How To: Apply Ethics to Clinical Audit

INTRODUCTION

The aim of this 'How To' guide is to provide advice on how to apply ethics to clinical audit. Unlike research, clinical audit projects do not need to be submitted to a Research Ethics Committee (REC) for ethical approval; this is one of the key reasons why you must ensure that your project is clinical audit rather than research. If you think that there are ethical issues with your project you must discuss these with your divisional Clinical Audit Facilitator at the planning stage. Aspects of this guide are discussed in more detail in:

- What is Clinical Audit?
- How To: Set an Audit Sample and Design your Data Collection & Data Collection Form.
- How To: Engage Patients, Service Users & Carers in Clinical Audit.

ETHICS, INFORMATION GOVERNANCE AND CLINICAL AUDIT

The starting point when considering ethics in relation to clinical audit is to remember that your audit project should benefit patients and not do harm.

Clinical audit must always be conducted within an ethical framework. At a practical level, this means ensuring patient and staff confidentiality and ensuring that data is collected and stored appropriately. As someone involved in clinical audit, you should be aware of the following pieces of legislation and national guidance:

CALDICOTT PRINCIPLES (1997)

The Caldicott Committee was established by the Chief Medical Officer to review all patient identifiable information which passes from NHS organisations to other NHS or non-NHS bodies for purposes other than direct care, medical research, or where there is a statutory requirement for information.

The Committee considered that, whilst no single data item could be relied upon to identify an individual with certainty, there were many items being transferred between organisations which, when taken together, could permit identity to be inferred. They concluded that **all** items of information which related to an attribute of an individual should be treated as potentially capable of identifying patients to a greater or lesser extent, and should be appropriately protected to safeguard confidentiality.

The principles and recommendations made by the Committee emphasised the need for controls over the availability of patient identifiable information and access to it. In particular a Caldicott Guardian, appointed in each NHS organisation, with specific responsibilities to oversee an ongoing process of audit, improvement and control.

The seven Caldicott principles that applied to the handling of patient identifiable information are:

- Justify the purpose(s) of using confidential information.
- Only use it when absolutely necessary.
- Use the minimum that is required.
- Access should be on a strict need-to-know basis.
- Everyone must understand his or her responsibilities.
- Understand and comply with the law.
- The duty to share information can be as important as the duty to protect patient confidentiality.

GENERAL DATA PROTECTION REGULATION (2016)

The European General Data Protection Regulation (GDPR) came into force in 2018 and its specific application to the Law of England and Wales is covered by the updated Data Protection Act 2018. This legislation regulates the processing of information relating to individuals, including the obtaining, holding, use or disclosure of such information. It relates to personal data; that is, data which relates to a living individual who can be identified from that data, or when combined with other information possessed or likely to come into possession.

Anyone processing personal information must comply with six enforceable principles of good information handling practice. These say that data must be:

1. Fairly, lawfully and transparently processed;
2. Processed for specified, explicit and legitimate purposes;
3. Adequate, relevant and limited to what is necessary for the purpose for which they are being processed;
4. Accurate and (where necessary) up to date;
5. Not kept in a form which permits identification of data subjects for longer than is necessary;
6. Kept securely.

A seventh principle of accountability requires individuals and organisations to take responsibility for what they do with personal information and how they comply with the other principles. You must have appropriate measures and records in place to demonstrate compliance.

Health information (i.e. data about a person's physical or mental health or condition) is classified as 'special category data'. The legislation allows for this to be lawfully processed where necessary for medical purposes, when undertaken by a health professional or a person who owes an equivalent duty of confidentiality. This includes the purposes of preventative medicine, medical diagnosis, medical research, the provision of care and treatment and the management of healthcare services.

NHS CONFIDENTIALITY CODE OF PRACTICE (2003)

This contains practical guidance for NHS staff and others on how to treat patient information with respect in the context of a modern health service. It is endorsed by the Information Commissioner, the General Medical Council and the British Medical Association and is consistent with Data Protection requirements.

It aims to ensure that all patient information is processed fairly, lawfully and as transparently as possible so that the public:

- Understand the reasons for processing personal information.
- Give their consent for the disclosure and use of their personal information.
- Gain trust in the way the NHS handles information.
- Understand their rights to access information held about them.

It states that there are situations where consent cannot be obtained for the use or disclosure of patient identifiable information, yet the public good of this use outweighs issues of privacy. Section 60 of the Health and Social Care Act 2001 currently provides an interim power to ensure that patient identifiable information, needed to support a range of important work such as clinical audit, record validation and research, can be used without the consent of patients. It also states that where reasonable efforts are made to ensure that patients understand how their information is to be used to support their healthcare, consent can be implied, providing that "need to know" principles are enforced.

