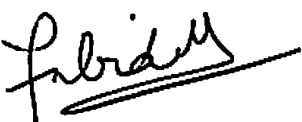




Clinical Audit Policy

| | | |
|--|---|-------------------|
| Policy number and category | C29 | Clinical |
| Version number and date | 8 | March 2022 |
| Ratifying committee or executive director | Trust Clinical Governance Committee | |
| Date ratified | September 2022 | |
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| Executive director | Medical Director | |
| Policy lead | Clinical Effectiveness Manager | |
| Policy author (if different from above) | As Above | |
| Exec Sign off Signature (electronic) |  | |
| Disclosable under Freedom of Information Act 2000 | Yes | |

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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1: 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.

The importance which the Department of Health and healthcare regulators attach to effective clinical audit is shown by the extent to which participation in national and local clinical audit is a statutory and contractual requirement for healthcare providers.

The NHS Standard Contract is mandated by NHS England for use by commissioners for all contracts for 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 & Solihull Mental Health NHS Foundation Trust. Providers must:

- Participate in national clinical audits within the National Clinical Audit and Patient Outcomes Programme (NCAPOP) relevant to their services
- Make national clinical audit data available to support publication of consultant-level activity and outcome statistics
- Implement and/or respond to all relevant recommendations of any appropriate clinical audit
- Implement an ongoing, proportionate programme of clinical audit of their services in accordance with best practice
- Provide to the co-ordinating commissioner, on request, the findings of any audits carried out, in particular locally-agreed requirements such as Commissioning for Quality and Innovation (CQUIN) audits.

In addition to this contractual requirement, the regulatory framework operated by the Care Quality Commission (CQC) requires registered healthcare providers to regularly assess and monitor the quality of the services provided. They must use the findings from clinical and other audits, including those undertaken at a national level, and national service reviews to ensure that action is taken to protect people who use services from risks associated with unsafe care, treatment and support. They must also ensure healthcare professionals are enabled to participate in clinical audit in order to satisfy the demands of the relevant professional bodies (for example, for revalidation),

The Board is required by NHS Improvement to declare via an annual governance statement the effectiveness of the system of internal control, the role and conclusions of clinical audit, and a plan to address weaknesses and ensure continuous improvement of the system – covering an outline of the actions taken, or proposed, to deal with any significant gaps in control

Under the Health Act 2009, the Trust is required to produce annual quality accounts, which must include information on participation in national and local clinical audits, and the actions that have been taken as a consequence to improve the services provided.

This policy is designed to fulfil these requirements, and all staff are required to ensure that any clinical audits they undertake are conducted in line with this policy.

1.2 Scope

The target audience

This policy applies to anyone engaged in the clinical audit process under the auspices of 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.

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, in order 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 Clinical Audit Team:

- For registering and approving clinical audit project proposals
- For developing and designing clinical audit projects

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

From March 2022 The national data opt-out 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. This however does not apply to local audits completed by the Trust. If the audit findings are to be shared externally, please seek advice from the Trusts information governance team regarding this.

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 audit cycle require the application of IG law and principles. In the first instance, confirming that a quality improvement study and subsequent health record access is essential. 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. 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.

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 Employment and development of clinical audit staff

The Trust will employ a team of suitably skilled clinical audit staff to support the programme of clinical audit activity. The Trust will also ensure that staff have access to further relevant training in order to maintain and develop their knowledge and skills. Clinical audit staff will be expected to participate in professional training and development activities including those organised by HQIP, the National Quality Improvement (including Clinical Audit) Network (N-QI-CAN) and West Midlands Effectiveness and Audit Network (MEAN).

3 The Procedure

3.1 Agreeing an annual programme of activity

Prior to the start of every financial year, the Trust Clinical Governance Committee will agree an appropriate planned programme of clinical audit activity. This programme should meet the Trust's corporate requirements for assurance but must be owned by clinical services.

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. It is important that these are registered with the Trust and reported through existing clinical governance structures to maximise organisational learning.

