CLINICAL EFFECTIVENESS & AUDIT STRATEGY
2015 - 2018

Excellence in Neuroscience
Summary

Clinical effectiveness is one of the quality elements contributing to achieving excellence in the safe, effective and efficient delivery of services.

This document outlines the strategy and programmes by which the Trust will examine and ensure clinical effectiveness, and how it will monitor this through its Committee structures.

The Clinical Effectiveness and Services Group and Quality Committees will be responsible for monitoring the effectiveness via quarterly performance reports.
1. Clinical effectiveness and its assessment

Clinical effectiveness is an umbrella term describing a range of activities that support clinicians/health care professionals to examine and improve the quality of care. Probably the best known example is clinical audit, but effectiveness stretches beyond this to include the implementation of nationally agreed guidance as well as agreed standards/clinical performance indicators reflecting ‘best practice’ (where these exist and are relevant to our services). Clinical Effectiveness also incorporates a range of mechanisms required to measure and assess ‘effectiveness’ (e.g. clinical audit, clinical outcome measurement, service evaluation, benchmarking data, “clinical indicators” data capture).

Clinical effectiveness assessment needs structures and processes to scrutinise the results and disseminate the findings in terms of performance and lessons learned planning for service/practice modification and re-measurement. Its purpose therefore is not only to provide assurance but also to suggest ways in which to improve.
2. Strategy

The aim of the strategy is to set out how the Trust will assess clinical effectiveness and an overview of the structures and processes necessary to deliver and monitor it.

How to assess

The first and fundamental truth about clinical effectiveness is that no one technique exists to assess it adequately. Both in theory and in practice, each method has its strengths and weaknesses. The best approach can only come from looking at the services from different “angles” and in particular using different techniques. Furthermore, the most appropriate “balance” of the assessments may vary greatly from one service to another, according to clinical and other risks associated with the service, and also what is feasible with existing tools (both theoretically and in practice). It therefore follows that the Trust’s strategy needs to be “bespoke” to the clinical services it provides. Given the uniqueness of the Trust, and the specialist nature of almost all its services, this presents a challenge for clinicians, the Trust Board and external observers/scrutineers (e.g. our commissioners and regulators).

Accepting these challenges, this strategy will outline how the Walton Centre will assess “Clinical Effectiveness” as part of its overall quality strategy by:

1. Further development and prioritisation of annual audit programmes that are determined by agreed criteria (see Appendix A) and/or as reactions to risks flagged by adverse clinical events, critical incidents, breaches in patient safety and infection control priorities.

2. Further development of clinically-meaningful “clinical outcome measures” by which services can be monitored and periodically assessed over prolonged periods of time. Some of these involve national benchmarking against other Trusts or hospitals in the World. This is the method most favoured clinically.

3. Continuation of processes to ensure new procedures are developed in a way which minimises risk and optimises the chances of success and audits the results.

4. Continuation of the process developed for the assessment of our services against nationally agreed best practice guidance and agreed national guidance on service delivery where these are directly relevant to Trust services (e.g. NICE, NCEPOD), with implementation of action plans against any significant “deficiencies” identified.

The distinctions and borders between these may blur in places.

Reviews of each will be undertaken periodically in order to demonstrate good performance and intended continuous improvement in healthcare.

Clinical effectiveness programmes

- Clinical Outcome measures, both external (benchmarking) and internal
- Clinical Indicators
- Service Evaluation
- Clinical Audit
- Development of local guidelines and standards
- National Institute for Clinical Excellence (NICE)
- National Confidential Enquiries into Patient Outcome and Death (NCEPOD)
- Other Benchmarking Data (in the few places where available and relevant)

Where these relate to services provided by the Walton Centre
**Benchmarking data**

The Trust subscribes to Dr Foster and uses information on both performance and clinical governance indicators to improve services.

- All relevant divisional and governance leads have passwords to access this information
- Dr Foster provide reports which are presented at the Performance Committee.
- The information is utilised by the divisions to compile action plans for corrective action.
- Indicators on mortality, risk adjusted mortality, and complications rate are included within local Clinical Indicators for Quality Board and Trust Board, and Hospital Management Board.

