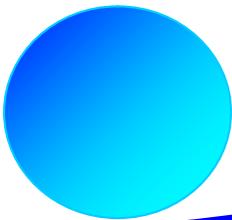


**The  
Simple Guide  
to  
Clinical Audit  
in  
NHSBT**



*The path to improving quality is endless...*

**Clinical Audit as a Quality Improvement Approach**

INFORMATION DOCUMENT INF449/1.2 EFFECTIVE: 17/06/13

## **Why practice clinical audit?**

Clinical audit can bring enormous benefits to patients, donors, health professionals and the organisation. The Department of Health explicitly identified participation in clinical audit as a responsibility of all clinicians. NHSBT is registered with the Care Quality Commission (CQC) as required by the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010. These regulations have statutory force to ensure organisations regularly evaluate and monitor the quality of services provided and make changes / improvements to care based on a number of sources including clinical audit. Clinical audit is also regarded as one of the cornerstones of clinical governance. This booklet provides an introduction to clinical audit and will help you to understand the clinical audit process and the support available to you.

## **Clinical audit in NHSBT**

Within NHSBT, the directorate CARE (Clinical Audit, Research and Effectiveness) groups are responsible for prioritising clinical audit projects and monitoring the completion of action plans.

The corporate CARE group (chaired by the Medical Director and attended by representatives from each directorate and from Statistics and Clinical Audit) reviews summaries of all reports and follows up uncompleted or disputed actions.

## **The Statistics & Clinical Audit team**

Clinical audit staff are situated in various locations with the aim of supporting and facilitating all stages of clinical audit. To find out more please visit the Intranet site at:

[http://nhsbtweb/group\\_services/clinical/statistics\\_clinical\\_audit/index.asp](http://nhsbtweb/group_services/clinical/statistics_clinical_audit/index.asp)

## **What is clinical audit?**

In simple terms, clinical audit is a quality improvement process that compares actual practice against agreed standards that describe

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best practice and then changes are made, based on the findings. Best practice can be found by reviewing research evidence, standards and guidelines.

There are several definitions of clinical audit but NHSBT agrees with and works to the definition as defined by the Healthcare Quality Improvement Partnership (HQIP), established to promote quality in health and social care services in the UK.

**“..a quality improvement process that seeks to improve practice and outcomes through systematic review of practice against explicit criteria and the implementation of change..  
*New Principles of Best Practice in Clinical Audit, HQIP 2010***

To get a clearer picture about clinical audit, it is useful to look at what clinical audit is not.....

### **Clinical audit is not the same as research**

Clinical audit and research are sometimes confused partly because they use similar methods to collect and analyse data.

Generally, research is driven by the need to generate new and generalisable knowledge and can inform best practice. For example, research can help decide whether drug A is more effective than drug B for a given condition.

The aim of clinical audit is to establish whether you are doing what you should be doing by asking if you are following agreed guidelines and applying best practice, then making changes where necessary. It is about quality improvement. So research tells us the best way to do something and clinical audit finds out whether we are doing it in the best way. If not, then we make changes.

### **Clinical audit is not just data collection**

A data collection exercise can be used for monitoring and reporting, but clinical audit converts the data into information used to improve practice.

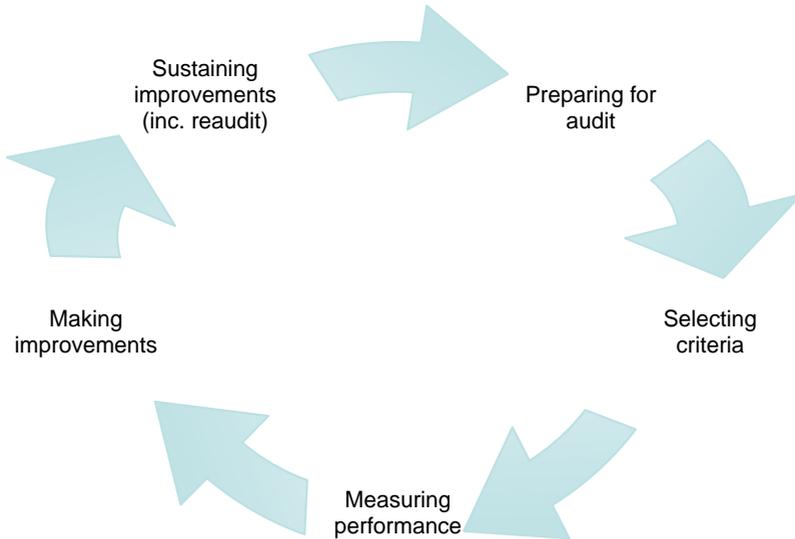
## Clinical audit is not a tool to criticise practice

Clinical audit is not used to blame individuals. Clinical audit measures practice and makes corrections to operational processes

It is useful to remember that most mistakes are due to limitations and failures within a system.

