POLICY DOCUMENT

Burton Hospitals
NHS Foundation Trust

NICE POLICY

Approved by:	**Trust Executive Committee**
On:	**25 January 2017**
Review Date:	**November 2019**
Corporate / Directorate	**Corporate**
Clinical/Non Clinical	**Clinical**
Department Responsible for Review:	**Medical Directors Office**
Distribution:	
• Essential Reading for:	**Medical Staff** **Nursing Staff** **Pharmacy Staff** **Therapies & Diagnostic Services Staff**
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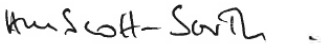
Signature:	 **Chief Executive**
Date:	

Burton Hospitals NHS Foundation Trust

POLICY INDEX SHEET

Title:	**NICE Policy**
Original Issue Date:	**June 2008**
Date of Last Review:	**June 2016**
Reason for amendment:	**Reached review date**
Responsibility:	**Executive Medical Director**
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Linked Trust Policies:	**Best Practice Policy** **Risk Management Strategy & Policy** **New Clinical Interventional Procedures Policy**
E & D Impact assessed:	**EIA 112**
Consulted:	**Executive Directors** **Head of Pharmacy** **Head Nurses** **Associate Divisional Medical Directors**

REVIEW AND AMENDMENT LOG

Version	Type of change	Date	Description of Change
4	Policy Reviewed	May 2014	
5	Policy Reviewed	October 2016	

NICE POLICY

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Burton Hospitals NHS Foundation Trust

NICE POLICY

1. INTRODUCTION

1.1. Rationale

This Policy has been created to establish a guidance framework for managing National Institute for Health and Clinical Excellence (NICE) guidance by Burton Hospitals NHS Foundation Trust, referred to hereafter as 'the Trust.' The Trust is committed to improving patient care wherever possible and introducing effective new procedures.

The Policy outlines the core principles for a collective approach to planning, enabling the consistent dissemination, implementation and evaluation of NICE Technology Appraisal Guidance (TAGs), Interventional Procedures (IPGs)*, Public Health Guidelines (PHs), Quality Standards (QS), Clinical Guidelines (CGs), (NG) NICE Guideline, (DG) Diagnostic Guidelines and any other type of guidance which NICE may publish. *Implementation of new clinical interventional procedures is covered in a separate policy.

This Policy provides a framework of systems for the receipt, dissemination, implementation, audit and monitoring arrangements as well as the exception reporting process which effectively informs senior management of compliance with NICE guidance. All exceptions will be entered onto the divisional risk registers in line with the Trust risk management process, as appropriate.

The main aim of this Policy is to provide strategic guidance for compliance with NICE guidance in the Trust. The key objectives are to:

- Identify overall responsibilities for NICE guidance in the Trust including a NICE Working Group and staff within the Trust.
- Define the key elements of NICE implementation including dissemination, review and reporting arrangements.
- Provide a fully transparent structure that complies with internal and external review processes.
- Ensure that new surgical or other invasive procedures 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.

1.2. Scope

This Policy is applicable to all staff across the Trust and confers responsibilities to individual clinicians and managers on specifically relevant guidance issued.

1.3. Principles of the Policy

All NHS organisations have a legal requirement to implement NICE guidance.

The Care Quality Commission will assess how NHS organisations perform against the guidance. Implementing NICE guidance will help organisations meet these standards.

Additionally NICE guidance on IPGs highlights the importance of establishing policies and protocols to manage the introduction of all new IPs so that risks to patients and staff can be reduced. This is covered in a separate policy – New Clinical Interventional Procedures Policy.

2. POLICY

2.1. National Background

The National Institute for Health and Clinical Excellence (NICE) was established as a Special Health Authority because of concern over the variation in quality of care provided by the NHS. This variation, results from both clinical and resource allocation decisions by Commissioners of Healthcare.

The role of NICE is to provide guidance to the NHS on:

- clinical effectiveness
- cost effectiveness

The Institute develops guidance after reviewing all available evidence through a standard process of appraisal. Health professionals are expected to fully consider the guidance when exercising clinical judgement. The guidance does not override individual responsibility for health professionals to make appropriate decisions considering individual patient circumstances in consultation with the patient and/or guardian and carer.