Other developing clinical datasets and clinical information systems may also be used. The National Neurosurgery Audit Programme and the developing Dr Foster “My Practice” are further examples of benchmarking data, which include mortality and some other measures extractable from SUS data, on a unit and an individual consultant basis. This data can only be extracted for those patients according to procedure or diagnostic codes. In the case of NNAP data, comparison can be made to all neurosurgical units in the UK at both unit and consultant levels.

In the case of Spine Tango, comparison is made to the most prominent spinal surgery services in Europe and Australasia.

**Clinical outcome measurement (see Appendix C)**

These measure the clinical outcomes of a service without reference to a particular pre-determined standard (in contrast to audits), and its aim is to give an indication of the standard achieved by the service. One of these indicators may be mortality, but others involving clinical treatment success (e.g. in terms of symptom improvement) and morbidity are available (e.g. Spine Tango, Botulinum toxin response rates) or are in development (part of NNAP).

Once set up, this type of assessment can be continued indefinitely and so there is at least a chance of demonstrating improvement with time (both in the service, and in the patient) and can assess clinically meaningful outcomes continuously (in contrast to most audits). Importantly, the application over a prolonged period can help to reduce problems arising from low patient numbers with a particular condition, in both running the study and in its statistical analysis. At the other extreme, they can also be very "generalisable", assessing service across a much wider range of patients than tends to be the case with audits.

They tend to involve collecting data about more clinically meaningful measures, which can more easily take account of the patient severity and other factors at the beginning.

The data tends to be that is or can be routinely collected in clinical practice or by use of a relatively simple but clinically meaningful tool.

**Clinical indicators**

A basket of clinical indicators relevant for our services has been developed over the years, with data collected from numerous sources including DATIX, Dr Foster, ICNARC, hospital PAS and e-patient (for a number of local data sets). These indicator data provide some pockets of readily collected information on quality, outcome, process, safety of care as well as the patient experience and specialist services. These indicators provide a cycle of continuous monthly monitoring for specific areas, and some of the indicators are now included in the Key Performance Indicator (KPI) report to provide assurance to Trust Board
on specific issues e.g. Surgical Site Infection and compliance with VTE Risk Assessments. These tend to relate to “exception reports” or alternatively to high volume data which can be collected with some validity each month.

**Clinical audit**

*True* clinical audit involves setting of one or more “targets” to be measured against within the clinical pathway for a certain group of patients (hopefully reasonably homogeneous), and these “targets” may be part of “process” or a clinical outcome. Measurement is then made against that target. According to the results, adjustments are then made to the pathway and the whole audit repeated: the so-called audit “cycle”.

In reality, lots of assessments labelled as “audits” by some doctors and/or other staff are not true audits of this nature, but rather various themes of clinical outcome or service evaluation.

The Clinical Audit Group at the Walton Centre has tried in the past to restrict its activities and support to the true clinical audits (as above). With the devolution of the Trust’s “audit” structures to within the divisions, and the increasing use of clinical outcomes assessment in the Trust, it is the intention to “relax” the remit of the Clinical Audit Group and the clinical audit support staff to include supporting any aspect of clinical effectiveness assessment.

**Service evaluation**

Service Evaluation is designed and conducted to define or judge current service. Participants will normally be those who use the service or deliver it. It involves assessment of different aspects of a defined service; these will usually involve measures of process but where possible should also include a component of measurement of clinical outcome. It involves gathering of data in routine practice and does not require ethical approval.

**New procedures**

Following national guidance nearly ten years ago, the Trust has processes for the management of new and existing interventional procedures which incorporates:

- Introduction of an Interventional Procedure which is a new technique to clinical practice at the Walton Centre
- Introduction of an interventional procedure which is new to an individual clinician but already practised at the Walton Centre
- That which is a requirement when interventional procedure guidance is issued by NICE

In addition, the Trust also developed its own bespoke similar processes for consideration of new non-invasive procedures.

The clinical and operational aspects of all these are considered by the Clinical Effectiveness & Services Group.

