

Clinical Audit Policy

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Document Abstract	
<p>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 and for developing and designing clinical audit projects.</p> <p>From April 2012, the NHS Litigation Authority (NHSLA) requires all scheme members to have 'an approved documented process for making sure that all clinical audits are undertaken, completed and reported on in a systematic manner'.</p> <p>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.</p>	

Document Change Control				
Date of Version	Version Number	Lead for Revisions	Type of Revision	Description of Revision
December 2005		Chris Swonnell	Major	Clinical Audit guidance re-issued in the form of a 'strategy' for clinical audit *
November 2007	1.0 (draft)	Chris Swonnell	Major	Fundamental re-write of document to update the previous 'strategy' and incorporate a number of specific policies developed around, e.g. governance of national clinical audits; student participation in clinical audit, etc.
December 2007	1.1	Chris Swonnell	Minor	Final amendments
August 2009	2.0	Chris Swonnell	Major	Fundamental re-write of document based on a) new Trust guidance on policy development and b) guidance issued by the Healthcare Quality Improvement Partnership regarding the development of local clinical audit policies. Delayed sign-off of updated policy in light of impending release of NHSLA standard for clinical audit.
May 2010	2.1	Stuart Metcalfe	Minor	Further amendments to draft 2.0, taking into account NHSLA requirements.
September 2010	2.2	Stuart Metcalfe	Minor	Clarification of requirements in respect on national clinical audits.
March 2012	3	Stuart Metcalfe	Major	Formatting in line with new Procedural Document Framework plus other amendments in relation to NHSLA Level 3 Standards
June 2014	3.1	Stuart Metcalfe	Minor	Reference to the Francis Inquiry Report 2013 within introduction Minor amendments to terminology to reflect roles of Clinical Chairs etc. Explicate links to Board Assurance Framework or other Corporate Objectives for local audit Explicate links to agreement and monitoring of forward plan activity through Divisions Update of CAG Chair and CA Convenor role descriptions (Appendix F & G) Minor update to the content of 'Definitions of Clinical Audit, Research

				<p>and Service Evaluation activity' section (Appendix E)</p> <p>Minor update to the Clinical Audit Code of Practice (Appendix H)</p>
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1. Introduction

- 1.1 The expectation for healthcare professionals to participate in regular clinical audit was first established in the 1989 Government White Paper 'Working for Patients'. This has been reinforced and extended by a succession of key national publications, including:
- The New NHS – Modern Dependable (Department of Health, 1997)
 - A First Class Service (Department of Health, 1998)
 - Clinical Governance - Quality in the NHS (Department of Health, 1999)
 - Learning from Bristol: the report of the public Inquiry into children's heart surgery at Bristol Royal Infirmary 1984-1995 [the 'Kennedy Report'] (Department of Health, 2002)
 - Good Medical Practice (General Medical Council, 2001)
 - Standards for Better Health (Department of Health, 2004)
 - National Standards, Local Action
 - Good Doctors Safer Patients (Department of Health, 2006)
 - Trust Assurance & Safety (Department of Health, 2007)
 - The NHS Next Stage Review final report - High Quality Care For All [the 'Darzi Report'] (Department of Health, 2008)
 - The Francis Inquiry Report 2013
- 1.2 Participation in clinical audit is also an expectation contained within the Care Quality Commission's Essential Standards of Quality and Safety (introduced 1st April 2010).

2. Purpose and Scope

- 2.1 The purpose of this policy is to develop and sustain a culture of best practice in clinical audit. The policy applies to anyone engaged in the clinical audit process under the auspices of the Trust, e.g. students, volunteers and patients, as well as clinical staff.

3. Definitions

3.1 Clinical Audit

- 3.2 The Trust adheres to the definition of clinical audit set out in *Principles for Best Practice in Clinical Audit* (NICE /CHI, 2002):

“Clinical Audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, processes and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery”

- 3.3 The Trust supports the view that Clinical Audit is fundamentally a quality improvement process, rather than data collection *per se* (although data analysis is an essential element of the clinical audit cycle). Clinical Audit also plays an important role in providing assurances

about the quality of services. However the Trust is also clear that clinical audit is not an appropriate mechanism for investigating matters relating to the performance of individual healthcare professionals. Appendix B provides further information about activities which the Trust does not consider to be within the remit of clinical audit.

- 3.4 In the autumn of 2007, the Trust agreed working definitions of Clinical Audit, Research, Service Evaluation and Service Improvement activity, making clear the differences between these disciplines. These definitions are reproduced at Appendix C. Clinical Audit staff may occasionally facilitate non clinical audit activity, if skills and workload allow, however the Clinical Audit & Effectiveness Team's priority must, by definition, be clinical audit.

4. Duties, Roles and Responsibilities

4.1 *Chief Executive*

- 4.2 The Chief Executive is responsible for the Trust's statutory duty of quality and has overall responsibility for this policy

4.3 *Medical Director*

- 4.4 The Medical Director is responsible for ensuring that the Trust makes adequate provision to support clinicians and managers in undertaking clinical audit.

4.5 *Head of Quality (Clinical Effectiveness and Patient Involvement)*

- 4.6 The Head of Quality is responsible for leading the development of Trust Policy and Strategy in relation to the practice of clinical audit.

