Cumbria Partnership
NHS Foundation Trust

Policy Title: NICE (Clinical Effectiveness) (CPFT)

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Policy On A Page

SUMMARY & AIM

This policy sets out the Trust processes for the implementation of NICE guidance.

Cumbria Partnership NHS Foundation Trust is committed to providing safe and effective care to its local communities. Using its skills, knowledge and expertise, the Trust aims to provide high quality, evidence-based care to the people of Cumbria, to promote and improve health and wellbeing according to clinical need.

TARGET AUDIENCE:

NICE guidance applies to anyone who is engaged in the planning, delivery, and monitoring of patient care and services, including clinical and non-clinical staff, partner organisations, students, volunteers, patients, service users and carers.

TRAINING:

Training has been provided and is available to NICE Leads, those appointed to undertake a guidance assessment or those with an overarching governance role relating to NICE Guidance

KEY REQUIREMENTS

This policy aims to provide assurance to the Board, Trust members and the public that the Trust has a clear process in place to ensure that best practice as defined in NICE guidance and quality standards is taken into account in the context of our services.

Implementation of NICE guidance is an integral part of the Trust's Quality Governance approach through the central Quality, Safety and Safeguarding (QSS) Team functions to support Care Groups around safety, effectiveness and learning lessons.

All clinical and non-clinical staff must take the necessary action and change practice as required to comply with ratified guideline assessment decisions.

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1. INTRODUCTION

NICE's role is to improve outcomes for people using the NHS and other public health and social care services by:

- Producing evidence based guidance and advice for health, public health and social care practitioners.
- Developing quality standards and performance metrics for those providing and commissioning health, public health and social care services.
- Providing a range of informational services for commissioners, practitioners and managers across the spectrum of health and social care. (NICE, 2016)

The Trust is expected to ensure that agreed best practice as defined in NICE guidelines is taken into account in the context of the clinical service we provide (NHSLA, 2012).

A Care Quality Commission (CQC) Inspection Manual key line of enquiry for effectiveness prompt states “How are relevant and current evidence-based guidance, standards, best practice and legislation identified and used to develop how services, care and treatment are delivered? (This includes from NICE and other expert professional bodies).” (CQC, 2014)

The NHSLA and CQC elements emphasise the requirement for Trusts to remain aware of all guidance and assess themselves against it.

The benefits of implementing NICE guidance include:

- Health organisations are helped to meet requirements set out in the NHS Constitution and the Health and Social Care Act 2012 (Section 8)
- Sharing information on comparisons against NICE recommendations demonstrates a culture of candour
- Using NICE guidance may help cut costs, while simultaneously maintaining and improving services, through costing tools to estimate local costs
- Using NICE guidance and quality standards can help meet CQC regulatory requirements
- Service users and carers receive care in line with the best available evidence of clinical and cost effectiveness, building confidence in services that are consistently evidence based
- Effective targeting of resources and efforts at the areas that offer the most significant health improvement
- Meet Litigation Authority (NHSLA) risk management standards and benefit from reduced claims and risk management premiums
- NHS Improvement and CQC Evidence
- Assist organisations with forward planning for service provision and commissioning, reflecting national priorities set by NHS England and Department of Health

2. PURPOSE

Cumbria Partnership NHS Foundation Trust is committed to providing safe and effective care to its local communities. Using its skills, knowledge and expertise, the Trust aims to provide high quality, evidence-based care to the people of Cumbria, to promote and improve health and wellbeing according to clinical need. This policy aims to provide assurance to the Board, Trust members and the public that the Trust has a clear process in place to ensure that best practice as defined in NICE guidance and quality standards is taken into account in the context of our services.

3. POLICY DETAILS:

Implementation of NICE guidance is an integral part of the Trust's Quality Governance approach through the central Quality, Safety and Safeguarding (QSS) Team functions to support Care Groups around safety, effectiveness and learning lessons.

3.1 Definitions

The following terms are used in this policy:

3.1.1 The National Institute for Health and Clinical Excellence (NICE)

The National Institute for Health and Care Excellence (NICE) is a Non Departmental Public Body (NDPB), as set out in the Health and Social Care Act 2012, and as such NICE is accountable to the Department of Health, but operationally is independent of government. NICE provides national guidance and advice to improve health and social care.

3.1.2 NICE Guidance

NICE produces the following types of guidance:

- Clinical guidelines: recommendations, based on the best available evidence, on the appropriate treatment and care of people with specific diseases and conditions.

- Public health guidelines: recommendations for populations and individuals on activities, policies and strategies that can help prevent disease or improve health.

- 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. They do this by making recommendations about best practice, drawn from current evidence-based research.

- Safe staffing guidelines: guidelines on safe staffing capacity and capability in the NHS

- Medicines practice guidelines: recommendations for good practice for those individuals and organisations involved in governing, commissioning, prescribing and decision-making about medicines.

- Technology appraisal guidance: recommendations on the use of new and existing medicines and treatments within the NHS.

- Interventional procedures guidance: procedures used for diagnosis or for treatment that involves making a cut or a hole to gain access to the inside of a patient's body, gaining access to a body cavity (such as the digestive system, lungs, womb or bladder) without cutting into the body or using electromagnetic radiation (which includes X-rays, lasers, gamma-rays and ultraviolet light).

- Medical technologies guidance: helps the NHS adopt medical technologies more rapidly and consistently by advising on efficacy and cost effectiveness.

- Diagnostics guidance: recommendations on the efficacy and cost effectiveness of new diagnostic technologies.

- Highly specialised technologies guidance: recommendations on the use of highly specialised technologies.

3.1.3 NICE Quality Standards

NICE quality standards are different from NICE guidelines. They 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. Derived from the best available evidence such as NICE guidance and other evidence sources accredited by NHS Evidence, they are developed independently by NICE, in collaboration with the NHS and social care professionals, their partners and service users, and address three dimensions of quality: clinical effectiveness, patient safety and patient experience.

3.1.4 NICE Support Resources

NICE Online

The NICE website is the hub for all information, including support and advice, guidelines, quality standards, evidence searches, British National Formularies, pathways and savings and productivity products. All guidance can be easily searched and downloaded, including associated tools such as the baseline assessments. The website address is www.nice.org.uk

NICE also has a social media presence with Twitter, YouTube, LinkedIn and Facebook accounts to further engage with people and as additional means to provide information and contact links.

