Policy:

Implementation of NICE Guidance (including Quality Standards)

Executive or Associate Director lead	Executive Medical Director
Policy author/ lead	360 Assurance (Internal Audit) and Jonathan Burleigh, Quality Improvement Manager
Feedback on implementation to	Jonathan Burleigh, Quality Improvement Manager

Document type	Policy
Document status	V4
Date of initial draft	October 2016
Date of consultation	October 2016
Date of verification	17 October 2016
Date of ratification	20 October 2016
Ratified by	Executive Directors Group
Date of issue	8 November 2016
Date for review	31/03/2020 (Extended from 30 September 2019)

Target audience	Senior Management & Clinical Directors

Keywords	NICE, guidance, quality, standards

Policy Version and advice on document history, availability and storage

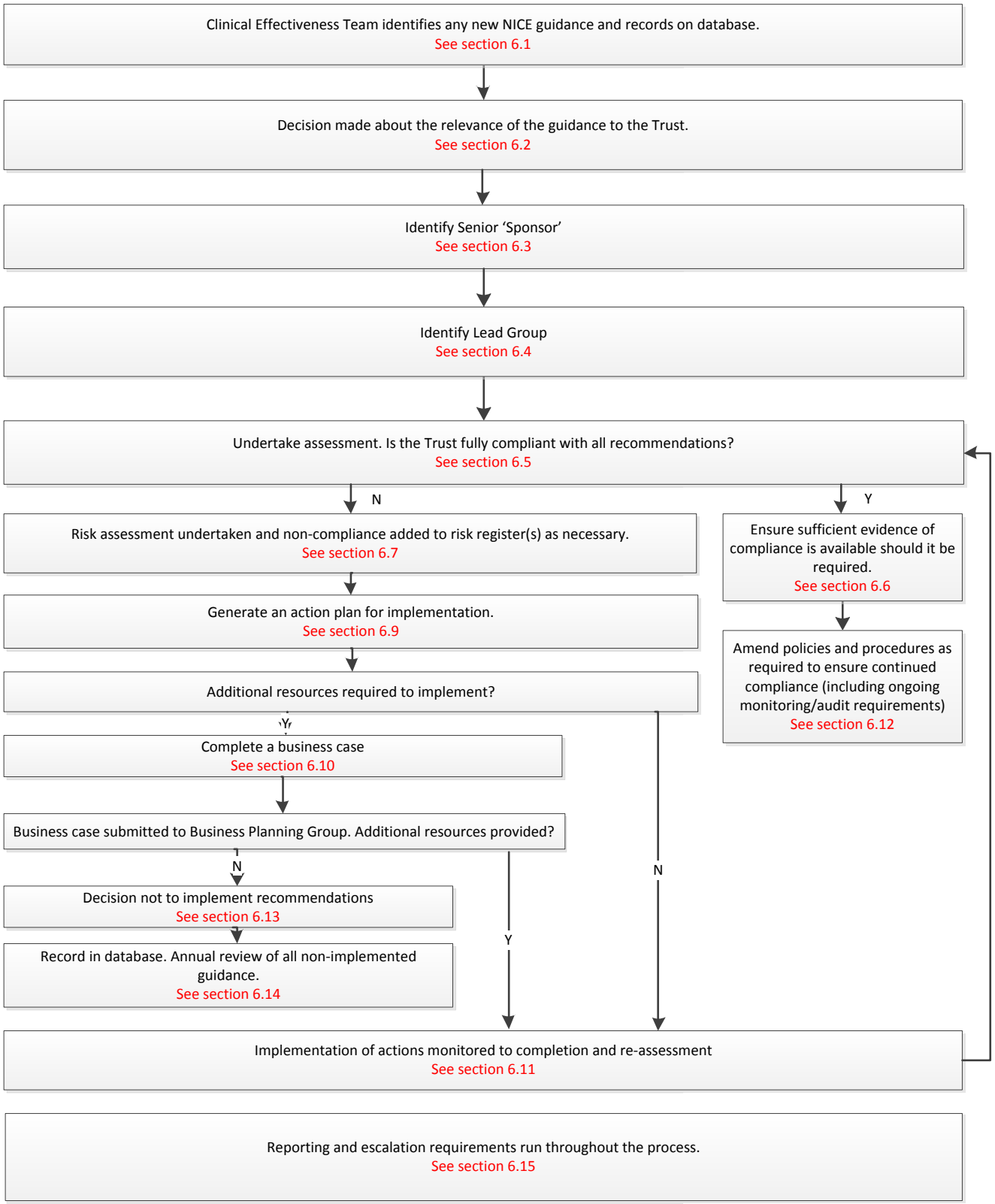
This is version 4 of this policy and replaces version 3.4, issued February 2016.

This policy will be available to all staff via the Sheffield Health & Social Care NHS Foundation Trust Intranet and on the Trust's website. The previous version will be removed from the Intranet and Trust website and archived. Word and pdf copies of the current and the previous version of this policy are available via the Director of Corporate Governance.

Any printed copies of the previous version (V3.4) should be destroyed and if a hard copy is required, it should be replaced with this version.

Contents

Flowchart


Clinical Effectiveness Team identifies any new NICE guidance and records on database.
See section 6.1
Decision made about the relevance of the guidance to the Trust.
See section 6.2
Identify Senior 'Sponsor'
See section 6.3
Identify Lead Group
See section 6.4
Undertake assessment. Is the Trust fully compliant with all recommendations?
See section 6.5
N
Y
Risk assessment undertaken and non-compliance added to risk register(s) as necessary.
See section 6.7
Ensure sufficient evidence of compliance is available should it be required.
See section 6.6
Generate an action plan for implementation.
See section 6.9
Amend policies and procedures as required to ensure continued compliance (including ongoing monitoring/audit requirements)
See section 6.12
Additional resources required to implement?
Y
N
Complete a business case
See section 6.10
Business case submitted to Business Planning Group. Additional resources provided?
N
Y
N
Decision not to implement recommendations
See section 6.13
Record in database. Annual review of all non-implemented guidance.
See section 6.14
Implementation of actions monitored to completion and re-assessment
See section 6.11
Reporting and escalation requirements run throughout the process.
See section 6.15

1. Introduction

National Institute of Health and Care Excellence (NICE) (https://www.nice.org.uk) recommendations are based on independent reviews of evidence for clinical and cost effectiveness of interventions. Once NICE guidance is published health professionals, commissioners and organisations are expected to take the guidance fully into account when deciding what services, treatments or advice to offer to service users and carers.