3.2 Systems for registering and approving audits

All clinical audits, including reaudits, require approval from the clinical governance department as well as a project clinical lead. This must be sought via the clinical audit registration process via the Transformation and Improvement Hub (TIH) on the Trust intranet. You can follow this link to the [form](#) here.

An audit will not be considered for approval without a submitted data collection tool and confirmation from the clinical lead for the audit.

Final approval and registration will be granted by the Clinical Governance Department once all of the above requirements have been met. It is only at this point that data collection for the clinical audit can commence.

Clinical audits must not be started prior to receiving confirmation of registration. Any audits started or completed without registration will **not** be registered retrospectively. A letter will be sent to the auditor and clinical lead informing them of this and reminding them to register prior to commencing any future audits. The consequences of this are that this audit project will not be counted as audit activity for the practitioner, the Service area and the Trust, the results will not be reviewed, and no action plans developed.

Data provided on registration will be used to compile a database of all clinical audit activity undertaken throughout the Trust. This database will be updated regularly by the clinical governance team. This information will be used by the Clinical Effectiveness Manager to report on the progress of the annual clinical audit programme.

Completed clinical audit project reports are stored with the audit registration form for future review and quality monitoring and assurance purposes.

3.3 The use of standards (or criteria) in clinical audit

All audit projects must ensure that the standards of best practise that they are measured against are constructed in line with the following definition:

- Standards are the expected level of achievement and have an attached target, usually expressed as a percentage of cases.

- Standards are written with criteria, which are statements that define what is being measured and represent elements of care that can be measured objectively
- Standards should be evidence based and explicit (for e.g. NICE, Trust policies/guidelines)

For further support please contact bsmhft.clinicaleffectiveness@nhs.net

3.4 Reporting

A report template is automatically issued by the Trust audit database to the auditor upon approval of their audit project. An example of this template can be found in appendix 10.3 on page 27. However, this is not a mandatory format and auditors may choose to use a different format for their reports. It is important to consider the target audience when writing the audit report as findings should be clearly visible to anyone with whom the report is shared.

The audit report should be communicated to all relevant areas of the organisation and Trust committees. An effective audit carried out in one area of the Trust may be transferable to other parts of the organisation. Once a round of data collection has been completed and the data has been analysed, the results and findings should be presented at specialty audit meetings, for discussion, agreement of action plans and a commitment to complete another audit cycle within a designated timeframe.

3.5 Action plans for improvement

The main purpose of clinical audit is to deliver improvements in clinical practice. Where the results of a clinical audit indicate sub-optimal practice, an action plan must be developed and implemented, and its effects monitored. Actions should be specific, measurable, achievable and relevant. They must have clear implementation timescales, with identified leads for each action. Action plans must be approved by the relevant head of service or department. Once the actions have been agreed they can be added to the Trusts action planning module on eclipse.

The clinical effectiveness advisory group (CEAG) will monitor the implementation of actions for level one and two audits, ensuring that any identified required changes are incorporated into practice and into relevant business plans and/or risk registers as appropriate.

Not all clinical audits will require an action plan, e.g. where an audit shows that standards are consistently and repeatedly being met, and practice is effective. For such audits there should be an explicit statement within the summary report that no further action is required, along with the reason(s) for this.

LCGC have responsibility for overseeing local audit action plan. The action planning module is available on eclipse to use for monitoring these actions.

3.6 Repeating audit cycles

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. Locally is up to the LCGC or equivalent governance committee to agree when it is appropriate to stop the audit cycle. For Trust wide audits this will be reviewed by CEAG and TCGC. The process for re-auditing is the same as initial audits and should be registered on the audit registration system (see above).

Some audits may indicate the need for a QI project prior to a reaudit. This is usually when actions may not be clear in order to improve the compliance with the audit standards. If this is the case please contact the QI team to discuss the potential project bsmhft.qualityimprovementteam@nhs.net.