Into Practice Guide

NICE provide an 'Into Practice Guide' which gives practical advice for staff on how to use their guidance and quality standards to achieve high quality care. It is also aimed at anyone who is leading on implementing a specific piece of guidance, or using a quality standard to improve quality across a team or service. In health, these people may include:

- NICE leads and clinical governance staff
- board members and lead clinicians (for example, medical directors, clinical directors and directors of nursing)
- clinicians who have a clinical governance responsibility as a major part of their role (for example, nominated directorate clinical governance leads)
- clinical teams working together to ensure a piece of NICE guidance is implemented into everyday practice, or a quality standard is used to drive improvements in care
- commissioners of NHS services, such as clinical commissioning groups (CCGs).

The Trust built its approach to NICE implementation around this guide, which is available on the NICE website via this link: https://www.nice.org.uk/about/what-we-do/into-practice/resources-help-put-guidance-into-practice

Implementation Consultants

NICE has a field-based team of implementation consultants who work with organisations to help to put our guidance into practice. Each consultant works with NHS, local authority and other organisations in their area, ensuring regular interaction with NICE stakeholders. Our Trust maintains links with the Implementation Consultant for the North of England.

3.1.5 Evidence Search

Evidence search is a free online search facility supporting the needs of frontline staff situated on the NICE website. Sources searched include the British National Formulary, Clinical Knowledge Summaries, SIGN, the Cochrane Library and Royal Colleges, Social Care Online and GOV.UK. It provides access to selected and authoritative evidence in health, social care and public health through:

- combining evidence on health, drugs and technologies, public health, social care, and healthcare management and commissioning in one place
- bringing together high quality consolidated and synthesised evidence from hundreds of trusted sources.
- including guidance, systematic reviews, evidence summaries and patient information.

3.1.6 The NHS Litigation Authority (NHSLA)

The NHS Litigation Authority (NHSLA) is a Special Health Authority set up to handle negligence claims and to improve risk management practices in the NHS. The NHSLA

risk management programme is provided by a range of NHSLA standards and assessments against these standards.

3.1.7 Care Quality Commission (CQC)

The Care Quality Commission (CQC) is an independent regulator of health and social care in England. (www.cqc.org.uk)

3.2 Pathway for the implementation of nice guidance and quality standards

3.2.1 Process for maintaining Trust awareness of published NICE guidance

The Clinical Effectiveness and Audit Facilitators monitor the NICE website on a daily basis, as well as taking account of the multiple sources for NICE guidance information, including, but not limited to:

- the monthly NICE newsletter
- the forward planner
- NICE emails received as a registered stakeholder for the Trust
- The NICE Twitter account

All new, updated and superseded guidance information is captured by the Clinical Effectiveness and Audit Facilitators within the Trust NICE database to ensure an accurate picture of the current NICE guidance.

The Clinical Effectiveness and Audit Facilitators continually provides information and reports to the Care Groups and Networks via the NICE SharePoint site. These reports are routinely updated, replacing previous versions with new, updated and superseded guidance being incorporated when known.

3.2.2 Process for identifying Trust relevant guidance

The Clinical Effectiveness and Audit Facilitators provide Care Group and Network 'Relevancy Checks Required' Excel documents for each Care Group, placing these on the applicable section of the NICE SharePoint site. NICE Leads review and complete these, either individually or through a meeting organised to undertake this process, and email the document with the decisions to the NICE Inbox to be incorporated into the NICE database. The information required for each piece of guidance includes:

- A relevancy decision for the Care Group
  NICE Leads must decide if each published guideline applies to any area of the services and care provided to the Care Group. This is done through reviewing the guidance document itself and the accompanying assessment tools, such as the baseline assessment. If a single recommendation applies to the area in question then the piece of guidance should be considered as relevant. Three choices exist:
    - Yes – the guidance must be assessed
    - No – nothing further is required
    - Info – the guidance doesn't directly relate to our services, but is worth circulating for information purposes only

- An overall RAG (Red, Amber, Green) rating for the Care Group
  Where a guideline does apply an overall Care Group RAG rating is applied to help prioritise the workload.

- A relevancy decision for the Networks
  As with the Care Group decision, the same decisions need to be recorded for the respective Networks with 'yes', 'no' and 'info'.

- A RAG rating for the Networks
  Where a guideline does apply a Network RAG rating is applied to help prioritise the workload.

- A guideline lead or leads
  A guideline lead or leads needs to be appointed for each relevant piece of guidance, at either Care Group or Network level according to the preferred Care Group approach. This person needs to be contacted by the NICE Lead to inform them of the reasons around their appointment and how to undertake the required work. Further support is also available through the Clinical Effectiveness and Audit Facilitators and / or NICE training.

The Care Groups have decided on slightly different approaches to achieve this requirement, but the fundamental elements listed above are required.

It is worth noting that Care Groups may record some guidance as not applicable or for information only that is relevant to the Trust, but does not fall to a specific Care Group or Network. This is guidance better assessed via central teams or directorates with overall responsibility, such as Pharmacy, Safeguarding, Infection Prevention or Workforce and Organisational Development. For these Trust-wide and non-Care Group specific pieces of guidance the same approach of relevancy checking, lead appointment and assessment apply through liaison with the Clinical Effectiveness and Audit Manager and / or the Clinical Effectiveness and Audit Facilitators with the relevant Leads and or Heads.

3.2.3 Process for providing relevant guidance document and tools

Once leads are appointed to lead on the assessment of a piece of NICE guidance and this information is provided via the NICE Inbox, the Clinical Effectiveness and Audit Facilitators provide, by email, the guideline and primary assessment tool to use, typically the baseline assessment or Quality Standards Service Improvement Template (QSSIT), along with the NICE Guidance Pathway (Appendix 1) and the Quick Reference Flow Chart (Appendix 2) to guide process.

Other NICE guidance tools of interest and available via the NICE website for specific guidelines include:

- Case scenarios
- Case studies
- Checklists
- Clinical audit tools
- Costing reports
- Costing templates

- Do not do recommendations
- Educational resource
- E-learning modules
- Research aspects
- Shared learning information
- Slide sets

These tools vary between individual pieces of guidance, but exist to help put the guidance into practice rather than undertaking the assessment of our Trust position against the guidance.

3.2.4 Process for assessing relevant NICE guidance

The assigned lead or leads for a piece of NICE guidance need to use, where available, the assessment tool produced by NICE for each piece of guidance. Generally this is the baseline assessment tool of QSSIT for a Quality Standard.

The guideline lead is expected to undertake the guidance assessment and provide it to the Clinical Effectiveness and Audit Facilitators, enabling a 'sense check' for any missed recommendations and sections of the assessment before going forward in the process.

NICE Leads for the respective Care Groups or Networks are there to provide support to guideline leads, as well as the support available through the Clinical Effectiveness and Audit Facilitators and Clinical Effectiveness and Audit Manager.