Implementing NICE guidance offers benefits to patients and carers, healthcare professionals and organisations. A clear process for the management of NICE guidance helps ensure that the care provided to patients is high quality and cost effective. It also helps organisations to meet standards set by the Care Quality Commission.

2. Scope

This policy is intended for all Trust staff involved with the implementation of NICE guidance. It should be read in conjunction with the Clinical Audit Policy. The policy covers all guidance issued by NICE.

This policy also applies to staff that work in Sheffield Health and Social Care NHS Foundation Trust services but are not employed by the Trust, including students, trainees, locum or temporary staff and staff on honorary contracts. Where staff employed by the Trust work in services provided by other organisations they have a duty to follow the policies of the organisation they are working in, and comply with their processes for NICE implementation.

3. Definitions

Best practice - A best practice is a technique or methodology that, through experience and research, has proven to reliably lead to a desired result. A commitment to using the best practices in any field is a commitment to using all the knowledge and technology at one's disposal to ensure success.

NICE Guidance – NICE Guidance covers the following classifications (as per the NICE website):

Diagnostics guidance		Focus on the evaluation of innovative medical diagnostic technologies in order to ensure that the NHS is able to adopt clinically and cost effective technologies more rapidly and consistently.
Highly specialised technologies guidance		Contain recommendations on the use of highly specialised technologies.
Interventional procedures guidance		These recommend whether interventional procedures - such as laser treatments for eye problems or deep brain stimulation for chronic pain - are effective and safe enough for use in the NHS.
Medical technologies guidance		Focus specifically on the evaluation of innovative medical technologies (including devices and diagnostics).
NICE guidelines From January 2015 all guidance previously released under the headings to the right are being classified as NICE guidelines (NG)	cancer service guidelines,	The focus is to guide the commissioning of services and is therefore different from clinical practice guidelines. Based upon the implementation of the NHS Cancer Plan
	clinical guidelines	Provide guidance on the appropriate treatment and care of patients with specific disease and conditions.
	medicines practice guidelines	Provide recommendations for good practice for those individuals and organisations involved in governing, commissioning, prescribing and decision-making

		about medicines. They have a wide range of audiences across both health and social care.
	public health guidelines	Make recommendations for populations and individuals on activities, policies and strategies that can help prevent disease or improve health.
	safe staffing guidelines	Following the Report of the Francis Inquiry and the Berwick Review into Patient Safety, NICE produced 2 guidelines on safe staffing capacity and capability in the NHS. From June 2015 NHS England will take forward staffing work as part of a wider programme of service improvement.
	social care guidelines	Aim to improve outcomes for people who use social care support by ensuring that social care services and interventions are effective and cost-efficient.
Quality Standards		Quality Standards are a set of specific, concise statements that act as markers of high-quality, cost-effective patient care, covering the treatment and prevention of different diseases and conditions.
Technology appraisal guidance		Technology Appraisals provide guidance on the use of new and existing medicines, treatments and procedures within the National Health Service (NHS) These follow a slightly different process for assessment and implementation within the Trust to the other NICE Guidance listed above and therefore at the end of each sub-section in section 6 a separate italicised statement has been made in relation to TAGs.

4. Purpose

This policy describes how NICE guidance is identified, disseminated, assessed and implemented within Sheffield Health and Social Care NHS Foundation Trust (SHSC).

5. Duties

Individual/Group	Duties
Chief Executive	The Chief Executive has ultimate responsibility for the quality of care and treatment and clinical effectiveness within the Trust, as well as the content of all policies and procedures and their implementation and review.
Medical Director	The Medical Director has lead executive responsibility for NICE Guidance implementation in the Trust and acts as a champion for NICE and evidence-based best practice. The Medical Director is responsible for providing assurance to the Board that an effective system exists to disseminate, implement and monitor compliance with NICE guidance. The Medical Director Chairs the Clinical Effectiveness Group (or may delegate this responsibility).
Associate Medical Director for Quality and Governance	Providing support and assistance to the Medical Director in respect of the NICE Guidance implementation process. Chairs the Clinical Effectiveness Group (delegated authority from Medical Director).
Quality Assurance Committee (QAC)	Receives an annual report related to NICE Implementation and Audit activity from the Executive Directors Group (EDG) and offers assurance to the Trust Board of Directors in relation to this.

	Receives assurance reports from EDG as necessary.
Executive Directors Group (EDG)	The Executive Directors Group is responsible for ensuring good quality care is delivered and best practice is followed by the staff within the directorates, teams and services and professional groups they manage. The EDG receives quarterly reports from the Clinical Effectiveness Group related to NICE implementation. Provides assurance to Quality Assurance Committee as required.
Clinical Effectiveness Group (CEG)	Oversight and monitoring of NICE activity. Provides a quarterly report to the Executive Directors Group (EDG) on whether services are implementing NICE guidance and providing evidence based treatment and support, and whether the process outlined in this policy is being followed. All Clinical Directors will be members of the CEG or included on the distribution list of the CEG.
Chairs of Lead Groups	Work with the Clinical Effectiveness Team to co-ordinate completion of relevant assessments. Identify individuals to act as assessors. Work with the Clinical Effectiveness Team to ensure an action plan is produced and submitted to CEG. Undertake ongoing monitoring of implementation of action plans where appropriate. Liaise with the Clinical Effectiveness Team on a quarterly basis.
Medicines Management Committee	Acts as Lead Group for all Technology Appraisal Guidance, unless otherwise notified to CEG (where the guidance does not concern medication).
Senior 'Sponsor'	A Senior 'Sponsor' will be identified for each piece of NICE Guidance. This will normally be an Executive Director, a Clinical Director or an Assistant Clinical Director. Act as a champion and advocate for implementation. Assist with resolving any difficulties in relation to the NICE assessment and implementation process.
Clinical Directors	Clinical Directors are responsible for ensuring NICE and other best practice guidance is disseminated to and implemented as much as possible by the health and social care staff they manage. Clinical Directors are expected to act as champions for NICE and evidence-based best practice within their directorates. Ensure all relevant staff within their directorate are notified of any NICE guidance which they need to consider (this may be limited to individuals responsible for writing policies/procedures or guidelines for staff). All Clinical Directors will be members of the CEG or included on the distribution list of the CEG.
Head of Clinical Governance	The Head of Clinical Governance is responsible for overseeing the work of the Clinical Effectiveness Team and ensuring they provide the support needed for the implementation of NICE guidance.
Clinical Effectiveness Team (including the Clinical Audit Manager/Facilitator	Day to day management of the NICE implementation and assurance process. Maintain the NICE database. Working with the Chairs of the Lead Groups to co-ordinate completion of assessments and action plans.