**National guidance consideration and implementation**

a) **NICE Guidance**

Currently, NICE produces three kinds of guidance:

- Technology appraisals - guidance on the use of new and existing medicines and treatments within the NHS in England and Wales.
• Clinical guidelines - guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS in England and Wales.

• Interventional procedures - guidance on whether interventional procedures used for diagnosis or treatment are safe enough and work well enough for routine use in England, Wales and Scotland.

A process for the implementation of relevant NICE Guidance has been in place for years which ensures that agreed best practice (as defined by NICE) is implemented Trust wide. The Trust’s policies on the Implementation of NICE Guidance are available on the Trust intranet.

The Effectiveness and Audit staff is responsible for producing quarterly exception reports which are monitored by the Quality Board. All activity and evidence in relation to NICE Guidance is held on CIRIS.

b) National Confidential Enquiries

NCEPOD undertakes confidential surveys reviewing the management of patients with defined conditions and publishes reports summarising key findings and also recommendations which aim to identify changes in clinical practice that will improve quality of care and ultimately improve patients’ outcomes.

The biannual NCEPOD Reports provide Quality Board with the current compliance status of NCEPOD’s relevant to the Centre. The main purpose is to provide Trust Board with assurance that necessary actions have been undertaken to ensure safe practice.

Existing practice at the Trust is baseline assessed against any NCE recommendations. Action plans are monitored by Clinical Effectiveness & Services Group who will report to the Quality Board by exception and risks will be managed via the Divisions and Governance Committee.

Once a baseline assessment is complete, a report will be made to the Quality Board on status of compliance with identified risks or areas of concern highlighted. Quality Board will consider the significance or otherwise of risks associated with non-compliance.

When a significant risk is identified, actions will be taken to minimise the risk and monitor progress. Significant risks will be recorded on the Trust’s or Division’s (depending on severity) Risk Assurance Framework and highlighted in service planning round.

The Effectiveness and Audit staff is responsible for producing quarterly exception reports which are monitored by the Quality Board.

Patient and public involvement

The Trust will continue to participate in relevant national patient surveys and Patient Reportable Outcome Measures (PROMs, e.g. in oncology services) to ensure feedback from service users systematically improves the quality of healthcare services. The Trust will aim to use patient views when:

• Developing clinical audits related to new pathways of care
• Planning clinical audit that it is aimed directly at patient experience.
• Evaluating services using measures of patient experience
Research and audit (see Appendix B)

Clinical audit and research have complementary roles in ensuring clinical effectiveness. However, confusion can occur in relation to defining these processes. Most commonly the difference is described in terms of research “determining the right thing to do” and that audit is to determine “whether the right thing is actually done and whether it is done well” (Smith, 1992, Audit & Research, BMJ 305: 905-906). Service evaluation and clinical outcome measurement represent a third strand, as outlined in Appendix B. It differs from audit in being an ongoing linear and often continuous process involving routinely collected data, ideally with review at regular scheduled intervals; whereas audit is a cyclical process which involves measuring against a pre-determined standard (and so which is necessarily narrow in its view).
3. Clinical effectiveness reporting structure

a) Quality Committee
Issues of clinical quality are addressed at the highest level by this Committee. This group is chaired by a non-executive director and members include executive Directors, non-executive Directors, the Director of Nursing, and the Medical Director.

b) Clinical Effectiveness and Services Group
The Clinical Effectiveness and Services Group is chaired by the Medical Director and is responsible for monitoring the effectiveness via quarterly performance reports from the divisions, and will then report in summary and by exception and with clinical comments, to the Quality Committee.

c) Divisional Structure
Work has taken place in developing Divisional Clinical Governance Structures. Divisional Medical Leads for Audit have been appointed in each division to support the management of audits including forward planning. They are involved in the process for selecting clinical audits (see below). Clinical Governance Managers are now embedded in the divisions and meet with members of the Divisional Team(s) on a monthly basis. The Divisions now have responsibility for progressing all issues locally.