4.7 *Clinical Audit and Effectiveness Manager*

- 4.8 The Clinical Audit and Effectiveness Manager is responsible for day-to-day operational matters in relation to delivery of the Clinical Audit Programme and line management of the Trust's team of Clinical Audit Facilitators.

4.9 *Clinical Audit Group*

- 4.10 The Clinical Audit Group is the Trust's lead assurance group in relation to all matters relating to the practice of clinical audit. This group will be responsible for monitoring adherence to this policy. The Group will also review outcomes and actions from completed projects to ensure that results are clearly understood and that robust action plans have been produced where appropriate (including plans for re-audit). Where this is not the case, the Group will seek further clarity from project leads before accepting the project as complete.

4.11 *Clinical Audit Convenors*

- 4.12 Clinical Audit Convenors are responsible for the leadership of Speciality/Division annual clinical audit programmes and the development of clinical audit within Specialties/Divisions. A full description of the role is found at appendix F

4.13 *Clinical Audit Facilitators*

4.14 The Trust will employ a team of staff to facilitate clinical audit, however healthcare professionals are expected to undertake data collection as part of the clinical audit cycle. In this sense, Clinical Audit Facilitators are not “Clinical Auditors”.

4.15 *Clinical Chairs*

4.16 Responsibility for ensuring that relevant and appropriate clinical audit activity is taking place within each clinical Divisions rests ultimately with Clinical Chairs

5. Commitment to Stakeholder Engagement, Collaboration and Partnership

5.1 *Involving patients and the public*

- (a) Patients and carers may assess quality of care in different ways to healthcare professionals, each offering a unique perspective based on their personal experience.
- (b) The Trust is committed to the principle of involving patients/carers in the clinical audit process either indirectly through the use of patient surveys / questionnaires or directly through participation of identified individuals on project steering groups or patient forums.
- (c) By definition, if a patient survey is being undertaken for the purposes of clinical audit, this should in order to obtain information from service users which enables the Trust to determine whether defined clinical standards are being achieved. Other patient surveys, for example those which ask questions about patient satisfaction, will usually more appropriately be undertaken as Patient & Public Involvement activity.
- (d) All surveys involving patients of the University Hospitals Bristol NHS Foundation Trust, other than those undertaken for the purpose of formal research, must be reviewed by the Trust’s Questionnaire Interview & Survey Group (QIS) and may only be undertaken subject to receiving prior approval from the Group. A policy governing the work of the Group is available via the Trust’s Connect (intranet) site.

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

- (a) The Trust encourages clinical audit undertaken jointly across clinical professions and 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.

5.3 *Involving clinical managers*

5.4 Managers are responsible for ensuring that service development and delivery is underpinned by clinical audit and forms part of Continuing Professional Development.

5.5 *Involving Medical Students & F1/F2 doctors*

- (a) As a Teaching Trust, the University Hospitals Bristol NHS Foundation Trust's policy is to actively encourage medical student involvement in its clinical audit programme.
- (b) In particular, support will be extended wherever possible to Year 3 and Year 5 Medical Students who choose clinical audit for the Student Selected Component of their studies. The Trust's preferred approach is to assign Medical Students to identified projects in the agreed Trust clinical audit programme. Trust guidance on student involvement, which has been agreed with the University, is provided at Appendix I. A similar approach is taken to participation by trainee medical staff.

5.6 *Working with commissioners*

- (a) The Trust is committed to seeking the views of NHS Bristol and specialist commissioners in determining its annual clinical audit priorities. The Trust will report the results and outcomes of local clinical audit activity to NHS Bristol on request. The results and outcomes of audits of NICE Technology Appraisal Guidance specifically will be reported to the local Clinical Commissioning Groups, via the BNSSG NICE College.

6. Process for Setting Priorities for a Clinical Audit Programme Including Participation in National and Local Audits

6.1 *Process for Agreeing the Clinical Audit Annual Programme.*

- (a) The Trust will agree an annual Clinical Audit Programme, focussing on 'must do' activity. The Trust will take a consultative approach to the development of the Programme. This consultation will seek input from:
 - Chairs/Operational Leads of Groups reporting directly/indirectly to the Clinical Quality Group
 - Divisional Directors/Clinical Chairs
 - Chairs of Divisional Governance/Quality & Safety Groups
 - Commissioners
 - The public, via a notice placed on the Trust's web site
- (b) The Clinical Audit & Effectiveness Manager will liaise with the above during the final quarter of the preceding financial year, setting a date for comments and proposals to be received by.
- (c) Forward plans will be agreed and monitored through Divisional Quality/Safety Groups. Reports on progress against identified activity will be provided by the Clinical Audit & Effectiveness Team.
- (d) Progress on this activity will also be monitored by CAG and reported to CQG and to the Trust Audit Committee on a regular basis.

6.2 *National Audits*

- (a) The Trust will seek to participate in any relevant national audits which form part of the Healthcare Quality Improvement Partnership's National Clinical Audit & Patient Outcome Programme (NCAPOP). The Trust will also seek to participate in other relevant national audits as resources permit.
- (b) The Trust will provide an IT infrastructure to support mandatory data returns for national clinical audits.