There is a variety of types of NICE guidance:

- Technology Appraisal Guidance (TAGs): covering health technologies – medicines, medical devices, diagnostic techniques and procedures.
- Clinical Guidelines (CGs): covering the clinical management of specific conditions.
- Interventional Procedure Guidance (IPGs): covering whether interventional procedures are safe and appropriate for routine use. The implementation of IPG's is covered in a separate policy.
- Public Health Guidance (PH): covering broader action for the promotion of good health and the prevention of ill-health.
- Quality Standards (QS): Concise set of priority statements designed to drive measurable quality improvement within a particular area of health or care.

- Cancer Service Guidance (CSG): published to support The NHS cancer Plan for England. All guidance has been published.
- Diagnostics Guidance (DG): Diagnostics technologies guidance is designed to help the NHS adopt efficient and cost effective medical diagnostic technologies more rapidly and consistently.
- Medical Technology Guidance (MT): Medical technologies guidance is designed to help the NHS adopt efficient and cost effective medical devices and diagnostics more rapidly and consistently.

2.1.1. Technology appraisals

In 1999, the Department of Health issued a health circular (1999/176) making it clear that the NHS should continue with local procedures for managing technologies where a NICE appraisal was ongoing or where NICE was not looking at a technology. Once technology appraisal guidance has been published, the Department of Health has directed that the NHS should provide funding for recommended medicines and treatments within three months, unless instructed otherwise by the Secretary of State.

In 2006 the Department of Health issued good practice guidance on managing the introduction of new healthcare interventions. This updates the health circular (1999/176) and further clarifies the guidance on funding of technology appraisal.

2.1.2. Interventional procedures

In 2003 the Secretary of State issued a health circular (2003/011) defining for the NHS in England the process for the introduction of new interventional procedures into clinical practice. (Covered in a separate policy) Policy number 261

NICE defines interventional procedures as:

- 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.
- 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.
- Using electromagnetic radiation (which includes X-rays, lasers, gamma-rays and ultraviolet light) - for example, using a laser to treat eye problems.

2.1.3. Clinical Guidelines and Public Health Guidelines

Organisations are expected to implement Clinical Guidelines and Public Health Guidelines **within their current resources**. There is no additional funding available for Clinical Guidelines. Organisations are expected to address the Clinical Guidelines in the same way as the TAGs; however Clinical Guidelines do not have to be implemented within three months of publication but within a 'reasonable' timescale.

2.2. NICE Guidance

It is recognised that adequate implementation of NICE guidelines requires a robust process that involves all Trust staff. Initial review of guidance is dealt with by the NICE Working Group. (See Terms of Reference, Attachment 2)

2.2.1 Stages of NICE guideline development

The process of development of NICE guidelines involves the following:

1. NICE Guidelines collated on a monthly basis by Clinical Audit for discussion at Monthly NICE Working Group where the appropriate clinician will be identified to lead on a guideline if deemed relevant to the Trust or the group are unsure.
2. Decision made by appropriate clinician in consultation with their colleagues as to relevance to Trust, proforma completed containing references to audits/policy numbers where necessary for assurance of compliance and returned via dedicated email address NICE@burtonft.nhs.uk
3. If the lead clinician is of the opinion that the Trust is non-compliant, a report prepared for Quality Review Group containing plans to ensure compliance with any risks being identified.

Monitoring, Audit and Feedback for NICE guidance

2.2.1. Monitoring and Audit

Audit/monitoring will be initiated on all guidance that is relevant to the Trust in priority order. Links with the Clinical Audit Department will be established and audit updates on NICE guidance topics discussed at NICE Working Group. The Trust supports the allocation of clinical audit projects among junior medical doctors in different specialties annually and this does form part of the monitoring processes for NICE implementation. The Trust stipulates an audit will be completed within 12 months of NICE guideline being issued to the relevant department. Any risks will be identified and recommendations implemented and monitored, through the Trust Clinical Audit process.

2.2.2. Feedback of results

The results of monitoring and audit will be reported to the NICE Working Group for discussion at QRG with any deficiencies identified within an action plan.

Progress with audit and monitoring arrangements of Quality Standards (QS) and Clinical Guidelines (CG) will be reported to the NICE Working Group.