3.2.5 Process for ratifying the completed baseline assessments

Assessed guidance needs to be ratified by the appropriate committee ideally within 6 months of the publication date (or a set work plan schedule for historical guidance assessment evidence according to priority). Committees are deemed appropriate provided that there are the right people around the table to review and ratify the assessment findings, actions required, identified leads and timescales.

Ratification is the sign off of the assessment by senior Trust staff and requires understanding of the aspect of care involved, recommendation relevancy decisions, evidence for relevant recommendations, findings identified and specific and measurable (SMART) actions required to address any potential issues outlined. Typically the clinician/s undertaking the assessment presents it to the appropriate committee.

Care Groups have opted for different approaches to this, but ratifying committees include, but are not excluded to, the following:

- Trust-wide Clinical Governance Group
- Care Group Clinical Governance Groups
- Care Group meetings specifically covering NICE and Clinical Audit
- Network Clinical Governance Groups
- Other Central Group Committees relevant to the topic

Evidence of ratification, including the code, title, discussion and decision, must be captured in the meeting minutes in line with the ratification guide table and provided to

the NICE Inbox to ensure the database is updated and the final actions are captured for monitoring and reporting of implementation. An excerpt of the minutes is also acceptable as evidence.

Please refer to the ratification guide (Appendix 2) for further information.

3.2.6 Process for ensuring that actions are implemented across the organisation

Lists of ratified actions are provided by the Clinical Effectiveness and Audit Facilitators to Care Groups and Networks via SharePoint. These are to support Care Group and Network Committees, supported by the respective NICE Leads, to monitor the progression of ratified actions in line with the stipulated completion deadlines and to take action to ensure overdue actions happen.

Actions can only be signed off and considered completed when the evidence of implementation has been emailed to the NICE Inbox for verification. Once verified by the Clinical Effectiveness and Audit Facilitators the evidence is saved in the relevant NICE folders and the database updated to reflect this.

The named persons for each person at the point of ratification are responsible for implementation, along with the NICE Lead and Clinical Governance Groups for the respective Care Group or Network.

3.2.7 Process for documenting any decision to deviate from NICE guidance recommendations

NICE guidelines are essentially only guidelines rather than mandatory requirements to be followed. Although the Trust aims to ensure that it assesses and is compliant with the guidance and the recommendations contained there will inevitably be occasions when a decision to deviate from the guideline occurs or, for other reasons, such as facilities or external funding, as a Trust we are unable to comply with the guidance. On these occasions as part of the assessments this needs to be clearly stated along with the reasons for deviation or non-compliance. Also, the action needs to be to add these non-compliant recommendations, including NICE guidance code, title and specific recommendation number and description, need to be added to the Risk Register by the Care Group or Network, stating a person responsible for doing so. This ensures that the deviation or non-compliance will, as a minimum requirement, be considered annually by the appropriate area.

Additionally, areas of non-compliance due to facilities or external funding can be used to help build cases for further funding or investment accordingly by the Care Groups or Networks, although not a requirement of the NICE implementation process.

4. TRAINING AND SUPPORT

There is no mandatory training in relation to this policy.
Training has been provided and is available to NICE Leads, those appointed to undertake a guidance assessment or those with an overarching governance role relating to NICE Guidance upon request to the Clinical Effectiveness and Audit Manager.

5. PROCESS FOR MONITORING COMPLIANCE

The process for monitoring compliance with the effectiveness of this policy is as follows:

Aspect being monitored	Monitoring Methodology	Reporting		
		Presented by	Committee	Frequency
All aspects set out in this policy.	Covered through the bi-annual Care Group NICE Assurance Reports incorporating database information and narrative, as well as the annual Trust Assurance Report to the Quality and Safety Committee	Clinical Effectiveness and Audit Manager	Clinical Effectiveness and Audit Committee (CEAC) / Quality and Safety Committee (QSC)	Annually

6. REFERENCES:

NHSLA (2012) NHSLA Risk Management Standards 2012-13 for NHS Trusts providing Acute, Community, or Mental Health & Learning Disability Services and Non-NHS providers of NHS care, London.

7. ASSOCIATED DOCUMENTATION:

Clinical Audit Policy CO/POL/001/069

8. DUTIES (ROLES & RESPONSIBILITIES):

8.1 Chief Executive / Trust Board Responsibilities:

The Chief Executive and Trust Board jointly have overall responsibility for the strategic and operational management of the Trust, including ensuring that Trust policies comply with all legal, statutory and good practice requirements. Ultimate responsibility for the assessment, implementation and monitoring of NICE guidance falls to the Chief Executive, but is devolved to the Director of Quality and Nursing.

8.2 Executive Director Responsibilities:

All policies have a designated Executive Director and it is their responsibility to be involved in the development and sign off of the policies, this should ensure that Trust policies meet statutory legislation and guidance where appropriate. They must ensure the policies are kept up to date by the relevant author and approved at the appropriate committee. The Director and Deputy Director of Quality and Nursing have Board-level responsibility for the implementation of NICE guidance in the organisation.

8.3 Board of Directors

The Board of Directors has overall accountability for the dissemination, implementation and monitoring of NICE guidance. The Board receives regular reports from the Quality and Safety Committee on key areas of assurance, including the implementation of NICE guidance.

8.4 Head of Clinical Governance

The Head of Clinical Governance is responsible for ensure that NICE guidance continues to operate as an integral part of the wider Quality, Safety and Safeguarding Team with spanned shared learning.

8.5 Clinical Effectiveness and Audit Manager

The responsibilities of the Clinical Effectiveness and Audit Manager include:

- Maintaining oversight of NICE Guidance across the organisation
- Shaping the NICE guidance approach across the organisation
- Ensuring the Trust remains in line with national approaches and requirements for NICE guidance implementation
- Remaining aware of the national picture for NICE guidance, including current guidance, forthcoming guidance and recommended guides and practices for ensuring implementation
- Ensuring evidence is available to demonstrate the assessment, ratification and action implementation for NICE guidance in the Trust
- Managing the CEAC meetings, including setting agendas, work plans, SharePoint folders, circulation etc.
- Ensure bi-monthly NICE metrics are reported to CEAC to monitor the Trust position
- Attending the Care Group Clinical Governance Committee meetings
- Ensuring rolling representation at Network Clinical Governance Groups through the Clinical Effectiveness and Audit Team
- Ensuring reliable links between ratified NICE guidance assessments and registered clinical audit topics to address identified gaps as appropriate
- Maintaining links with the regional NICE Implementation Consultant
- Attending the regional NICE network meetings and national conference / forum
- Management and support of the Clinical Effectiveness and Audit Facilitators for all elements pertaining to NICE guidance
- Support for managers and clinicians relating to NICE guidance
- Ensuring NICE information is made available to the Care Groups and Networks
- Ensuring NICE training is available within the Trust
- Preparing Trust-wide NICE assurance reports, along with other ad-hoc report requests, for the Associate Medical Director of Quality to deliver to the QSC
- Writing and maintaining the Care Group level assurance report templates for CEAC assurance purposes
- Writing and maintaining the NICE / Clinical Effectiveness Policy

