MPD406/4 – Undertaking Clinical Audit Involving Third Party Organisations

NHS Blood and Transplant
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Policy

To explain the process of conducting clinical audit involving third party organisations (predominantly NHS Trusts)

Objective

To ensure that all collaborative clinical audit projects requiring data collection from other organisations are carried out competently and in compliance with relevant legislation and guidance.

Changes in this version

Updated with process for email acceptance and for staff changes within the Clinical Audit Team

Roles

- **Clinical Audit staff -** Be aware of and use the document processes when undertaking clinical audit that requires data from other organisations.
- **Hospital Caldicott Guardian -** Authorises audit activity by third party for collaborative audits

Process Description

1 Introduction

1.1 This MPD applies to clinical audits led by NHSBT which require the collection of data from Third Party organisations (usually, but not limited to, NHS Trusts) but excludes those undertaken as part of the National Comparative Audit programme or Patient Blood Management remit.

1.2 This MPD applies to all such clinical audits, regardless of whether the clinical audit requires access to patient identifiable or sensitive data.

1.3 Most collaborative clinical audit projects where NHSBT is regarded as a Third-Party organisation and intends to act as a data processor require permission from the relevant partner.

1.4 In most cases, permission for the data to be collected will be granted by the Hospital / Trust Caldicott Guardian.

1.5 Non-NHS organisations may not have a nominated Caldicott Guardian. In such circumstances, a reasonable effort must be made to identify a relevant individual with an equivalent level of authority and responsibility.

2 Process for securing permission to collect data.

2.1 Permission should be obtained by submitting: -

- a letter detailing the outline of the request and providing contact details for further information.
- a copy of the completed clinical audit protocol / planning template (FRM3720) which is sufficiently detailed for the Caldicott Guardian to understand the impact of the clinical audit on their organisation.
- examples of any data collection form(s) which will allow Caldicott Guardians to see exactly what data items are intended to be collected.
- a completed copy of the Sharing Protocol for Clinical Audit within NHSBT (FRM1272) which sets out other relevant information including what will happen with the data collected and who already has knowledge of the audit within that organisation.

2.2 In some situations, it may be more appropriate for clinical audit staff to negotiate access to identifiable or sensitive information through a nominated individual within the third-party organisation. In such cases, a completed FRM1272 may not be required – however evidence that permission has been granted for access must be gained, evidenced, and kept for reference.

2.3 The audit cannot go ahead until clearance has been secured from either the Caldicott Guardian or their nominated representative.

2.4 In the majority of cases patient identifiable information will not be required and the Caldicott Guardian should therefore be assured that confidentiality will not be breached.

2.5 Hospital / Trust Clinical Audit Departments or equivalent should be informed of the audit but in some instances, it may be more suitable to pass this responsibility to staff within the Trust, rather than NHSBT staff.

2.6 The responsibility for providing information to other Trust staff rests with the relevant Trust committees (e.g., Hospital Transfusion Committee (HTC) for blood transfusion or tissues and organ donation / transplantation equivalent).

3 Sharing Protocol for Clinical Audit within NHSBT – FRM1272

3.1. FRM1272 sets out the framework in which an individual clinical audit will operate.

3.2. It is intended to provide the Caldicott Guardian with information around how the Clinical Audit team will manage the data collected as part of the clinical audit. This, along with the other documents described in 2.1 will allow the Caldicott Guardian to make an informed decision on the participation of their organisation.

3.3. The Lead Clinical Audit Facilitator is responsible for the completion of Section 1 of FRM1272 whilst section 2 should be completed by the Trust Caldicott Guardian or nominated representative.

3.4. Email acceptance of section 2 in lieu of physical / electronic completion is acceptable, providing the email comes directly from the Trust Caldicott Guardian or nominated representative.

4 Instances where permission from the Caldicott Guardian is not required

4.1. Permission from Caldicott Guardians is not required where the data to be collected for audit purposes meets either of the following conditions:

- the data is non-clinical in nature, e.g., timings of processes in organisations other than NHSBT
- the data is already routinely shared with NHSBT, and the use of such data is strictly for audit purposes only

5 Staff changes within the Clinical Audit Team / NHSBT

5.1 Section 1 of FRM1272 details the NHSBT staff who will be required to access the data collected from a third party organisation. In the event of a staff change which results in an individual named in section 1 no longer having a need to access the data, FRM1272 should be updated with new names. A copy of the revised FRM1272 should be provided to the third party organisation, with a covering email / letter explaining the changes.

Definitions

- **Lead Clinical Audit Facilitator –** member of the Clinical Audit team with responsibility for the clinical audit project
- **Caldicott Guardian** – Person taking responsibility for use of confidential patient or donor information in their organisation
- **Clinical Audit –** A clinically led initiative to improve the quality and outcome of patient or donor care. Comparison of clinical practice against agreed explicit criteria
- **Project Lead** – Doctor, Nurse, Scientist or Manager with responsibility for the clinical audit and for taking actions forward
- **Stakeholder** - an individual or group of people with a particular involvement in a project or someone whose work may be affected by the audit recommendations

Related Documents / References

- **FRM1272** – Sharing Protocol for Clinical Audit within NHSBT
- **FRM3560** – Clinical Audit Ethics Screening Tool
- **FRM3720** – Clinical Audit Protocol / Planning Template
- **MPD764** – Clinical Audit Process Manual
- **POL2** – Confidentiality and Data Protection
- **POL132** – Clinical Audit in NHSBT
- **POL133** – Ethics & Clinical Audit in NHSBT

Appendices

None