2.2.3 Exception Reporting

Areas of non-compliance will be reported to **QRG** on a Bi-annual basis. Any risk issues will be identified and fed into the Divisional Risk Registers. These will be monitored by the NICE Working Group

2.2.4 Reporting

A report will be produced quarterly for QRG and a quarterly report will be produced and circulated to CQRM (Clinical Quality Review Meeting), which is monitored by the CCG

3. DUTIES

3.1. Chief Executive

The Chief Executive of the Trust is ultimately accountable for the implementation of all NICE guidance.

3.2. Executive Medical Director

The Executive Medical Director will initially consider all applications for new IPs submitted and refer them on to the QRG.

3.3. Divisional Medical Directors

The Divisional Medical Directors or Divisional Directors will support the implementation of NICE in their Divisions by:

- Ensuring that the implementation process and compliance requirements of new guidance are fully embedded in the specialties of the respective Division.
- Ensuring that the approval and registration processes of new techniques are fully embedded within the specialities of each respective Division.
- Identifying any gaps in the implementation process and communicate this to QRG.
- Producing implementation plans with the support of the business managers to effect the timely implementation of guidance into practice.
- Defining clear accountability and structures within each Division to ensure that the required time scale is met, documentation completed and reports provided to respective forums.

3.4. Lead Clinician and Clinical Directors

Named clinicians for NICE both medical and non-medical will be identified as part of the implementation planning process; they will work with the NICE Working Group and the wider Divisions to produce evidence and assurance that we are compliant or implementation plans for each piece of guidance issued as required.

3.5. NICE Working Group

The group coordinates the NICE implementation. Membership includes the Executive Medical Director, Deputy Medical Director, Associate Director (Medical Directors Office) Head of Pharmaceutical Service, Clinical Audit Manager and Corporate Nursing Representative See Appendix 4 for the Terms of Reference.

3.6. All Staff

Individual Trust staff is responsible for ensuring that they:

- Read and comply with disseminated NICE Guidance relevant to their role.

- Attend training to ensure familiarity and compliance with NICE Guidance relevant to their role.
- Raise any queries about implementation with their Line Manager.
- Play their role in delivering the Equality and Diversity Strategy in the implementation of NICE into practice.

4. POLICY IMPLEMENTATION PROCESS

4.1. Identifying and disseminating relevant documents

All new NICE guidance is published on the NICE website (www.nice.org.uk) on the last Wednesday of each month. In addition, the Trust receives a notification via e-mail of all published guidance. Published guidance is added to the NICE database each month and each piece of guidance assessed as to whether or not it is relevant to the Trust.

If the guidance is relevant or the NICE Working Group are unsure, a lead clinician will be assigned to lead on the assessment and/or implementation, the named clinician in conjunction with their colleagues will receive a link to the Guideline on the NICE website together with a pro-forma to complete (CG, TAG, IPG, PH, appendix 3, QS appendix 4).

A response is anticipated within a month for those non-relevant to Trust and non-compliant and within 3 months for those we are compliant with to include assurances in the form of policies and/or audits. If an audit is required, this should be initiated within 3 months and completed within 12 months of the guidance being issued.

4.2. Organisational framework for implementation of NICE guidelines and completion of an organisational gap analysis

Awareness of this Policy and implementation of NICE guidelines will be achieved through the following mechanisms:

- Clinical Leads for each piece of guidance undertake an organisational gap analysis by completion of the relevant NICE Guideline Compliance Indicator Proforma (Appendices 3 and 4).
- The Deputy Medical Director and clinical lead will prepare an action plan, with timescales, to ensure recommendations arising from the gap analysis are acted upon. The progress against the action plan will be monitored by the NICE Working Group and reported Quarterly at QRG and TEC .
- Involvement and contribution to the annual Trust business plans.
- A link, for all NICE Drugs, through the Pharmacy intranet webpage available to staff.
- Promotion of NICE guidance via clinical and managerial leads at Divisional meetings.
- Local dissemination of guidance by the NICE Working Group to relevant clinicians.

4.3 Process for ensuring that recommendations are acted upon throughout the organisation (Appendix 1)

Completed NICE compliance indicator proformas are reviewed and monitored by the NICE Working Group and QRG.

4.4 Process for documenting any decision not to implement NICE recommendations

The decision not to implement a NICE recommendation will be discussed at QRG.