In addition to this managerial structure, there are meetings within each division at which clinical outcome and benchmark data are presented for scrutiny by peers; the frequency of such presentation will depend upon the frequency of the procedures (e.g. for most, e.g. some skull base procedures, this may just be annually), and the outcomes and time of assessment will need to be tailored to the procedure. This should be a multi-disciplinary process and be minuted and subsequently reported as part of that Division’s governance report to the Clinical Effectiveness and Services Group and Quality Board.

d) The Clinical Audit Group (CAG)
This group is chaired by the Assistant Medical Director and has as its membership the clinical audit leads and staff from the divisions. The new Terms of Reference are in the process of being agreed, but the roles of the group are:
1. to provide oversight of clinical audit within the Trust
2. to provide advice to divisions in establishing and conducting clinical audit projects and other clinical effectiveness measures as appropriate
3. the development of the clinical audit programme in collaboration with the Clinical Directors, Divisional General Managers, Divisional Medical Leads for Audit, and
4. the development of the clinical audit programme according to the prioritisation process outlined in Appendix A.
5. to report an annual review of the audit programme to ensure that it has met the organisation’s objectives and priorities
6. to receive reports relating to completion of the audit cycle (action planning and re-audit). Having identified problems or deficiencies in structures or processes or poor outcomes, an action plan will be developed by the Divisions to improve them, outlining the individuals responsible for delivery, and a timescale, and the reporting structure back to CAG.

The Clinical Audit Group will report quarterly to the Clinical Effectiveness & Services Group and the Quality Committee.
APPENDIX A: Prioritisation of audits

Since the resources of the Audit Department are finite, there is always going to be a need to prioritise studies. In considering these decisions, it is important that the following are acknowledged and recognised:

a. Many factors will need to be considered in such a decision, and sometimes these are aligned but at other times they may be competing with one another.
b. The unique and restricted extent of our services.
c. The specialised nature of most of our services.
d. That the services need to be provided within a more generic clinical (e.g. hospital inpatient, hospital outpatient, community) and regulatory frameworks (CQC, Monitor, NHS England and Specialist Commissioning, GMC and GNC).
e. In view of the above four points, it is an important principle to be established that the Walton Centre should make its own decisions, which should be bespoke for the clinical services it provides.
f. Numerous factors may be involved:
   - External body/internal (regulation or other, e.g. professional, NHSLA)
   - Whether the audit is obligatory or our choice
   - Whether the audit is addressing specific known risks (arising from incident etc)
   - Size of potential impact on meeting Trust objectives
   - Size of potential risk to derailing Trust objectives (e.g. cost and/or volume)
   - Practicalities/feasibility of performing the audit
   - Practicalities/feasibility of completing the audit within a reasonable timeframe
   - Measures (clinical relevance, ease of collection, quantification)
   - Service nature: size, homogeneity, numbers of providers involved
   - Feasibility of meaningful results (patient numbers, data collection etc)
g. Availability of external resources for the study; for running the audit or evaluation, for example Spine Tango, TARN, NNAP, and/or existence of a validated audit tool.
h. Track record of individuals involved.

There are therefore obviously many factors involved in shaping this decision. Furthermore the weight attached to each one will inevitably depend upon others. In consequence

- it is impossible at this time to quantify or in any meaningful way "score" different studies as to how they should be prioritised. This will remain a matter of judgement.
- these judgements should be made by clinicians, though with input from the Governance Department, Executive and Trust Board.
- this will also need to be backed by a supporting infrastructure, including elements from the Audit and Outcomes Department, IT and Finance.

The prioritisation process should be transparent and pre-agreed, and involve

A. A filtering system, to involve inclusion and exclusion criteria,

   AND THEN

B. A weighting system to take into account the variables outlined above
Filtering system

Whilst these criteria should divide potential studies quite neatly, it is recognised that there may be a grey area between a few studies.