8.6 Clinical Effectiveness and Audit Facilitator

The role of the Clinical Effectiveness and Audit Facilitator is to:

- Remain aware of the national picture for NICE guidance, including current guidance, forthcoming guidance and recommended guides and practices for ensuring implementation
- Develop and maintain the Trust NICE database to ensure the ability to provide detailed information for all stages of the NICE process to the Clinical Effectiveness and Audit Manager, CEAC, NICE Leads, Networks, Care Groups and other ad-hoc requests
- Collate all the information from NICE Leads, Networks and Care Groups to ensure the database remains up to date in terms of guidance relevancy, RAG rating, lead appointment, assessment progress, ratification and actions
- Ensure evidence of ratified actions is sufficient to demonstrate action implementation before marking actions as complete
- Provide regular information to all Care Groups and Networks for their Clinical Governance Committees using the NICE database
- Provide Clinical Effectiveness and Audit Facilitators with relevant NICE information to be imparted at Network level Clinical Governance Committees
- Update the NICE SharePoint site to reflect the latest Trust position with NICE and latest guidance
- Produce and circulate the Trust NICE Newsletter in collaboration with the Clinical Effectiveness and Audit Manager
- Provide NICE guidance training to clinicians appointed as leads for pieces of guidance in line with Trust need and available resource
- Monitor and maintain the NICE Inbox
- Be the first point of contact for clinicians on NICE

8.7 Service User and Carer (SUAC) Representatives on CEAC

SUAC Representatives attend the CEAC meetings and as such have oversight and input on the position of NICE guidance within the organisation. SUAC Representatives have a duty to raise any NICE related issues to the appropriate person, whether centrally, to Care Groups or both.

8.8 Governor Representatives on CEAC

Governor Representatives attend the CEAC meetings and as such have oversight and input on the position of NICE guidance within the organisation. Governor Representatives have a duty to raise any NICE related issues to the appropriate person, whether centrally, to Care Groups or both.

8.9 Clinical Lead for Clinical Effectiveness and Audit / CEAC Chair

The Clinical Lead for Clinical Effectiveness and Audit has the operational responsibility for the implementation of NICE and will ensure that the CEAC has agreed and implemented its Terms of Reference and annual programme of activity.

The Chair of the CEAC is also responsible for awarding Care Group level assurance based on bi-annual Care Group NICE Assurance Reports completed by the NICE Leads for their respective Care Groups.

8.10 Care Group Associate Medical Directors and Associate Directors of Nursing

Associate Medical Directors and Associate Directors of Nursing have overall responsibility for NICE guidance being assessed, ratified and actions implemented within their respective Care Groups, as well as being on the agenda at each tier of governance meetings.

8.11 Clinical Directors

Clinical Directors are responsible for ensuring that NICE guidance has been considered and helped guide the services and care provided, as well as ensuring that when Trust service provision changes that the latest NICE guidance is reviewed and adhered to accordingly.

8.12 Quality and Safety Leads

As NICE is a means of ensuring the delivery of consistent quality care and services, Quality and Safety Leads are effectively a conduit between the Care Groups, Networks, NICE Leads and central supporting roles to ensure any potential issues or solutions are raised appropriately.

8.13 NICE Leads

NICE Leads are appointed clinicians who have responsibility for NICE guidance in their respective Care Groups and / or Networks.

NICE Leads are appointed at either the Care Group and / or Network level. Their responsibilities generally remain the same, but at different levels. NICE Leads are responsible for:

- Relevancy assessing all current, new and updated NICE guidance for their respective Care Group or Network
- RAG rating of relevant guidance to prioritise the long term NICE work plan
- Appointing leads to undertake relevant guidance assessments, informing them of why they have been appointed and to clearly outline the requirements of the task
- To fully understand the NICE process and support clinicians designated as leads for specific NICE guidance in the required Trust process steps from assessment to ratification
- Monitoring all the guidance in their Care Group or Network remit and taking action to support and assist accordingly
- Ensuring all steps are fed back to the Clinical Effectiveness and Audit Facilitators via the NICE Inbox: NICE@cumbria.nhs.uk
- Reviewing completed guidance prior to it going for ratification
- Ensuring NICE guidance and ratified actions progress and complete
- Ensuring that relevant NICE guidance is disseminated to appropriate Networks and Teams in their Care Group / Networks
- Liaising closely with the Clinical Effectiveness and Audit Manager and the Clinical Effectiveness and Audit Facilitators for support and advice

- Care Group NICE Leads are required to attend the bi-monthly CEAC meetings to represent the Care Group for NICE. If unable to attend a deputy must be appointed.
- Care Group NICE Leads are required to write a six-monthly NICE Assurance Report for their Care Group and respective Networks using the latest Care Group NICE Assurance Report template. This is required the week before the meeting and needs to be presented by the NICE Lead at the CEAC meetings.
- To take action to increase / maintain assurance levels as appropriate following feedback from the CEAC

8.14 NICE Guidance Leads

Trust staff appointed to undertake an assessment of a piece of NICE guidance or quality standard are responsible for:

- Completing the assessment using the NICE tools available, such as baseline assessments or the Quality Standard Service Improvement Tool (QSSIT), including determining required actions to address possible gaps with deadlines and designated persons responsible for implementation
- Ensuring that the assessment incorporates the entire area they are undertaking it for. This is typically for a whole Network, Care Group or Trust-wide and varies according to Care Group or guidance subject.
- Liaising with their appointed NICE Lead to ensure the assessment is sufficient
- Submitting the draft assessment to the Clinical Effectiveness and Audit Facilitator prior to ratification for 'Sanity Checking' to identify any missed aspects, elements requiring further input or concerns around the specific requirements.
- Post 'Sanity Checking' to submit the final draft to the relevant and suitable clinical governance committee for ratification, potentially presenting the assessment in line with the respective Care Group or Network requirements.
- Informing the Clinical Effectiveness and Audit Facilitators of the progress of the assessment

8.15 Individual Staff Members

All clinical and non-clinical staff must take the necessary action and change practice as required to comply with ratified guideline assessment decisions.