and the Quality Improvement Manager)	Supporting the implementation of action plans. Monitor and report the progress of all NICE implementation activity through monthly reports to CEG and quarterly reports to EDG and the Commissioners. Co-ordinating the inclusion of compliance with NICE guidance into clinical audits being undertaken or facilitating bespoke clinical audits where necessary.
Assessors	Complete relevant assessment and risk assessment as requested by Lead Group/Clinical Effectiveness Team.
Policy Authors	When reviewing existing policies and procedures, or writing new ones, authors are responsible for ensuring that relevant NICE Guidance recommendations are incorporated and that these documents describe a "NICE Compliant" service. They should consult the NICE database (available via the Clinical Effectiveness Team) to help determine if there is applicable guidance.
All staff providing care and treatment	All staff providing care and treatment have a fundamental responsibility to provide care and treatment that is safe and effective. They must therefore comply with Trust policies and procedures, which will incorporate NICE guidance where applicable.

6. Processes/Procedures to be followed

6.1 Identifying new guidance

NICE produce a forward planner, available via their website, which identifies upcoming guidance and its planned publication date. The Clinical Effectiveness Team will review this database on a monthly basis and include a list of guidance that is due to be published in the next three months within the monthly report to CEG.

NICE guidance is published every month. Members of the Clinical Effectiveness Team receive this information via a monthly NICE e-newsletter and by reviewing the NICE website.

Once a piece of NICE guidance is published on the NICE website, the Clinical Effectiveness Team will record the newly issued guidance on the Trust's NICE database, along with its month of publication, reference number/ID and the type of guidance (see table in section 3 – definitions).

Technology Appraisal Guidance (TAGs) will be identified by the Clinical Effectiveness Team, recorded on the NICE database, and immediately forwarded to the Chair of the Medicines Management Committee. There is a requirement for TAGs to be implemented by CCGs, NHS England and Local Authorities within 3 months and therefore the relevant medicines or equipment should be accessible within this time period.

6.2 Determining if the guidance is relevant

The Clinical Effectiveness Team and the Associate Medical Director for Quality and Governance will make a recommendation regarding the relevance to the Trust of each piece of newly published guidance for presentation to the CEG.

On a monthly basis the CEG meeting will receive a report which identifies:

- Newly published NICE Guidance (title & reference);

- Date of publication;
- Recommendation regarding relevance

Where there is uncertainty regarding the relevance, the guidance will be included within the papers of the CEG meeting so that members can read the guidance prior to the meeting to enable a decision to be made about whether it is relevant.

On reviewing this report each month, the CEG will confirm and approve the relevance to the Trust and determine which directorates the guidance applies to.

The outcome agreed by CEG will be recorded on the NICE database.

A quarterly report will be presented to EDG which includes all NICE guidance published within the quarter and the decision regarding relevance approved by CEG.

The Medicines Management Committee will determine if the TAG is relevant to the Trust and inform the Clinical Effectiveness Team of this decision. Where the TAG does not relate to Medication the Medicines Management Committee will alert the Clinical Effectiveness Team as soon as possible and the TAG will be processed in the same way as other NICE Guidance (noting the expectation within the Quality Schedule that these will be implemented within 6 months).

6.3 Identifying a Senior 'Sponsor'

At the same time as approving the decision regarding relevance, the CEG will identify a proposed Senior 'Sponsor' for each piece of guidance. This will be the most appropriate person from the Trust's senior management to act as an advocate for implementation. Identification of this individual will be dependent on the subject matter of the guidance and the breadth of coverage. The Senior 'Sponsor' will therefore normally be an Executive Director, a Clinical Director or an Assistant Clinical Director.

Wherever possible, the agreement of the Senior 'Sponsor' to act in this capacity should be sought prior to their name being proposed and agreed by CEG (using the list of forthcoming guidance identified in section 6.1).

Any issues arising during the process of assessment of compliance with guidance or the implementation of guidance experienced during the processes outlined below should be escalated to the Senior 'Sponsor'.

The Medical Director will be the Senior 'Sponsor' for all TAGs being managed by the Medicines Management Committee. Where TAGs have been referred back to CEG, the above process for identifying a Senior 'Sponsor' will apply.

6.4 Identifying a Lead Group

Using the monthly report produced by the Clinical Effectiveness Team (as per 6.2 above), the CEG will identify the most appropriate group within the Trust governance structure to work with the Clinical Effectiveness Team to co-ordinate the initial assessment against the particular piece of NICE Guidance, dependent on the subject matter and spread of directorate relevance.

The Lead Group will provide the source of specialist knowledge and information regarding the subject area. The Clinical Effectiveness Team will provide support and advice on the assessment process and ensure timeframes are clear.

Preference should always be given to identifying an existing group to act as the Lead Group. In exceptional circumstances, the CEG is authorised to establish a task and finish group to

assess and implement a particular piece/ set of NICE guidance, where an appropriate group does not currently exist. The CEG will identify the Chair and membership of a task and finish group as appropriate. The Chair should be agreed by the relevant Senior 'Sponsor'. Membership should reflect all directorates to which the guidance applies and be agreed with the Chair of CEG.

A member of the Clinical Effectiveness Team will contact the Chair and the administrator of the identified Lead Group, within 1 week of the CEG meeting, to advise them that the group has been nominated to work with the Clinical Effectiveness Team to co-ordinate the initial assessment against the particular NICE guidance and provide the following information:

- The nominated Senior 'Sponsor';
- The directorates to which the guidance is believed to apply;
- The timeframes in which the assessment should be reported back to CEG (this will normally be within 3 months – date of relevant CEG and papers deadline to be provided);
- Copies of the relevant assessment tool to be used.

