“Any practitioner who is using research-based evidence in practice and can show that they have improved patient outcomes as a result, can claim to be practising clinical effectiveness.”

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INTRODUCTION

Clinical effectiveness is defined (Department of Health, 1996) as “the application of the best knowledge, derived from research, clinical experience and patient preferences to achieve optimum processes and outcomes of care for patients. The process involves a framework of informing, changing and monitoring practice.”

Clinical effectiveness is an essential component of the Clinical Governance agenda to improve and assure quality. As with all aspects of Clinical Governance, clinical effectiveness is about improving patients’ total experience of their healthcare. Clinical effectiveness is aimed at making clinical practice more explicitly evidence based with the goal of improving the effectiveness of clinical practice and service delivery.

Clinical effectiveness is about doing the right thing at the right time for the right patient and is concerned with demonstrating improvements in quality and performance:

- the right thing (evidence based practice requires that decisions about health care are based on the best available, current, valid and reliable evidence)
- in the right way (developing a workforce that is skilled and competent to deliver the care required)
- at the right time (accessible services providing treatment at the point of need)
- in the right place (location of treatment / services)
- with the right outcome (clinical effectiveness / maximising health gain)

Clinical effectiveness is thinking critically about what you do, questioning whether it is having the desired result and making a change to practice if required. It is based on evidence of what is effective in order to improve patient care and experience. All members of the Trust are responsible for clinical effectiveness.

The purpose of this strategy is to present a 2-year plan for delivering a programme of Clinical Effectiveness throughout Southport and Ormskirk NHS Trust. This strategy will be reviewed annually to accommodate any changes in priorities or direction. With the desire to achieve Foundation Status and the autonomy that this provides, it is important the Trust is able to demonstrate services are robust, meet and exceed national standards and are at the vanguard of NHS performance.

DEFINITIONS

Clinical Effectiveness
In 1996 the NHS Executive (NHSE) defined clinical effectiveness as: ‘The extent to which specific clinical interventions when deployed in the field for a particular patient or population do what they are intended to do, that is, maintain and improve health and secure the greatest possible health gain from the available resources.”
Clinical effectiveness has three distinct parts:

Obtaining evidence – from research, either published in journals or available on databases; from national level studies based on research, for example, clinical guidelines, systematic reviews or national standards

Implementing the evidence – by changing practice to include the research evidence and, where possible, locally adapting national standards or guidelines.

Evaluating the impact of the changed practice and readjusting practice as necessary, usually through clinical audit and patient feedback.

Research
In the broadest sense of the word, the definition of research includes any gathering of data, information and facts for the advancement of knowledge

Scientific research is performing a methodical study in order to prove a hypothesis or answer a specific question.

Research must be systematic and follow a series of steps and a rigid standard protocol.

Translational research facilitates the translation of findings from basic science to practical applications that enhance human health and well-being. Translational research helps turn early-stage innovations into new health products.

Research usually requires Ethics Committee review.

Clinical Audit
Audit is defined as assessing the level of service being provided against a set of predetermined standards. This generally involves analysing existing data with results usually being used/distributed locally in order to effect change to improve/change the level of service currently being provided. It does not require ethical approval.

Service Evaluation
Service Evaluation is undertaken so that service users can help inform and improve a particular service and is designed and conducted solely to define or judge current service. Participants will normally be those who use the service or deliver it. It involves an intervention where there is no change to the standard service being delivered (e.g. no randomisation of service users into different groups). Service evaluation does not require ethical approval.
AIM AND OBJECTIVES

Aim

The Trust's aim is to provide safe, clean and friendly care and the aim of this strategy is to promote high quality audit and research, to inform the delivery of 'best value', clinically effective health care for the population served by Southport & Ormskirk NHS Trust.

Objectives

1. To ensure that individual roles and responsibilities within the organisation, relating to clinical audit and research, are clear

2. To outline the governance arrangements through which the quality of audit activity will be monitored and appropriate dissemination of outcomes take place.