All clinical staff have a responsibility to familiarise themselves with the NICE guidelines that are relevant to their role, apply and promote those guidelines consistently to ensure that nationally agreed best practice becomes embedded in the practice of all our clinical teams, and to report any instances of non-compliance to the guideline lead.

8.16 Central Heads of Departments

Central Heads of Departments that cover areas not sited within specific Care Groups have a responsibility to ensure that NICE guidance pertaining to their practice is considered and assessed accordingly. These areas include, but are not limited to Safeguarding, Infection Control and Medicines Management.

An example would be the Chief Pharmacist ensuring that medicine related Technology Appraisal guidance is assessed, acted upon and evidence provided to the NICE Inbox for the Clinical Effectiveness and Audit Facilitators to update the Trust NICE database.

8.17 Central Trust Directors

Central Directors are responsible for ensuring that NICE guidance that relates to their areas that encompass aspects wider than singular Care Groups, are considered and assessed, mirroring the approach for Care Groups. An example would be the Director of Workforce and Organisational Development ensuring that 'NG13: Workplace health: management practices' is assessed acted upon and evidence provided to the NICE Inbox for the Clinical Effectiveness and Audit Facilitators to update the Trust NICE database.

8.18 Trust Policy Authors

Authors of Trust policies have a responsibility to ensure that policies are based on evidence-based best practice and in particular on NICE and other national guidelines where these are available. The author of any new or amended Trust clinical policy will ensure that all relevant national guidelines are taken account of, and clearly referenced in the policy.

8.19 Trust Local Clinical Guideline Authors

Authors of Trust local clinical guidelines have a responsibility to ensure that they consider relevant NICE guidance when creating, reviewing, updating or amending them, along with other available guidance, such as from Royal Colleges.

8.20 Quality and Safety Committee (QSC)

The QSC awards assurance levels for NICE Guidance at a Trust-wide level, ranging from full to no assurance.

The QSC receives Trust-wide reports from the Clinical Effectiveness and Audit Manager, presented by the Associate Medical Director of Quality, the frequency of these being determined by the Trust-wide assurance level attained, typically annually if full or significant assurance is awarded and more frequently if limited or no assurance is awarded as determined by QSC.

8.21 Trust-wide Clinical Governance Group

The Trust-wide Clinical Governance Group is chaired by the Associate Medical Director and is the escalation route for highlight reports to go to from CEAC in order to ensure that the issue is discussed with suitable senior representation from all Care Groups.

8.22 Clinical Effectiveness and Audit Committee (CEAC)

The CEAC is a sub-committee of the QSC, and links with the following groups and committees:

- Quality and Safety Committee – assurance reporting route
- Trust-wide Clinical Governance Group – escalation route
- Audit Committee – oversight of clinical audit and related internal audit actions
- Care Group Clinical Governance Groups / Central Directorates – links maintained via NICE Leads and circulation to non-attending membership of senior roles
- Service Users and Carers – via attending SUAC representatives
- Governor's Council – via an attending Trust Governor
- Medicines Management Committee – links maintained via Chief Pharmacist

The principal functions for NICE of the CEAC are:

- To seek assurance from Care Groups / Networks and Trust-wide services that robust systems are in place to support NICE
- To seek assurance on engagement of clinicians in NICE implementation
- To review and agree the annual relevance assessment of forthcoming NICE guidelines and Quality Standards
- To seek assurance from Care Group / Network Clinical Governance Meetings that appropriate action has been taken in response to all relevant NICE guidelines and Quality Standards
- To monitor NICE Guidance and Quality Standards Metrics
- To review and agree plans to monitor NICE guidance and Quality Standards activity
- To review the annual NICE elements for the Quality Report
- To review and agree the Trust's NICE (Clinical Effectiveness) Policy
- To ensure that NICE activity meets the required standards of external bodies (Care Quality Commission, NICE Into Practice Guide, HS England, Department of Health).

The function of the CEAC for NICE are:

- To ensure clinical effectiveness tools are used to improve the quality of care for service users and carers
- To encourage clinical effectiveness to be valued by individuals throughout the organization
- To review and ratify the Trust's NICE implementation policy and monitor adherence to it
- To oversee the dissemination, recommendation of relevance and monitoring of actions identified with NICE guidance and Quality Standards
- To seek assurance from the Medicines Management Committee that medicine related Technology Appraisals have evidence of review within 3 months of publication (Legal requirement)
- To seek assurance from the Safeguarding Committee and Infection Control Committee that relevant NICE Guidelines and Quality Standards are being assessed Trust-wide
- To seek assurance that robust systems are in place to support NICE implementation across the Trust
- To seek assurance on engagement of clinicians in NICE guidance and Quality Standards
- To remain abreast of NICE development and approaches

- To support Care Groups and Networks
- To be assured of training for staff, CEAC members and Service User and Carer representatives
- To escalate issues to the Trust-wide Clinical Governance Group

The CEAC may delegate its duties and commission working groups, or task & finish groups, to drive forward specific NICE implementation activity and projects.

8.23 Care Group Clinical Governance Committees

Responsibilities at the Care Group level include:

- Ensuring that NICE is a fixed agenda item and discussed at all Care Group Clinical Governance Committees and, dependent on individual Care Group structure, in detail at the devolved Care Group level meetings to discuss NICE and clinical audit
- Ensuring that the monthly NICE information is monitored and any concerns acted upon, including:
    - Relevancy decisions
    - RAG rating
    - Lead appointments
    - Assessment progression
    - Ratification requirements
    - Resulting action implementation
- Ensuring that completed NICE guidance assessments are ratified at the appropriate committee with suitable staff present to fulfil this stage of the process in line with the NICE Ratification Guide (Appendix 1)
- Recording the guidance code, full title, ratification discussion and decision in the minutes and sending these, or an excerpt of them, to NICE@cumbria.nhs.uk for evidence of ratification
- To ensure NICE guidance and assessments are shared with suitable Networks and Teams where appropriate, as well as possible sharing with other Care Groups with a shared interest

8.24 Network Clinical Governance Committees

Responsibilities at the Network level include:

- Ensuring that NICE is a fixed agenda item and discussed at all meetings so that NICE guidance is embedded in the clinical work
- Ensuring that the monthly NICE information is monitored and any concerns acted upon, including:
    - Relevancy decisions
    - RAG rating
    - Lead appointments
    - Assessment progression
    - Ratification requirements
    - Resulting action implementation

- Ensuring that completed NICE guidance assessments deemed suitable for Network level ratification are ratified with suitable staff present in line with the NICE Ratification Guide (Appendix 1)
- Recording the guidance code, full title, ratification discussion and decision in the minutes and sending these, or an excerpt of them, to NICE@cumbria.nhs.uk for evidence of ratification
- To ensure NICE guidance and assessments are shared with appropriate teams, as well as possible sharing with other Networks with a shared interest

8.25 Team Clinical Governance Meetings

To ensure that NICE Guidance aspects are discussed to ensure learning and understanding of agreed practices in line with the ratified guidance assessment.