The Clinical Effectiveness Team will record on the NICE database: the Lead Group, the date of 'notification' and the expected date of report back to CEG.

The Medicines Management Committee will automatically be the Lead Group for all TAGs. Where the TAG is not regarding Medication and is referred back to the CEG, the Lead Group will be identified in the same way as described above.

6.5 Completion of Relevant Assessment

The Chair of the Lead Group, with support from the Clinical Effectiveness Team and the Clinical Directors, will identify suitable individuals to complete the initial assessment (or baseline assessment) across all relevant directorates.

NICE produce some standardised 'Baseline Assessment Tools' which will be utilised where appropriate. In other cases, Trust documentation will be used. The Clinical Effectiveness Team will supply the relevant assessment tool to be completed to the Chair of the Lead Group and the identified assessors.

The initial assessment is intended to identify whether there is currently sufficient evidence available that each recommendation within the guidance is being followed/standard is being met. The evidence may come in different forms and consideration should be given to:

- Relevant policies and procedures (and the associated policy monitoring reports) may identify whether the NICE recommendation is already incorporated into Trust expectations.
- Electronic systems may hold information which supports assessment of whether the recommendation is being followed. Alternatively, it may be identified that electronic systems do not capture the necessary information or do not capture it in a way which enables assessment of compliance.
- The Clinical Effectiveness Team will be able to provide previous audit data which may be of use. Directorates/Teams may also have their own audit data which demonstrates compliance or otherwise. The assessors are not expected to undertake new audits in order to determine if the recommendation is being followed.
- Where information is not available this should be flagged within the relevant assessment tool.

Any evidence used to support completion of the assessment should be identified within the relevant assessment tool. It should also be clearly identified where data is not currently captured that is needed to determine compliance and therefore what data is needed in the future (for inclusion in the action plan).

The assessment tool will prompt the assessor to identify the level of risk where there is insufficient evidence currently available that the Trust is fully compliant with each recommendation.

The completed assessment should be presented to the Lead Group for scrutiny and approval before being submitted to CEG.

It is expected that approved assessments will be reported back to CEG within 3 months. The Chair of the Lead Group will therefore need to determine which meeting of the Lead Group the relevant assessment needs to be presented to for approval prior to onward submission to CEG. The Clinical Effectiveness Team should be advised of the date of this meeting.

The Clinical Effectiveness Team will record in the NICE database the date that the relevant assessment is due to be presented to the Lead Group.

The Medicines Management Committee will arrange for assessment against TAGs. Where the TAG is not regarding Medication and is referred back to the CEG, the Lead Group will identify assessors and review the assessment in the same way as described above.

6.6 Evidence to Support Assessment

In completing the relevant assessment tool (either as an initial assessment or a re-assessment), assessors are expected to describe what evidence they have to substantiate a status of compliance with each recommendation in the NICE Guidance. This might include clinical audit results, patient surveys, policies, reports, data generated from an electronic system, service leaflets and other documentation.

The evidence identified should be sent to the Clinical Effectiveness Team for central storage so that hyperlinks/filepaths can be included in the NICE database.

Where evidence is not currently available, steps to obtain evidence should be included in the action plan.

The Medicines Management Committee will identify evidence of compliance for relevant TAGs and send to the Clinical Effectiveness Team. Where the TAG is not regarding Medication and is referred back to the CEG, evidence should be sent to the Clinical Effectiveness Team as described above.

6.7 Risk Assessment

The assessment tool provided to the assessor(s) will include space for identification of risks where there is currently insufficient evidence of current compliance with each recommendation.

The Lead Group, in scrutinising the completed assessment tool, will be expected to consider the overall risk to quality of care where full compliance is not being declared. .

Determination of risk should consider:

- How many recommendations do not have sufficient evidence of compliance;
- The significance of these recommendations;
- Whether it is believed that the Trust is compliant but there is a lack of evidence available at this time, or whether it is believed that the Trust is not compliant;
- The amount of work required to implement the recommendations.

This overall assessment of risk should accompany the completed assessment when it is submitted to CEG.

The Medicines Management Committee will assess the risk posed by non-compliant TAGs and report this back to the Clinical Effectiveness Team. Where the TAG is not regarding Medication and is referred back to the CEG, the Lead Group will identify and report risk in the same way as described above.

6.8 Approval of Assessment

All completed assessments will be reported to CEG, accompanied by the Lead Group's assessment of the overall risk posed to the quality of care of the non-compliant elements.

The CEG will review and approve each assessment, including the level of risk identified, requesting any further information where necessary.

Where the assessment indicates that there is available evidence to support compliance with each recommendation within the guidance and this assessment is approved by CEG, the Clinical Effectiveness Team will check the relevant Trust policies to ensure they:

- Refer to the relevant NICE guidance;
- Describe a 'NICE compliant' service; and
- The ongoing monitoring arrangements for the policies will provide ongoing evidence of NICE compliance.

Where the assessment indicates that there are recommendations with which the Trust is not compliant, or there is insufficient evidence of compliance, the CEG will discuss the level of risk this poses and approve an overall risk rating.

The CEG, supported by the Clinical Effectiveness Team, will take responsibility for identifying the relevant risk registers which any risk should be entered onto and notifying the risk register owner.

6.9 Action Plan

Following the approval of the assessment and risk by CEG, the Clinical Effectiveness Team will work with the Lead Group to generate an action plan to bring the Trust to a position where it is compliant with the NICE guidance and/or is able to generate sufficient information to demonstrate this compliance.

The action plan should be drafted ready for scrutiny at the next meeting of the Lead Group (following the meeting where the initial assessment was presented).

A template action plan will be provided by the Clinical Effectiveness Team to ensure all relevant fields are included.

Common elements on an action plan may be:

- Undertaking further detailed assessment;
- Amendments to relevant policies/procedures, including ongoing monitoring requirements (to provide ongoing evidence of compliance);
- Training for staff;
- Communication to staff of changes to policy;
- Changes to template documents/ data capture on electronic systems;
- Audit (local/isolated or inclusion on clinical audit plan);
- Re-assessment (this should be included on all action plans as re-assessment will need to occur once other actions are implemented).