3.7 Confidentiality agreements

There may be occasions when a request is received to undertake a clinical audit by a medical student who is not on a placement with the Trust. Such requests should be referred to the Research and Innovation Department. Links have been developed with the medical school at the University of Birmingham to improve access for medical students for research, audit and service evaluations. The Research and Innovation Department will assess the project; obtain a copy of the CRB and Occupational Health check for the student; ensure they have a BSMHFT collaborator (usually the clinical lead); provide induction for Trust policies and procedures; provide IT access and issue a 'Letter of Access'.

The student will be required to provide a copy of the Letter of Access to the Clinical Governance department when registering their audit project.

3.8 Training and development

Provision of clinical audit training

The Trust will make available suitable training, awareness and support programmes to all relevant staff regarding the systems and arrangements for participating in clinical audit. This will ensure:

- An introductory clinical audit training session is available to any member of staff
- An ongoing programme of clinical audit training of different levels is available to all staff to enable them to undertake clinical audit
- Training for local, regional, and national clinical audit activities, and bespoke training, will be given to groups and individuals on request
- Appropriate training is available to any service users/EBEs and other members of the public who participate in clinical audit activities.

3.9 Priority levels for clinical audit

There are four levels of clinical audit priority, these are detailed below. Audits are allocated a priority level based on the definitions shown:

Audit priority levels:

| Level | Description | Examples |
|--------------|------------------------------------|---|
| 1 | National Priority | National Clinical Audit, Confidential Enquiries, CQC obligations |
| 2 | Trust Priority | Quality account, Business Plans, Response to incidents/homicide enquiries, CQUIN's |
| 3 | Department/Service priority | Medicines code, review implementation of policies and guidelines |
| 4 | Clinician Interest | Locally initiated audits not covered by the above |

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 audits allow the Trust to compare performance with other providers and against nationally agreed standards. These audits are coordinated through the Clinical Governance Department and the Clinical Governance team will provide full support with data collection.

The results arising from these audits will be presented initially to the Clinical Effectiveness advisory group and then to the relevant Service areas via their local clinical governance committees. Trust Wide action plans will be developed and overseen by the Clinical Effectiveness Advisory Group (CEAG). Action plans should be SMART - Specific, Measurable, Achievable, Relevant, and Time based. They must have clear implementation timescales with identified leads for each action and will be incorporated into the committee's action plans or work programmes. These actions will be recorded on the Trusts action panning module on eclipse and reviewed by CEAG bi-monthly

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

These are trust priority audits and will link to key objectives for the Trust. Many of these clinical audits will arise from governance issues or high-profile local initiatives, and may include national initiatives with local relevance, without penalties for non-participation. They may 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
- Priorities identified via patient and public involvement initiatives.
- Commissioner priorities and specifications, including Commissioning for Quality and Innovation frameworks (CQUINs), Best Practice Tariffs (BPTs),

National policies such as the NHS Long Term Plan, and NHS Standard Contract requirements

- Professional revalidation, appraisal, and training needs.
- Audits that must be undertaken in order to comply with provider policies, particularly those that are subject to external review

These audits can be coordinated through the Clinical Governance Department and the Clinical Governance team can provide full support with data collection. All CQUINs will be coordinated by the clinical lead with support from the Clinical Governance department.

These audits will be presented to a sub-committee of the Trust Clinical Governance Committee, for example, the Physical Health Committee and then to areas with involvement in the audit for learning. Action plans will be developed and monitored by these sub-committees. CQUIN audits will be submitted directly to our Commissioners. Action plans should be SMART - Specific, Measurable, Achievable, Relevant, and Time based. They must have clear implementation timescales with identified leads for each action and will be incorporated into the committee's action plans or work programmes. Actions arising from CQUIN audits will be developed and monitored by the clinical lead for the CQUIN.

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

Priority level 3 consists of Service area priority audits as well as corporate team priority audits. They may include:

- Audits undertaken to meet organisational objectives and service developments
- Clinical risk issues
- Audits undertaken in response to local serious incidents/ near-misses/complaints
- Audits that must be undertaken in order to comply with policies and guidelines

The involvement of the Clinical Governance team differs for these audits so a breakdown of both is provided below.

