

What is Clinical Audit?

INTRODUCTION

The aim of this guide is to provide a brief summary of what clinical audit is and what it isn't. Aspects of this guide are covered in more detail in the following 'How To' guides:

- How To: Choose and Prioritise Topics.
- How To: Set an Audit Sample & Plan Your Data Collection.
- How To: Engage Patients, Service Users & Carers in Clinical Audit.
- How To: Apply Ethics to Clinical Audit.

WHAT IS CLINICAL AUDIT

“Clinical audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria...Where indicated, changes are implemented...and further monitoring is used to confirm improvement in healthcare delivery.”

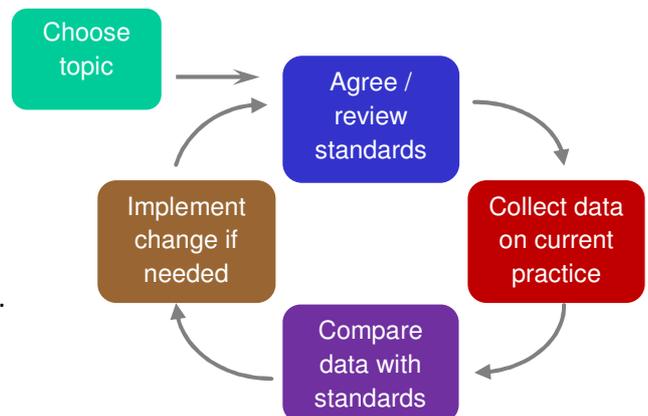
Principles for Best Practice in Clinical Audit (2002, NICE/CHI)

The key messages being that:

1. Clinical audit is not just a data collection exercise:
 - It involves measuring current patient care and outcomes against explicit audit criteria (also termed standards).
 - There is an expectation from the outset that practice will be improved.
2. Further clinical audit may be required to confirm that practice has improved.

The main stages of the clinical audit process are:

- 1) Selecting a topic.
- 2) Agreeing standards of best practice (audit criteria).
- 3) Collecting data.
- 4) Analysing data against standards.
- 5) Feeding back results.
- 6) Discussing possible changes.
- 7) Implementing agreed changes.
- 8) Allowing time for changes to embed before re-auditing.
- 9) Collecting a second set of data.
- 10) Analysing the re-audit data.
- 11) Feeding back the re-audit results.
- 12) Discussing whether practice has improved.



This process is called the Audit Cycle and is summarised in the diagram above.

THE HISTORY OF CLINICAL AUDIT

Medical audit undertaken by doctors was first formalised in 1989. Prior to this audit activity was isolated and infrequently undertaken. Four years later, in 1993, Medical, Nursing and Therapy audit were brought together to form the multi-disciplinary activity that we now recognise as clinical audit.

Since 2008 there has been a shift in the national clinical audit strategy, which has seen the ‘reinvigoration’ of clinical audit at a local level. In line with this the Health Quality Improvement Partnership (HQIP) and the National Clinical Audit Advisory Group (NCAAG) have been tasked, by the Department of Health, to oversee national audits and to lead the ‘reinvigoration’ of local clinical audit by promoting quality in healthcare, and in particular increasing the impact that clinical audit has on healthcare quality in England and Wales.

At a local level clinical audit links into both clinical effectiveness and clinical governance.

Firstly, clinical effectiveness aims to identify and appraise existing evidence of best practice. Once identified, if necessary, local practice may be amended to ensure that it is conforming to best practice. Once implemented a clinical audit project might be undertaken to ensure that:

- a. Best practice is being followed.
- b. That patient outcomes are the desired ones.

Secondly, concerns regarding clinical care are often identified through other clinical governance structures. These concerns can often be used to inform a clinical audit project. This includes:

1. User views or complaints.
2. Adverse incident/near miss reporting, aka clinical/critical incident reporting.
3. Identified local priorities or concerns e.g. areas of high volume, risk or cost.

WHAT CLINICAL AUDIT IS NOT

Not all ‘audit’ that takes place within the health service is clinical audit. Clinical audit is a specific activity that measures clinical care against explicit audit criteria (standards) as part of a quality improvement cycle. The term ‘audit’ has a range of meanings and whilst people might want to ‘audit’ something it does not necessarily mean that they are doing or want to do a clinical audit project.