6.3 *Local Audits*

- (a) In addition to participation in national audits, the Trust will develop a programme of activity which embraces:
 - Clinical audit activity relating to the Board Assurance Framework or other Corporate Objectives
 - Clinical audits of NICE guidance (in its various forms)
 - Clinical audits resulting from gap analyses following the publication of practice recommendations by the National Confidential Enquiry into Patient Outcome and Death (NCEPOD)
 - Clinical audits of guidance issued by the Patient Safety bodies
 - Clinical audits which enable the Trust to demonstrate compliance with NHS Litigation Authority risk management standards.
 - Clinical audits required to provide evidence in relation to CQUIN requirements agreed with commissioners
 - Clinical audits which provide evidence to support Divisional Quality Objectives
 - Clinical audits of Medicines Management (NPSA Alerts)
 - Clinical audits which reflect topics highlighted by Trust Risk Registers
 - Local clinical concerns/specialty priorities
- (b) The Trust is also committed to supporting, where possible, clinical audits of other topics of particular interest/concern to individual clinicians. These may include audits prompted by patient safety concerns and patient feedback. In determining the choice of local projects, the Trust expects Clinical Divisions to take the following questions into account:
 - Does the proposed audit reflect Divisional priorities (as identified in business plans, etc)?
 - Can patients and other service users be involved in this project?
 - Will the audit be multi-professional and encourage multi-professional working?
 - Will the audit help to develop links with external partners?
 - Is the audit a re-audit, thereby enabling confirmation of improvements in practice?

7. Governance of Clinical Audit

7.1 System for registration and approval of clinical audits

- (a) All clinical audit project proposals must be formally registered with the Clinical Audit & Effectiveness Team using the appropriate forms prior to the project commencing. The latest proposal form can be found on the Trust's web site at:

<http://www.uhbristol.nhs.uk/for-clinicians/clinicalaudit/carrying-out-projects-at-uh-bristol/>
- (b) Proposal forms should be approved by the relevant Clinical Audit Convenor or specialty audit lead. This should happen before the project commences. Data from the proposal form is entered onto a central database for monitoring and reporting purposes (see 7.4).
- (c) Where patient surveys are to be used as part of a clinical audit, these surveys must also be approved by the Trust's Questionnaire Interview & Survey (QIS) Group. The latest proposal form can be found on the Trust's Connect (intranet) site and QIS Workspace.

7.2 The use of standards in clinical audit

- (a) By definition, clinical audit involves measuring clinical practice against predetermined standards of best practice. The Trust expects clinical standards to be presented in a format which conforms to *Principles for Best Practice in Clinical Audit* (NICE, 2002), including measurable criteria, target percentage compliance. This is reflected in the structure of the Trust's clinical audit proposal form (see 7.1). Data collection tools should be submitted as part of the registration process to ensure that they reflect the standards outlined within the policy/guidance being audited.
- (b) Wherever possible, clinical audit standards should be based on robust research evidence.
- (c) Process-based clinical audit project proposals which do not make reference to standards will not be registered as clinical audit.

7.3 Equality & Diversity

- (a) Clinical Audit Policy and Clinical Audit Strategy documents will be subject to an Equality Impact Assessment.
- (b) The Trust is committed to ensuring that the manner in which project patient samples are drawn up does not inadvertently discriminate against any groups based on their race, disability, gender, age, sexual orientation, religion and belief

7.4 Information Governance: collection, storage and retention of data; confidentiality

- (a) All clinical audit activity must take account of the Data Protection Act (1998) and the Caldicott Principles (1997). This means, for example, that data should be:
 - Adequate, relevant and not excessive

- Accurate
 - Processed for limited purposes
 - Held securely
 - Not kept for longer than is necessary
- (b) The Department of Health publication Records Management: NHS Code of Practice (2006) requires “audit records” to be retained for a period of five years, although the document does not define the term “record” in this context. The Trust is currently committed to retaining clinical audit project reports indefinitely. Raw data should however be destroyed once a project has been completed, i.e. a report has been presented and the project lead is content that there is no further purpose for holding the raw data.
- (c) The NHS Confidentiality Code of Practice (2003) states that “Patients must be made aware that the information they give may be recorded, may be shared in order to provide them with care, and may be used to support local clinical audit” (p21). The Trust currently makes provision for this in its patient leaflet entitled ‘What we do with your personal information’ and therefore patient identifiable data may be collected for the purposes of clinical audit under the terms of Section 60 of the Health & Social Care Act 2001. This leaflet can be found at the following link:

<http://nww.avon.nhs.uk/dms/download.aspx?did=1655>

However the Trust’s policy is to anonymise clinical audit data unless there is a compelling reason not to do so.

- (d) The Trust will maintain a central database containing details of all registered clinical audit activity. These records will be used for internal monitoring and assurance purposes, e.g. quarterly and annual programme reports. Access to the database will normally be restricted to members of the Clinical Audit & Effectiveness Team and Clinical Audit Group.
- (e) Reports written at the end of clinical audit projects should also be anonymised, i.e. not mentioning the names of patients or clinicians (for example where the relative ‘performance’ of different clinicians might otherwise be revealed in a report – the purpose of clinical audit being quality assurance and improvement, not performance management).
- (f) Clinical audit practice must conform to the Trust’s policies regarding storage of data on removable devices, e.g. memory sticks.
- (g) There may be occasions when the Trust engages individuals in its clinical audit activities who are not directly employed by the Trust, e.g. staff with honorary contracts, volunteers, patients and the public. Individuals who work with the Trust in these capacities will be required to sign a confidentiality agreement.