In scrutinising and reviewing the action plan, the Lead Group should identify whether they believe additional resources will be required to complete the actions, which actions this affects, and the extent to which the identified risk can be mitigated without additional

resources being made available. An initial assessment should also be made of the costs. These considerations should be submitted to the CEG at the same time as the action plan.

The action plan should be submitted to CEG within 3 months of the completed assessment being submitted. CEG will approve the action plan or request that it is amended and resubmitted for approval.

By approving each action plan, CEG will ensure that implementation of multiple NICE guidance recommendations is co-ordinated and prioritised across the Trust.

Common elements will be brought together and actioned 'en-masse' e.g. if 3 action plans contain amendments to Insight then these will be brought together and 1 request for amendments made to the relevant technical team.

Clinical Audit requirements will be taken from the action plans and co-ordinated by the Clinical Effectiveness Team to ensure they are incorporated in an efficient and effective manner.

Following approval of the action plan by CEG, the Clinical Effectiveness Team, CEG and Chair of the Lead Group will identify where the actions should be monitored through to implementation.

The Medicines Management Committee will develop, implement and monitor action plans in relation to relevant TAGs. Where the TAG is not regarding Medication and is referred back to the CEG, the Lead Group and CEG will develop and approve the action plan as described above.

6.10 Business Case

When reviewing and approving the action plan, the CEG will consider any submissions made by the Lead Group regarding additional resources required and the residual risk if additional resources are not secured, as well as the costing indicated for implementation of actions.

Where CEG consider it necessary and appropriate they will agree for a Business Case to be developed and submitted.

The Clinical Effectiveness Team will complete the Business Case with support from the Chair of the Lead Group and any other identified individuals, using the approved Trust template.

The Business Case must make clear the risks associated with not implementing the relevant recommendations as well as the anticipated cost of implementation.

The Business Case, once completed, should be submitted to CEG for approval before onwards submission to the Business Planning Group.

Submission of a Business Case should not delay implementation of other actions on the action plan, not dependent on additional resources.

The Medicines Management Committee will develop any Business Cases necessary for implementation of relevant TAGs. Where the TAG is not regarding Medication and is referred back to the CEG, the Lead Group and CEG will develop the Business Case as described above.

6.11 Monitoring Implementation of Action Plan

Following approval of the action plan by CEG, the Clinical Effectiveness Team, CEG and Chair of the Lead Group will identify where the actions should be monitored through to implementation.

Each individual/group responsible for monitoring the implementation of actions will be expected to liaise with the Clinical Effectiveness Team on a quarterly basis (as a minimum) to identify progress.

Failure to provide an update will result in an Amber flag which will be reported to CEG.

Once the individual/group believe that all the relevant actions are complete, CEG should be informed. The CEG & Clinical Effectiveness Team will arrange for a re-assessment to determine if the necessary evidence is now available. The action plan and re-assessment should be submitted together to CEG, who will assess the evidence as necessary, including the re-assessment and approve the close down of the action plan.

The Medicines Management Committee will monitor the action plans to implementation for relevant TAGs. Where the TAG is not regarding Medication and is referred back to the CEG, the Lead Group will monitor the action plan as described above.

6.12 Ongoing Evidence of Compliance with NICE Guidance

Before a piece of NICE guidance is deemed 'implemented' (to the extent that it is agreed it will be implemented by the Trust) the Clinical Effectiveness Team will ensure that the relevant policy(ies):

- Refers to the relevant NICE guidance;
- Describes a 'NICE compliant' service; and
- The ongoing monitoring arrangements for the policy will provide ongoing evidence of NICE compliance.

Ongoing evidence of compliance will therefore be linked to policy monitoring and will be the responsibility of whichever group is identified in the policy as having those responsibilities.

The Clinical Effectiveness Team will coordinate ongoing evidence of compliance. As well as reassessments of guidance, and implementation of Trust policies, ongoing evidence may also include 'additional evidence' which will include other activities/developments within the Trust that address recommendations and standards contained within the NICE guidance. The Clinical Effectiveness Team will ensure any 'additional evidence' identified is included in the NICE database.

6.13 Decision not to implement recommendations

Where there are insufficient resources available to implement recommendations contained within NICE guidance, and a Business Case to secure funds has been unsuccessful, the CEG will request approval from EDG for a decision not to implement particular recommendations.

The date of this approval from EDG and the particular recommendations to which it relates will be recorded on the NICE database.

6.14 Annual review of recommendations not previously implemented

The CEG will receive a report prepared by the Clinical Effectiveness Team which identifies all guidance where a decision was approved by EDG between 7 & 18 months previously not to implement particular recommendations, as well as guidance from the previous annual report of this nature.

The CEG will decide, on the basis of reviewing the risk assessment and the costs of implementation, whether to approve a continued decision not to implement the particular recommendations.

Revised NICE guidance will be treated as a new piece of guidance and therefore this provides a safety check on guidance or recommendations previously deemed to be 'not relevant' to the Trust.

When a new service is commissioned it is the responsibility of the service implementation lead to check the NICE database to determine if any guidance previously deemed 'not relevant' to the Trust applies to the new service and inform the Clinical Effectiveness Team so that the guidance can re-enter the process.

6.15 Reporting (and monitoring of the process)

The Clinical Effectiveness Team will maintain a NICE database. This will include all the information necessary for monitoring the application of this policy. Some elements within the NICE database will be colour-coded according to a Red-Amber-Green (RAG) rating, to easily monitor compliance with process as well as current status and progress. The detail of this is shown at **Appendix G**.

Each (monthly) meeting of the Clinical Effectiveness Group will receive:

- List of guidance due to be published in the next 3 months (see section 6.1) for information and planning;
- List of newly published guidance, identifying relevance of guidance (see section 6.2) for approval of determined relevance;
- Current stage of all NICE guidance 'in process' (i.e. not including guidance that is deemed 'not-relevant' or is otherwise not to be implemented nor guidance with which the Trust is deemed 'fully compliant') for information and monitoring;
- Exception report identifying all instances where the expected timeframes outlined in this policy have been exceeded;
- Current status of all approved action plans.