Any decision not to implement will be reported to the Risk and Compliance Committee and may be escalated by the Executive Medical Director to the Board of Directors.

The risk posed by non-implementation is assessed and placed on the Generic Risk Corporate Register. This will be the responsibility of the Associate Director (Medical Directors office) and/or Clinical Audit Manager

4.5 Publication and Distribution

This Policy will be available on the intranet document library and will be distributed to the senior teams of the Directorates.

4.6 Communication

All clinicians across the Trust will be notified of this Policy on ratification.

5. POLICY MONITORING, AUDIT AND FEEDBACK PROCESS

5.1. Monitoring / Audit

Monitoring will be established in order to ensure the Trust that the Policy is effective in managing the risks associated with implementation of NICE guidance. Results of gap analyses carried out by individual clinical leads will be reviewed at meetings of the NICE Working Group.

Specific audits will be identified and undertaken if required in order to identify compliance and to evaluate the effectiveness of the Policy. Audits against NICE guidelines will be supported by the Trust's Clinical Audit Department. Results of audits will be assessed for evidence of compliance with NICE Quality Standards. Any audit that indicates a failure to comply with standards will be brought to the attention of the NICE Working Group.

Quarterly reports of Trust compliance with newly published guidance are submitted to the host CCG via QRG (Clinical Quality Review Meeting).

5.2. Feedback of Results

The results of monitoring and audit will be presented to (CQRM) in a quarterly report. Interim reports may be required if results indicate that urgent action is needed.

Relevant risk assessments will be considered for inclusion in departmental or Divisional risk registers. Significant risks will be escalated to the Risk and Compliance Committee.

5.3. Funding NICE Guidance

NICE funding is allocated for TAG implementation only. Clinical guidelines should be implemented within current resources with exceptional increases in costs submitted as part of the implementation plan to the Divisional/Clinical Management Board for approval on a 'one off' basis.

All implementation plans should ideally include net costs as well as taking into account offsetting savings or cost neutral provisions. Where possible costs should be calculated using the templates provided by NICE as well as data from information services.

Funding for NICE Technology Appraisal Guidance will be made available to ensure the implementation within three months from the date of publication, in accordance with the Directions under the NHS Act (1977) to Health Authorities, PCTs and NHS Trusts.

Funding for TAGs within tariff will be undertaken as part of the annual budget planning process within the Trust. For TAGs outside tariff, the Trust will make the necessary arrangements to inform the CCG through meetings of the NICE Working Group, Drugs and Therapeutics Group and regular Commissioning meetings.

6. REFERENCE DOCUMENTS

1. Directions under NHS Act (1977) to Health Authorities, Primary Care Trusts and NHS Trusts. The Direction states that a CCG "shall apply such amounts of sums paid to it…. so as to ensure that a health care intervention that is recommended by the Institute in a Technology Appraisal is, from a date not later than three months from the date of the Technology Appraisal, normally available…"