7.5 Ethics and consent

- (a) By definition, clinical audit projects should 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 (see 7.3).

8. Reporting, Dissemination of Results and Making Improvements

8.1 Presenting and reporting results

- (a) Clinical audit results should be presented at Divisional/specialty audit or team meetings where the findings can be discussed, and an action plan agreed where necessary.
- (b) A formal project report should be produced for all registered clinical audit projects; this is the responsibility of the project lead. The latest report and presentation templates can be found on the Trust's web site at:

<http://www.uhbristol.nhs.uk/for-clinicians/clinicalaudit/carrying-out-projects-at-uh-bristol/>

8.2 Action plans

- (a) Where the results of a clinical audit indicate the need for improvement, a SMART action plan will be produced. This will state the agreed actions, the member/s of staff responsible for delivering each action, and the target date for completion in each instance.
- (b) The project lead or supervisor is responsible for co-ordinating and overseeing the production of the action plan. If the project lead is of the view that an action plan is not required, this information is relayed to the Clinical Audit & Effectiveness Team, recorded on the clinical audit database, and open to scrutiny by Divisional and corporate committees (see 8.3). The possibility of re-audit should be considered as part of this process (see 8.4).
- (c) It is the responsibility of the project lead/team to produce and implement any actions identified as a result of an audit. The implementation of action plans will be monitored by the Clinical Audit & Effectiveness Team and reported to the Clinical Audit Group via a standing quarterly report. Any outstanding actions identified (those that have passed the date of completion and have yet to be implemented) will be followed up with the project team.

8.3 Reporting outcomes and actions

- (a) Summary reports of outcomes and actions will be reported to the Trust Clinical Audit Group on at every meeting. These reports are automatically generated from project information held on the Clinical Audit Project Management Database.

8.4 Re-audit

- (a) Re-audit is important to confirm the implementation and impact of agreed actions. The Trust's current target is for approximately 25% of clinical audit activity to be re-audit.

9. Training and Development

9.1 *Clinical Audit Training*

- (a) Training raises the profile of clinical audit and builds capacity and capability of all staff involved in clinical audit, so acting a driver for quality improvement. The Trust's Clinical Audit & Effectiveness Team is therefore committed to providing clinical audit training in formats which reflect clinicians' needs. This currently ranges from intensive one-day clinical audit courses to bespoke training for individual clinicians upon request.
- (b) The Trust is committed to employing a team of suitably skilled clinical audit staff to support its clinical audit activity. The Trust will also ensure that these staff have access to relevant training in order to maintain and develop their knowledge and skills.

10. Appendix A - Monitoring Table for this Policy

What will be monitored?	How?	When?	By whom?
Duties			
How the organisation sets priorities for audit, including local and national requirements	Forward planning consultation process and annual clinical audit forward plan sign off	Annual	Clinical Audit Group
Requirement that audits are conducted in line with the approved process for audit	Key Performance Indicator - registration of clinical audit proposals prior to project commencing	Each meeting	Clinical Audit Group
Format for all audit reports, including methodology, conclusions, action plans, etc.	Key Performance Indicator - clinical audit report produced	Each meeting	Clinical Audit Group
How the organisation makes improvements	Outcomes and actions of recorded clinical audit activity.	Each meeting	Clinical Audit Group
	Key Performance Indicator – action plan produced	Each meeting	Clinical Audit Group
How the organisation monitors action plans and carries out re-audits	Standing report- Outstanding action report	Each meeting	Clinical Audit Group
	Key Performance Indicator – action plan produced	Each meeting	Clinical Audit Group
Provision of staff training	Feedback forms	Whenever training takes places	Clinical Audit & Effectiveness Manager
Stakeholder involvement in clinical audit activity	Key Performance Indicator – Interface and PPI participation	Each meeting	Clinical Audit Group
Multi-disciplinary participation in clinical audit	Key Performance Indicator – Multi-disciplinary participation	Each meeting	Clinical Audit Group
Participation in national audits	Standing report - National Audit Register	Each meeting	Clinical Audit Group

Progress of local clinical audits	Standing report - Project progress report	Each meeting	Clinical Audit Group
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11. Appendix B - Dissemination, Implementation and Training Plan

11.1 The following table sets out the dissemination, implementation and training provisions associated with this Policy.

Plan Elements	Plan Details
The Dissemination Lead is:	Clinical Audit & Effectiveness Manager
This document replaces existing documentation:	Yes
Existing documentation will be replaced by:	Existing Clinical Audit Policy
This document is to be disseminated to:	[DITP - Document to be disseminated to]
Training is required:	No
The Training Lead is:	N/A

Additional Comments
[DITP - Additional Comments]

12. Appendix C - Document Checklist

12.1 The checklist set out in the following table confirms the status of ‘diligence actions’ required of the ‘Document Owner’ to meet the standards required of University Hospitals Bristol NHS Foundation Trust Procedural Documents. The ‘Approval Authority’ will refer to this checklist, and the Equality Impact Assessment, when considering the draft Procedural Document for approval. All criteria must be met.

