




Clinical Audit Policy

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Policy context

The purpose of this policy is to set out a framework for the conduct of clinical audit within the Trust. It provides standards and guidance for all staff participating in clinical audit activities. It includes the Trust's procedures and expectations:

- for registering and approving clinical audit project proposals.
- for developing and designing clinical audit projects.
- sets out the support that is available from the Clinical Audit Team. All clinical audit activity undertaken in the Trust must comply with the requirements of this policy.

Policy requirement (see Section 2)

The purpose of this policy is to set out the rationale for clinical audit and provide a framework for such activity, including standards, guidance, and procedures, as well as details of the support available from the Clinical Audit Team.

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Date	Version	Author (Name & Role)	Reasons for review / Changes incorporated	Ratifying Committee
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Introduction

1.1 Rationale

Statutory and Mandatory Requirements for Clinical Audit

When carried out in accordance with best practice standards, clinical audit:

- Provides assurance of compliance with clinical standards;
- Identifies and minimises risk, waste and inefficiencies;
- Improves the quality of care and patient outcomes.

Statutory Basis

Chapter 2 of Part 1 introduces a new registration system for health and adult social care providers (now including NHS providers), and in some cases, managers. Only those registered will be allowed to carry out certain regulated activities, as set out in the regulations. This system replaces the previous registration requirements detailed in the 'Care Standards Act 2000' in England. The Commission will assess and monitor compliance, with the authority to issue penalties, suspend registrations and use a wider range of enforcement powers than its predecessors.

This is the statutory basis for the system of registration and regulations under which the CQC now operates. Please refer to **Reference Document 2** for more information on this document.

CQC Guidance – Regulations

Healthcare providers must ensure healthcare professionals are enabled to participate in clinical audit in order to satisfy the demands of the relevant professional bodies. It is also important to note that CQC inspections within the Trust commonly refer to compliance audits as clinical audits, which are two different types of audit. The points below can be referred to in **Reference Document 2**.

The registered person (or provider or manager) must protect service users and others from unsafe or inappropriate care by having effective systems in place to:

- Regularly assess and monitor service quality / risks.
- Consider feedback from service users, staff, complaints, investigations, records, professional advice, CQC reports, and relevant reviews / audits.
- Make necessary changes to care or treatment based on incident analysis, reviews, audits or new information.
- Seek and consider the views of service users, their representatives and staff to improve care quality.
- When requested by the CQC, the registered person / provider must provide a written report on how these requirements are being met, and outline any improvement plans to ensure service users' health and welfare.

NHS England – Standard Contract

The NHS Standard Contract is mandated by NHS England for use by commissioners for all contracts and healthcare services (other than primary care). The contract terms apply to new agreements from April 2021 for NHS Foundation Trusts, including services provided by Birmingham and Solihull Mental Health Foundation Trust.

- Providers must participate in the NCAPOP clinical audits which are relevant to the services they provide, and make national clinical audit data available to support the publication of consultant level outcomes.
- Commissioners may charge penalties in respect of any breach of quality requirements.
- Providers must implement all relevant recommendations of any appropriate clinical audit.
- Providers must implement a programme of clinical audit. Findings of any clinical audit must be made available to the coordinating commissioner on request. They can also appoint an auditor to audit quality and outcomes, as well as recording and coding of clinical activity.
- Provide to the co-ordinating commissioner, on request, the findings of any clinical audits carried out.

Further information from this document is available in **Reference Document 2**.

Department of Health: Quality Accounts

This Act and its regulations provide the statutory basis for the requirement for specified healthcare providers to produce Quality Accounts. Section 2 of the schedule to the regulations specifies the content required in respect of clinical audits. **Reference Document 2** provides the template which lays out the expectations of both national and local clinical audit participation.

The Trust complies with this by including submissions from all national clinical audit (Level 1) participations from that fiscal year, and all Level 2 local clinical audit participations from that fiscal year too. A selection of Level 3 local clinical audits are also to be included in the local submissions in order to demonstrate the continuous improvement work being undertaken by clinical staff within the Trust.

NHS Improvement

NHS Improvement requires NHS Foundation Trusts to follow an annual planning and reporting cycle, in the form of an annual audit planner and annual Quality Account submission. This is how the Trust displays the quality of care provided in terms of improvement (in this case clinical audit) activities.

This also outlines how a Trust reviews their effectiveness processes. With regards to clinical audit, the Trust is to provide assurance of these processes through registration / completion of national and local clinical audits, reporting of said projects, and the monitoring of outcomes from these projects.

Further information from this document is available in **Reference Document 2**.

AMaT – A System to Enable Effective Clinical Audit Processes

With AMaT now fully implemented at the Trust with regards to clinical audit, this allows the following:

- Registration of all clinical audit projects through AMaT. This applies to Level 1, 2 and 3 clinical audit projects.
- A means of reporting on these projects. Report creation can be done through AMaT, and projects can be brought through to their respective committees.

- All national clinical audit projects are reported through to Trust CGC, CEAG and PTC (when required). Any national clinical audits that pertain to specific directorates are also to be brought through to their directorate CGC.
- Outcomes, i.e. action planning and monitoring can also be done through AMaT, whereby measured improvement can be recorded.
- Reaudits can also be monitored through AMaT.
- General reporting of clinical audits of all priority levels can also be procured through AMaT by any staff registered with AMaT (and having a responsibility to report on such processes).
- Ultimately, comply with the aforementioned regulations, standards and health care acts to display involvement in clinical audit across the Trust.

1.2 Scope

The Target Audience

This policy applies to anyone engaged in the clinical audit process within the Trust. This includes:

- All staff, both clinical and non-clinical, including staff on short-term or honorary contracts
- Students and trainees in any discipline
- Service users, carers, volunteers and members of the public.

This policy also applies when clinical audit is undertaken jointly across organisational boundaries (such as national clinical audits).

Multi-disciplinary and multi-professional audit, and partnership working with other organisations

The Trust encourages clinical audit undertaken jointly across professions and across organisational boundaries. Partnership working with other local and regional organisations will be encouraged where improvements to the patient journey may be identified through shared clinical audit activity. The Trust also supports collaboration on multi-professional clinical audits of interest to other parts of the local health and care economy, both within and outside of the NHS, e.g. community/secondary care, local authorities, independent health and social care providers, etc.

1.3 Principles

Involving service users and the public

The Trust promotes a commitment to the principle of involving service users/carers in the clinical audit process either indirectly through the use of service user surveys/questionnaires or directly through participation of identified individuals on project steering groups or patient forums.

The Trust positively supports individuals with learning disabilities and ensures that no-one is prevented from accessing the full range of mental health services available. Staff will work collaboratively with colleagues from learning disabilities services and other organisations, to ensure that service users and carers have a positive episode of care whilst in our services. Information is shared appropriately in order to support this.

Ethics and Consent

Clinical audit projects do not require formal approval from a Research Ethics Committee. However, one of the principles underpinning clinical audit is that the process should do good and not do harm. Clinical audit must always be conducted within an ethical framework. Any ethical issues with the audit will be discussed with the Research and Development Department before approval of the project.

The Clinical Effectiveness Advisory Group is responsible for the ethical oversight of clinical audit across the organisation and any person who has concerns regarding the ethics of clinical audit should refer them to the Chair of the Committee.

