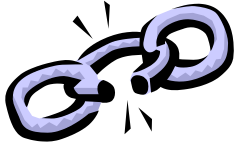


Disclosure of Clinical Audit Results

Under the terms of the Freedom of Information Act (2000), **anyone** is entitled to apply for copies of clinical audit reports. Therefore, when reporting clinical audit results, you should ensure that there is no stated link between audit conclusions and patients / donors or clinicians.



Presentation of clinical audit results should always have the approval of **stakeholders**.

All information collected for the purposes of clinical audit should be stored, handled and destroyed in line with the NHSBT Guide to Good Practice for Clinical Audit (see Important Further Reading).

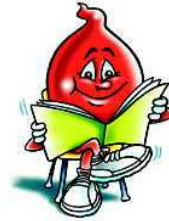
Blood donors consent to the use of their records for clinical audit purposes on the Donor Health Check. For collaborative audits involving patient records outside of NHSBT you must have the permission of the Hospital / Trust Caldicott Guardian. The NHSBT sharing protocol can be helpful in these situations.



You have a professional duty to ensure your clinical audit is performed within an ethical framework and that all information collected is anonymous and no individual patient / donor or clinician can be identified.

Important Further Reading

This leaflet only covers the basic issues around ethics and confidentiality. A lack of awareness of these issues will not protect you if they are breached. To ensure you fully understand your responsibilities, you should read the following documents:-



- Undertaking Clinical Audit Involving Third Party Organisations [MPD406](#)
- Ethics & Clinical Audit in NHSBT [POL133](#)
- Sharing Protocol for Clinical Audit within NHSBT [FRM1272](#)
- NHS Code of Confidentiality - Department of Health available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4069253
- Caldicott Principles: available at www.dh.gov.uk
- Data Protection Act: <http://transparency.dh.gov.uk/dataprotection/>

Contact details and further information on any part of this leaflet can be found at: http://nhsbtweb/group_services/clinical/statistics_clinical_audit/index.asp



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NHS

Blood and Transplant

Clinical Audit, Ethics and Confidentiality

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Statistics & Clinical Audit

Ethics and Confidentiality

Clinical audit by definition does not involve anything being done to patients and donors other than their normal clinical management. Therefore, it does not require formal ethical approval.

However, clinical audit **must** be performed within an ethical framework that includes consent, confidentiality and disclosure of audit results. The following points should be considered when designing, performing and reporting your audit.

Ethics and Clinical Audit



Ensure your project is a clinical audit and not a research study.

All research on patients / donors requires ethical approval, so you need to be sure that your project is a clinical audit and not research (See leaflet 2 - The difference between clinical audit and research).

Clinical audit should never involve: -

- experiments on patients
- comparing new and old treatments
- randomisation or control groups

However, there may be 'grey areas' where you are uncertain whether your project is research or audit. In these situations, you must seek the advice of clinical audit staff. Just calling your project a clinical audit does not remove the requirement to seek ethical approval.

Other Ethical Issues

Although your audit project may not require ethical approval, there are still several areas you need to consider carefully before initiating your audit.



Your clinical audit should do good and not cause harm!

You should not audit the work of **anyone** without their knowledge.

Clinical audit projects should involve **minimal disturbance to the patient / donor**. Intrusive methods, such as the use of questionnaires / interviews should be **discussed fully** with a senior member of the NHSBT clinical audit staff.

The wishes of patients and donors should be respected at all times. All patients / donors directly involved in clinical audit should be approached in a sensitive and respectful manner and given full written information about the audit and be given the opportunity to withdraw if they wish. Audit samples should be representative of the audit population, and if this involves ethnic groups, provision for non-English speaking groups should be made.

Due regard should be paid to subjects' explicit wishes, for example do not include donors whose PULSE records state "Do Not Contact".

All health professionals are **responsible for their own performance** and steps should be taken to improve performance if audit results indicate the need.

Confidentiality and Clinical Audit



All NHS staff have a personal and common law duty to keep patient and donor information confidential.

All data relating to a living individual is subject to the conditions of the Data Protection Act, (1998). This includes both paper and electronic records. Subjects should be aware of the potential uses of their information and have a legal right to its access.



All patient/donor information is covered by the Caldicott Principles, which establish a clear set of guidelines for best practice in the handling of confidential patient information.

You should ensure that all information held for a clinical audit project is anonymised to safeguard confidentiality. This involves the removal of all elements that may disclose the identity of a patient / donor. This includes, names, identification numbers such as NHS number and in some cases date of birth.



Personal medical information collected for clinical audit must not be used for any other project.

The clinical lead of an audit is bound by professional and organisational Codes of Conduct and these include responsibility for any breaches of confidentiality. It is vital that they ensure that everyone involved in a clinical audit understands their role and responsibilities.