Checklist Subject	Checklist Requirement	Document Owner’s Confirmation
Title	The title is clear and unambiguous:	Yes
	The document type is correct (i.e. Strategy, Policy, Protocol, Procedure, etc.):	Yes
Content	The document uses the approved template:	Yes
	The document contains data protected by any legislation (e.g. ‘Personal Data’ as defined in the Data Protection Act 2000):	No
	All terms used are explained in the ‘Definitions’ section:	Yes
	Acronyms are kept to the minimum possible:	Yes
	The ‘target group’ is clear and unambiguous:	Yes
	The ‘purpose and scope’ of the document is clear:	Yes
Document Owner	The ‘Document Owner’ is identified:	Yes
Consultation	Consultation with stakeholders (including Staff-side) can be evidenced where appropriate:	No
	The following were consulted:	[DCL - Consulted]
	Suitable ‘expert advice’ has been sought where necessary:	Yes
Evidence Base	References are cited:	No
Trust Objectives	The document relates to the following Strategic or Corporate Objectives:	[DCL - Trust Objectives]
Equality	The appropriate ‘Equality Impact Assessment’ or ‘Equality Impact Screen’ has been conducted for this document:	Yes
Monitoring	Monitoring provisions are defined:	Yes
	There is an audit plan to assess compliance with the provisions set out in this procedural document:	Yes
	The frequency of reviews, and the next review date are appropriate for this procedural:	Yes

Checklist Subject	Checklist Requirement	Document Owner's Confirmation
Approval	The correct 'Approval Authority' has been selected for this Procedural Document:	Yes

Additional Comments
[DCL - Additional Comments]

13. Appendix D - Other associated activities which are not clinical audit

Counting numbers of operations, etc

The collection of data which is not related to clinical standards (criteria) is not considered to be clinical audit. Whilst data collection with the explicit purpose of setting standards of best practice may sometimes be considered to be a legitimate audit activity (called 'pre-audit'), it is important that the audit cycle is observed and that standards are established as a result of the project.

Investigations

Similarly, clinical audit staff are sometimes asked to "find out more about what's happening here". Whether or not these kinds of request constitute clinical audit is also dictated by the presence or absence of clinical standards.

Morbidity & Mortality Review

Although early NHS definitions of Clinical Audit mention peer review, this is notably absent from more recent NHS-approved literature. M&M review is an essential part of Good Governance and issues raised may potentially feed into the Clinical Audit programme. However M&M review is not itself clinical audit, and clinical audit staff are not responsible for organising the M&M process.

14. Appendix E - Definitions of Clinical Audit, Research and Service Evaluation activity

	Research	Clinical Audit	Service Evaluation	Service Improvement
Definition	<p>Aims to derive new knowledge which is potentially generalisable or transferable.</p> <p>Asks the question – “what is best practice?”</p>	<p>Aims to improve the quality of local patient care and clinical outcomes through peer-led review of practice against evidence-based standards and the implementation of change where subsequently indicated.</p> <p>Asks the questions – “are we following best practice?” and “what is happening to patients as a result?”</p>	<p>Aims to judge a service’s effectiveness or efficiency through systematic assessment of its aims, objectives, activities, outputs, outcomes and costs.</p> <p>In different contexts, may also be referred to as “activity analysis”, “benchmarking”, “organisational audit”, “non-clinical audit”, etc.</p> <p>Asks questions like – “has this service been a success?”</p> <p>May also be used to compare the effectiveness or efficiency of a new practice/service (where supported by evidence) with an existing one - however this would be for the purposes of local comparison, i.e. not with a view to derive generalisable or transferable results (which would be research).</p> <p>Whilst benchmarking may be used to compare services, the evaluation will not involve measurement against agreed standards (which would be clinical audit)</p>	<p>Aims to improve patient care through continuous improvement of clinical outcomes and patient experience through group-led activity which focuses explicitly on quality and safety as routes to improving services, whilst also delivering essential productivity and efficiency gains.</p> <p>In different contexts may also be referred to as “service development”.</p> <p>Asks questions like – “how can we make this service safer, more efficient, better for patients?”</p>
Initiated by	Usually initiated by researchers.	Initiated by national bodies (e.g. Healthcare Commission, Royal Colleges, NICE, etc), commissioners (PCTs) or service providers (including local healthcare staff and managers)	Usually initiated by service managers/leads.	Initiated in numerous ways: <ul style="list-style-type: none"> • as a corporate priority to support the delivery of the Trust’s objectives • as part of a national initiative (e.g. DH, NHS Institute for Innovation & Improvement) • by individuals and/or teams in a department or speciality area • by service managers and/or clinical lead

