All Clinical Staff, Divisional Senior Management Teams, Clinical Audit Facilitators, Clinical Governance Facilitators, Drugs and Therapeutics Group					
Training and Dissemination: Publicised on Intranet and disseminated via Trust Clinical Audit team.					
To be read in conjunction with: Trust Policy and Procedure for Change in Clinical Practice					
In consultation with and Date Quality Review Group, Divisional Management Teams, Clinical Audit Team.					
EIRA stage One		Completed Yes			
stage Two		Completed Yes			

Approving Body and Date Approved	Trust Delivery Group – 02/12/2019 Minor amendments approved by the Interim Executive Medical Director – 22/12/2022
Date of Issue	December 2022
Review Date and Frequency	December 2025
Contact for Review	Associate Director to the Medical Director
Executive Lead Signature	 James Crampton, Interim Executive Medical Director

Contents

Section		Page
1	Introduction	4
2	Purpose and Outcomes	4
3	Definitions Used	5
4	Key Responsibilities/Duties	6
4.1	The Trust Board	6
4.2	Executive Medical Director	6
4.3	Divisional Medical Director and Clinical Director	6
4.4	Assistant Clinical Director	6
4.5	Medical Directors Office Manager	6
4.6	Clinical Audit Team	7
4.7	Health Professionals	7
4.8	Drugs and Therapeutics Group	7
5	Management of NICE Guidance	7
5.1	Dissemination of NICE Guidance	7
5.2	Assessing Compliance with NICE Guidance	8
5.3	Partial or Non-Compliance	8
6	NICE Guidance Review and Sign Off	9
7	Monitoring Compliance and Effectiveness	9
8	Appendix 1 – NICE Implementation Flowchart	10

TRUST POLICY AND PROCEDURES FOR THE MANAGEMENT OF NICE GUIDANCE

1 **Introduction**

The National Institute for Health and Care Excellence (NICE) is an independent organisation responsible for providing national guidance on the promotion of good health and the treatment of ill health. The successful implementation of NICE Guidance helps ensure high standards of care and patient safety in line with the best available evidence regarding clinical and cost-effectiveness. NICE Guidance provides national guidance on treatment and care for use by health care professionals, patients and carers to aid decision making about treatment and healthcare. This policy has been developed to inform clinicians of the systems and processes in place for the management of NICE Guidance.

NICE Guidance is available in a number of forms and can be found on the NICE website (www.nice.org.uk).

2 **Purpose and Outcomes**

The Trust must demonstrate to stakeholders that NICE Guidance is being reviewed and implemented within the Trust and across the health community. This is a regulatory requirement which is subject to scrutiny by the CQC and other regulatory bodies. Assurance of compliance is also required as part of the NHS Standard Acute Services Contract.

The aim of this Policy is to ensure that:

- There is an approved process for ensuring that agreed best practice as defined in NICE Guidance is taken into account and implemented within the clinical services provided by the Trust
- There is a process for receipt, dissemination and compliance recording of a baseline position via gap analysis, implementation and monitoring of all NICE Guidance
- Relevant recommendations are acted upon throughout the Trust
- Where deficiencies are identified through monitoring there is a process for exception reporting and action planning for the implementation of relevant changes.

3 Definitions Used

NICE	National Institute for Health and Care Excellence
Technology Appraisals	Recommendations on the use of new and existing medicines and treatments. Technology Appraisals must be implemented and funded within 3 months from the date of their issue.
Clinical Guidelines	Recommendations on the appropriate treatment and care of people with specific diseases and conditions.
Interventional Procedures	<p>Procedures used for diagnosis or treatment which involve:</p> <ul style="list-style-type: none"> • Making a cut or hole to gain access to the inside of the body • Gaining access to a body cavity without cutting e.g. endoscopies • Using electromagnetic radiation e.g. X Rays or laser treatments <p>The guidance covers the safety of the procedure, whether it works well and advice on special arrangements necessary for consent. It will also advise where procedures should not be used or may only be used within a specialist centre or as part of a controlled research study.</p> <p>Introduction of a new procedure must be approved via the Trust's Clinical Change Management</p>
Public Health Guidance	<p>There are 2 types:</p> <ul style="list-style-type: none"> • Public health intervention guidance which makes recommendations on interventions that promote a healthy lifestyle or reduce the risk of developing diseases • Public health programme guidance which deals with broader activities for promoting good health and preventing ill health
Patient Safety Guidance	NICE worked with the National; Patient Safety Agency (now the NHS Commissioning Board Special Health Authority to produce this joint guidance). The first guidance was published in January 2008.