3. To summarise the audit priorities of Southport & Ormskirk NHS Trust.

4. To promote patient and public involvement in clinical audit, in order to ensure opportunities for capturing feedback from patient experiences and wider public views are optimised.

5. To outline the training and support available for staff participating in audit and research activity and the mechanisms through which audit capability will be developed within the workforce.

6. To safeguard patients, researchers and the Trust by ensuring research is carried out according to all research governance, ethics and regulatory requirements.

7. To develop the capacity of the Trust to support quality research activity.

8. To collaborate with the National Institute for Health Research (NIHR) and Clinical Research Networks to contribute to the national research programme.

9. To promote inter-departmental collaborations to facilitate staffs’ access to evidence / publications.

10. To develop a system for sharing and review of outputs of post graduate courses for non medical staff.

11. To raise public and service user awareness of research ongoing in the Trust.

12. Increase training opportunities that would promote clinical effectiveness

13. To identify and protect innovation and intellectual property

SCOPE
This strategy applies to all staff within Southport & Ormskirk Hospital NHS Trust.

PRIORITISATION

Clinical Audit

The audit programme prioritises audits required for:

- National Clinical Audit Programme
- Nice guidance
- NSFs
- NHSLA / CNST
- Confidential Enquiries
- Local Audits on the quality of care, complaints, litigation, critical incident reporting and risk management

Research

There is not the same hierarchical structure to prioritising research studies. However, research activity carried out within Southport & Ormskirk NHS Trust generally falls under the following categories:

- NIHR Clinical Research Network portfolio
- Industry
- Charitable organisation funded research
- Higher Education Institute collaborative research including student research
- Own account research

ROLES AND RESPONSIBILITIES

Clinical Audit

- All projects registered have to have an audit plan which states the role and responsibility of the auditor and the audit sponsor completed.
- All specialities within the Trust must participate in local/national audits

Research

- All Job Descriptions contain a statement regarding adherence to the Research Governance Framework.
- Roles and Responsibilities of investigators are highlighted within the Trust research study approval letter
- All research studies must have an identified sponsor responsible for the overarching management and conduct of the study.
- All research studies must receive approval from both a Research Ethics Committee and from the Trust before the study starts.
PATIENT AND PUBLIC INVOLVEMENT

Clinical Audit

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

- Developing clinical audits related to new or existing pathways of care
- Planning clinical audit that it is aimed directly at patient care.
- Planning clinical audit related to a new service development.
- Evaluating services.

Research

The Trust will encourage all researchers to actively consider how patients and the public can inform the research agenda and engage in individual research projects in line with the national initiative to promote patient and public involvement in the design, management and dissemination of research.

The Trust will develop systems to inform the public and service users of studies appropriate to their clinical need that they may be able to participate in.

EVIDENCE BASED PRACTICE

The application of the best knowledge, derived from research, clinical experiences and patient preferences to achieve optimum processes and outcomes of care for patients. The process involves a framework of informing, changing and monitoring practice.

(‘Promoting Clinical Effectiveness’, DOH, 1996)

Use of Evidence & Literature Searching

The importance of ensuring that all NHS staff and students in the Trust have access to, and the ability to evaluate best evidence is recognised by the organisation. Best evidence underpins all effective and efficient clinical, commissioning and policy making. The Trust Library and Knowledge Service is core to providing access to best evidence and the skills to obtain and evaluate it.

To ensure that best evidence underpins every clinical and policy decision, all Southport and Ormskirk NHS Trust NHS staff and students will have the opportunity to use the library information services and resources. These services will be available to support their knowledge needs regardless of their location, job function or time of day.
Membership of the library service should be taken up by all staff, and all new staff will be encouraged to join at induction. The Hanley Library at Southport and Sanderson Library at Ormskirk are staffed from Monday to Friday, 8.30 am to 5.00 pm, although 24 hour access is available to all staff and students by arrangement with the library staff.