Service area priority audits

These consist of service area audits which link to topics at services area level. The Service area will be responsible for selecting their own audits. The clinical governance team will provide support when requested to and as per the need of the service area. These audits will be presented at Service area CGC level, and they will be responsible for owning the results, identifying appropriate actions and seeing any recommendations through to completion. Action plans should be specific, measurable and achievable/realistic. They must have clear implementation timescales with identified

leads for each action. Actions will be monitored via the work programme, action log and risk registers if needed of the Service area level Clinical Governance Committee.

Progress against agreed audit activity will be monitored locally and reported through the governance and quality structures.

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.

Corporate team audit priorities

Other level 3 priority audits are identified by corporate departments and professional leads at the start of the year.

These audits will be presented to a sub-committee of the Trust Clinical Governance Committee, for example, the Physical Health Committee and then to areas with involvement in the audit for learning.

Action plans will be agreed by these sub-committees. They should be specific, measurable and achievable/realistic. They must have clear implementation timescales with identified leads for each action and will be incorporated into the committee's action plans or work programmes and risk logs. An individual must be allocated to each action even though the action plan is owned by this committee. Actions will be updated on the Trust audit database by the clinical governance team

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 4

These are audits undertaken by clinicians with an interest in a particular topic or based on local need. The clinical governance team will not provide support to these audits other than general audit advice.

The audits should be presented at Service area level Clinical Governance Committees or sub-committees of these meetings and then to local teams/ areas involved in the audit for learning. The clinical lead will be responsible for agreeing and monitoring actions arising from these audits

Updated action logs can be provided to the clinical governance team however they will not actively chase updates on these actions.

4 Duties and responsibilities

4.1 Roles and 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 | The Clinical Effectiveness Manager is the operational lead for Clinical Audit. They support the executive Medical Director and Associate Medical Director of Quality and Safety and is responsible for: | |

| | | |
|--------------------------------------|--|--|
| | <ul style="list-style-type: none"> • Compile the annual Trust Clinical Audit Programme • Ensuring the Trust delivers the clinical audit programme • Ensuring all registered clinical audits adhere to data protection principles and have outlined a sound methodology • 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 there is high quality clinical audit support and training for clinical staff | |
| <p>Executive Director</p> | <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 | |
| <p>Clinical Audit sponsor</p> | <p>The purpose of a Clinical Audit sponsor is to lead a clinical service in the completion of clinical audits, including through facilitating the implementation of actions needed to improve patient care when required. Key responsibilities include:</p> <ul style="list-style-type: none"> • Explain and promote the importance of clinical audit and the Trust's policies relating to clinical audit to colleagues, including doctors and other healthcare professionals in training • Lead the development of a plan or programme of clinical audits to be carried out in a clinical service, which reflects the Trust's and the service's priorities • Ensure that people working in the service carry out clinical audits • Monitor and manage progress on clinical audits • Facilitate both the analysis of shortcomings of patient care shown by clinical audits and the resulting actions aimed at improving the quality or safety of care | |

| | | |
|--|---|--|
| | <ul style="list-style-type: none"> • Support colleagues to carry out individual clinical audits, including junior doctors • Ensure that the work being carried out on clinical audits is communicated within the clinical service including to management and governance-related groups, as well as to the Trust's clinical governance functions • Ensure that any problems associated with the clinical audit programme are addressed responsibly | |
| Clinical Governance Facilitators | <p>The Clinical Governance Facilitators are required to:</p> <ul style="list-style-type: none"> • Support the audit programme through the monitoring of the audit registration system. • Ensuring all registered clinical audits adhere to data protection principles and have outlined a sound methodology • Support staff with training that will enable staff to conduct meaningful, robust audit projects • Be a source of advice on the methodology of project and management of the day to day support of the clinical audit programme | |
| 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 timetable. They will receive and review reports from the Clinical Effectiveness Advisory Group.</p> | |
| 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 Audit Timetable in Quarter 4 of the financial year. • Monitoring the progress of the audit timetable • Adding projects where necessary in response to local and national priorities. • Review audit reports for level 1 and 2 audits • Developing, implementing and overseeing the completion of recommendations from clinical audit whilst focusing on quality improvement. • Oversight of those recommendations developed, actioned and monitored by the Pharmacological Therapies Committee (PTC). | |