Medical Technologies Guidance	Guidance to assist the NHS in the adoption of Medical Technologies rapidly and consistently by advising on efficiency and cost effectiveness.
Diagnostics Guidance	Makes recommendations to the NHS on the effectiveness and efficiency of new Diagnostic Technologies.
Quality Standards	A set of specific statements that are markers of high quality care including prevention and treatment of diseases and conditions.

4 Key Responsibilities/Duties

4.1 The Trust Board

The Trust Board is responsible for ensuring high level support for evidence based practice.

4.2 Executive Medical Director

The Executive Medical Director will act as the Trust Lead for the management of all NICE Guidance.

4.3 Divisional Medical Directors and Clinical Directors

Divisional Medical Directors and Clinical Directors will support with ensuring responses to requests are received in a timely manner and engage with the escalation process to support the receipt of timely responses.

4.4 Assistant Clinical Directors

The Assistant Clinical Director (or nominated deputy) will:

- Receive any new NICE Guidance relevant to their speciality
- Co-ordinate a response to the NICE Guidance issued, ensuring that all clinical areas who are impacted by the NICE Guidance publication are consulted with
- Ensure completion of the relevant baseline assessment tool and agree action plans where relevant.

4.5 Medical Directors Office Manager

The Medical Directors Office Manager will:

- Support the Executive Medical Director in overseeing the implementation and monitoring of compliance with NICE Guidance
- Report issues of non-compliance, where full compliance is considered inappropriate or implementation is not possible within agreed timescales, to the Quality Review Group

4.6 Clinical Audit Team

The Clinical Audit Team will:

- Establish and maintain systems for the receipt, dissemination, implementation and monitoring of all NICE Guidance. Divisions will be supported to ensure that compliance reporting meets set timescales and is reported to the relevant Groups and Committees
- Maintain a database containing all relevant information relating to the management of NICE Guidance. The database will be continuously updated and linked to the Clinical Audit Forward Programme for each Division
- Distribute newly published NICE Guidance to the relevant Assistant Clinical Director on a monthly basis
- Report the details of responses to guidance to the appropriate Business Unit / Divisional Governance meeting, highlighting details of non-compliance to NICE Guidance and ensuring appropriate identification of additions to the Trust Risk Register by the Division
- Monitor and record the approval of implementation of Technical Appraisals within the central database
- Escalate any non-engagement to the Medical Directors Office Manager in line with the escalation process.

4.7 Health Professionals

Health professionals are expected to take NICE Guidance fully into account when treating patients.

However NICE Guidance does not override the professional's individual judgment to make decisions about the care and treatment of patients. If NICE Guidance is not followed the reasons for not doing so must be fully documented within the patient health record.

This Group receives a monthly report on new guidance and outstanding compliance from the Medical Directors Office Manager and escalates issues of non-compliance to the Quality Review Group

4.8 Drugs and Therapeutics Group

Implementation of Technical Appraisals will be monitored by the Drugs and Therapeutics Group. This Group provides strategic direction for prescribing and therapeutics within the Trust and will consider and respond to NICE Guidance relating to medicines.

5 Management of NICE Guidance – (Refer to Appendix 1)

5.1 Dissemination of NICE Guidance

All guidance will be sent out from the Clinical Audit Department on a monthly basis. An electronic copy of the guidance plus a baseline assessment tool will be e-mailed to the relevant Assistant Clinical Director or nominated deputy.

Trust Wide guidance will be discussed at the relevant divisional meetings and where relevant a clinical lead designated.