Other forms of audit can include:

- Financial audit - Looking at accounts to establish whether they provide a true and fair view of the organisation's financial position at a given time.
- Internal audit - An internal mechanism that traces non-clinical activities and systems along 'audit paths' to see if things happened the way they should have. For example, tracing a patient complaint from the initial letter of complaint through to resolution to establish whether Trust guidelines were followed appropriately.
- Organisational audit - An external, independent and voluntary audit of the whole organisation, based on a framework of explicit standards. Organisational audit looks at how well the organisation is set up and runs on a daily basis. The King's Fund is an example of an independent service that undertakes organisational audits.
- Counting things/ Investigations - The collection of data which is not related to explicit audit criteria (standards) is not considered to be clinical audit.
- Routine monitoring of clinical outcomes - The identification and measurement of clinical outcomes that are explicitly linked to the change process may form part of a clinical audit project. However routine monitoring of outcome data for purposes such as performance monitoring is not considered to be clinical audit.
- Peer review including Mortality & Morbidity (M&M) - Peer review is a process whereby a group of clinicians collectively assess a small sample of patients recently under their care to establish whether the best possible care was provided or whether things might have been done differently. M&M reporting is a specific peer review process that looks at specific, non-random, cases with adverse outcomes, such as death or injury, to see what lessons can be drawn.
- Staff, patient, service user, carer surveys - Surveys are usually carried out as part of a research project or as an engagement activity. They are primarily used to gain the opinions of staff, patients, service users or carers regarding treatment and/or the quality of care in order to see if improvements can be made.

Surveys should only be used for clinical audit if the data sought cannot be collected from another source and it is related to processes or outcome of care i.e. were standards of best practice being met.

CLINICAL AUDIT & RESEARCH: WHAT IS THE DIFFERENCE?

“Research is concerned with discovering the right thing to do; audit with ensuring that it is done right”

Smith R. Audit & Research. BMJ 1992; 305: 905-6

Research addresses clearly defined questions and hypotheses using systematic processes to generate new evidence to refute, support or develop a hypothesis, by asking the question ‘what is best practice?’ As a result of which a new service or new practice may be developed. The methodology is designed so that it can be replicated and so that the results can be generalised to other similar groups.

Research may involve a completely new treatment or practice, the use of control groups or placebo treatment for purposes of comparison, or allocating service users randomly to different treatment groups. Patients should be involved in the design, implementation and analysis of the work.

Research must comply with Research Governance, and be registered with the Research and Development Department. It also has to be submitted to the Research Ethics Committee (REC) for approval. The contact details for the Research Development Department are listed at the end of this guide.

Alternatively, clinical audit aims to improve the quality of local patient care and clinical outcomes through the peer-led review of practice against evidence-based standards, implementing change where necessary. It asks the questions ‘are we following best practice?’ and ‘what is happening to patients as a result?’

Clinical audit is initiated by national bodies, commissioners (PCTs) or service providers, including local healthcare staff and managers. The methodology is designed to address clearly defined audit questions that establish whether a specific clinical standard is being met. Results are specific and local to a particular team or service although the audit tool may be used by more than one team or service.

A clinical audit project will never involve a completely new treatment or practice, never involve the use of control groups or placebo treatments, nor does it involve allocating patients randomly to different treatment groups. It may, however, involve input from patients, service users or carers at a number of levels, e.g.

- Participation in surveys which help to determine whether standards have been met.
- Involvement in the design of individual clinical audit projects or whole programmes of activity.

Clinical audit projects must be registered with the Clinical Audit Team, and therefore will have been approved by the relevant Clinical Audit Convenor. The use of survey methodologies as part of a clinical audit is also subject to approval by the Trust’s Questionnaire Interview & Survey Group (QIS). Whilst clinical audit projects should be scrutinised for ethical implications, REC approval is not required.

CLINICAL AUDIT & RESEARCH: WHY IT IS IMPORTANT TO KNOW THE DIFFERENCE

As outlined above research projects and clinical audit projects have very different purposes, and therefore use different methodologies; they are also managed and funded in different ways.

It is sometimes suggested that research is more rigorous than audit but research and audit can both either be rigorous i.e. done according to protocol and producing valid results or not rigorous enough i.e. done carelessly, producing flawed results, and in the case of clinical audit, not leading to improvements in clinical practice.

Whilst research requires REC approval, clinical audit does not. However, clinical audit should still be conducted within an ethical framework. By approving and registering a project as a clinical audit, the Trust is

stating that the project fulfils the methodological criteria that allows for patient data to be accessed and analysed.