Equality and Diversity

The Trust aims to ensure that its healthcare and facilities are not discriminatory and, wherever possible, attend to the physical, psychological, spiritual, and social and communication needs of any patient or visitor showing no discrimination on the grounds of ethnic origin or nationality, disability, gender, gender reassignment, marital status, age, sexual orientation, race, trade union activity or political or religious beliefs.

The process for determining choice of clinical audit projects, and the manner in which project patient samples are drawn up, should not inadvertently discriminate against any groups in society based on their race, disability, gender, age, sexual orientation, religion and belief. Any person who has concerns regarding the ethics of clinical audit activity within the Trust should refer them in the first instance to the Clinical Effectiveness Advisory Group, who may require equality impact assessments to be undertaken and / or equality data to be collected as part of clinical audits in order to determine whether any particular groups of patients are experiencing variations in practice.

2. Policy

2.1 Statement of purpose

The purpose of this policy is to set out the rationale for clinical audit and provide a framework for such activity, including standards, guidance, and procedures, as well as details of the support available from the Senior Clinical Effectiveness Manager, and Clinical Governance Facilitators (where appropriate):

- For registering and approving clinical audit project proposals
- For support in completing clinical audit projects
- For support in setting up reaudits

This policy aims to support a culture of best practice in the management and delivery of clinical audit, and to clarify the roles and responsibilities of all staff involved.

2.2 National Data Opt-Out (NDOO)

The NDOO allows a patient to choose if they do not want their confidential patient information to be used for purposes beyond their individual care and treatment. The Information Commissioner's Office (ICO) Guidance relates to data anonymisation.

Reference Document 3 4 shows the two policies / guidance in full.

The policy itself intertwines with the Information Commissioner's Office (ICO) Guidance on data anonymisation. Below are three important excerpts from the policies:

From the NDOO Operational Policy:

Section 2.5, Page 4 – 'The National Data Opt-Out applies when confidential patient information is disclosed for purposes beyond individual care, for example, for research or planning purposes.'

From the NDOO Operational Policy:

'2. Is the use or disclosure confidential patient information? Data is recorded whenever a patient has contact or interaction with the health and care system. The opt-out only applies to confidential patient information (CPI) – data that includes both:

- Information that identifies or could be used to identify the patient*
- Information about their health care or treatment*

The NDOO does not apply to information that is anonymised in line with the ICO Code of Practice on Anonymisation or is aggregate or count type data.'

From the ICO Code of Practice:

Chapter 3 – 'Pseudonymisation therefore refers to techniques that replace, remove or transform information that identifies an individual. For example, replacing one or more identifiers which are easily attributed to individuals (such as names) with a pseudonym (such as a reference number). While you can tie that pseudonym back to the individual if you have access to the additional information, your technical and organisational measures should ensure that you hold this information separately.'

Through these two policies, and the aforementioned excerpts, it is the Trust's understanding that the following is true:

- National clinical audits must apply for exemption from NDOO where confidential patient information is requested.
- Some national clinical audits do not require confidential patient information to be disclosed and therefore NDOO does not apply.
- Local clinical audits are exempt from NDOO in totality.

What is not made clear is what happens when a local clinical audit is taken outside the Trust. The above second statement works on the assumption that local clinical audits stay local, however historically, the NHS sees many local clinical audits undertaken by resident doctors, students, placement students etc. Many will be required to present their findings outside of the Trust network. Therefore, after discussion with the Information Governance Team, and using the aforementioned excerpts above, the Trust works on the following:

- Sensitive data collected through AMaT (can only be RiO number and Date of Birth) cannot be exported by auditors. It is viewable within the AMaT system when accessed by a Trust device, but cannot be exported. This prevents the disclosure of sensitive patient information.
- Pseudonymisation (simply assigning a number to each patient as the means of identification as opposed to their hospital number) is sufficient to call the data anonymised when it is exported outside of the Trust walls (or within).

In application, if a student on placement presents their findings at university, as they are unable to extract sensitive information, and as the exported information only contains a random number as a means of identification, the NDOO does not apply.

2.3 Information Governance: Collection, Storage and Retention of Data and Confidentiality

All clinical audits must adhere to information governance policies and standards. Numerous stages of the clinical audit cycle require the application of IG law and principles.

Clearly defining the purpose of the study, target population, and sample size, helps to ensure that information collected is minimised as far as possible, so that it is adequate but not excessive. This is now done with AMaT through the registration process (see **Appendix 2** for the full flowchart).

Anonymisation or pseudonymisation of information at the earliest possible opportunity, along with secure storage and timely destruction of collected data, are essential to protect personal confidential data throughout a clinical audit. Pseudonymisation is explained in clinical audit training sessions, with examples of how it works. It is also illustrated in individual training sessions run by the SCEM.

The Data Protection Act and the Caldicott Principles state that data should be:

- Adequate, relevant, and not excessive
- Accurate
- Processed for limited purposes
- Held securely
- Not kept for longer than is necessary

2.4 Development of Clinical Audit within the Trust

The SCEM will set up clinical audit training sessions throughout each year. These sessions are to be done over Teams, and can be signed up for through the Trust's internal Learning and Development system.

The SCEM also provides individual sessions upon request and capacity permitting. With AMaT being a new system, individual sessions can be valuable to help staff understand the registration and project sections of clinical audits on there. The SCEM also presents on a regular basis at PGME to a large number of doctors.

The Trust also takes part in Clinical Audit Awareness Week each year where stalls are set up at Uffculme to encourage staff to take part in local and national clinical audits.

The Trust are also invited to an annual conference by AMaT where all participating Trusts meet for presentations on updates around clinical audit, AMaT etc. The SCEM and CGFs are invited to this.

3 The Process

3.1 Agreeing an Annual Programme of Activity

With each financial year, a working planner of clinical audit activity of all priorities will be created by the SCEM and confirmed in CEAG. This will be added to / removed

from throughout the year as more clinical audits come through either nationally or locally. The audit planner can also be confirmed at Trust CGC.

Each year has certain known clinical audits that will always go on to the planner. These include national audits such as POMHs, level 2 audits such as pharmacy based clinical audits, and level 3 audits such as pharmacy-based assurance audits, pressure ulcer quarterly audits etc. It is important to note that the audit planner also includes non-clinical audits (such as pressure ulcer quarterly audits). These are fed through to the Quality Account each year too.

Choosing and Prioritising Local Clinical Audit Topics

The Trust is committed to supporting other locally determined clinical audit activity as a significant contributor to the continuous process of quality improvement. It is acknowledged that individual clinicians may initiate a clinical audit project on the basis of local clinical priority, personal development or as part of an educational or training programme, or all of the above. Selections of these local clinical audits are to be included in the Quality Account each year to demonstrate some of the important improvement work being undertaken at a team level within the Trust.