All new guidance will be added to the Trust NICE database.

5.2 Assessing compliance with NICE Guidance

A baseline assessment which identifies the current level of compliance with the guidance should be carried out for all guidance. With the exception of Technology Appraisals whereby addition to the trust formulary will substitute completion of a baseline assessment.

Where the Trust is fully compliant no further action is necessary. The Clinical Lead must complete the baseline assessment tool and return it to the Clinical Audit Team.

Where there are delays in responses the Clinical Audit Team will contact the relevant Clinical Director and then Divisional Medical Director who will be responsible for ensuring compliance forms are completed. The ACD or nominated deputy must ensure that a completed compliance form or action plan is returned within three months of publication of the guidance.

Where the Trust is not compliant issues that may need consideration include:

- Will major changes in practice be necessary
- Will protocols/care pathways need to be updated
- What patient and public involvement issues need consideration e.g. patient information
- Are there capacity or resource issues
- Will there be additional costs and do these need to be added to the business plan
- Are there workforce/training implications
- Are there potential risks and should they be added to the Risk Register
- Can implementation occur within the agreed timescales
- Does the implementation impact on other services/health communities.

5.3 Partial or Non-Compliance

Where the Division is partially or non-compliant to a piece of NICE Guidance, the baseline assessment tool must be completed, and actions identified for achieving compliance with the guidance. All partial or non-compliance must be added to the Trust Risk Register. It is the responsibility of the Division to record, monitor and update any risks in relation to NICE Guidance.

Action plans must include clear, named responsibilities linked to specific timescales. A progress report on the action plan must be submitted to the Clinical Audit Team within the specified time frame.

Successful implementation of NICE Guidance will require “ownership” locally. Therefore the local context must be considered and potential barriers to change including cultural, organisational, resource-related and personal must be recognized.

Implementing guidance may require health professionals to change long held patterns of behaviour and change management skills are essential. Where clinicians need to change practice to achieve compliance the potential impact on other services must be taken into account.

Where compliance is not considered appropriate, this will be agreed within the Division and escalated for discussion and further escalated to the Quality Review Group and onwards to the Quality Improvement Group

It is recognised that complex guidance will often take longer than six months to implement due to the need for service change, staff training or resource issues. In these cases an initial baseline assessment tool should still be submitted within 3 months to show that planning is in progress. The action plan will then be monitored by the relevant designated Business Unit and Divisional Governance Group.

Where a group or individual is concerned that NICE Guidance may not represent best practice for example because further evidence has been published, the new evidence should be submitted to the relevant Divisional Group

6 NICE Guidance Review and Sign Off

All responses and completed baseline assessment tools for NICE Guidance will be reviewed and signed off at the most appropriate Business Unit and / or Divisional meeting.