8.26 Medicines Management Committee

The Medicines Management Committee has responsibility for ensuring that NICE Technology Appraisal Guidance relating to medicines are relevancy assessed for the Trust, specifying which Care Groups and Networks they are relevant to, ensure relevant guidance is considered, provides minutes as evidence of assessment / ratification including required actions, ensure this information is shared with the Clinical Effectiveness and Audit Facilitators via NICE@cumbria.nhs.uk for input into the NICE database and maintaining links with the Clinical Effectiveness and Audit Manager and the CEAC through the Chief Pharmacist and / or Principal Pharmacist - Governance and Medicines Safety role/s.

8.27 Approving Committee Responsibilities:

The Chair of the approving committee will ensure the policy approval is documented in the final section of the Checklist for Policy Changes. The committee will agree the approval of the final draft of the policy.

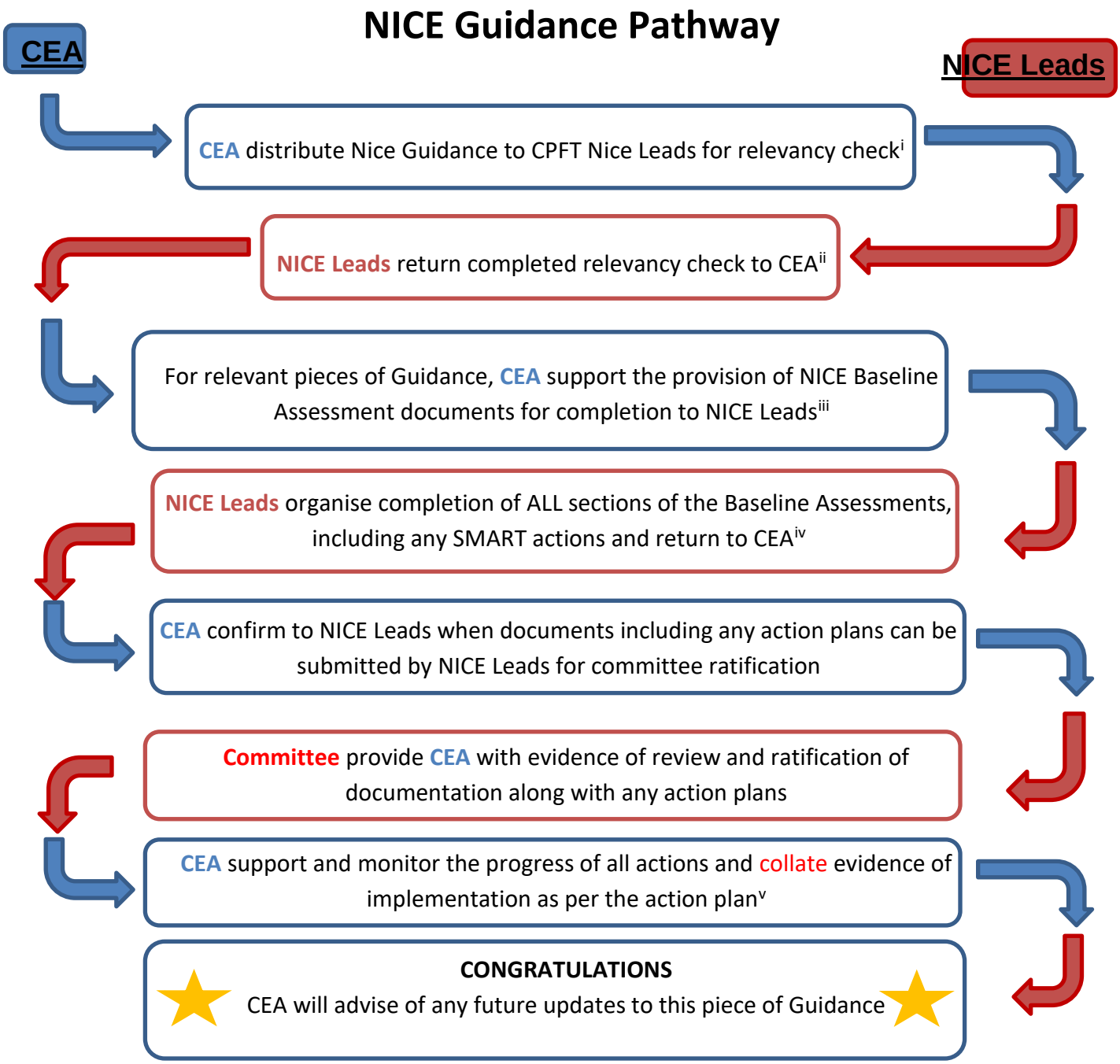
9. ABBREVIATIONS / DEFINITION OF TERMS USED

Keep lists in alphabetical order

ABBREVIATION	DEFINITION
CQC	Care Quality Commission
NHSLA	NHS Litigation Authority
NICE	The National Institute for Health and Clinical Excellence

TERM USED	DEFINITION
-	-

APPENDIX 1 – NICE GUIDANCE PATHWAY 1:



Notes:

i – The Clinical Effectiveness and Audit (CEA) Team will email NICE Guidance, along with a relevancy spreadsheet for completion, to Cumbria Partnership Foundation Trust (CPFT) NICE leads for clarification of relevancy. Relevancy = 'Yes', 'No' or 'Info'. Where 'Yes' is selected, these pieces of guidance are to be RAG rated 'Red' (high priority), 'Amber' (medium priority) or 'Green' (low priority).

ii – NICE Leads to complete and return relevancy spreadsheet via email to nice@cumbria.nhs.uk

iii – Completion of a Baseline Assessment will count towards evidence of continuing professional development (CPD) for medical and nursing staff. CEA can provide individuals who fully complete a Baseline Assessment with a letter confirming this for their CPD portfolio.