Inclusion criteria

Audits, service evaluations and clinical outcome measures which

- are predominantly clinically orientated drawn up by doctors, therapists or nurse specialists
- involve data which are measurable and clinically meaningful
- have an identified local clinical lead who is responsible for organisation and completion

Exclusion criteria

Whilst it is recognised that these may well be worthwhile, they should not be part of the remit of the Clinical Audit Department;

- diagnostic departmental regulatory audits
- infection control audits
- audits dealing with technical issues within the Department
- safety or quality issues based upon individual case reporting (e.g. morbidity and mortality)

Weighting system

As noted above, we do not have a meaningful scoring system for prioritising different studies. We can try and plagiarise a suitable one, or develop one of our own going forward, though this will inevitably take considerable time. In the meantime, we can apply a rough “weighting” of criteria into major, intermediate and minor:

Major

a) Audits which are important to our services AND/OR relevant to our specialist services, from
   - NICE
   - NCEPOD
   - NHSLA Acute Standards
   - Other NHS bodies (including commissioners)
   - Royal Colleges
b) Studies involving a major patient safety issue, as identified by any means, external (e.g. CQC, Deanery review) or internal information, including from other clinical governance structures (e.g. complaints, claims, clinical incidents, never events, appraisals)
c) Studies which may have a major impact on the Trust’s strategic objectives and/or risks, as identified on the Board Assurance Framework, or Trust or divisional risk registers

Intermediate:

a) Other NICE-, NCEPOD-, Royal College- or other NHS - derived studies which are not specifically relevant or important to our services
b) Studies which may have a moderate impact on the Trust’s strategic objectives and/or risks, as identified on the Trust, divisional or departmental risk registers
c) Prior availability of an appropriate tool

Minor:

a) Track record of those intending to perform the audit
b) Relevant to our services but without major impact
c) Studies which may have a minor impact on the Trust’s strategic objectives and/or risks, as identified on the divisional or departmental risk registers
d) Whether the audit is multidisciplinary in nature

Where possible, the Trust will promote audits which are:

- prospective
- engage and interest multi-disciplinary & multi-professional teams
- across service providers
- multi-divisional
- seeking to involve patients and/or carers
APPENDIX B: Differentiating audit, service evaluation and research

<table>
<thead>
<tr>
<th>RESEARCH</th>
<th>CLINICAL AUDIT</th>
<th>SERVICE EVALUATION / CLINICAL OUTCOME MEASUREMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>The attempt to derive generalisable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them.</td>
<td>Designed and conducted to produce information to inform delivery of best care.</td>
<td>Designed and conducted to define or judge current care.</td>
</tr>
<tr>
<td>Quantitative research – designed to test a hypothesis. Qualitative research – identifies/explores themes following established methodology.</td>
<td>Designed to answer the question: “Does this service reach a predetermined standard?”</td>
<td>Designed to answer the question: “What standard does this service achieve?”</td>
</tr>
<tr>
<td>Addresses clearly defined questions, aims and objectives.</td>
<td>Measures against a standard.</td>
<td>Measures current service without reference to a standard.</td>
</tr>
<tr>
<td>Quantitative research - may involve evaluating or comparing interventions, particularly new ones. Qualitative research – usually involves studying how interventions and relationships are experienced.</td>
<td>Involves an intervention in use ONLY. (The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.). In practice, in audits one or only a limited number of “interventions” can be studied at once.</td>
<td>Involves an intervention in use ONLY. (The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.). The outcome is expressed for the entire patient group.</td>
</tr>
<tr>
<td>Usually involves collecting data that are additional to those for routine care but may include data collected routinely. May involve treatments, samples or investigations additional to routine care.</td>
<td>Usually involves analysis of existing data but may include administration of simple interview or questionnaire.</td>
<td>Usually involves analysis of existing data but may include administration of simple interview or questionnaire.</td>
</tr>
<tr>
<td>Quantitative research - study design may involve allocating patients to intervention groups. Qualitative research uses a clearly defined sampling framework underpinned by conceptual or theoretical justifications.</td>
<td>No allocation to intervention groups: the health care professional and patient have chosen intervention before clinical audit.</td>
<td>No allocation to intervention groups: the health care professional and patient have chosen intervention before service evaluation.</td>
</tr>
<tr>
<td>May involve randomisation</td>
<td>No randomisation</td>
<td>No randomisation</td>
</tr>
<tr>
<td>Usually time limited</td>
<td>Usually time limited and cyclical</td>
<td>Longitudinal, and can be continued indefinitely</td>
</tr>
<tr>
<td>Usually highly selected patient group</td>
<td>Usually selected patient group</td>
<td>More generalised patient population usually, including “all comers”</td>
</tr>
</tbody>
</table>