## The clinical audit cycle

The Care Quality Commission (CQC) views the five stages of clinical audit as shown in the adapted diagram below.



Adapted from Royal College of Pathologists – Clinical Audit <http://www.rcpath.org/clinical-effectiveness/clinical-audit> (accessed 18th March 2013)

There are 9 steps to undertaking a clinical audit project, each of which are important to get right in order to get the most benefit.

### 1. Choosing the topic

Clinical audit normally looks at an aspect of practice where there is a concern or room for improvement. These topics can be put into

categories based on high cost, volume and risk. Your audit can look at practice on a local, regional or national level. Undertaken correctly, clinical audit can be used as a problem solving tool.

At this stage, it is useful to define the aim and objectives of the audit, e.g. why you are doing the audit and what you want to achieve.

Clinical audit is a team effort and it is vital to involve the relevant stakeholders right from the beginning. A stakeholder is an individual or group of people with a particular involvement in a project or someone whose work may be affected by the audit findings. Before going further, discuss the topic with your local clinical audit team who can provide appropriate support and help to identify the necessary methodologies for the audit and the relevant clinical or management group from whom approval is required.

## 2. Reviewing the literature

This stage will help to identify relevant standards and background information from various sources. Ideally, the literature search should focus on present guidelines and standards from within and external to NHSBT, along with the research-based evidence.

It is useful to look for similar audits which may have been carried out in the past – all NHSBT clinical audit reports are available on the intranet and can be found at:-

[http://nhsbtweb/group\\_services/clinical/statistics\\_clinical\\_audit/index.asp](http://nhsbtweb/group_services/clinical/statistics_clinical_audit/index.asp)

Clinical audit reports are split in to directorate and function.

## 3. Developing standards and criteria

A **standard** describes the care we expect patients or donors to receive

Standards consist of an overall general statement of practice and are then broken down into measurable criteria which are explicit and describe what should be done.

**Criteria** are written in a measurable way as individual statements that define the best or required practice

Any standards and criteria that you are planning to use should be appropriate to the current settings and should be definable as well as measurable (standards should be agreed prior to an audit starting).

An example of a good standard is “all patients undergoing transfusion should have their identification checked prior to transfusion”.

Using the example standard given above, criteria may be as shown in the table below:-

| <b>Criteria</b>   | <b>Level of Performance</b> | <b>Exceptions</b>  |
|---|-----------------------------|--|
| Patients undergoing transfusion must have their ID wristband checked against the request form prior to transfusion. | 100%                        | None   |
| Patients undergoing transfusion must be asked their surname, first name and DOB prior to transfusion.               | 100%                        | Patients who are unable to communicate verbally e.g. patient unconscious |

The table also highlights ‘level of performance’ and ‘exceptions’. A level of performance is the target for the proportion of cases that comply with the criteria.

Exceptions are justifiable situations where the criteria may not apply, either due to unforeseen circumstances or because they do not meet the individual needs of those patients / donors.

It is best practice for clinical audit to measure practice against explicit criteria which conform to the “**S.M.A.R.T**” framework.

This gives a list of 5 things that all criteria used for clinical audit should be:-

|                |   |
|----------------|---|
| Specific       | Need to be precise on what is being measured                                      |
| Measurable     | Able to measure actual practice<br>e.g. – observation or documentation review     |
| Achievable     | Needs to be practical e.g. - staff and resource available within the organisation |
| Research based | Ideally obtained from published literature  |
| Timely         | Reflect most current practice in a timely manner                                  |

#### 4. Designing and planning the audit

Key aspects to a successful clinical audit include being clear about your objectives and careful planning. In particular:-

- Ensuring that all the relevant stakeholders are informed and involved in the project as you may need them to play a key role later in the process.
- Having all the pertinent facts when choosing the most appropriate method for your project (including factors such as available time, budget, data collectors and the data sources).
- Remembering that there is not one “ideal” method to collect data as every method has limitations. At this stage, the team should consider all practical implications relating to data collection e.g. is the data held locally, in what format is it held, can it be easily accessed.