3.2 Priority Levels for Clinical Audit

There are now three levels of clinical audit priority, these are detailed below. Clinical audits are allocated a priority level based on the definitions shown:

Clinical Audit Priority Levels:

Priority Level	Description	Example
1	National Priority	POMH, NACEL, NAD
2	Trust Priority / Trustwide	Rapid Tranquilisation, Trustwide Guidance Review Audit, Trustwide Inpatient Weight Gain Audit, Trustwide Medicines Review Audit
3	Team or Service Priority / Local Project	Pharmacy (Medicines Code), Consultant-led, Annual Service Standards Audit, Student-led

Priority Level 1

National Clinical Audit and Patient Outcomes Programme (NCAPOP) and other national clinical audits relevant to the services provided, and/or where participation must be reported in quality accounts. These clinical audits allow the Trust to compare performance with other providers and against nationally agreed standards.

The Trust also continues to take part in Prescribing Observatory of Mental Health (POMH) national clinical audits. These are non-mandated, and focus heavily on the prescribing aspect in mental health Trusts. These national audits are co-owned by the Pharmacy team and the SCEM. The process of preparing for data collection, collecting the data, and reporting is run by the SCEM, and officially reported to MOC and CEAG, as well as any relevant CGCs. This is also fed through to Trust CGC.

Any actions that arise from national clinical audits are owned by the department / team / directorate that they relate to. For example, the National Audit of Dementia (NAD) would see any actions owned by the Memory Assessment Service (MAS) that sits within the Dementia & Frailty directorate. Any actions arising from a POMH will tend to be owned by the Pharmacy team, but may also involve specific areas if required.

National clinical audit actions are monitored and reported to CEAG on a quarterly basis, which in turn is fed through to Trust CGC on a quarterly basis. Any national clinical audits which result in risks being identified may also have risks added to the risk register (with approval from either MOC or CEAG).

Any concerns raised from clinical audit findings will be highlighted via the appropriate reporting mechanisms to the Trust CGC. They may also be included in the appropriate risk register.

Priority Level 2

Level 2 clinical audits cover a variety of topics. With how the Quality Account is reported on, these also include non-clinical audits (technically speaking). They can include:

- Audits undertaken in response to serious incidents/ adverse incidents/near-misses/complaints/ homicide enquiries, to ensure corrective actions taken to prevent a recurrence have been implemented.
- Organisational clinical priorities, such as Weight Gain in Inpatients.
- Priorities identified via patient and public involvement initiatives.
- Audits that must be undertaken in order to comply with provider policies, particularly those that are subject to external review. This can include pharmacy-based audits such as Clozapine Guidance Review, Safeguarding (where appropriate) etc.
- Local reaudits of national clinical audit topics such as POMH.

These audits will be presented to a sub-committee of the Trust Clinical Governance Committee, for example, the Physical Health Committee, the Medicines Optimisation Committee, the Reducing Restrictive Practice Group, and then to areas with involvement in the audit for learning. They will also always go through CEAG. Any concerns raised from clinical audit findings will be highlighted via the appropriate reporting mechanisms to the Trust CGC. They may also be included in the appropriate risk register.

Priority Level 3

Level 3 has been adjusted to align with other Trusts as well as AMaT. Previously, there were 4 levels. Level 3 now includes the combination of what was previously split between Level 3 and Level 4. These can include:

- Pharmacy-led audits such as Medicines Reconciliation audits.
- Team-led clinical audits such as compliance with service standards.
- Nursing-led clinical audits that measure against team/service standards.
- Consultant-led clinical audits which can include placement/junior/resident staff.

Pharmacy-led Audits

Whilst these audits are technically not considered clinical audits, they are reported on by the SCEM in the annual Quality Account submissions for clinical audits. These ward-based audits consist of service area audits which are led by the Pharmacy team. There is a nominated 'Super-User' from the Pharmacy team who is able to add/remove/adjust these audits as necessary. The SCEM is also able to offer support on these to ensure that reports can be pulled effectively from the AMaT system. Reporting of actions on these audits is owned by the Pharmacy team. Reporting at meetings such as MOC or TCGC is also owned by the Pharmacy Team.

Team-led / Nursing-led Clinical Audits

This category of clinical audits are often run by a team within a directorate. They will look at simple topics such as compliance with their service standards, which will generally have a low number of criteria to audit against. The SCEM oversees approval of these audits and will also assist in setting them up, managing them and closing them off. This type of clinical audit will also fall under CGF territory in terms of monitoring.

These audits will be presented to a sub-committee of the Trust Clinical Governance Committee, for example, the Physical Health Committee Reporting, but can also be brought to their respective CGCs. The SCEM will typically offer to have them present at CEAG too as this committee oversees effectiveness work.

Actions will be individually owned by respective team members, but progress and oversight will be monitored through CEAG via quarterly reporting of actions.

Consultant-led Clinical Audits

These are audits undertaken by clinicians with an interest in a particular topic or based on local need. They will often be overseen by the clinicians, who will support resident doctors, placement clinical staff in training etc.

The SCEM will help get these clinical audits set up on AMaT, as well as assist in showing how to manage their project on AMaT too. As per **section 2.2** and **section 2.3**, as it is these types of clinical audit that are commonly presented outside of the Trust, clear guidance on how to collect data safely will be provided via either provision of training documents or through Teams sessions.

These clinical audits will be presented on a local level, and potentially outside the Trust. For example, if placement students have been requested to produce a poster on their project, they will likely present their findings at university or equivalent. These posters / reports will only ever include general data, and nothing that can be considered confidential patient information. An offer will also be made to present their report / poster at CEAG if the project has been closed out during their placement / rotation.

Any actions will be owned by the overseeing clinician, but will also be monitored through quarterly reporting at CEAG.

3.3 System for Registering, Approving and Managing Clinical Audits

All clinical audits, including reaudits, require approval from the SCEM. Any clinical audit must be registered through AMaT. The SCEM is notified via email of any registrations on the Clinical Audit module of AMaT. Please see **Appendix 2** for a detailed walkthrough flowchart on registering a clinical audit via AMaT.

There is also a section when registering that will allow an 'Audit Mentor' to be attached. This should be the clinical lead who has approved the project. Of course, if the staff member is the 'lead' undertaking the project, then no mentor needs to be added.

When a clinical audit is registered through AMaT, any gaps requiring further information will be needed before approval is given. The SCEM will email out to the auditor requesting any further information needed, and will also offer out a Teams call to go over the system and how it works once approved.

Once approved, the clinical audit will open up several new sections whereby the auditor can enter information as their clinical audit progresses.

If a clinical audit is completed without being registered onto AMaT, it is important to bear in mind that said audit will have had no oversight from the SCEM. A report can be added retrospectively onto the system, however this is not good practice and should be avoided where possible.

Any local clinical audits will have a code (LC-XXX) added by the SCEM once approved. This is an indicator that the CGFs can also use to identify approved and open clinical audits. Any Trustwide clinical audits will have a code (TW-XXX) added once approved on the system.

For any national clinical audits, there is no code required due to the nature of the categorising used on AMaT. Any local or Trustwide clinical audits will be categorised as 'Local' on AMaT. Any national clinical audits are categorised as 'National' on AMaT.

3.4 The Use of Standards (or Criteria) in Clinical Audit

The core of a clinical audit project is the standards upon which you are measuring against. It is important to note that standards and criteria are often used to describe this aspect. On AMaT, they are referred to as criteria.

Standards are a quote from your policy, service standards, guidance etc. that you are auditing against. Criteria (singular criterion) are slightly adjusted forms of the standard, which are not a direct quote.