2. National Institute for Clinical Excellence. http://www.nice.org.uk

3. How to put NICE guidance into practice http://www.nice.org.uk/page.aspx?o=283871[accessed 07.03.2007]

4. Department of Health good practice guidance - December 2006 21/12/2006

5. Legal context of NICE guidance 11/06/2004

6. Health Service Circular 1999/176 18/05/2004

7. Secretary of State's Direction on the funding of technology appraisals 07/06/2004

8. Health Service Circular HSC 2003/011 21/04/2004

9. Welsh Health Circular WHC (2003) 58 23/05/2003

10. Health Department Letter HDL (2004) 04 09/03/2004

11. National Cancer Director's report on variations in usage of cancer drugs 14/06/2004

12. Minister of State's letter on implementation of NICE guidance 14/06/2004

13. Scottish Executive advice re IPs
http://www.show.scot.nhs.uk/sehd/mels/HDL2004_04.pdf

14. NICE information about IPs http://www.nice.org.uk/page.aspx?o=ip

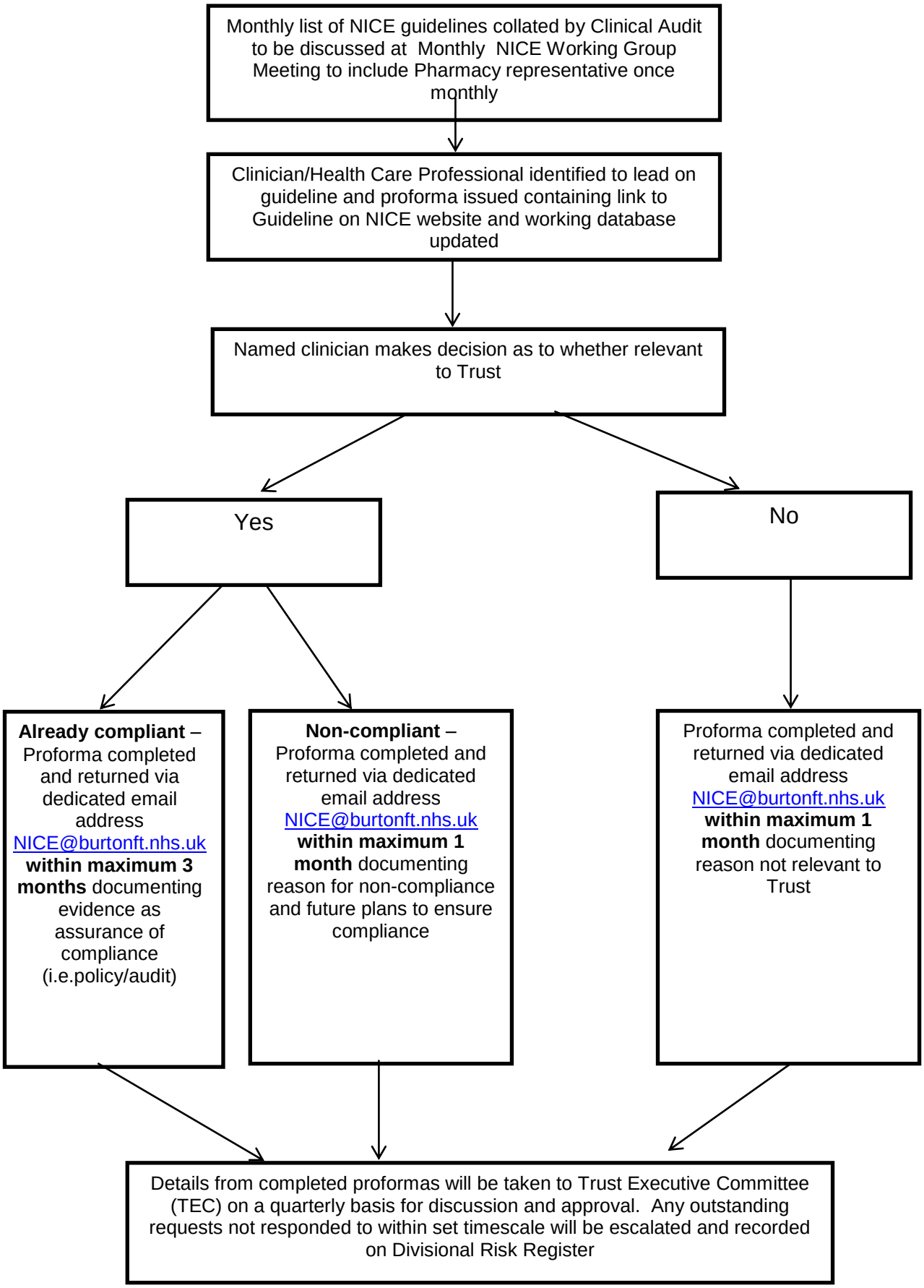
15. HSC IPs Programme
http://www.dh.gov.uk/assetRoot/04/06/49/25/04064925.PDF

16. Department of Health HSC 2003/011
http://www.dh.gov.uk/PublicationsAndStatistics/LettersAndCirculars/HealthServiceCirculars/HealthServiceCircularsArticle/fs/en?CONTENT_ID=4064922&chk=u6E7Kn

17. CE Marking:
http://ec.europa.eu/enterprise/newapproach/legislation/guide/document/chap07.pdf

18. NHS LA Standards:
http://www.nice.org.uk/usingguidance/benefitsofimplementation/nhsla.jsp

Appendix 1 PROCESS FOR COMPLIANCE WITH NICE GUIDELINES



Appendix 2

BURTON HOSPITALS NHS FOUNDATION TRUST

NICE WORKING GROUP

TERMS OF REFERENCE

Constitution

In order to develop a coherent response to published guidance from the National Institute for Health and Clinical Excellence (NICE) there is a need to ensure that the Trust consider such guidance and responds to/implements the guidance in an equitable and uniform manner. To ensure that NICE guidance is considered appropriately there is a requirement for a NICE Working Group (NWG) to be constituted which represents Burton Hospitals NHS Foundation Trust and which will liaise with other locality based organisations as appropriate.