| | | |
|------------------------------|---|--|
| | The committee will also escalate concerns where results of audits are not compliant with best practise principles to Trust CGC. | |
| 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: Development and Consultation process:

| Consultation summary | | |
|--|----------------------------|---------------------------|
| Date policy issued for consultation | 5 th May 2022 | |
| Number of versions produced for consultation | 1 | |
| Committees / meetings where policy formally discussed | Date(s) | |
| Clinical Effectiveness Advisory Group | 5 th May 2022 | |
| | | |
| Where received | Summary of feedback | Actions / Response |
| | | |
| | | |

6: Reference documents

Best Practice in Clinical Audit HQIP 2020

7: Bibliography:

Clinical Audit policy

Clinical Audit Programme

Clinical Audit reporting guide

HQIP guide for clinical audit leads

8: Glossary:

Locally accepted definition of clinical audit

‘Clinical audit is a quality improvement cycle that involves measurement of the effectiveness of healthcare against agreed and proven standards for high quality and taking action to bring practice in line with these standards so as to improve the quality of patient care and health outcomes.’ Best Practice in Clinical Audit HQIP 2020

The four stages of the audit cycle are:

- Stage 1 – Preparation and Planning: to agree required standards and clinical audit methodology
- Stage 2 – Measuring Performance: data collection in order to evaluate performance against required standards
- Stage 3 – Implementing Change: using action planning where shortfalls are identified
- Stage 4 – Sustaining Improvement: through monitoring and service development, with repeated clinical audit cycles as required

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: Audit and Assurance

Monitoring

Monitoring the effectiveness of clinical audit activity

Monitoring of clinical audit activity will take place at all levels of the Trusts governance structure.

The Trust Clinical Governance Committee will monitor the progress of implementing the recommendations made as a result of corporate / divisional programmed or mandatory audits. They will also monitor progress against the trust annual audit program.

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 supports the view that whilst Clinical Audit is fundamentally a quality improvement process, it also plays an important role in providing assurances about 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:

- It participates in all national clinical audits, national confidential enquiries and inquiries and service reviews which are relevant to the services which it provides
- 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)
- The annual programme of clinical audit activity meets the requirements of the Board Assurance Framework, and includes all of the clinical audits necessary to meet regulatory and commissioner requirements

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 Arrangements | Acting on Recommendations and Lead(S) |
|---|---------------------------------------|--|--------------------------------------|---|--|
| Priority setting process for audit. | Clinical Effectiveness Advisory Group | Annual audit programme submitted to the TCGC | Annually | Reported annually to the TCGC | Clinical Governance Committee |
| Clinical audits are conducted in line with the approval process for audit | Clinical Governance team | Registration process | Every time a new audit is registered | Daily review of audits going through registration system | Clinical Audit Leads |
| Level 1 & 2 Audit reports are shared | Clinical Effectiveness Manager | Clinical Governance Meetings | For every level 1 & 2 clinical audit | Audit leads are asked who they are disseminating their audits to on the registration form | Clinical Governance Committee |
| The format for audit reports, including methodology, conclusions and action plans | Clinical Effectiveness Manager | Audit report template (sent with registration) | For every clinical audit | Final reports are submitted to clinical governance facilitators | Clinical governance Facilitators |
| How the organisation makes improvement, monitors action plans and carries out re-audits (for level 1 & 2 clinical audits) | Deputy Medical Director | Clinical Effectiveness Advisory Group | For every level 1 & 2 clinical audit | Clinical Effectiveness Advisory Group develops actions and timescales. These are chased up by Trust Clinical Audit Lead and if no progress escalated to Governance committees in quarterly reports. | Chairs of local Clinical Governance Committees |
| Escalation of clinical audit outcomes and delivery of programme | Clinical Effectiveness Manager | Report | Quarterly | Clinical Governance Committee | Clinical Audit Leads |