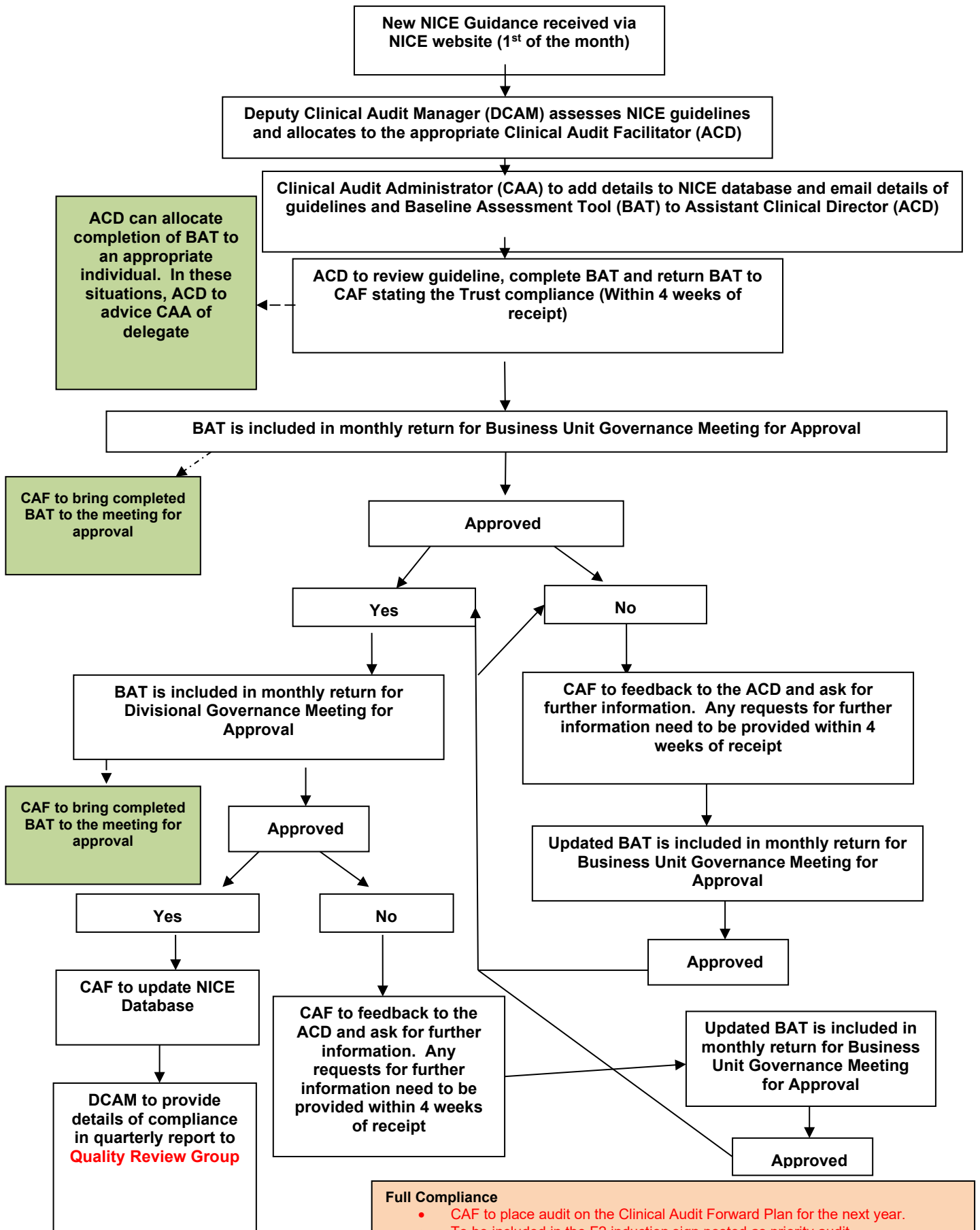
The Clinical Audit Team will ensure that the responses and completed baseline assessment tools are made available for review prior to the meeting and a member of the Clinical Audit Team will also be in attendance at the meeting to facilitate the sign off process.

For those pieces of guidance where partial or non-compliance has been identified, the sign off process also needs to identify an appropriate person to make the addition to the Trust Risk Register.

7 Monitoring Compliance and Effectiveness

Monitoring Requirement :	<ul style="list-style-type: none"> • Process for conducting an organisational gap analysis • Process for ensuring that recommendations are acted upon throughout the organisation
Monitoring Method:	<ul style="list-style-type: none"> • Review of the NICE guidelines database in relation to completion of gap analysis • Review of monthly Divisional reports to the Clinical Governance Department to measure compliance with completion of action plans
Reports Prepared by:	Medical Directors Office Manager
Report presented to:	Quality Review Group
Frequency of Report	Monthly reports

NICE GUIDANCE IMPLEMENTATION FLOW CHART



- Full Compliance**
- CAF to place audit on the Clinical Audit Forward Plan for the next year.
 - To be included in the F2 induction sign posted as priority audit
 - Reported monthly to Div Gov meeting to be audited
- Partial or Non-Compliance**
- Action plans to be submitted to demonstrate how the Trust will work towards compliance – to include details of any business case required
 - Add to the Trust Risk Register – responsibility identified at BU Governance Meeting
 - 6 monthly reviews to be undertaken – these will be requested by the CAF