Membership

- Deputy Medical Director
- Associate Director (Medical Directors Office) – Chair
- Divisional Medical Director Medicine
- Divisional Medical Director Surgery
- Head of Pharmacy or nominated representative
- Clinical Audit Manager or nominated representative
- Corporate Nursing representative

Quorum

The number of members present for a meeting to be quorate will be three, which as a minimum will include: -

- The Chair (Deputy MD)
- Clinical Audit Manager or nominated representative
- One other

Frequency of meetings

The NWG will meet at monthly intervals to consider the NICE guidance published in the previous month and to track the progress of previously published guidance.

Responsibilities

- Receive and review all new NICE guidance, including Technology Appraisal Guidance, Interventional Procedures, Clinical Guidelines Public Health Guidelines and any other as issued by NICE
- To decide upon optimal named clinician/health care professional to lead on guideline on behalf of the Trust
- Maintain a database of all NICE guidance received and appropriate action plans and assurance of compliance
- Monitor proposed business plans for implementation of guidance
- Oversee the monitoring/audit of implementation of NICE guidance across the Trust
- Monitor the Trusts' Risk Register in relation to NICE guidance
- Monitor progress and outcomes of audits related to NICE guidelines and act in accordance with the NICE Policy
- Prepare reports as required for the Quality Review Group

Reporting

The NWG will report to the Trust's Quality Review Group, which in turn reports to the Quality Committee.

Review

The Terms of Reference of the NWG shall be reviewed by the members at least annually.

Reviewed: 13 October 2016
Date for review: 12 October 2017

Version 6 (originally created 28.2.08)

Appendix 3 **NICE GUIDELINE COMPLIANCE INDICATOR**

Burton Hospitals NHS
NHS Foundation Trust

NICE Guidance Name/Number: -

Responsible Individual:

Please detail other clinicians, i.e. Doctors, Nurse, Pharmacy etc that you have discussed this guidance with:

……

This form is designed to assist you with the process of considering the Trust's current compliance and discussing any actions required to bring in line with the recommendations.

Please sign and return the completed form, along with any supporting evidence, including any audit results or evidence to: Kim Bonner, The House, Burton Hospitals FT

Compliance Indicator				
Is the Trust compliant with the Guideline		Please provide further evidence of compliance with the guideline	Please give any reason for non-compliance, or outline any plans to ensure future compliance	Does the compliance of this guideline present as being a risk to the Trust
Yes	If Yes, please provide any further evidence, i.e. Policy, Audit, Evidence			
Partially	If partial compliant, please confirm and provide evidence of which areas are compliant and which areas are non-			

	compliant within the Trust			
No	If the Trust is not compliant, please explain why and if implementation and full compliance can be achieved			

Any further comments	
Responsible Individual	
Signature	
Date compliance indicator	

completed	
Agreed and Signed off by the Divisional Medical Director	
Date signed off by the Divisional Medical Director	

Appendix 4 **QUALITY STANDARDS COMPLIANCE INDICATOR**

Burton Hospitals NHS
NHS Foundation Trust

You have been identified as the lead individual/group responsible for the assessment of compliance against the NICE Quality Standard

Responsible Individual;

Quality Statement Title:

QS Number:

This form is designed to assist you with the process of considering the Trust's current compliance and discussing any actions required to bring in line with the recommendations.

Please sign and return the completed form, along with any supporting evidence, including any audit results to: NICE@burtonft.nhs.uk

Statement Number	Quality Standard Statement	Compliance			
		Yes	If Yes, please provide any further evidence, i.e. Policy, Audit	No	If No, please give any reasons for non-compliance
1					
2					
3					
4					
5					

6					
7					
8					

Any further comments	
Named Clinician	
Statement numbers to be completed by named clinician	
Signature	
Date	