10. Appendices:

Appendix 1 - Equality assessment

Appendix 2 - Clinical Audit registration process

Appendix 3 - Clinical Audit report and action plan template

aPPENDIX

Equality Analysis Screening Form

A word version of this document can be found on the HR support pages on Connect
<http://connect/corporate/humanresources/managementsupport/Pages/default.aspx>

| | | | |
|---|------------------------------|-----------------------|--------------------------------|
| Title of Proposal | Clinical Audit Policy | | |
| Person Completing this proposal | Louise Wright | Role or title | Clinical Effectiveness Manager |
| Division | Governance | Service Area | Clinical Effectiveness |
| Date Started | May 2022 | Date completed | May 2022 |
| Main purpose and aims of the proposal and how it fits in with the wider strategic aims and objectives of the organisation. | | | |
| 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 | | | |
| Who will benefit from the proposal? | | | |
| This policy applies to anyone engaged in the clinical audit process under the auspices of the Trust. This includes all staff, both clinical and non-clinical, including staff on short-term or honorary contract, students and trainees in any discipline and patients, carers, volunteers and members of the public. | | | |
| Do the proposals 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> | | | |
| The proposal will have a positive affect on services users, employees and wider community. The policy provide a framework for activity, including standards, guidance, and procedures, as well as details of the support available from the Clinical Audit Team | | | |
| Do the proposals significantly affect service delivery, business processes or policy? <i>How will these reduce inequality?</i> | | | |
| 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. | | | |
| Does it involve a significant commitment of resources? | | | |

| How will these reduce inequality? | | | | |
|---|--------------------------|------------------------|---|--|
| The proposal relates to Trust wide and will affect all areas/staff and service users in a positive way. | | | | |
| Do the proposals relate to an area where there are known inequalities? (e.g. seclusion, accessibility, recruitment & progression) | | | | |
| N/A | | | | |
| Impacts on different Personal Protected Characteristics – Helpful Questions: | | | | |
| <i>Does this proposal 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 | | | ✓ | It is anticipated that age will not have a negative impact as this policy applies to anyone engages in clinical audit irrespective of their characteristics. Age is often collected as part of demographic information but should not affect the outcome of the clinical audit. Age can be a criterion for inclusion in an audit sample if the audit is reviewing care in an age specific service. This can have a positive impact as clinical audit is used to improve the quality of care and health outcomes and does not directly affect the service the participants receive. |
| Including children and people over 65 Is it easy for someone of any age to find out about your service or access your proposal? Are you able to justify the legal or lawful reasons when your service excludes certain age groups | | | | |

| | | | | |
|--|---|--|---|---|
| Disability | | | ✓ | It is anticipated that disability will not have a negative impact as this policy applies to anyone engages in clinical audit irrespective of their characteristics. Mental health diagnosis can be recorded if relevant and can be a criterion for inclusion but should not affect the outcome of the clinical audit. This can have a positive impact as clinical audit is used to improve the quality of care and health outcomes and does not directly affect the service the participants receive. |
| <p>Including those with physical or sensory impairments, those with learning disabilities and those with mental health issues Do you currently monitor who has a disability so that you know how well your service is being used by people with a disability? Are you making reasonable adjustment to meet the needs of the staff, service users, carers and families?</p> | | | | |
| Gender | | | ✓ | It is anticipated that gender will not have a negative impact as this policy applies to anyone engages in clinical audit irrespective of their characteristics. Gender can be recorded if relevant but should not affect the outcome of the clinical audit. This can have a positive impact as clinical audit is used to improve the quality of care and health outcomes and does not directly affect the service the participants receive. |
| <p>This can include male and female or someone who has completed the gender reassignment process from one sex to another Do you have flexible working arrangements for either sex? Is it easier for either men or women to access your proposal?</p> | | | | |
| Marriage or Civil Partnerships | ✓ | | | It is anticipated that Marriage or Civil Partnerships will not have a negative impact as this policy applies to anyone engages in clinical audit irrespective of their characteristics. Marriage or Civil Partnerships is rarely recorded and should only be if relevant but should not affect the outcome of the clinical audit. |
| <p>People who are in a Civil Partnerships must be treated equally to married couples on a wide range of legal matters Are the documents and information provided for your service reflecting the appropriate terminology for marriage and civil partnerships?</p> | | | | |