Without clearly defining your criteria, a clinical audit cannot be approved on AMaT. The importance of this section has multiple aspects. By defining the criteria, the proforma with which you collect the data can be easily created based upon them. When it comes to reporting your data, clearly defined criteria will also allow the auditor to present the essence of the clinical audit in a digestible manner.

3.5 Collecting of Data for Clinical Audits

Data collection should also be done on AMaT via the proforma section. By collecting data on using AMaT, as per section 2.2, we are able to adhere to ICO guidance, as any data considered CPI cannot be extracted from the system.

As per clinical training guidance (please refer to slides 38 and 50 from **Reference Document 5**) there should be no instance where names of patients are collected in data collection. It is advised that at most, the RiO Number and Date of Birth are used when drawing a sample of patients to audit.

As mentioned previously in section 2.2, these can be collected on AMaT but cannot be exported, which is where the importance of pseudonymising the data comes in. By adding a third question to indicate your patient number (for example if you are auditing 50 patients, numbers 1-50 will suffice), when your data is exported, this will be used as your identifier, in line with ICO guidelines.

As per GDPR laws (slide 38 from **Reference Document 5**), all data collection should be done via a Trust device. No data samples should be stored outside of a Trust device. Please see section 2.3 for more detail.

3.6 Reporting of Clinical Audits

Reporting of clinical audits can be assisted within AMaT. The flowchart in this **Appendix 3** describes which sections are required to be completed in order for a satisfactory report to be pulled from AMaT. For substantive staff within the Trust, this is the simplest option to create a report that contains the important information around their project.

For staff on placement who are required to complete a poster, this can be uploaded in lieu of the above whereby the SCEM can check through and close off the clinical audit (if there are no actions arising from this project).

Reporting of current clinical audit data including total projects opened, total projects completed with or without actions, and data for each directorate is to be fed through to CEAG in clinical audit agenda updates. This is also reported through to Trust CGC on a quarterly basis, and QPESC upon request. All reports described above can be pulled directly from AMaT.

Any completed projects will be available to all staff registered on AMaT for viewing.

3.7 Action Planning (Post-Project) Process

Action planning can also be done on AMaT. Recommendations are made which can then be confirmed as an action, where a staff member will be assigned to each action. They will receive an email from AMaT to notify them of the action that has been added in their name.

In some cases, recommendations will be made without actions. The Trust encourages staff undertaking these projects to design actions for improvement, however if placement students are undertaking the project, actions may or may not be confirmed after recommendations. If no actions are confirmed, the clinical audit can be closed off.

If actions are approved, they must be created with the SMART methodology in mind (Specific, Measurable, Achievable, Relevant, Time-Based). When creating an action through AMaT, the recommendation must first be created. The recommendation can then be pulled through to create an action. Here, an owner can be assigned, a RAG rating applied (see slide 46 in **Reference Document 5** for a description of each rating), and a target date set. If the owner is a staff member different to the person creating the action, they will still get an email notifying them of the action.

Some projects will have sufficient compliance with standards whereby actions are not required. In these instances, the 'No actions required' with reasoning provided can be done to close off the project. This is more likely to be seen in 'successful' reaudits.

CEAG will monitor the outstanding actions of projects quarterly. The CGFs will also be chasing for updates quarterly. The CGFs quarterly chasing forms a part of their effectiveness agendas which are done quarterly at CGC. Updates are given by auditors at CGC here. These two processes combined aim to help prevent clinical audits going dormant, which was a common issue using the old clinical audit system.

Some directorates also have their own clinical audit groups. These groups meet to go through specific issues, projects and discuss them in greater detail than in CGCs. The SCEM or CGF can attend these (where capacity allows) to further assist staff in their clinical audit projects.

3.8 Repeating Clinical Audit Cycles

Clinical audit cycles are a closed loop – this means that in theory, at the end of the first cycle, you would implement actions, monitor the progress, and then reaudit after an agreed time period (usually 6 or 12 months). The clinical audit cycle is not complete until agreed actions are implemented according to the corresponding action plan, and evidence is obtained of the impact of the action plan on compliance with standards. This may be achieved by repeating data collection or by instituting a programme of ongoing monitoring.

Repeated cycles of clinical audit may be carried out to ensure standards and criteria are consistently and repeatedly met, and practice is effective. With AMaT, reaudits become much less of a burden to complete. By selecting the original round of auditing, most of the previous sections will be pulled through into the reaudit. This includes registration information, data results, criteria (and corresponding results) and the proforma (data collection tool).

Original clinical audit cycle rounds have an option of selecting whether it will be reaudited or not. If 'yes' is selected, the participants can set a date, and nearer to this date, those same participants will be emailed to say the reaudit is due.

If after this reaudit, little to no improvement is found, it may be that this project is moved into QI methodology, where it can be run through PDSA cycles to try and determine which changes (if any) can help improve compliance with standards. In these cases, the participants will be referred to the QI team on bsmhft.qualityimprovementteam@nhs.net.

3.9 Local Clinical Audits where Placement/Student Staff Leave

If a local clinical audit is being conducted by a clinician whereby they are supervising placement staff who are undertaking the clinical audit, and these staff leave whilst the project is ongoing, it is the responsibility of the clinician to ensure that either the project is finished prior to the leaving date, or the project is continued by staff within the Trust. It may also be put on pause until new students / placement staff come through to their team.

3.10 Training and Development

The SCEM provides clinical audit training sessions each year. This can be up to 4 sessions whereby any clinical staff member (or any staff involved with clinical audits) are able to sign up through the Learning and Development system on Connect.

The SCEM also runs clinical audit training sessions for teams / individuals on an ad-hoc basis. When capacity allows, this will usually be done during the registration process so that clarifications can be made on any missing information, and how the process works once the clinical audit is 'open' on AMaT.

The SCEM also attends PGME (when invited) to provide an insight into clinical audit within the Trust, on both a national and local level.

4 Duties and Responsibilities

4.1 Roles, Responsibilities and Key Committees

Post(s)	Responsibilities	Ref
All Staff	All staff employed by the trust have a responsibility for the quality of the service which they provide, and all clinically qualified staff are individually accountable for ensuring they audit their own practice in accordance with their professional codes of conduct and in line with the standards set out within this policy.	
Service, Clinical and Corporate Directors	<p>All Clinical Directors must ensure that a senior clinician within their Service area is nominated as the Service area Lead for Clinical Audit (they may choose to take on this role themselves). The responsibilities of the Service area Leads for Clinical Audit are:</p> <ul style="list-style-type: none">- To ensure that this policy is implemented throughout their Directorates.- To ensure that all clinical audit activity within their directorate is registered and complies with nationally accepted best practice standards.- To ensure that their Directorate participates in all national clinical audits and local clinical audits relevant to the services which it provides and ensure that action plans resulting from these audits are implemented where necessary.- To work with clinicians, service managers, Divisional Governance and Quality Managers and clinical audit staff to ensure that the clinical audit programme for their Service area meets all clinical, statutory, regulatory, commissioning and other Trust requirements.- To give guidance to their Clinical Audit Leads and to understand the role for appraisal purposes.	

