



Leaflet 4

Clinical Audit Ethics and Confidentiality

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 individual 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 Indicators for Best Practice in Clinical Audit (see *Important Further Reading*).

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



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

Important Further Reading

This leaflet covers basic issues around ethics and confidentiality. A lack of awareness of these will not protect you if they are breached. To fully understand your responsibilities, please 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 Confidentiality - Department of Health:
<https://www.gov.uk/government/publications/confidentiality-nhs-code-of-practice>
(accessed 16th October 2023)
- Caldicott Principles
<https://www.gov.uk/government/publications/caldicott-information-governance-review-department-of-health-response>
(accessed 16th October 2023)
- Data Protection Act: <https://www.gov.uk/data-protection/the-data-protection-act>
(accessed 16th October 2023)

Further information about clinical audit is available from SharePoint on the clinical audit pages:
<https://nhsbloodandtransplant.sharepoint.com/sites/Clinical/SitePages/Clinical%20Audit.aspx> where full details of all completed clinical audit reports can be found. (accessed 16th October 2023)

All leaflets in this series (INF450-INF460) are available via the controlled document library on NHSBT Intranet (Link)

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Ethics and Confidentiality

Clinical audit by definition involves nothing 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



Remember - 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 INF451 - 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.



Remember - 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 data collection 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. They must be given full written information about the audit and have an opportunity to withdraw if they wish. Audit samples should be representative and inclusive of the audit population.

Due regard should be paid to the explicit wishes of patients or donors, e.g. *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



Remember - 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 Data Protection Act, (1998). This includes paper and electronic records. Individuals 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 prescribe 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, such as name, NHS identification numbers and date of birth.



Remember - personal medical information collected for clinical audit must not be used for any other project.

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