Where these reports identify that individuals/groups have not complied with the processes and timeframes outlined in this policy, the Chair of CEG will contact the individual/chair of the group to request explanation and agree a method of getting the process back on track as soon as possible.

The Clinical Effectiveness Group should also receive the following in all instances, as soon as available:

- Completed relevant assessment and accompanying risk assessment;
- All action plans for approval;
- Business Cases for scrutiny and onward submission to Business Planning Group.

On an annual basis CEG will receive:

- A report outlining guidance where it has been decided not to implement particular recommendations, for re-approval.

On a quarterly basis EDG will receive:

- A list of newly published guidance, identifying relevance of guidance (see section 6.2);
- Exception report identifying the number of instances where the expected timeframes outlined in this policy have been exceeded, resulting in a Red rating, identifying action taken by CEG to date to resolve the issues;
- The number of assessments reviewed by CEG in the quarter and their resultant level of risk and confirmation that the risk register owner has been notified of the risk;
- A list of progress status against current action plans;
- In the relevant quarterly report (on an annual basis) a copy of the annual report submitted to CEG re-confirming decision not to implement.

Business Planning Group should receive the following in all instances, as soon as available:

- Completed Business Cases for approval/onward submission to EDG/CCG.

EDG will provide assurance to QAC, as required by QAC.

7. Dissemination, storage and archiving (Control)

The Corporate Governance Team is responsible for the storage and dissemination of this policy.

This policy will be disseminated via the Sheffield Health and Social Care NHS Foundation Trust intranet and be made available to all staff.

The Director of Corporate Governance is responsible for making sure the new policy is inserted on the Trust intranet in the policies section.

An 'All SHSCT staff' email alert should be sent to all staff telling them of the new policy and where to find it. Clinical and Service Directors are responsible for ensuring that all staff in their directorates are aware of new policies and know where to find them.

Additional promotion of the policy will take place through further publicity such as articles in Sheffield Health and Social Care Trust newsletters and other staff briefings.

Some teams have paper policy files or archives for easy reference. It is the responsibility of the locality team manager to ensure that paper policy files are kept up to date and comprehensive, and that staff are made aware of new or revised policies. Older versions should be destroyed to avoid confusion. It is the responsibility of the team manager to make sure the latest version of a policy is available to all staff in the team.

It is the responsibility of the Director of Corporate Governance to maintain an archive of previous versions of policies, and to make sure that the latest version is the one which is posted on the Trust intranet. They will circulate a list of all Sheffield Health and Social Care Trust policies at least annually to team managers and directors throughout the Trust.

8. Training and other resource implications

There are no specific training implications with regards to this policy. The majority of tasks described within this policy fall within the skills, knowledge and job descriptions of senior managers and clinicians in the Trust.

The Clinical Effectiveness Team will provide informal training and development for staff implementing NICE guidance and guide them through the processes described in this policy.

The Head of Clinical Governance will ensure the Clinical Effectiveness Team and colleagues in the Medical Directorate are fully aware of their responsibilities in this Policy.

This revised policy will be ratified by the EDG before being cascaded to directorate teams.

9. Audit, monitoring and review

Monitoring Compliance Template						
Minimum Requirement	Process for Monitoring	Responsible Individual/ group/committee	Frequency of Monitoring	Review of Results process (e.g. who does this?)	Responsible Individual/group/ committee for action plan development	Responsible Individual/group/ committee for action plan monitoring and implementation
The relevance of newly published guidance is determined by CEG in a timely manner	NICE database	CEG	Quarterly	EDG	CEG	EDG
Lead group is notified within 1 weeks of CEG	NICE database	Clinical Effectiveness Team	Monthly Quarterly	Exception report to CEG Exception report to EDG	CEG	EDG
Initial assessment and risk assessment is presented to CEG within 3 months of the Lead Group being notified	NICE database	Chairs of Lead Groups	Monthly Quarterly	Exception report to CEG Exception report to EDG	CEG	EDG
Action Plan submitted to CEG for approval within 3 months of initial assessment submission	NICE database	Chairs of Lead Groups	Monthly Quarterly	Exception report to CEG Exception report to EDG	CEG	EDG
Action plans progress according to approved timeframes	NICE database	Chairs of Lead Groups	Monthly Quarterly	Exception report to CEG Exception report to EDG	CEG	EDG
Action plan is completed and re-assessment submitted within the original timeframes approved	NICE database	Chairs of Lead Groups	Monthly Quarterly	Exception report to CEG Exception report to EDG	CEG	EDG

This policy will be reviewed by September 2019.

10. Implementation plan

Action / Task	Responsible Person	Deadline	Progress update
Upload new policy onto intranet and remove and archive old version	Corporate Governance Team	31st October 2016	
A communication will be issued to all staff via the Communication Digest immediately following publication.	Corporate Governance Team	Within 5 working days of issue	
Specific Email to membership of EDG, CEG, Clinical Directors & Chairs of potential Lead Groups	Head of Clinical Governance	Within 5 working days of issue	
Review TOR for CEG	Associate Medical Director for Quality & Governance	31st January 2017	
Standard phrasing to be developed for inclusion in the TOR for any group asked to co-ordinate NICE guidance assessment and implementation	Head of Clinical Governance	31st January 2017	
Review NICE database to ensure it covers all required elements	Clinical Effectiveness Team	31st December 2016	
Develop Relevant assessment document for use when there is not a specific tool provided by NICE	Clinical Effectiveness Team	31st December 2016	
Develop template Action Plan	Head of Integrated Governance	31st December 2016	
Review Trust intranet site and ensure there is linkage to o NICE website o Relevant assessment tools o Action Plan template	CET	31st January 2017	
Develop format of: o Monthly report to CEG o Quarterly report to EDG	Clinical Effectiveness Team	31st December 2016	
Review this policy	Head of Clinical Governance/Clinical Effectiveness Team	30th September 2019	

11. Links to other policies, standards and legislation (associated documents)

The following Sheffield Health and Social Care NHS Foundation Trust policies are available on the Trust website on www.shsc.nhs.uk