Whilst clinical audit projects may be published without ethical approval, e.g. the Quality Improvement Reports published by the British Medical Journal, journal editors may refuse to publish articles if there are ethical concerns and REC ethical approval has not been granted. If you want to publish because of the results of your project, rather than to share the methodology, you should question whether you are undertaking research, rather than a clinical audit project.

SERVICE EVALUATION

The aim of service evaluation is to judge a service’s effectiveness or efficiency through the systematic assessment of its aims, objectives, activities, outputs, outcomes and costs. It addresses specific questions about the service concerned and results are specific and local to a particular team or service and may lead to service redesign and reconfiguration in that particular area. The evaluation tool may, however, be used by more than one team or service.

Service evaluation never involves completely new treatment practices, the use of control groups or a placebo treatment nor does it involve allocating service users randomly to different treatment groups. It may, however, involve input from patients, service users or carers through their participation in surveys, which help to determine the effectiveness or efficiency of a service, or through their involvement in the design of individual projects or whole programmes of activity.

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, however it should be noted that neither team currently has expertise in the field of service evaluation.

Importantly, whilst service evaluation projects should be scrutinised for ethical implications, REC approval is not required.

PATIENT, SERVICE USER, CARER ENGAGEMENT

Research, clinical audit or service evaluation projects may all include a patient, service user or carer survey. In terms of clinical audit, surveys can be a useful tool, where measuring compliance against your audit criteria requires information that can only be obtained from the patient or service user e.g. ‘Did the doctor introduce themselves at the beginning of your appointment?’ ‘Did the doctor listen to what you had to say?’

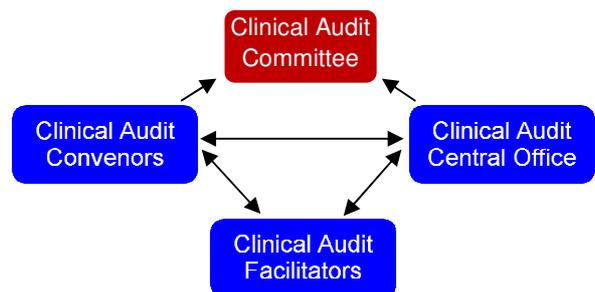
Surveys can be construed as doing something ‘beyond normal clinical management’; therefore it is important to get advice on the design of your survey as some questions might touch upon potentially sensitive matters, which would give rise to ethical concerns. It is extremely important that all surveys are designed to cause minimum possible disruption.

If you are including a survey as part of your project it must be submitted to the Questionnaire, Interview and Survey (QIS) Group for approval. The contact details for the QIS group are listed at the end of this guide.

UNDERTAKING A CLINICAL AUDIT PROJECT AT UHBRISTOL

CLINICAL AUDIT STRUCTURES AT UHBRISTOL

Clinical audit at UHBristol is supported by divisional Clinical Audit Facilitators and co-ordinated by a Central Office. The Clinical Audit Facilitators are geographically situated in their divisions, whilst the Clinical Audit Central Office is located at Trust Head Quarters.



- **Clinical Audit Facilitator** - This is the first person you should contact when you have an idea for a project. Your Facilitator will help you focus your project design and complete the project proposal paperwork (available on the clinical audit website - website and contact details are listed at the end of this guide). They will provide support and advice throughout the clinical audit process, e.g. sample selection, data analysis, presentation writing. However, Facilitators do not assist in data collection.
- **Convenors** - Your divisional Convenor is a senior clinician responsible for promoting clinical audit in your area. The Convenor actively supports the Clinical Audit Facilitator in day-to-day activities and liaises with the Facilitator to agree the annual audit programme and to approve all clinical audit projects.
- **Clinical Audit Central Office** - Produces activity reports including the Clinical Audit Annual Report, coordinates trust-wide and interface audit, organises the trust-wide training and recruits to and supports the Clinical Audit Team.
- **Clinical Audit Committee** - Provides assurance of the clinical audit programme on behalf of Trust Board, to which it reports via the Audit & Assurance Committee. It provides a forum for the Convenors to discuss any issues they are experiencing, which can be fed through to Medical Director via his Assistant Director who sits on the Committee.

CLINICAL AUDIT STRATEGY

In summary the UHBristol Clinical Audit Strategy states that all healthcare professionals are expected to participate in clinical audit; it defines what is and is not considered to be clinical audit (as outlined above); it states that audits relating to the National Agenda should be prioritised; and it places an emphasis on multi-professional clinical audit, and direct/indirect patient engagement.