Policy Lead	<p>The Senior Clinical Effectiveness Manager is the operational lead for Clinical Audit. They support the executive Medical Director and Deputy Medical Director of Quality and Safety and are responsible for:</p> <ul style="list-style-type: none"> - Compiling the annual Trust Clinical Audit Planner (TCAP). - Ensuring the Trust delivers the clinical audit programme. - Ensuring all registered clinical audits use AMaT, which provides a means to ensure sufficient details of project are on the system. • Ensuring that all Level 1 National Audits and Level 2 Trust Priority audit results are presented at the Clinical Effectiveness Advisory Group for oversight as well as the development and monitoring of action plans. • Ensuring that where capacity allows, clinical audit training is provided each year. 	
Executive Director	<p>The executive/board lead for clinical audit is the Medical Director. Their responsibilities in respect of clinical audit are:</p> <ul style="list-style-type: none"> - To ensure that the Trust clinical audit strategy and annual programme of work are allied to the Boards strategic interests and concerns. - To ensure that clinical audit is used appropriately to support the Board Assurance Framework - To ensure this policy is implemented across all clinical areas. - To ensure that any serious concerns regarding the Trust's policy and practice in clinical audit, or regarding the results and outcomes of clinical audits, are brought to the attention of the Board. - The executive medical director will delegate some responsibility to the Deputy Medical Director such as chairing CEAG. 	
Clinical Governance Facilitators	<p>The Clinical Governance Facilitators are required to:</p> <ul style="list-style-type: none"> - Support the clinical audit programme through the monitoring of the ongoing clinical audits within their directorate. - Encourage and support staff undertaking clinical audits within their directorates. - Support the SCEM (where required) in clinical audit training. 	
Senior Manager(s) / Managers	<p>Managers are responsible for ensuring that service development and delivery is underpinned by an effective programme of clinical audit, which forms part of the Continuing Professional Development regime for their team.</p>	
Trust Clinical Governance Committee	<p>The Trust's Clinical Governance Committee will contribute to and agree in conjunction with its sub-committees and Service area Clinical Governance Committees the trusts annual audit</p>	

	timetable. They will receive and review reports from the Clinical Effectiveness Advisory Group.	
Clinical Effectiveness Advisory Group	<p>The Clinical Effectiveness Advisory Group is the corporate committee tasked with overseeing the Trust's clinical audit activities. This includes:</p> <ul style="list-style-type: none"> - The development and oversight of the annual Trust Clinical Audit Planner (TCAP). - Monitoring the progress of clinical audits on the TCAP. - Adding new projects where necessary in response to local and national priorities. - Review audit reports for level 1, 2 and 3 clinical audits on a quarterly basis. - Providing advice (and support where required) on action planning from local clinical audits. - Provide support and oversight to MOC regarding clinical audit-related action planning. - To escalate issues (when required) relating to clinical audit via Trust CGC quarterly reporting. 	
Local Audit Committee	<p>Directorates may benefit from local clinical audit meetings. Use clinical audit meetings to discuss in stages:</p> <ul style="list-style-type: none"> - The designs of clinical audits. - The findings of data collection. - What happened to the patients whose care is not consistent with quality-of-care measures. - The problems identified by audits and their root causes. - The improvements in care needed and the actions to achieve the improvements. - Progress in implementing actions. - Evidence from repeat data collection on the effectiveness of actions. 	

5.0 Development and Consultation Process

Consultation summary		
Date policy issued for consultation	August 2025	
Number of versions produced for consultation	1	
Committees / meetings where policy formally discussed	Date(s)	
Clinical Effectiveness Advisory Group	TBC	
Where received	Summary of feedback	Actions / Response

6.0 Reference Documents

1. Clinical Audit Policy (Trust - 2022) - [Clinical Audit Policy - Trust Sharepoint Link](#)
2. HQIP Statutory and Mandatory Requirements in Clinical Audit Guidance - [HQIP statutory and mandatory requirements in clinical audit guidance – HQIP](#)
3. Information Commissioning Office (Guidance) - [Anonymisation | ICO](#)
4. National Data Opt-Out - [National Data Opt-Out - NHS England Digital](#)
5. Trust Clinical Audit Training PowerPoint (by SCEM) - [Clinical Audit Management](#)

7.0 Bibliography

Sources of inspiration for refreshed clinical audit policy:

6. AMaT Website - <https://bsmhft.amat.co.uk/trust/>
7. Tutorials - Audit Management and Tracking (amat.co.uk) – [Tutorials - Audit Management and Tracking \(amat.co.uk\)](#)
8. Connect Guidance Website (Training Videos / Flowcharts created by SCEM) - [Clinical Audit Management](#)

8.0 Glossary

Locally Accepted Definition of Clinical Audit

Clinical audit can be described as a quality improvement cycle that involves measurement of the effectiveness of healthcare against agreed and proven standards (that derive from evidenced-based practice).

Quality improvement (QI)

Although there are similarities, the clinical audit cycle should not be confused with the Plan, Do, Study, Act cycle, which is a separate quality improvement tool used to drive and increase compliance with a standard against which there is an identified shortfall, or to investigate the impact of changes to practice within a defined timeframe.

Research

This policy does not include research projects. There are significant differences between clinical audit and research. Therefore, there are separate procedures to be followed if undertaking a research project and advice should be sought from the research department.

Service Evaluation

Service evaluations are a procedure used to judge a service's effectiveness or efficiency through systematic assessment of its aims, objectives, activities, outputs, outcomes and costs. Whilst benchmarking may be used to compare services, the evaluation will not involve measurement against agreed standards. They are not, therefore, clinical audits and this policy does not apply to service evaluations. In some circumstances it may be more appropriate for a service area to carry out a service evaluation rather than a clinical audit.

9.0 Audit and Assurance

Monitoring the Effectiveness of Clinical Audit Activity

Monitoring of clinical audit activity will take place at all levels of the Trusts governance structure. The annual clinical audit planner is updated as the year goes on. It contains all clinical audits from level 1 (national) and level 2 (Trustwide / high priority). Pharmacy-based level 3s are also on this planner. Level 3 local clinical audits also get added as they are

completed and brought through to CEAG. This planner is monitored quarterly at CEAG for any major updates / changes.

Service area Clinical Governance Committees will be expected to monitor the activity of and results from local/mandatory audits.

Improvement and Assurance

While clinical audit is fundamentally a quality improvement process that provides the opportunity for ongoing review and service development, it also plays an important role in providing assurance on the quality of services.

The Trust considers that the prime responsibility for auditing clinical care lies with the clinicians who provide that care. The Trust is committed to supporting clinicians who carry out clinical audit by providing advice and assistance from appropriately trained and experienced clinical audit staff, and advice and training in clinical audit processes and practice. Appropriate advice and training will also be made available to non-clinical staff and patients who may be involved in clinical audit projects.

In addition, the Trust is committed to ensuring that:

1. It participates in all national clinical audits, national confidential enquiries and inquiries and service reviews which are relevant to the services which it provides
2. All clinical audit activity within the trust, or conducted in partnership with external bodies, is registered and conforms to nationally agreed best practice standards (see 'Best Practice in Clinical Audit HQIP 2020').
3. The annual TCAP meets the requirements of the Board Assurance Framework, and includes all of the clinical audits necessary to meet regulatory and commissioner requirements.
4. Records of reviews of the annual programme of clinical audit, individual clinical audit projects, as well as the results of national clinical audits, national confidential enquiries and inquiries, and national service reviews, are maintained, to help facilitate effective clinical audit activity through robust governance systems as well as to demonstrate compliance with requirements of regulators and commissioner.