Risk Management Policy
Clinical Audit Policy

12. Contact details

Title	*Name*	*Phone*	*Email*
Medical Director	Mike Hunter (Interim)	64838	Mike.Hunter@shsc.nhs.uk
Executive Director for Nursing, Professions & Care Standards	Liz Lightbown	16395	liz.lightbown@shsc.nhs.uk
Associate Medical Director for Quality and Governance	Jonathan Mitchell	50720	Jonathan.Mitchell@shsc.nhs.uk
Head of Clinical Governance	Tania Baxter	63279	Tania.Baxter@shsc.nhs.uk
Quality Improvement Manager (Clinical Effectiveness Team)	Jonathan Burleigh	18540	Jonathan.Burleigh@shsc.nhs.uk

13. References

All NICE guidance is available on the NICE website. A full list of the guidance can be found on http://guidance.nice.org.uk/

'Into Practice Guide', NICE, http://guidance.nice.org.uk/

Relevant assessment tools (for guidance published since April 2010) and costing tools are available linked to specific guidance on the NICE website

Appendix A – Version Control and Amendment Log

Version No.	Type of Change	Date	Description of change(s)
4	Revision following Internal Audit review	Oct 2016	Further detail included on the specifics of the process, responsibilities and reporting/monitoring.

Appendix B – Dissemination Record

Version	Date on website (intranet and internet)	Date of "all SHSC staff" email	Any other promotion/ dissemination (include dates)
4	Oct 2016	Oct 2016	

Appendix C – Stage One Equality Impact Assessment Form

Equality Impact Assessment Process for Policies Developed Under the Policy on Policies

Stage 1 – Complete draft policy

Stage 2 – **Relevance** - Is the policy potentially relevant to equality i.e. will this policy potentially impact on staff, patients or the public? If **NO** – No further action required – please sign and date the following statement. If **YES –** proceed to stage 3

This policy does not impact on staff, patients or the public (insert name and date)

Stage 3 – **Policy Screening** - Public authorities are legally required to have 'due regard' to eliminating discrimination , advancing equal opportunity and fostering good relations , in relation to people who share certain 'protected characteristics' and those that do not. The following table should be used to consider this and inform changes to the policy (indicate yes/no/ don't know and note reasons). Please see the SHSC Guidance on equality impact assessment for examples and detailed advice. This is available by logging-on to the Intranet first and then following this link https://nww.xct.nhs.uk/widget.php?wdg=wdg_general_info&page=464

	Does any aspect of this policy actually or potentially discriminate against this group?	**Can equality of opportunity for this group be improved through this policy or changes to this policy?**	**Can this policy be amended so that it works to enhance relations between people in this group and people not in this group?**
AGE	**No**	**No additional opportunities were identified.**	**The need for further action was not identified.**
DISABILITY	**No**		
GENDER REASSIGNMENT	**No**		
PREGNANCY AND MATERNITY	**No**		
RACE	**No**		
RELIGION OR BELIEF	**No**		
SEX	**No**		
SEXUAL ORIENTATION	**No**		

Stage 4 – **Policy Revision** - Make amendments to the policy or identify any remedial action required (action should be noted in the policy implementation plan section)
Please delete as appropriate: Policy Amended / Action Identified / no changes made.

Impact Assessment Completed by (insert name and date) SC Stewardson, Interim Policy Governance Manager (17.10.2016)

Appendix D - Human Rights Act Assessment Form and Flowchart

You need to be confident that no aspect of this policy breaches a person's Human Rights. You can assume that if a policy is directly based on a law or national policy it will not therefore breach Human Rights.

If the policy or any procedures in the policy, are based on a local decision which impact on individuals, then you will need to make sure their human rights are not breached. To do this, you will need to refer to the more detailed guidance that is available on the SHSC web site
http://www.justice.gov.uk/downloads/human-rights/act-studyguide.pdf
(relevant sections numbers are referenced in grey boxes on diagram) and work through the flow chart on the next page.

1. Is your policy based on and in line with the current law (including case law) or policy?

☒ **Yes. No further action needed.**

☐ **No. Work through the flow diagram over the page and then answer questions 2 and 3 below.**

2. On completion of flow diagram – is further action needed?

☐ **No, no further action needed.**

☐ **Yes, go to question 3**

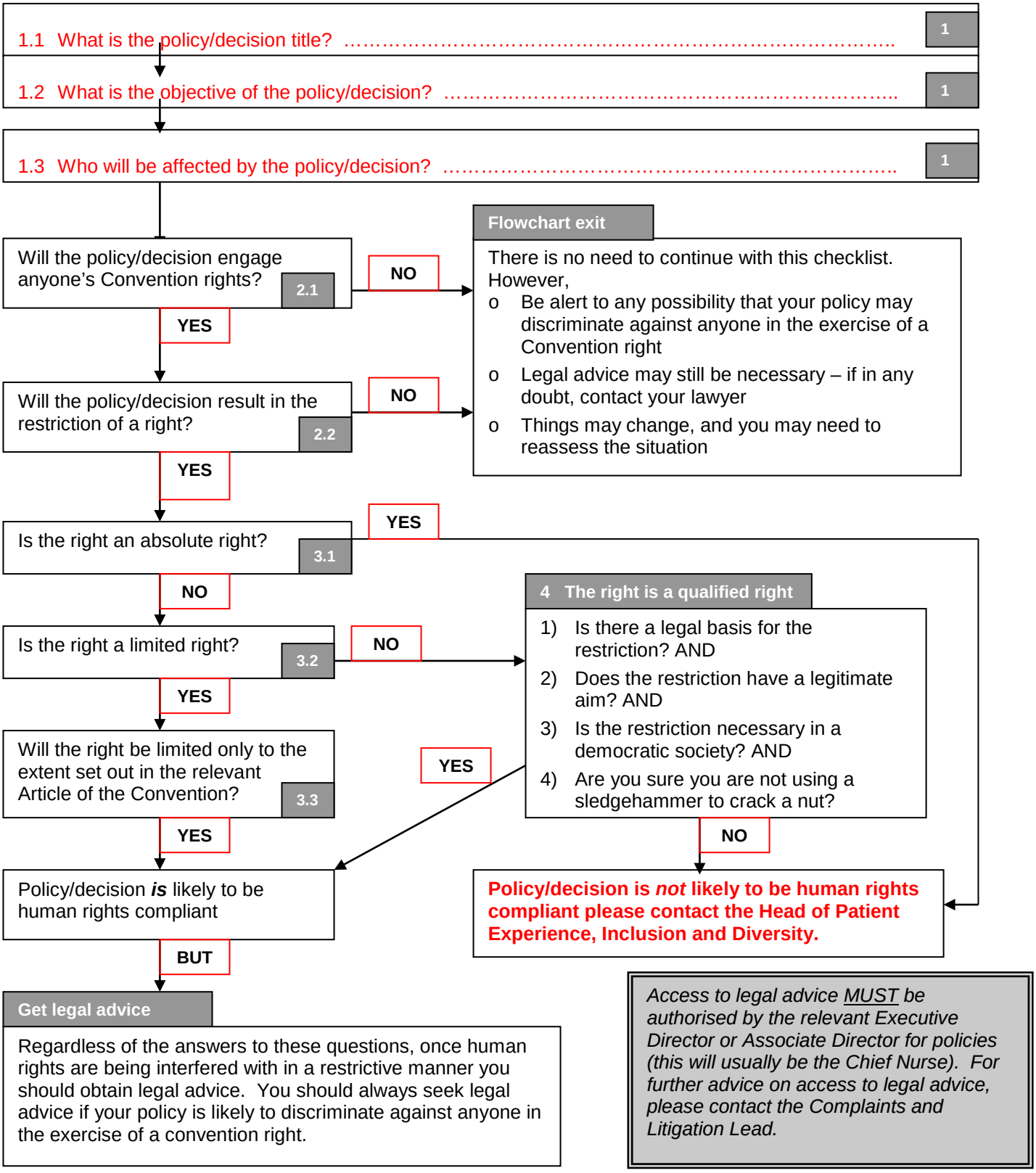
3. Complete the table below to provide details of the actions required