The General Medical Council has also published its own Confidentiality Code of Practice (see References and Further Reading below).

HQIP GUIDE TO MANAGING ETHICAL ISSUES (2017)

The Healthcare Quality Improvement Partnership have published guidance on managing ethical issues in quality improvement or clinical audit projects, which recommends that projects should meet the following criteria:

- "Favourable benefit/risk balance" — The project should maximise benefits to patients and patient care and limit any risks for patients, such as breaches in confidentiality or privacy;
- "Scientifically valid" — The project must be well-designed with sound methodology, and evidence should be provided that any changes in practice, processes or systems implemented as a result of the project show benefits for patients and patient care;
- "Equitable and reflecting priorities" — Within an organisation, audit activity should cover all clinical services, patient conditions and professional groups, and a system should exist to set priority topics;
- "Value" — The anticipated improvement should justify the effort in the use of time and resources
- "Awareness of conflict of obligation to patients" — Efforts to reduce cost of care through improvement projects should be carefully considered so as not to compromise quality of care.

WHAT ARE THE IMPLICATIONS FOR CLINICAL AUDIT?

Essentially, the documents outlined above allow for the use of patient data for the purposes of clinical audit, that is, to review and improve healthcare. The legal basis for Clinical Audit is Article 6(1)(e) of the GDPR: the processing is necessary for you to perform a task in the public interest or for your official functions, and the task or function has a clear basis in law. The legal basis for processing special category data is 9(2)(h): processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services.

Audit projects will usually involve clinical members of staff who already provide care for the group of patients concerned. All Trust staff are automatically bound by common law and contractual duty of confidentiality. However, data should not be reviewed by non-Trust staff unless a similar duty of confidentiality is in place, for example in the case of medical students.

Note that UHBristol has published detailed information on its public facing website about how the Trust collects, uses and shares information, including its use for clinical audit. This can be found at: http://www.uhbristol.nhs.uk/privacy/.

Specific implications for the audit process are as follows:

- Data Collection - In order to comply with data protection rules and to ensure patient anonymity, personal details, including hospital ID number, name, address, date of birth etc, should not be recorded on the data collection form. The best approach is to number each of your forms using a unique identifier. A separate piece of paper, or 'code sheet', should then be kept as a key, linking each unique identifier to the patient's hospital number. Without this list, data collection forms cannot be linked to specific patients. The key would need to be destroyed when the audit analysis is complete. This also applies to data held on databases. Occasionally it might be necessary to record patient identifiable information on the data collection form. For example, during a prospective data collection exercise the data collection form might have to follow a patient through their pathway of care. In this instance the only patient identifiable information that should be recorded on the form is their hospital ID number; Name, date of birth, etc. should never be recorded. The hospital number should be removed and each patient coded at the earliest opportunity, i.e. once all data has been collected.

- Adequate, relevant and limited to what is necessary. Ensure data is being collected for the stated purpose of clinical audit (rather than research) and collect only the data you need to answer your audit objectives and standards. HQIP's guide on information governance (2017) recommends clearly defining

the purpose of the project, so that it is clear why you are holding and using the data, and precisely defining the target population, as it would be excessive to collect data on patients outside that.

- Data should be kept securely - This relates to both electronic and hard copies of data. Any patient-identifiable clinical audit data must be kept securely. Audit proformas should be locked in a filing cabinet, electronic files should be password-protected or kept on a secure, restricted access server and only clinical professionals and audit team with a duty of confidentiality should be able to access the data. Person-identifiable information should not be stored on personal devices not authorised under the Trust's Bring Your Own Device (BYOD) Policy. Identifiable data should only be emailed within the Trust network or from one NHS.net address to another (more details on secure email can be found in a Trust guideline, the link for which is provided in the references section at the end of this guide). Situations should be avoided that might allow public access to personal data, such as leaving patient files in the boot of your car. Your car could be stolen with the files in it!

- Data should not be kept for any longer than necessary - Records relating to Clinical Audit must be retained for five years following their creation. After this time, they should be reviewed and securely disposed of if they are no longer needed.

CLINICAL STAFF CONFIDENTIALITY

It is also important to remember that clinical audit reports and presentations should not identify clinicians by name unless the people concerned have agreed to this.

DO YOU NEED ETHICS APPROVAL FOR AUDIT?

Whilst research needs to be submitted to REC for ethical approval, clinical audit does not. However, whilst clinical audit by definition does not involve anything being done to patients beyond their routine clinical management and therefore does not require formal ethical approval, it 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.

However, before assuming that you do not require ethical approval, it is important to consider:

1. IS YOUR PROJECT REALLY A CLINICAL AUDIT PROJECT?

Decisions about whether projects need ethical approval often hinge on the question of whether they really are clinical audit, or whether they are actually research. Remember that clinical audit asks the questions "are we following best practice?" and "what is happening to patients as a result?"