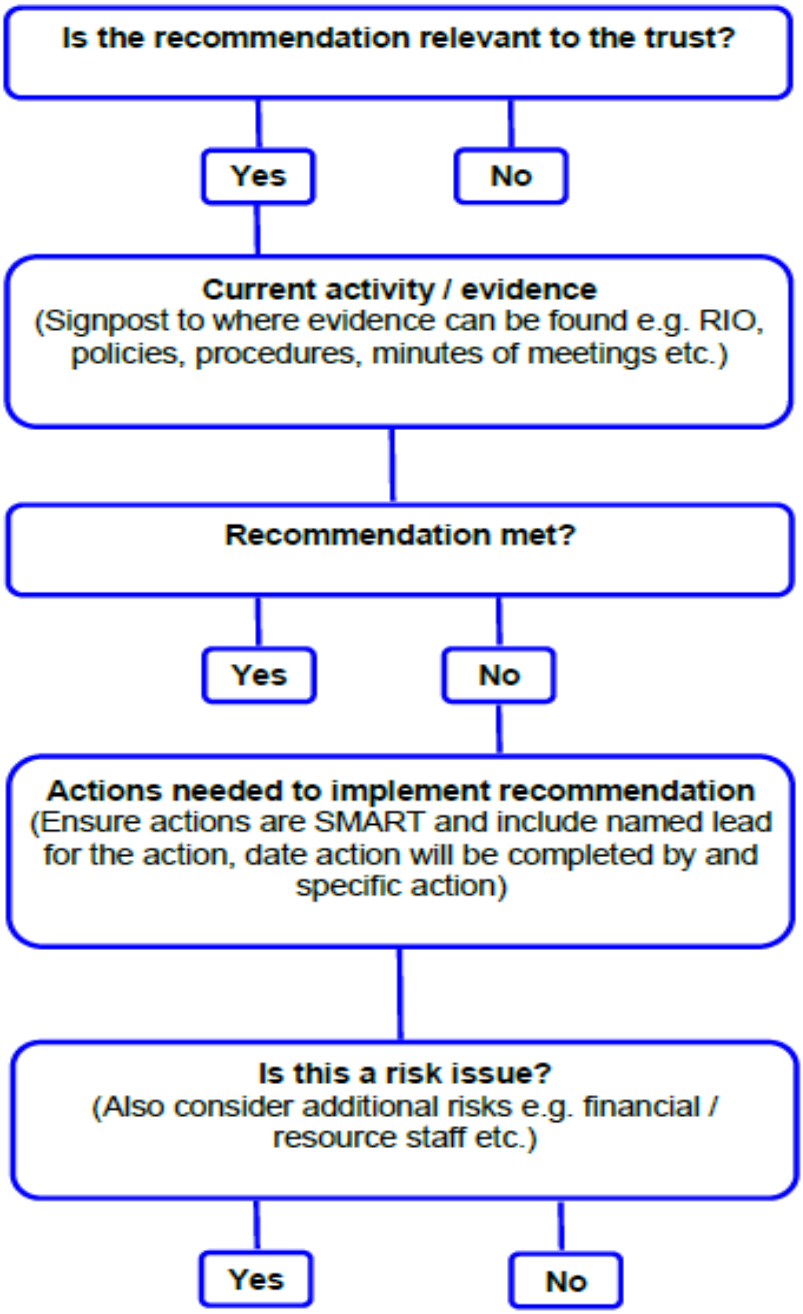
iv – ALL sections of the Baseline Assessment must be completed. Where full compliance is not met, SMART actions must be set to enable compliance, clearly identifying the following:-

1. Specific action
2. Named person responsible for overseeing the action
3. Realistic due date for completion of action (this is not flexible unless in exceptional circumstances)
4. Format that the evidence that will be provided once the action has been met (e.g. minutes of meeting, evidence of registered audits etc.)

v – Care Groups and Networks have the option to deviate from elements of NICE Guidance provided, that as part of the assessment, the reason for this is stated. Where NICE Guidance is deviated from and has an associated risk, this risk requires to be added to the risk register by the Care Group or Network.

APPENDIX 2 – QUICK REFERENCE FLOW CHART:

Quick Reference Flowchart for Completing NICE Guidance Baseline Assessments



APPENDIX 3 – RATIFICATION GUIDE FOR CLINICAL EFFECTIVENESS (NICE) GUIDANCE:

Ratification Guide for Clinical Effectiveness (NICE) Guidance

Cumbria Partnership Foundation Trust

Robert Donlevy – Clinical Effectiveness and Audit Manager

July 2018

Scope

This guide is intended to support Cumbria Partnership Foundation Trust Care Group and Network committees to ratify completed clinical effectiveness guidance.

Definition

Ratification has several definitions attributable to a clinical governance process:

- To approve and give formal sanction to; confirm
- making something valid by formally ratifying or confirming it; "the ratification of the treaty"; "confirmation of the appointment"
- An act of confirming officially

Outline

Ratification is an important element of any clinical governance approach.

Ratification is required at the point after a NICE assessment has been completed and is the means by which a Network, Care Group or other appropriate committee can review, alter and / or agree and officially sign off a final version of an assessment in hand, including the proposed actions contained.

Without having a ratification stage as part of a clinical governance process there is potentially a lack of control as NICE guidance assessments contain actions to address any issues identified. These actions need to be agreed as correct, realistic and achievable. Without ratification in place there is the potential to start following an inappropriate path, which itself could be the view, or even an agenda, of just an individual or team.

Clinical Effectiveness (NICE) Guidance Types

The National Institute for Health and Care Excellence (NICE) publish clinical effectiveness guidance, among other elements of their work. To reach the point of ratification as a Trust we will have first identified which guidance is relevant to us, RAG rated for a priority status, appointed a lead and set a start date. Assessing with the tools provided enables the Trust to assess our care in line with the guidance, or deviate from the guidance with an explanation of why, as well as identifying areas of required improvement and determining addressing actions.

There are various types of NICE Guidance currently in existence:

- Clinical Guidelines
- Public Health Guidelines
- Social Care Guidelines
- Safe Staffing Guidelines
- Medicines Practice Guidelines
- Technology Appraisal Guidance
- Interventional Procedures Guidance
- Medical Technologies Guidance
- Diagnostics Guidance
- Highly Specialised Technologies Guidance

NICE also produce Quality Standards, which are not guidelines as such, but combine elements of published guidelines, and still require assessment, sometimes utilised by Clinical Commissioning Groups as evidence of improvement activities.

Further information is available via the NICE site: http://www.nice.org.uk/

Ratification Documentation and Completion Approach

NICE are continually improving and altering their supporting documentation, but essentially there will be the guidance itself available, as well as a supporting Excel assessment tool. For the most commonly used guidance, such as Clinical Guidelines, this is known as the baseline assessment. Other types of guidance may have other pre-built assessment tools to use too. Each baseline assessment can be downloaded from the NICE site from the 'Tools and resources' tab against each specific guideline.