Methodology & Design	<p>Addresses clearly defined questions / hypotheses using systematic and rigorous processes.</p> <p>Designed so that it can be replicated and so that its results can be generalised to other similar groups.</p>	<p>Addresses clearly defined audit questions using robust methodology – usually asking whether a specific clinical standard has been met.</p> <p>Results are specific and local to a particular team or service although the audit tool may be used by more than one team/service</p>	<p>Addresses specific questions about the service concerned.</p> <p>Results are specific and local to a particular team or service although the evaluation tool may be used by more than one team/service.</p>	<p>The approach includes:</p> <ul style="list-style-type: none"> • Awareness and engagement of individuals/teams so that there is agreement that improvement is necessary/possible • Analysis of the current process/pathway highlighting areas that cause unnecessary waits and delays for patients and are wasteful of staff time • Understanding the bottlenecks, existing demand on the process and current capacity to deliver, as well as the variation that exists within the process • Designing the desired future process/pathway and agreeing the steps needed • Developing a project implementation plan that gets us to the future state • Ensuring the changes are sustained and that there is continuous improvement.
Coverage	<p>Research projects may be service-specific, trust-wide, regional or national.</p>	<p>Clinical audit projects may be service-specific, trust-wide, regional or national.</p>	<p>Service Evaluation projects may be service-specific, or trust or community-wide.</p>	<p>Service improvement projects can be patient pathway specific, service/specialty specific, trust-wide, health and social care economy wide, regional or national</p>
New treatments	<p>May involve a completely new treatment or practice</p>	<p>Will <u>never</u> involve a completely new treatment or practice.</p>	<p>Will <u>never</u> involve a completely new treatment practice (but see Definition box above).</p>	<p>Will <u>never</u> involve a completely new treatment or practice.</p>
Controls & Placebos	<p>May involve use of control groups or placebo treatment for purposes of comparison</p>	<p>Will <u>never</u> involve use of control groups or placebo treatment</p>	<p>Will <u>never</u> involve use of control groups or placebo treatment</p>	<p>Will <u>never</u> involve use of control groups or placebo treatments</p>

<p>Patient involvement and Randomisation</p>	<p>May involve allocating service users randomly to different treatment groups.</p> <p>Patients should be involved in the design, implementation and analysis of the work.</p>	<p>May involve input from patients at a number of levels, e.g.</p> <ul style="list-style-type: none"> • Patients may be asked to participate in surveys which help to determine whether standards have been met • Patients may be involved in the design of individual audit projects or indeed whole programmes of activity (e.g. as members of steering groups) <p><u>Never</u> involves allocating patients randomly to different treatment groups.</p>	<p>May involve input from patients at a number of levels, e.g.</p> <ul style="list-style-type: none"> • Patients may be asked to participate in surveys which help to determine the effectiveness or efficiency of a service • Patients may be involved in the design of individual projects or indeed whole programmes of improvement activity (e.g. as members of steering groups) <p><u>Never</u> involves allocating service users randomly to different treatment groups.</p>	<p>May involve input from patients at a number of levels:</p> <ul style="list-style-type: none"> • Patients may be asked to participate in surveys which help to determine the effectiveness or efficiency of a service • Systematic use of tools such as discovery interviews, patient diaries etc. and on-going feedback mechanism through patient involvement in redesign and service user groups • Patients may be involved in the design of individual projects to ensure the needs of different groups are met (equality and diversity issues). <p><u>Never</u> involves allocating service users randomly to different treatment groups.</p>
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<p>Governance arrangements</p>	<p>Must comply with Research Governance.</p> <p>Must be registered with the Research and Development Department.</p>	<p>Must be registered with Clinical Audit Team (and therefore implicitly have been approved by the relevant Clinical Audit Convenor). Use of patient survey methodologies as part of clinical audits is also subject to approval by the Trust's Questionnaire Interview & Survey Group (QIS).</p>	<p>UBristol does not have a department of Service Evaluation; nor does it have known expertise in this field.</p> <p>If Service Evaluation activity is undertaken via the Clinical Audit Team or the Research & Development Department, it will be subject to the scrutiny and advice of those teams, <u>however it should be noted that neither team currently has expertise in the field of Service Evaluation.</u></p> <p>A proposal has been agreed to create a 'projects' database which will attempt to capture non-clinical audit and non-research activity in one place. This should enable Divisions to monitor project activity via their local governance arrangements, and for the Trust to capture additional evidence in support of compliance with Core Healthcare Standard C5d.</p> <p>Use of patient survey methodologies as part of service evaluations is also subject to approval by the Trust's Questionnaire Interview & Survey Group (QIS).</p>	<p>Delivery of the improvement programme is overseen by the Innovation Board and objectives relating to improving performance are monitored at the Trust Operational Group.</p> <p>Use of patient survey methodologies as part of service improvement activity is also subject to approval by the Trust's Questionnaire Interview & Survey Group (QIS).</p>
<p>Ethical Approval required?</p>	<p>Research ethics committee (REC) approval required</p>	<p>Should be scrutinised for ethical implications but REC approval not needed</p>	<p>Should be scrutinised for ethical implications but REC approval not needed</p>	<p>Should be scrutinised for ethical implications but REC approval not needed</p>
	<p>Research</p>	<p>Clinical Audit</p>	<p>Service Evaluation</p>	<p>Service Improvement</p>