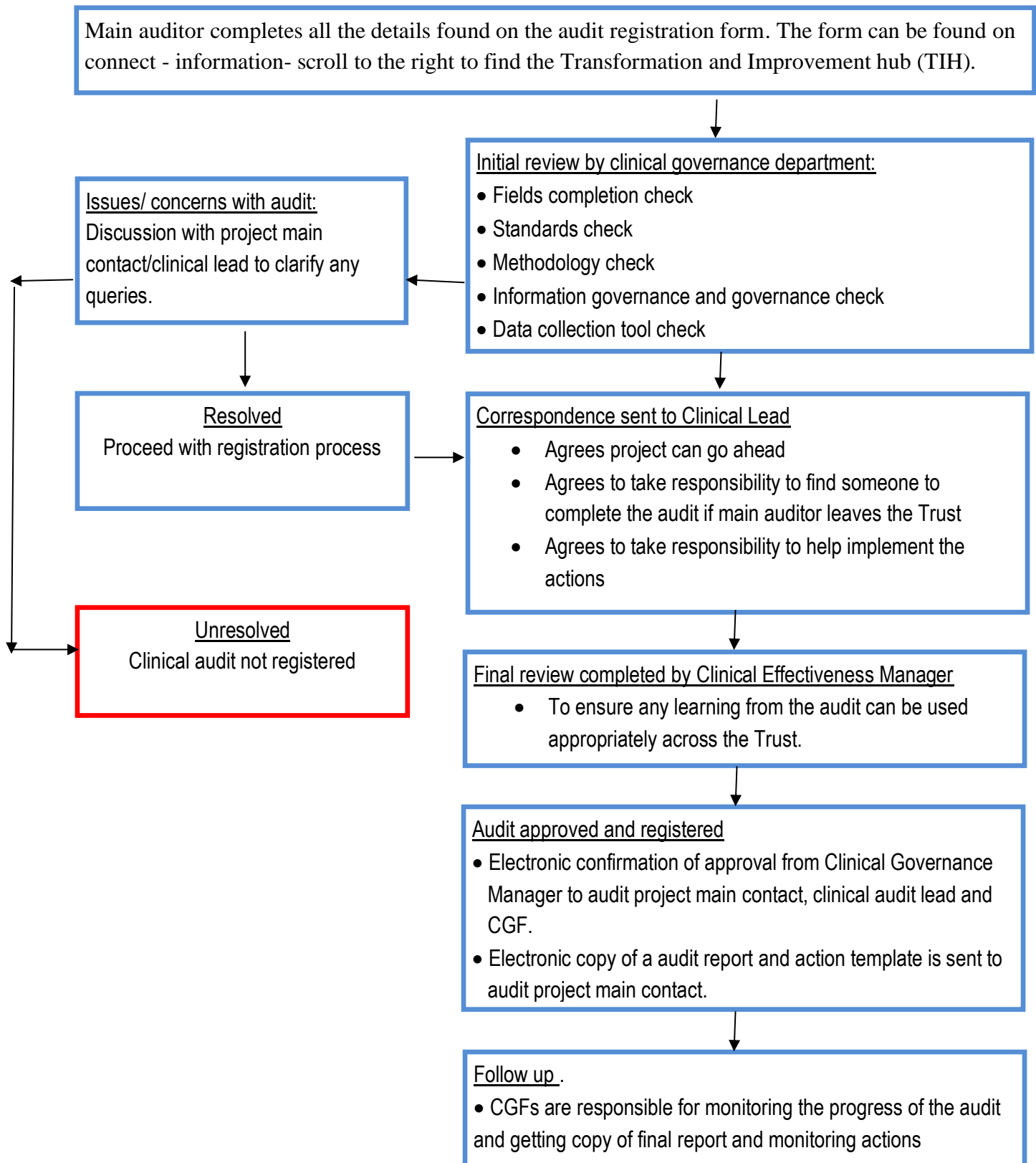
| | | | | |
|---|---|--|---|---|
| Pregnancy or Maternity | | | ✓ | It is anticipated that Pregnancy or Maternity will not have a negative impact as this policy applies to anyone engages in clinical audit irrespective of their characteristics. Pregnancy or Maternity can be used as an audit topic if relevant to the service. This can have a positive impact as clinical audit is used to improve the quality of care and health outcomes and does not directly affect the service the participants receive. |
| <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> | | | | |
| Race or Ethnicity | | | ✓ | It is anticipated that race or ethnicity will not have a negative impact as this policy applies to anyone engages in clinical audit irrespective of their characteristics. Race or ethnicity can be recorded if relevant but should not affect the outcome of the clinical audit. This can have a positive impact as clinical audit is used to improve the quality of care and health outcomes and does not directly affect the service the participants receive. |
| <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> | | | | |
| Religion or Belief | ✓ | | | It is anticipated that Religion or Belief will not have a negative impact as this policy applies to anyone engages in clinical audit irrespective of their characteristics. Religion or Belief is rarely recorded and should only be if relevant but should not affect the outcome of the clinical audit. |
| <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> | | | | |