Element to be monitored	Lead	Tool	Frequency	Reporting Committee
Priority setting process for audit.	Senior Clinical Effectiveness Manager	Trust Clinical Audit Planner (Annual)	As and when a new clinical audit is added.	Reported annually to the TCGC
Clinical audits are conducted in line with the approval process for audit	Senior Clinical Effectiveness Manager	AMaT Registration Process	Every time a new clinical audit is registered.	N/A
Level 1 & 2 Clinical Audit reports are shared	Senior Clinical Effectiveness Manager	AMaT Reporting	Whenever a Level 1 / 2 Clinical Audit is completed.	Dependent on topic of clinical audit. All go through CEAG +

				Primary Committee.
The format for Clinical Audit Reporting	Senior Clinical Effectiveness Manager	Either AMaT Reporting Functions or Poster/Similar	For all Clinical Audits.	Reported locally as and when completed. Reported at CEAG quarterly in summary form, and ad-hoc when clinical auditors are invited to present.
How the organisation makes improvement, monitors action plans and carries out re-audits (for level 1, 2 & 3 clinical audits).	Deputy Medical Director / Senior Clinical Effectiveness Manager	Clinical Effectiveness Advisory Group	As and when clinical audits come through.	CEAG on a quarterly basis.
Escalation of clinical audit outcomes and delivery of programme	Senior Clinical Effectiveness Manager	Report	Quarterly	Trust Clinical Governance Committee

10.0 Appendices:

Document Title	Appendix No.
Equality Assessment	1
AMaT – Clinical Audit Registration Flowchart	2
AMaT – Clinical Audit Project Management Flowchart	3

Appendix 1 - Equality Analysis Screening Form

A word version of this document can be found on the HR support pages on Connect

Title of Policy	Clinical Audit Policy		
Person Completing this policy	Jonny Cook	Role or title	Senior Clinical Effectiveness Manager
Division	Corporate	Service Area	N/A
Date Started	July 2025	Date completed	August 2025
Main purpose and aims of the policy and how it fits in with the wider strategic aims and objectives of the organisation.			
To ensure a fixed process for oversight and management of clinical audit processes for the Trust.			
Who will benefit from the policy?			
Staff will benefit from having a policy to refer to in terms of managing their local clinical audits. The Trust will also benefit from the policy as it provides detail on how we provide assurance on clinical audit work from a National, Trustwide and Local level. It will also benefit the service users in instances where they wish to understand this improvement process and how it works within the Trust.			
Does the policy affect service users, employees or the wider community?			
<i>Add any data you have on the groups affected split by Protected characteristic in the boxes below. Highlight how you have used the data to reduce any noted inequalities going forward</i>			
Clinical audits themselves are an improvement process. The aim is to improve overall compliance against measured standards. By default, these processes can improve both staff working lives and service user care.			
Does the policy significantly affect service delivery, business processes or policy?			
<i>How will these reduce inequality?</i>			

Potentially. Some clinical audits will include data on ethnicity, gender etc.				
Does it involve a significant commitment of resources?				
<i>How will these reduce inequality?</i>				
This is entirely dependent on the size and scope of the clinical audit. National and Trustwide audit require significant commitment from staff. Local clinical audits are likely to involve fewer staff and with less time pressures.				
Does the policy relate to an area where there are known inequalities? (e.g. seclusion, accessibility, recruitment & progression)				
No.				
Impacts on different Personal Protected Characteristics – Helpful Questions:				
<i>Does this policy promote equality of opportunity?</i> <i>Eliminate discrimination?</i> <i>Eliminate harassment?</i> <i>Eliminate victimisation?</i>		<i>Promote good community relations?</i> <i>Promote positive attitudes towards disabled people?</i> <i>Consider more favourable treatment of disabled people?</i> <i>Promote involvement and consultation?</i> <i>Protect and promote human rights?</i>		
Please click in the relevant impact box and include relevant data				
Personal Protected Characteristic	No/Minimum Impact	Negative Impact	Positive Impact	Please list details or evidence of why there might be a positive, negative or no impact on protected characteristics.
Age	Yes			Clinical audits can involve service users from any service / team, which includes all ages.

<p>Including children and people over 65</p> <p>Is it easy for someone of any age to find out about your service or access your policy?</p> <p>Are you able to justify the legal or lawful reasons when your service excludes certain age groups</p>				
Disability	Yes			It is anticipated that disability will not have a negative impact in terms of discrimination as this policy ensures that all employees should be treated in a fair, reasonable and consistent manner irrespective of their disability. However, reasonable adjustments should be offered where required.
<p>Including those with physical or sensory impairments, those with learning disabilities and those with mental health issues</p> <p>Do you currently monitor who has a disability so that you know how well your service is being used by people with a disability?</p> <p>Are you making reasonable adjustment to meet the needs of the staff, service users, carers and families?</p>				
Gender	Yes			It is anticipated that gender will not have a negative impact in terms of discrimination as this policy ensures that all employees should be treated in a fair, reasonable and consistent manner irrespective of their gender.
<p>This can include male and female or someone who has completed the gender reassignment process from one sex to another</p> <p>Do you have flexible working arrangements for either sex?</p> <p>Is it easier for either men or women to access your policy?</p>				
Marriage or Civil Partnerships	Yes			It is anticipated that marriage / civil partnerships will not have a negative impact in terms of discrimination as this policy ensures that all employees should be treated in a fair, reasonable and consistent manner irrespective of their marriage / civil partnerships.