#### 5. Collecting the data

Data collection involves the retrieval of accurate data to determine whether the criteria and level of performance were met i.e., are we conforming to best practice?

Particular areas to focus on include:-

- Ensuring a relevant, valid and reliable method of data collection.

- Designing a simple and easy to complete data collection form (sometimes known as a proforma). Data can be collected retrospectively (looking back at practice) if data is from established sources and the information is well documented or prospectively (as care/service is given) when data is not readily available.
- Ensuring a representative sample - if the total group is very large, it may be more appropriate to take a smaller random sample from a given time period. You should consider the appropriate sample size and whether any cases should be excluded.
- Testing the method in a pilot audit. This can be done by picking a small sample and performing a "mini" data collection and analysis exercise to determine if you are able to obtain the information that you require. It is much better to realise this before undertaking the main audit as the opportunity to make changes/improvements to the method of data collection is still there before resources and time are spent.
- Communicating the agreed data collection method to everyone involved, so they understand what is happening and why it is happening.

## 6. Analysing the data

Data analysis involves interpreting data that has been retrieved, with the purpose of determining if the standards have been met and if not, to identify reasons behind this.

The analysis will also help to produce evidence, which will inform the decisions that need to be made regarding the next stages of the audit cycle.

Depending on your topic, the analysis can be simple or complex. However, most audit projects do not require statistical or computer expertise in order to carry out data analysis.

## 7. Presenting the findings

A report is used to communicate the findings of each clinical audit, giving readers a rationale and evidencing the data behind any resultant changes in practice.

A well-designed report can affect how well your message is conveyed and, consequently, how well any changes are adopted.

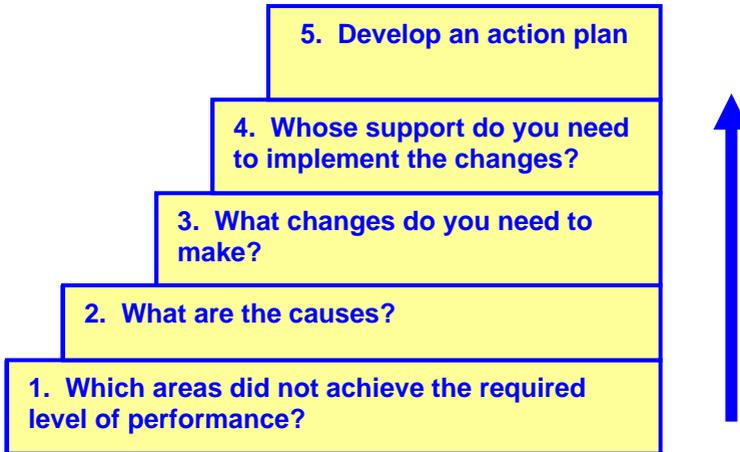
Full clinical audit reports should be concise and structured in accordance with reporting template ([FRM3596](#)) to include:-

- Background, Audit Rationale, Aims and Objectives – A description of why it was done, what was the trigger (e.g. a quality incident) and what you aimed to achieve.
- Standards – Criteria, Levels of performance and any exceptions.
- Methodology – How it was done.
- Results / Key Findings – What was found.
- Conclusion/Discussion – What those findings mean.
- Benefits
- Re-audit – When/If a re-audit is planned.
- Recommendations and Action Plan – What you are going to do about it with a description of who is to do what, by when.
- Audit Caveat – An explanation of any issues that need to be brought to the reader's attention that may explain some of the results.
- References – A list of any applicable documents/previous audits that have played a role in undertaking the audit.

For each clinical audit report, a set approval process ([DAT1485](#)) must be followed. Reports must be submitted to the relevant functional group followed by the directorate CARE (Clinical Audit, Risk and Effectiveness) group for approval. Once approval has been given, audit reports can be widely distributed.

## 8. Implementing change

Ensuring that any agreed changes actually happen is pivotal to the value of any audit. A key to successful implementation is to discuss the results with all relevant staff, involve appropriate user groups and develop a detailed action plan.