End product	Generates evidence to refute, support or develop a hypothesis. May lead to development of new services or new practices.	Generates evidence to demonstrate level of compliance with agreed standards. This may lead to changes in practice.	Generates evidence of effectiveness of a service which may lead to service redesign and reconfiguration.	<ul style="list-style-type: none"> • Generates evidence of improvements by comparing new service performance against the baseline position at the start of the project. • Generates ideas for continuous improvement • Demonstrates skills transfer, in terms of individuals and teams understanding and applying the methodology
One-off or ongoing?	Will often be a one-off study.	May be one-off, however approximately 25% of Trust audit activity involves re-audit (seeking to confirm improvements in practice). Some audits are ongoing	Usually a one-off study, but may be repeated to compare changes over time	On-going. The approach promotes sustaining the improvements made and identifying new opportunities for improvement to develop a culture of continuous improvement

15. Appendix F - Role of Chair of Clinical Audit Group

Appointed by:	Medical Director
Reports to:	Medical Director
Key working relationships:	Clinical Audit and Effectiveness Manager Divisional/Specialty CA Convenors Divisional Clinical Chairs/Service Leads Head of Quality (Patient Experience and Clinical Effectiveness)
Term of office:	3 years (longer by agreement)

Introduction

The Clinical Audit Group is the Trust's lead Group for matters relating to the practice of clinical audit, supporting both the 'Clinical Effectiveness' and 'Patient Safety' dimensions of the NHS model of Quality. In discharging its duties, CAG will be expected to work closely with the Clinical Effectiveness Group, Patient Safety Group and the Quality Intelligence Group.

Personal Characteristics

- The Chair of Clinical Audit Group (CAG) will be a key advocate for the practice of clinical audit, and will be an important link between Executive leadership, corporate assurance and Divisional operational implementation.
- The Chair of CAG will have a clinical background at consultant level (medical or nurse/AHP) or equivalent, with knowledge and experience of using clinical audit as a methodology for both improving practice and providing assurance.
- The Chair of CAG must be an advocate/champion of multi-professional working and comfortable working with a wide range of professionals and specialities.
- The Chair of CAG should have an aptitude and interest in group management, leadership and facilitation skills and demonstrate highly developed interpersonal and team-working skills.

Key responsibilities

- To Chair meetings of the Trust's Clinical Audit Group (currently 5 meetings per year)
- To help ensure that the Trust has a clear strategy for Clinical Audit and that any objectives outlined within this Strategy are met.
- To meet regularly with the Clinical Audit & Effectiveness Manager to agree agendas, agree minutes, review actions, etc.
- To work closely with the Clinical Audit & Effectiveness Manager in providing regular reports (currently on a quarterly basis) to the Trust Audit Committee and the Clinical Quality Group (CQG), highlighting any assurance issues on behalf of the Group. The Chair will attend meetings to present these reports.
- To fulfil the role of Clinical Audit Convenor for Trust-wide projects
- To identify Clinical Audit Convenors who will lead on specific issues on behalf of the CAG (as necessary)
- To work collaboratively with the Chair of the Clinical Effectiveness Group, particular in respect of the audit of NICE guidance, and the development of systems for clinical outcomes monitoring.

16. Appendix G - Role of Divisional Clinical Audit Convenors

Last update: May 2014 (Original job description written by the Director of Human Resources in March 2001)

This is a generic outline of the role of Clinical Audit Convenor. Individual roles may differ in their detail and additional duties and responsibilities may be included by agreement.

1. Summary of Role

The Clinical Audit Convenor is responsible for the leadership of a Speciality/Division annual clinical audit programme and the development of clinical audit within the Specialty/Division.

2. Appointment

The Clinical Audit Convenor must be a healthcare professional with sufficient seniority and credibility in clinical audit activities to command the respect and confidence of staff within their Specialty/Division. The general expectation is that a Convenor serves in this role for three years, however this arrangement is flexible.

3. Accountability

Accountable to the Divisional Clinical Chair

4. Working Relationships

The Clinical Audit Convenor will work closely with clinicians, managers and clinical audit staff within their Specialty, Division and where appropriate, across Divisions.

5. Main Responsibilities

- 5.1 To encourage a culture of openness and participation in clinical audit across all health professions
- 5.2 To attend Trust Clinical Audit Group in order to:
 - i. Represent their Specialty/Division
 - ii. Enable the CAG to discharge its corporate assurance function. For example, by critically evaluating proposals and reports presented to the Group
 - iii. Share experiences, problems and lessons learned
 - iv. Actively contribute to discussions about future directions and developments in clinical audit
- 5.3 To liaise with other audit convenors within the Trust, particularly those within the postholder's own Division
- 5.4 To ensure that clinical audit is represented in Divisional governance/assurance arrangements
- 5.5 To provide guidance and support to Clinical Audit Facilitators and liaise regularly with them in order to:
 - i. Establish and maintain a structure for clinical audit within the Speciality/Division (this may include an audit committee/steering group and should include appropriate

forums whereby the results of audit projects can be presented to a Speciality/Divisional audience)

- ii. To identify an appropriate annual clinical audit programme within their Specialty/Division
- iii. Ensure collection of information to facilitate the production of appropriate reports to the Clinical Audit Central Office and Clinical Audit Committee (i.e. enabling CAC to assure the Trust Board about clinical audit activity within the Speciality/Division)
- iv. To promote patient involvement in clinical audit wherever appropriate