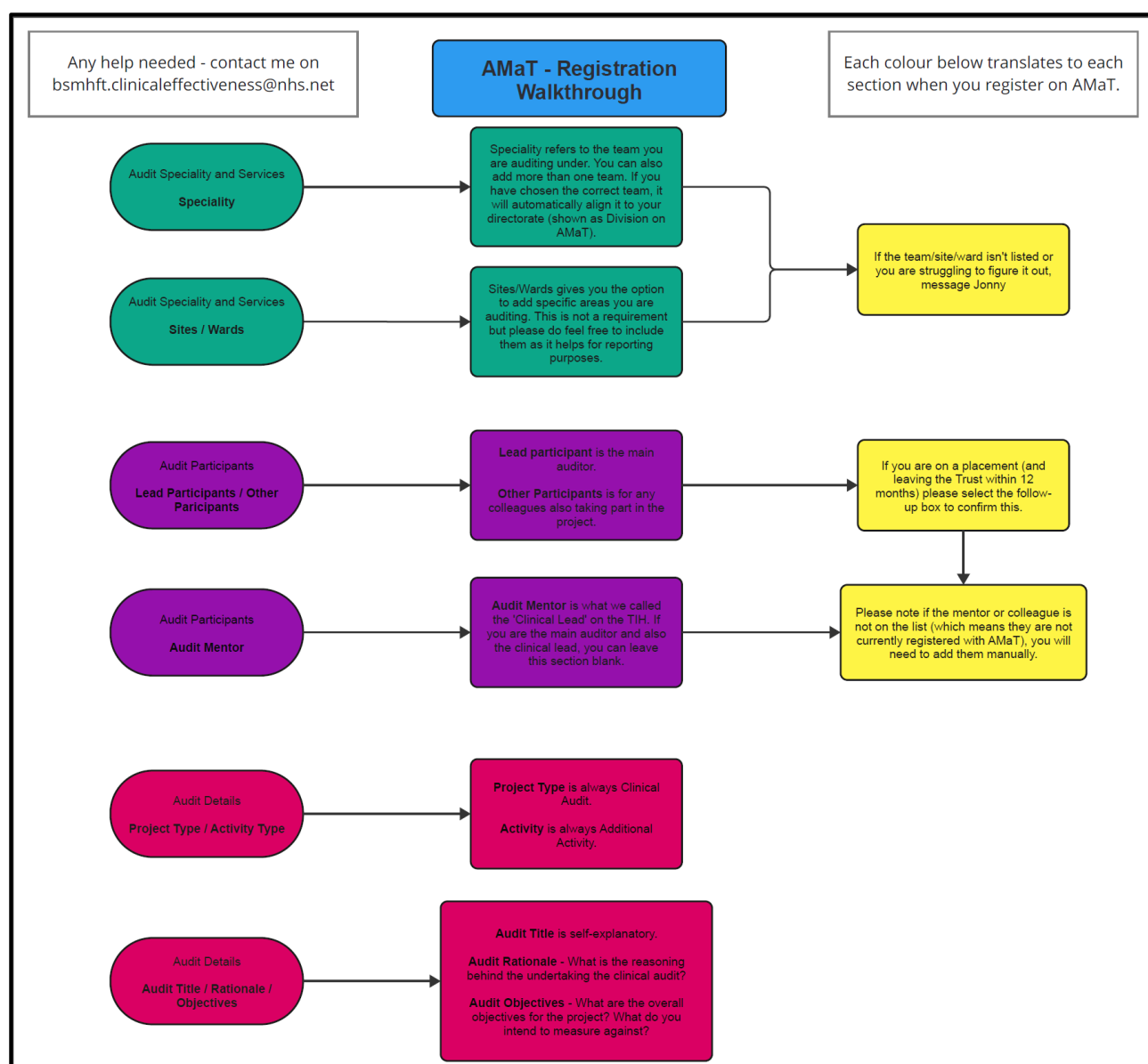
<p>People who are in a Civil Partnerships must be treated equally to married couples on a wide range of legal matters</p> <p>Are the documents and information provided for your service reflecting the appropriate terminology for marriage and civil partnerships?</p>				
<p>Pregnancy or Maternity</p>	<p>Yes</p>			<p>It is anticipated that pregnancy / maternity will not have a negative impact in terms of discrimination as this policy ensures that all employees should be treated in a fair, reasonable and consistent manner irrespective of their pregnancy / maternity.</p>
<p>This includes women having a baby and women just after they have had a baby</p> <p>Does your service accommodate the needs of expectant and post natal mothers both as staff and service users?</p> <p>Can your service treat staff and patients with dignity and respect relation in to pregnancy and maternity?</p>				
<p>Race or Ethnicity</p>	<p>Yes</p>			<p>It is anticipated that race will not have a negative impact in terms of discrimination as this policy ensures that all employees should be treated in a fair, reasonable and consistent manner irrespective of their race. If a service user / carer / EBE does not speak English as their first language, a translator would be arranged through the EBE service leads.</p>
<p>Including Gypsy or Roma people, Irish people, those of mixed heritage, asylum seekers and refugees</p> <p>What training does staff have to respond to the cultural needs of different ethnic groups?</p> <p>What arrangements are in place to communicate with people who do not have English as a first language?</p>				
<p>Religion or Belief</p>	<p>Yes</p>			<p>It is anticipated that religion will not have a negative impact in terms of discrimination as this policy ensures that all employees should be treated in a fair, reasonable and consistent manner irrespective of their religion.</p>