Clinical audit projects never involve:
- A completely new treatment or practice;
- The use of control groups or placebo treatments;
- Any disturbance to the patient beyond that required for routine clinical management;
- Allocating patients randomly to different treatment groups.

Clinical audit may, however, involve input from patients at a number of levels, e.g.
- 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.

Sometimes healthcare professionals undertake what they mistakenly think is 'clinical audit', when what they are really doing is research. Research always requires ethical approval**;** calling research by any other name does not remove this requirement.

If you are unsure whether or not the project that you want to undertake is clinical audit or research, your divisional Clinical Audit Facilitator will be able to advise. Very occasionally liaison might be required between your divisional Clinical Audit Facilitator, the Research & Innovation Department and the local REC. If the conclusion is that you are undertaking research, you must formally submit the appropriate paperwork to the local REC for ethics approval.

If on the other hand your project contains an element of both clinical audit and research, you will need to obtain formal ethical approval for the research component of the project from REC and submit a completed copy of the clinical audit proposal form to your divisional Clinical Audit Facilitator for the clinical audit component.

2. DOES YOUR PROJECT INCLUDE A PATIENT SURVEY?

Patient surveys can be construed as doing something to patients 'beyond normal clinical management'. It is therefore important to take advice on the design of patient surveys. Planned questions could touch upon potentially sensitive matters, giving rise to ethical concerns. Any patient surveys should be designed in such a manner as to cause minimum possible disruption to patients.

All structured surveys, staff or patient, administered by post, in hospital, or via a one-to-one interview, undertaken for clinical audit are subject to approval by the Questionnaire, Interview and Survey (QIS) Group. The group offers advice on survey design and is responsible for monitoring all survey activity at the Trust. Please contact Paul Lewis, Patient Experience and Involvement Team Manager for advice on structured surveys/ questionnaires. If you require advice on unstructured interviews and focus groups, this should be discussed with Tony Watkin, the Trust's Public Involvement Project Lead. The contact details for QIS, Paul Lewis, and Tony Watkin are listed at the end of this guide.

Formal Research projects involving questionnaires are subject to ethical approval by the local REC and therefore do not require QIS approval.

When undertaking a survey it is important to consider the patient's, service user's or carer's rights, dignity and time. Should you wish to undertake a survey as part of your clinical audit project there are a number of ethical questions that you should consider. These are:

- Is the information that you are seeking already available? The QIS group may not approve projects if it feels that one group of patients is being excessively targeted.
- Is it necessary to carry out a survey? Surveys should only ask for information that cannot be collected from another source and that is related to processes or the outcome of care, i.e. were standards of best practice being met.
- Will it add value to the clinical audit project? Carrying out a survey unnecessarily, or asking more questions than necessary, will not add value to your project. Keep your questionnaire succinct. It is important not to bombard patients with too many questions as they might choose not to participate if the questionnaire looks too long; up to 20 questions is usually sufficient.
- Have you checked your sample? Your sample, if postal survey, should be checked against the latest hospital records, as sending questionnaires to deceased patients is a frequent error that can cause distress to relatives. Similarly, getting patients' names or other details slightly wrong can also cause offence.
- What written information will be given to the subject to explain what the survey is about? Include a covering letter with all patient questionnaires. A template covering letter is available on the QIS intranet site. The intranet details are listed at the end of this guide. The letter should include contact details should the patient have any queries that they wish to be answered quickly about the questionnaire, the background to project and reason for contacting the patients, instructions on how to return the completed questionnaire, a statement on how you will protect the patient's confidentiality, ideally this should be achieved through developing completely anonymised questionnaires, and what you intend to do with the data collected.

- How will you ensure that patients freely consent to taking part? Patients must not be coerced into taking part and must have the option to decline or withdraw at any time without detriment or antagonism.
- Is your survey addressing a sensitive topic? Where patients are being asked questions about their clinical care, it is important that questions are not phrased inappropriately/insensitively, as this might inadvertently cause harm or distress.
- Will the survey interfere with the treatment of the patient? Your survey should not cause the patient to reflect negatively upon their course of treatment, thereby jeopardising clinical outcomes.

If you are in any doubt about whether your survey raises ethical concerns please discuss with your divisional Clinical Audit Facilitator.

3. ARE YOU PLANNING TO PUBLISH?

Clinical Audits are usually published because the topic and/or methodology may be of interest to a wider audience, for instance, demonstrating how an audit cycle was successfully followed after initially poor results against standards, by implementing changes and demonstrating an improvement in practice with a re-audit.

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 publish the methodology for use by others, you should question whether you are undertaking a research activity, rather than a clinical audit project, that should have been submitted to REC for ethical approval. If you intend to publish your clinical audit project this should be discussed with your Clinical Audit Facilitator at the beginning of your project.