17. Appendix H - Clinical Audit Code of Practice

Clinical Audit Facilitators will:

- Assist clinical staff with the completion of audit paperwork
- Register the project on the trust clinical audit database
- Reach agreement with the speciality audit convenor and the audit project lead as to the level of support that the facilitator will provide to the project – the decision will take account of Divisional and Trust priorities
- This advice and support may include the following:
 - a) Appropriate methodology for the proposed project
 - b) Literature searching and developing measurable clinical standards
 - c) Design of audit tools
 - d) Choosing sample size
 - e) Organising availability of clinical case-notes
 - f) Extraction of data from hospital information systems (where available)
 - g) Data analysis and reporting
 - h) Producing presentation materials
- Participate in and help organise meetings within the Division to allow presentation of audit proposals and results
- Attend Divisional Governance/Quality meetings to enable the discussion and escalation of issues relating to clinical audit activity

Project leads¹ are expected to:

- Ensure they are suitably conversant with the principles and practice of clinical audit
- Register the audit
- Ensure that all ‘interested parties’ have been consulted before the proposed project commences (data should not be gathered about clinicians’ practice for clinical audit purposes without their prior knowledge)
- Ensure that due consideration has been given to the involvement of patients
- Ensure that a prior commitment is obtained from senior clinicians and management (as appropriate) that due consideration will be given to the implementation of any changes in practice indicated by the results of the audit
- Ensure that the proposed audit has clearly defined aims/objectives relating to achievable improvements in quality, and uses (or sets) explicit standards of care.
- Actively engage in all aspects of the audit cycle – including data collection – as appropriate
- Be sensitive to the possible consequences of any audit findings
- Ensure that no healthcare professional or patient can be identified directly or indirectly from a report without their explicit approval
- Present audit findings in appropriate meetings in their own speciality/division and beyond, according to the nature of the subject
 - Ensure that the summary and action plan documentation is completed (this enables the Clinical Audit Group to provide necessary assurances to Trust Board about clinical audit activity)
 - Ensure that an audit report is produced at the end of the project (completion of summary and action plan documentation may suffice – see audit facilitator for advice on this)
 - Ensure that any external publication of audit results receives the prior approval of the speciality/division audit convenor and ethics committee approval where required

¹ The ‘lead’ being the clinician or manager responsible for the day-to-day management of the project

- In cases where the lead clinician leaves the Trust before the project is completed, to arrange for another clinician to take over, and to agree this with the speciality/division audit convenor

All staff actively engaged in the clinical audit process will:

- Take care not to discriminate against any ethnic group, religion, sex or other social/economic group when identifying an audit population/sample
- Not knowingly engage or collude in selective methods designed to produce misleading findings
- Seek to prevent distortion or suppression of audit findings, and will not condone falsification or distortion of audit data
- Adhere to Caldicott principles and the requirements of the Data Protection Act

18. Appendix I - Statement on Medical Student involvement

Date: Last updated May 2010

University Hospitals Bristol welcomes the involvement of medical students in its clinical audit programme. In order to maximise the benefit to students and to the Trust, the following guidance is provided.

The underpinning principle of medical student participation in clinical audit at UHBristol is that students should seek involvement in appropriate projects which are already being planned as part of Divisional clinical audit programmes. All clinical audits should be undertaken with a view to benefiting the organisation and improving patient care – audits with student involvement are no exception, i.e. these audits must do more than simply meet an academic requirement on the part of the individuals concerned. If a student comes up with their own idea for a project which meets these criteria, we will do our best to accommodate this request – however we would anticipate such audits being the exception, rather than the rule. Whilst the ideal is for students to participate in projects from beginning to end, it is possible that they may get involved in projects which have already begun, or which will not complete by the end of their involvement: they will still be able to produce a report based on their involvement and the knowledge they have acquired, even if this is not the actual project report that will be required by the Trust at the end of the project.

Clinical Audit Facilitators will:

- give students an overview of the clinical audit process
- assist with topic selection
- discuss the audit project and the relevant scope for involvement
- introduce the student to the Personal Supervisor
- act as a link/liaison person throughout the project

Please note:

- although clinical audit facilitators are able to offer general advice about identifying a Personal Supervisor for an audit project, it is not their function to arrange links between students and specific consultants
- similarly, whilst clinical audit staff will make every effort to meet students' requests, we cannot guarantee a project being available to meet their timescales – and hence the importance of an early discussion about potential projects

Students must:

- Contact a Clinical Audit Facilitator as soon as relevant dates are known
- where there is preference for a specific specialty, contact the relevant audit facilitator (list attached)
- arrange an appointment with the Clinical Audit Facilitator in order to meet and discuss needs and timescales
- adhere to arranged appointments with both the facilitator and the project Supervisor (senior clinical involved in the project) if different from the project lead.
- agree role in the project with the Personal Supervisor
- turn up for work strictly as agreed with Project Supervisor/Project Lead
- sign a confidentiality form before accessing patient information
- time and interest permitting, the student may remain in contact with the project until its conclusion

Important note: a student's Personal Supervisor may very possibly be a different person to the Project Lead: the Supervisor may not be personally connected with the audit project that the student participates in.