| | | | | |
|--|---|--|---|---|
| Sexual Orientation | ✓ | | | It is anticipated that Sexual Orientation will not have a negative impact as this policy applies to anyone engages in clinical audit irrespective of their characteristics. Sexual Orientation is rarely recorded and should only be if relevant but should not affect the outcome of the clinical audit. |
| <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> | | | | |
| Transgender or Gender Reassignment | ✓ | | | It is anticipated that Transgender or Gender Reassignment will not have a negative impact as this policy applies to anyone engages in clinical audit irrespective of their characteristics. Transgender or Gender Reassignment is rarely recorded and should only be if relevant but should not affect the outcome of the clinical audit. |
| <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 proposal or service?</p> | | | | |
| Human Rights | | | ✓ | It is anticipated that human rights will not have a negative impact as this policy applies to anyone engages in clinical audit irrespective of their characteristics. Sometimes information relating to the MHA status is recorded if relevant but should not affect the outcome of the clinical audit. This can have a positive impact as clinical audit is used to improve the quality of care and health outcomes and does not directly affect the service the participants receive. |
| <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 |
| | | | | ✓ |
| <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 proposal 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? | | | | |
| N/A | | | | |
| How will any impact or planned actions be monitored and reviewed? | | | | |
| N/A | | | | |
| How will you promote equal opportunity and advance equality by sharing good practice to have a positive impact 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 proposal 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

Clinical Audit registration process



Appendix 3

Clinical Audit report and action plan template

Title

By:

| | | |
|-----------------------------|--------------------|-------------|
| Audit ID | [AuditID] | |
| Audit project clinical lead | [ClinicalLead] | |
| Auditors | [Auditors] | |
| Division | [Division] | |
| Programme/zone | [Programme/zone] | |
| Teams | [Teams] | |
| Audit Type | [Audit type] | Local audit |
| Project start date | [ProjectStartDate] | |
| Project completion date | [ProjectEstiComp] | |

Introduction:

Audit description:

Audit Aims/objectives:

Standards:

| Standards | Target | Standards Reference: |
|-----------------|--------|----------------------|
| [StandardsList] | | |

Method:

| | |
|-------------------|--------------------|
| Audit methodology | [AuditMethodology] |
| Data sources | [AuditMethods] |

| | |
|-----------------------------------|-------------------|
| Sampling Method | [Samplingmethods] |
| Population size | [Population] |
| Sample size | [SampleSize] |
| Data collection for the period of | |

Results:

Key Findings:

Conclusion/ Summary:

Recommendations:

Action plan:

| No. | Recommendations/ issue to be addressed | Outcome/ expected improvement | Action (SMART) | Action Lead (job title) | Start date and target end date |
|-----|---|----------------------------------|-------------------|----------------------------|--------------------------------------|
| | | | | | |
| | | | | | |
| | | | | | |

References

Appendices