Action required	By what date	Responsible Person

Human Rights Assessment Flow Chart

Complete text answers in boxes 1.1 – 1.3 and highlight your path through the flowchart by filling the YES/NO boxes red (do this by clicking on the YES/NO text boxes and then from the Format menu on the toolbar, choose 'Format Text Box' and choose red from the Fill colour option).

Once the flowchart is completed, return to the previous page to complete the Human Rights Act Assessment Form.



Appendix E – Development, Consultation and Verification

The Implementation of NICE Guidance Policies from 10 other NHS Trusts were reviewed to ensure all aspects were covered.

Omissions and risks identified by the 360 Assurance Internal Audit Review were rectified through inclusion of further information and detail.

Consultation was undertaken within the Clinical Effectiveness Team. The draft policy was verified by the Chair of the Clinical Effectiveness Group.

Appendix F –Policies Checklist

Please use this as a checklist for policy completion. The style and format of policies should follow the Policy Document Template which can be downloaded on the intranet.

1. Cover sheet ✓

All policies must have a cover sheet which includes:

- The Trust name and logo ✓
- The title of the policy (in large font size as detailed in the template) ✓
- Executive or Associate Director lead for the policy ✓
- The policy author and lead ✓
- The implementation lead (to receive feedback on the implementation) ✓
- Date of initial draft policy ✓
- Date of consultation ✓
- Date of verification ✓
- Date of ratification ✓
- Date of issue ✓
- Ratifying body ✓
- Date for review ✓
- Target audience ✓
- Document type ✓
- Document status ✓
- Keywords ✓
- Policy version and advice on availability and storage ✓

2. Contents page ✓

3. Flowchart ✓

4. Introduction ✓

5. Scope ✓

6. Definitions ✓

7. Purpose ✓

8. Duties ✓

9. Process ✓

10. Dissemination, storage and archiving (control) ✓

11. Training and other resource implications ✓

12. Audit, monitoring and review ✓

This section should describe how the implementation and impact of the policy will be monitored and audited and when it will be reviewed. It should include timescales and frequency of audits. It must include the monitoring template as shown in the policy template (example below).

Monitoring Compliance Template						
Minimum Require-ment	Process for Monitoring	Responsible Individual/ group/ committee	Frequency of Monitoring	Review of Results process (e.g. who does this?)	Responsible Individual/group/ committee for action plan development	Responsible Individual/group/ committee for action plan monitoring and implementation
A) Describe which aspect this is monitoring?	e.g. Review, audit	e.g. Education & Training Steering Group	e.g. Annual	e.g. Quality Assurance Committee	e.g. Education & Training Steering Group	e.g. Quality Assurance Committee

✓

13. Implementation plan

14. Links to other policies (associated documents) ✓

15. Contact details ✓

16. References ✓

17. Version control and amendment log (Appendix A) ✓

18. Dissemination Record (Appendix B) ✓

19. Equality Impact Assessment Form (Appendix C) ✓

20. Human Rights Act Assessment Checklist (Appendix D) ✓

21. Policy development and consultation process (Appendix E) ✓

22. Policy Checklist (Appendix F) ✓

Appendix G – Red-Amber-Green definitions

	Date Lead Group & Lead Individuals notified	Date relevant assessment submitted to CEG	Date action plan submitted to CEG	Current status of action plan	Date action plan closed by CEG	Risk to quality of care
Red	>2 weeks since CEG	>4 months since notification	>4 months since relevant assessment	All actions delayed – limited progress made	Exceeded original timeframe by >2 months	High
Amber	>1 week, <2 weeks since CEG	>3 months, <4 months since notification	>3 months, <4 months since relevant assessment	Some actions delayed OR update not provided by LG	Exceeded original timeframe by <2 months	Medium
Green	Within 1 week of relevant CEG	Within 3 months of notification	Within 3 months of relevant assessment	All actions on track for completion	Within original expected timeframe	Low
Inclusion in the exception report to CEG	Any instance of Red or Amber	Any instance of Red or Amber	Any instance of Red or Amber	Any instance of Red or Amber	Any instance of Red or Amber	N/A
Inclusion in the exception report to EDG	The number of instances of Red	The number of instances of Red	The number of instances of Red	The number of instances of Red	The number of instances of Red	The number of instances of each