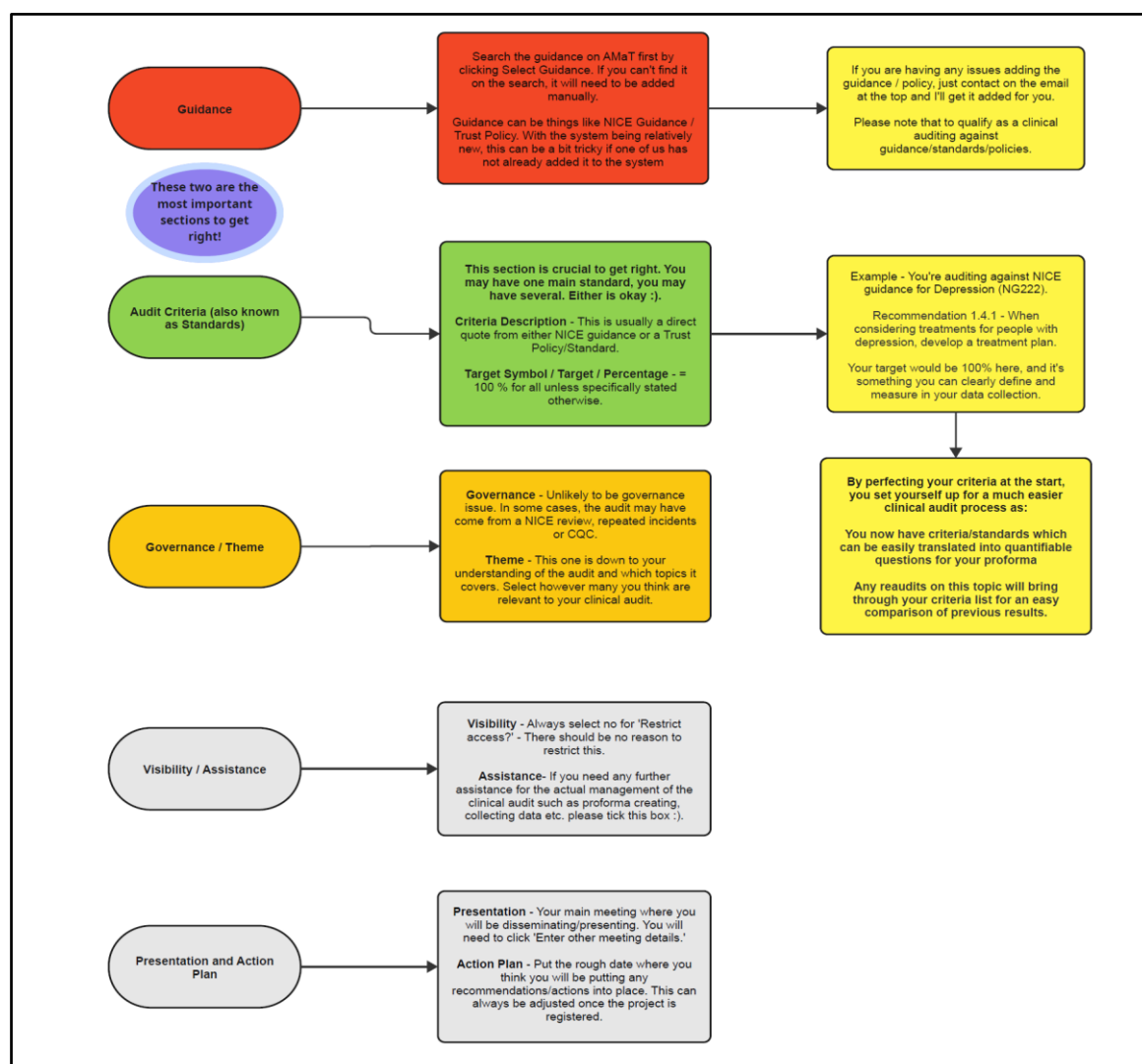
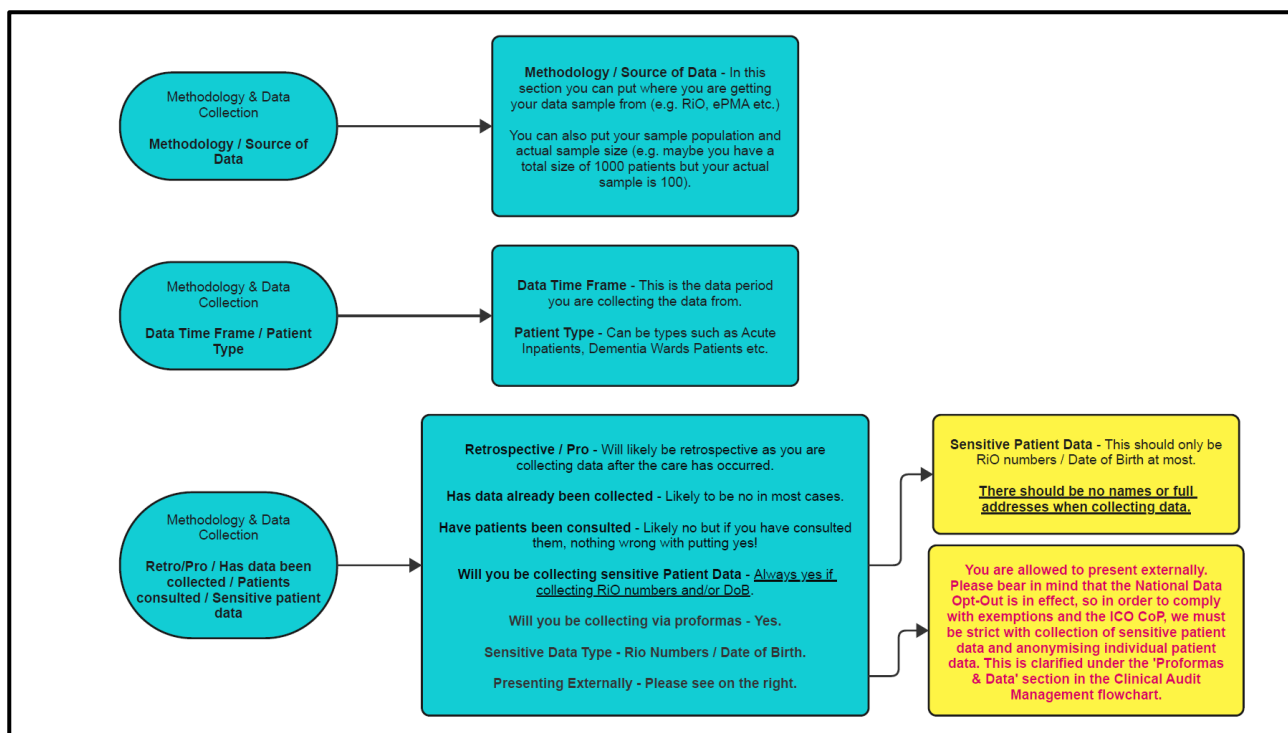
<p>Including humanists and non-believers</p> <p>Is there easy access to a prayer or quiet room to your service delivery area?</p> <p>When organising events – Do you take necessary steps to make sure that spiritual requirements are met?</p>				
<p>Sexual Orientation</p>	<p>Yes</p>			<p>It is anticipated that sexual orientation will not have a negative impact in terms of discrimination as this policy ensures that all employees should be treated in a fair, reasonable and consistent manner irrespective of their sexual orientation.</p>
<p>Including gay men, lesbians and bisexual people</p> <p>Does your service use visual images that could be people from any background or are the images mainly heterosexual couples?</p> <p>Does staff in your workplace feel comfortable about being 'out' or would office culture make them feel this might not be a good idea?</p>				
<p>Transgender or Gender Reassignment</p>	<p>Yes</p>			<p>It is anticipated that gender will not have a negative impact in terms of discrimination as this policy ensures that all employees should be treated in a fair, reasonable and consistent manner irrespective of their gender.</p>
<p>This will include people who are in the process of or in a care pathway changing from one gender to another</p> <p>Have you considered the possible needs of transgender staff and service users in the development of your policy or service?</p>				
<p>Human Rights</p>	<p>Yes</p>			<p>This policy is written to promote equality and remove any discrimination to ensure that everyone can fulfil their full potential within a Trust that is inclusive, compassionate, and committed. This is keeping in line with our Trust values, the NHS People's Plan</p>

			commitment to equality, diversity and inclusion and reflects the provisions of the Equality Act 2010.	
<p>Affecting someone's right to Life, Dignity and Respect?</p> <p>Caring for other people or protecting them from danger?</p> <p>The detention of an individual inadvertently or placing someone in a humiliating situation or position?</p>				
<p>If a negative or disproportionate impact has been identified in any of the key areas would this difference be illegal / unlawful? I.e. Would it be discriminatory under anti-discrimination legislation. (The Equality Act 2010, Human Rights Act 1998)</p>				
	Yes	No		
What do you consider the level of negative impact to be?	High Impact	Medium Impact	Low Impact	No Impact
				Yes
<p>If the impact could be discriminatory in law, please contact the Equality and Diversity Lead immediately to determine the next course of action. If the negative impact is high a Full Equality Analysis will be required.</p> <p>If you are unsure how to answer the above questions, or if you have assessed the impact as medium, please seek further guidance from the Equality and Diversity Lead before proceeding.</p> <p>If the policy does not have a negative impact or the impact is considered low, reasonable or justifiable, then please complete the rest of the form below with any required redial actions, and forward to the Equality and Diversity Lead.</p>				
Action Planning:				
How could you minimise or remove any negative impact identified even if this is of low significance?				

Any clinical staff can take part in clinical audits, and this is encouraged by the SCEM wherever possible.
How will any impact or planned actions be monitored and reviewed?
There are no actions.
How will you promote equal opportunity and advance equality by sharing good practice to have a positive impact on other people as a result of their personal protected characteristic.
N/A.
Please save and keep one copy and then send a copy with a copy of the policy to the Senior Equality and Diversity Lead at bsmhft.edi.queries@nhs.net. The results will then be published on the Trust's website. Please ensure that any resulting actions are incorporated into Divisional or Service planning and monitored on a regular basis

Appendix 2 – AMaT – Clinical Audit Registration Flowchart





Appendix 3 – AMaT – Clinical Audit Project Management Flowchart