ALTHOUGH ANY OF THESE THREE MAY RAISE ETHICAL ISSUES, UNDER CURRENT GUIDANCE:

<table>
<thead>
<tr>
<th>RESEARCH REQUIRES R.E.C. REVIEW</th>
<th>AUDIT DOES NOT REQUIRE R.E.C. REVIEW</th>
<th>SERVICE EVALUATION DOES NOT REQUIRE R.E.C. REVIEW</th>
</tr>
</thead>
</table>
Appendix C: clinical outcome measurement

These measure the clinical outcomes of a service without reference to a particular pre-determined standard (in contrast to audits), and the aim is to give an indication of the standard achieved by the service.

Once set up, this type of assessment can be continued indefinitely and so there is at least a chance of demonstrating improvement with time (both in the service, and in the patient). Importantly, the application over a prolonged period can help to reduce problems arising from low patient numbers with a particular condition, in both running the study and in its statistical analysis. At the other extreme, they can also be very "generalisable", assessing service across a much wider range of patients than tends to be the case with audits.

They tend to involve collecting data about more clinically meaningful measures, which can more easily take account of the patient severity and other factors at the beginning.

The data tends to be that routinely collected in clinical practice or a relatively simple but clinically meaningful tool is used.

The main problems with clinical outcome measurements are:

1) identification of one or a few measures which are
   a) Clinically meaningful
   b) Quantifiable
   c) Easy for patient and clinician to collect
   d) Suitable for routine data collection in clinical practice

2) Resources for collection/analysis/presentation of data as a routine (as opposed to "one-off" audit).

Undoubtedly, clinical outcome measurement is on the increase, at both the Trust/service level and at the individual consultant level. This is partly driven by external demand, though there are major problems in the weak-witted misinterpreting the results, and the "league-table" mentality and so-called "benchmarking" that sometimes accompanies their presentation.

The Trust has an enviable track record in this. It is one of only four neurosurgical units in the country to submit data to Spine Tango routinely. Furthermore, it has hosted and half-funded (with SBNS) the mis-named National Neurosurgical Audit Programme (NNAP) which has produced a service-level and individual consultant level mortality data for neurosurgery for the first time. There are other national networks to which the Trust also submits data routinely (e.g. TARN, UKROC, ICNARC, IVlg database, neuro-oncology) and an increasing number of disease-specific national registries some of which are coming under the umbrella of NNAP (see appendix D). To these can be added a number of locally-originating measures.
Appendix D: clinical audit registration and follow-up

Clinical audit registration process

Before commencing any audit project, it is expected that an audit registration (proforma) is completed by the project lead and authorised as meeting divisional priorities by the Divisional Medical Audit Lead. It is then submitted to the Clinical Audit Lead, who will ensure that is considered at the Clinical Audit Group. All appropriate audit topics are entered onto the audit database which holds information about completed, ongoing and planned audit projects in relation to:

- Reason for audit
- Audit Methodology
- Clinical Audit results
- Recommendations / suggested changes to practice

All proposed audits are then considered against the prioritisation criteria (appendix A) by the Clinical Audit Group. Additionally, this process addresses what level of assistance would be required to undertake the work and determines the resources required to ensure it is achievable and to enable implementation of the findings. Clinical audit/effectiveness staff/resource will give advice on the potential sources of data, sampling and information on the use of guidelines, standards etc in the development of audit criteria and audit tools.

For local areas of clinical/care priority, clinical/care teams should identify the strengths and weaknesses of present provision and measure against standards (preferably evidence-based) in order to identify where services could be improved, ensuring that any changes that are planned are achievable.

All audit projects are required to have an identified lead responsible for ensuring data collection, dissemination of findings and reporting to the Divisional General Manager and Divisional Medical Audit Lead to agree local action on recommendations. Importantly if recommendations are not implemented but still carry a level of risk they should be placed on the Divisional Risk Register.

Completing the audit cycle (action planning and re-audit)

Having identified problems or deficiencies in structures or processes or poor outcomes, an action plan will be developed to improve them, outlining the individuals responsible for delivery, and a timescale, and the reporting structure.