Clinical audit projects are either unidisciplinary e.g. involving only one staff group or multidisciplinary e.g. involving more than one discipline or profession. At UHBristol we believe that it is important that a clinical audit project assesses patient care as provided by the whole clinical team to identify how their care can be improved. Therefore if your project has implications for a profession or discipline other than your own, whether within or outside the clinical area you work in, it is important to ensure that they are represented on the project team.

If your clinical audit project is looking at the patient journey across different care sectors i.e. 'interface' audit, try to include staff representatives from these other care sectors in your project team. An example of an interface audit would be looking at the process of referral into the hospital from primary care.

You should also consider including a patient, service user and/ or carer representative(s) on your project team or gaining their views on what they would like to see from the service. Engagement is important as healthcare is a partnership between clinicians and their patients/ service users. Whilst we strive to provide the best quality of care as we see it, patients/ service users might want something different. Direct engagement is best e.g. through participation of identified individuals on project steering groups or divisional/specialty audit committees. However, indirect engagement is another possibility e.g. through the completion of a survey, usually at the end of an episode of care.

SUMMARY

- Clinical Audit is a quality Improvement process that measures current patient care and outcomes against agreed standards of best practice.
- Not all 'audit' is clinical audit.
- Be aware of the differences between project categories:
 - Clinical audit - audit against agreed standards of best practice.
 - Research - aims to create new knowledge.
 - Service Evaluation - assesses the effectiveness of a service.
- If you are unsure whether the project you wish to undertake is a clinical audit project, your divisional Clinical Audit Facilitator will be able to advise.

CONTACT DETAILS/ USEFUL INFORMATION

CLINICAL AUDIT

- The UHBristol **Clinical Audit website** is available [online] via: <http://www.uhbristol.nhs.uk/healthcare-professionals/clinical-audit.html>
- Contact details for the UHBristol **Clinical Audit Team** are available from the Clinical Audit Central Office or [online] via: <http://www.uhbristol.nhs.uk/healthcare-professionals/clinical-audit/contacts.html>
- The full range of UHBristol **'How To' guides** are available [online] via: <http://www.uhbristol.nhs.uk/healthcare-professionals/clinical-audit/how-to-guides.html>
- A copy of the UHBristol **Proposal Form, Presentation Template, Report Template, Summary Form, and Action Form** are available [online] via: <http://www.uhbristol.nhs.uk/healthcare-professionals/clinical-audit/doing-projects-at-ubht.html>
- The UHBristol **Clinical Audit Central Office** can be contacted on tel. (0117) 342 3614 or e-mail: stuart.metcalfe@uhbristol.nhs.uk
- **Clinical Audit Training Workshops** can be booked through the Clinical Audit Central Office.

CLINICAL EFFECTIVENESS

- For advice on **Clinical Effectiveness**, including how to write guidelines, contact James Osborne, Clinical Effectiveness Co-ordinator, tel. (0117) 342 3753 or e-mail: james.osbourne@uhbristol.nhs.uk

PATIENT ENGAGEMENT

- For advice on **Patient Involvement**, including **designing structured surveys and questionnaires** contact Paul Lewis, Patient Involvement Facilitator, tel. (0117) 342 3638 or e-mail: paul.lewis@UHBristol.nhs.uk
- For advice on **Patient Involvement**, including **unstructured surveys and focus groups** contact Tony Watkin, Public Involvement Lead, tel. (0117) 342 3729 or e-mail: tony.watkin@UHBristol.nhs.uk
- Surveys MUST be approved by the Trust's **Questionnaire, Interview and Survey (QIS) Group**. Proposals should be submitted to Paul Lewis using the QIS proposal form. The proposal form is available [online] via <http://www.uhbristol.nhs.uk/healthcare-professionals/clinical-audit/doing-projects-at-ubht.html>
- A copy of the UHBristol **Covering Letter** template is available [online] via the internal intranet site <http://connect/Governance/patientexperience/ppi/Pages/QISGroup.aspx>

RESEARCH

- For advice on research projects contact the **Research & Development Department**, tel. (0117) 342 0233 or e-mail: r&doffice@uhbristol.nhs.uk

LITERATURE REVIEWS

- For advice on literature reviews contact the **Learning Resource Centre**, tel. 0117 342 0105 or e-mail: learningresources@UHBristol.nhs.uk

SAMPLE SIZES

- The **Sample Size Calculator** is available [online] via: <http://www.uhbristol.nhs.uk/healthcare-professionals/clinical-audit/how-to-guides.html>