*Five main steps to implement change*

Detailed action plans consist of what needs to change, how this can be achieved, who is responsible for the completion and when it will be completed.

## 9. Re-auditing to ensure improvement

Re-audit involves a second audit cycle to find out if the changes have led to an improvement. Re-audit should never commence until the action plan has been completed. Re-audit will confirm whether expected improvements have taken place or not.

### Ethical framework

Although, unlike research, clinical audit does not require formal ethical approval, it must be performed within a framework which ensures confidentiality and compliance with data protection

legislation. It should be remembered that clinical audits are open to Freedom of Information requests and will rarely be exempt.

Clinical audit **must** not involve anything being done to patients and donors other than their normal clinical management.

NHSBT has a policy on Ethics in Clinical Audit ([POL133](#)) which details the ethical issues that can be identified and how these can be addressed. It also provides details of a screening process to ensure that ethical implications of carrying out clinical audit are identified and discussed as part of the clinical audit approval process.

### **Clinical audit resources on the NHSBT intranet**

There are a variety of resources on the Statistics and Clinical Audit intranet pages

([http://nhsbtweb/group\\_services/clinical/statistics\\_clinical\\_audit/index.asp](http://nhsbtweb/group_services/clinical/statistics_clinical_audit/index.asp)) to support the undertaking of clinical audit including:-

- Clinical audit proposal form ([FRM3561](#)) – for requesting support for clinical audits and for registering clinical audits on Q-Pulse.
- Clinical audit information leaflets – a series of guides outlining all stages of the clinical audit process and providing more detail on everything covered in this booklet. There are 11 guides:
  - Quick Guide to Clinical Audit in NHSBT ([INF450](#))
  - The Difference Between Clinical Audit & Research ([INF451](#))
  - How to Identify Clinical Audit Topics ([INF452](#))
  - Clinical Audit, Ethics and Confidentiality ([INF453](#))
  - Developing Aims and Objectives ([INF454](#))
  - How to Set and Develop Clinical Audit Standards and Criteria ([INF455](#))
  - How to Select an Audit Sample ([INF456](#))
  - How to Collect Clinical Audit Data Effectively ([INF457](#))

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- How to Analyse Your Clinical Audit Data ([INF458](#))
- How to Present your Clinical Audit Data ([INF459](#))
- Making Improvements Through Change and Re-audit ([INF460](#))
- Clinical audit reports – copies of clinical audit reports from all specialities.
- Web links – links to clinical audit resources

## Support available from Statistics and Clinical Audit

Help and support is available throughout the clinical audit process from designing and planning to writing up the report.

Specifically, support is available for:-

- Help with literature searching, sourcing relevant standards and undertaking data collection, data entry and analysis.
- Facilitating the dissemination of clinical audit results with reports, presentations and posters.
- Facilitating the change process by assisting with the development of action plans and follow up.

## How to obtain support for clinical audit

If you have a topic that you think is suitable for a clinical audit, please contact a member of Statistics & Clinical Audit.

All clinical audits should be approved according to the process described in [DAT1484](#) and be registered on [Q-Pulse](#).

To do this, you will need to submit a clinical audit proposal ([FRM3561](#)) for approval so that your audit can be included in the Annual Clinical Audit Programme— a member of Statistics & Clinical Audit can help you complete [this](#).

## Clinical audit training

Two training programmes are available to all NHSBT staff:-

**Introductory workshop** – For those with little or no clinical audit experience, this session provides a basic introduction to clinical audit.

**Advanced workshop** – This workshop provides staff with the theoretical knowledge and practical skills necessary to design and undertake a clinical audit project. This workshop is aimed at those who have previous clinical audit experience.

To register, or for more information contact the Clinical Audit Administrator / Secretary on Ext. (5)8611.

## Summary

### Clinical audit:-

- **Is a quality improvement process**
- **Measures and compares practice against evidence based standards**
- **Is not research or mere data collection**
- **Is a cyclical process**
- **Looks at the structure and process not at the individual**
- **Support and training is available to all NHSBT staff**

Further information on any aspect of this booklet or clinical audit in general is available from local clinical audit staff. Contact details and other resources can be found on the Statistics and Clinical Audit intranet site at:

[http://nhsbtweb/group\\_services/clinical/statistics\\_clinical\\_audit/index.asp](http://nhsbtweb/group_services/clinical/statistics_clinical_audit/index.asp)