Where a pre-built tool is not available, as is the case for older guidance that is still live, a member of the Clinical Effectiveness and Audit Team will construct the tool and provide as required.

Essentially it is the 'Data sheet' part of each clinical guideline baseline assessment that needs to be completed and ratified, rather than an additional report document.

Each data sheet contains a number of recommendations with the same eight simple and straight-forward elements to consider:

1. Is the recommendation relevant?
   This needs to be completed without exception with either 'Yes' – indicating it is relevant, 'No' – indicating it is not relevant or 'Info' – indicating that although it is not relevant, but that it is of interest to know.

From this point onwards the following only have to be completed if the recommendation is deemed relevant.

2. Current activity / evidence
   If an element is relevant this section needs to record

3. Recommendation met? - Yes or no.
4. Actions needed to implement recommendation - List any actions needed to meet each recommendation
5. Is there a risk associated with not implementing this recommendation? State yes and further detail or state no
6. Is there a cost saving? - State yes and further detail or state no
7. Deadline - State the date of the deadline
8. Lead - State a named lead to implement each action

A NICE 'sense check' is a support measure offered by the Clinical Effectiveness and Audit Team, via NICE@cumbria.nhs.uk, to ensure that all elements have been addressed as part of undertaking the assessment prior to going for ratification, as well as checking that the actions are SMART. This needs to have happened before a guideline goes forward to ratify by committee.

Appropriate Committees to Ratify

As part of the initial assurance process following the Trust restructure in 2014/15 the newly formed Care Groups were asked to outline their structures for clinical effectiveness to the Clinical Effectiveness and Audit Committee (CEAC). Having the appropriate Care Group structures in place remains an element of the Care Group assurance to the CEAC process.

As the structures of each Care Group are unique and self-determined, it also falls to Care Groups to decide which committee / committees will ratify, but essentially ratification needs the right people around the table. Options include:

- The Care Group Clinical Governance Group to keep a senior central level of authority
- The Individual Network Clinical Governance Groups to ensure that the most relevant clinicians and staff are present at the care specific level
- At a Care Group meeting specifically set up to cover Clinical Effectiveness and Clinical Audit ensuring appropriate authority and expertise while keeping the Care Group / Network committees mainly free of these necessary, but time consuming requirements
- Or via other meeting approaches as yet to be determined

Occasionally there will be Trust-wide guidance assessments to review which encompass more than that of an individual Care Group. These assessments may need to be ratified at the Trust-wide Clinical Governance Group or at a separate appropriate senior committee. An example of this could be a NICE Guideline on staff wellbeing being covered by Workforce and OD or the majority of Technology Appraisals that are drug related and need a Trust-wide Medicines Management review.

Ratification Process

Whichever committee has the responsibility to ratify an individual completed clinical audit report the process remains essentially the same, as does ensuring those with the right seniority and knowledge are present to take the decision.

Some Care Groups have requested that the clinician/s who undertook the assessment present the assessment to ensure that questions / concerns can be answered there and then. This can be simply talking through the paper or using slides specifically for this.

The ratifying committee needs to review the assessment document and consider the following:

- Are there any gaps in the data, i.e. where a recommendation is relevant, but further information is not present or where cells have been left blank
- Do you agree with the relevant and not relevant recommendation decisions?
- Is the current activity / evidence stated accurate?
- Do you agree with the recommendation met decisions?
- Where a recommendation is not met is the action stated SMART? (Specific, Measurable, Achievable, Realistic and Timely)
- Do you agree with the risk decision if action is required for a recommendation not met?
- Do you agree with the cost saving decision if the action is implemented?
- Do you agree with the deadline for the action?
- Do you agree with the stated person (not a group or title) to complete the action?
- Is there anything indicated that needs to be added to the Trust risk register, such as when an action cannot be taken by the Trust to solve an identified issue, such as due to resource or funding?
- If there is a clinical variation that indicates there is a risk to patient safety, steps must be taken to minimise this risk.
- The ratifying committee should consider if clinical variations should be escalated where a risk may be wider than their ratifying remit:
    - to Care Group level if being ratified at Network level
    - to the Trust-wide Clinical Governance Committee (TWCGG) if being ratified at Care Group level

If the committee are satisfied with these elements then the assessment can be ratified.

Ratification Evidence

The ratifying committee also needs to record the discussion and decision in a way which provides the Clinical Effectiveness and Audit Team with clear evidence of not just ratification taking place and the outcome, but also clearly recording the NICE code and title. This is because there are over fifteen-hundred pieces of current NICE Guidance in existence, although far from all will apply to our Trust.

As with any committee the minutes needs to reflect this.

The Clinical Effectiveness and Audit Manager created the table below to assist ratifying committees:

Clinical Effectiveness Report Ratification Table	
NICE Code	
Guidance Title	
Area Assessment Covers	Care Group or List Specific Networks / Specialties
General Discussion Points	
Ratification Decision	Ratified or Ratified pending minor alteration outlined above or Not ratified and to return at the next available meeting pending alterations outline above

It is recommended that this table is used when recording ratification discussion and decision.

The minutes with the ratification discussion and decision then need to be submitted to the Clinical Effectiveness and Audit Team via NICE@cumbria.nhs.uk so this aspect of the process can be saved and the monitoring systems updated. This ensures that we can demonstrate the full process has been completed when external bodies enquire, as well as providing assurance information for the Trust to the Quality and Safeguarding Committee (QSC), plus ensuring we are in line with the NICE Into Practice Guide.

DOCUMENT CONTROL

Equality Impact Assessment Date	
Sub-Committee & Approval Date	*CPMG 2/8/18*

History of previous published versions of this document:

Version	Ratified Date	Review Date	Date Published	Disposal Date
POL/001/030	02/11/19	02/11/19	02/11/19	-

Statement of changes made from version

Version	Date	Section & Description
1.1	31/07/18	Corrected job descriptions from Clinical Audit Facilitators and Clinical Effectiveness Facilitators to reflect new roles of Clinical Effectiveness and Audit Facilitators
1.1	31/07/18	Removed Associate Medical Director of Quality as post no longer exists.
1.1	31/07/18	Altered 'Monitor' to NHS Improvement
1.1	31/07/18	Alter order of appendices to fit flow of document better
1.1	31/07/18	Replace ratification guide with new version signed off by CEAC in July 2017

List of Stakeholders who have reviewed the document

Name	Job Title	Date
All Clinical Audit Leads	By email	01/08/18
All CEAC membership	By email	01/08/18
All AMDs and ADNs	By email	01/08/18
Policy Steering Group		02/08/18