REFERENCES AND FURTHER READING

- General Data Protection Regulation (2016)
  https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32016R0679
- Data Protection Act (2018)
  http://www.legislation.gov.uk/ukpga/2018/12/contents/enacted
- Caldicott Committee Report (1997)
  http://webarchive.nationalarchives.gov.uk/20130124064947/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4068404.pdf
- NHS Confidentiality Code of practice (2003)
  https://www.gov.uk/government/publications/confidentiality-nhs-code-of-practice
  Note that figure 5 (p19) contains practical advice on keeping information secure, and figure 6 (p20) nicely summarises the relevant Caldicott principles.
- GMC Confidentiality Code of Practice (2017)
  https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/confidentiality
- Health & Social Care Act (2001), Section 60
  http://www.legislation.gov.uk/ukpga/2001/15/contents
- *"What we do with your personal information",* UHBristol Patient Information leaflet (2018)
  http://nww.avon.nhs.uk/dms/download.aspx?did=19101
- "*Guidance on sending confidential information by email*", UHBristol guideline (2016)
  http://nww.avon.nhs.uk/dms/download.aspx?did=17132
- "*Managing ethical issues in quality improvement or clinical audit projects*", HQIP guide (2017)
  https://www.hqip.org.uk/resource/guide-to-managing-ethical-issues-in-quality-improvement-or-clinical-audit-projects/
- "*Information governance in local quality improvement*", HQIP guide (2017)
  http://www.hqip.org.uk/resources/information-governance-in-local-quality-improvement

CONTACT DETAILS/ USEFUL INFORMATION

CLINICAL AUDIT

- The UHBristol **Clinical Audit website** is available via http://www.uhbristol.nhs.uk/for-clinicians/clinicalaudit/
- Contact details for UHBristol **Clinical Audit Facilitators** are available via http://www.uhbristol.nhs.uk/for-clinicians/clinicalaudit/contacts/
- The full range of UHBristol Clinic Audit **'How To' guides** are available via http://www.uhbristol.nhs.uk/for-clinicians/clinicalaudit/how-to-guides/
- Copies of UHBristol **Clinical Audit Proposal Form, Presentation Template, Report Template, Summary Form, and Action Form** are available via http://www.uhbristol.nhs.uk/for-clinicians/clinicalaudit/carrying-out-projects-at-uh-bristol/
- The UHBristol **Clinical Audit & Effectiveness Central Office** can be contacted on 0117 342 3614 or e-mail: stuart.metcalfe@uhbristol.nhs.uk
- **Clinical Audit Training Workshops** can be booked through the Clinical Audit & Effectiveness Central Office as above.

CLINICAL EFFECTIVENESS

- For advice on **Clinical Effectiveness (NICE, NCEPOD, PROMS, guidelines)** matters contact Stuart Metcalfe, Clinical Audit & Effectiveness Manager, 0117 342 3614 or e-mail: stuart.metcalfe@uhbristol.nhs.uk

PATIENT EXPERIENCE

- For advice on carrying out **surveys, interviews and questionnaires** please contact Paul Lewis, Patient Experience and Involvement Team Manager (Surveys & Evaluations), 0117 342 3638 or e-mail: paul.lewis@UHBristol.nhs.uk
- For advice on conducting **qualitative and Patient Public Involvement Activities (focus groups, community engagement, co-design, workshops)** please contact Tony Watkin, Patient Experience Lead (Engagement & Involvement), 0117 342 3729 or e-mail: tony.watkin@UHBristol.nhs.uk
- All surveys that are being carried out for service evaluation or audit purposes should be discussed with Paul Lewis in the first instance. Patient experience surveys will also usually need to 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 and covering letter template is available via http://www.uhbristol.nhs.uk/for-clinicians/patient-surveys,-interviews-and-focus-groups/

RESEARCH

- For advice on research projects contact the **Research & Innovation Department** on 0117 342 0233 or e-mail: research@UHBristol.nhs.uk
- Further information can be found via http://www.uhbristol.nhs.uk/research-innovation/contact-us/

LITERATURE REVIEWS/EVIDENCE

- For advice on literature reviews, NHS Evidence, article/book requests and critical appraisal contact the **Library and Information Service** on 0117 342 0105 or e-mail: Library@UHBristol.nhs.uk

SAMPLE SIZES

- The **Sample Size Calculator** is available via: http://www.uhbristol.nhs.uk/for-clinicians/clinicalaudit/how-to-guides/

QUALITY IMPROVEMENT

- Further information about clinical audit and wider quality improvement is available via the Healthcare Quality Improvement Partnership (HQIP) - http://www.hqip.org.uk/