All staff and students will be encouraged to use NHS Evidence, available via the Trust Library Services Intranet pages and the World Wide Web at www.evidence.nhs.uk

All staff and students are eligible for an NHS Athens account, which will enable them to undertake literature searches via the health care databases and link in to the full text of electronic resources. Staff can obtain an Athens account by visiting the Hanley or Sanderson libraries and asking the library staff for assistance. Alternatively, staff can register directly at www.library.nhs.uk

The Trust has increased the provision of electronic rather than paper evidence resources available by using an Athens password. The trend towards having an all electronic journal collection will continue over the next three years.

To ensure that all Trust staff and students understand what best evidence is, how to identify and access it and then evaluate it, monthly literature searching training sessions have been scheduled on both hospital sites. Details of sessions are available via the Trust Library Services Intranet pages. To book a place on a training session, staff should contact the Library Service.

In addition to the dedicated literature searching training sessions, the Library Service has collaborated with the Research Department to deliver a joint Literature Searching and Critical Appraisal of Research course on a quarterly basis.

The present strong programme of information skills training already in place will be further developed over the next three years, enabling all the Trust staff to search effectively and efficiently for the best available evidence. (Access to computers are available in the library and in staff canteens)

The use of the Library’s Heritage system will be extended to incorporate a catalogue of Trust staffs’ publications to celebrate the volume and quality of research activity within the Trust and to facilitate access to publications.

**The Interface Between Audit And Research**

Clinical Audit and Research are explicitly linked: without research we won’t know what clinically effective practice is; without audit we won’t know whether best practice is being implemented. More specifically:

- Clinical audit can be legitimately viewed as the final stage of a good clinical research programme.
- Alternatively research could be viewed as a precursor to the clinical audit process.
- Research can identify areas for audit.
- Audit can pinpoint areas where research evidence is lacking.
- The audit process assists with the dissemination of evidence-based practice.

Learning Lessons and Improving Quality

Audit reports will be produced explaining the outcomes and recommendations from audit projects.

The Trust will support and encourage the development of action plans where necessary to address identified opportunities to improve quality of care provided.

The Trust will ensure that all action plans include an objective, actions required, by whom, timescales and the monitoring group or meeting.

It is important to recognise that there may be barriers to the effective implementation of the findings of Clinical Effectiveness and audit activities. These may include:

- Structural Factors
- Organisational Factors
- Peer Group
- Individual Factors
- Professional

These will be managed through the action plans and by the relevant group or committee. For barriers that cannot be resolved at a local level the issue will be escalated to the Operational Trust Quality Committee. The Operational Trust Quality Committee has finance and Primary Care Trust representation so any funding or external barriers can be discussed and addressed.

STRATEGIC LEADERSHIP

The Director of Nursing and Quality has overall responsibility for Clinical Effectiveness. The Director of Research & Clinical Lead for Audit has delegated responsibility for overseeing the implementation and development of the strategy within the Trust. Each speciality has a designated Audit & Research lead.

The Head of Audit and Effectiveness is responsible for the delivery of the clinical audit programme across the Trust.
The Research and Development Manager is responsible for the operational management of the Research Department, supporting delivery of NIHR standards and timelines, and establishing a programme to address competencies and training needs of Trust staff to develop research capability and capacity.

The Trust will reconfigure the research services provided in line with the developing NIHR implementation plans. Research governance will become nationally managed with local performance indicators and targets.

The Trust is to meet the objectives set out for R&D in the NHS Constitution and NHS Operating Framework 2009/10 (Patients should have exposure to up to date therapies). The newly formed Clinical Commissioning Groups will be charged with the responsibility to ensure all Trusts conduct and promote research.

The R&D Department will continue to develop strategic partnerships with other NHS organisations, life sciences industries and higher education institutes to collaborate in high quality research as a core function of the Trust. The Department of Health NIHR has created a national framework for professional local management of health research adopting standard operating procedures and a risk based approach to improve speed and efficiency for commercial and non commercial trials in the UK. Key performance indicators include time to NHS approval to open studies and recruitment to time and target.

Research will aim to become further integrated in Trust business by establishing closer linkages with Trust services including Divisional Business Units, human resources, finance, pharmacy, other support services etc.

Clinical Audit and Research Meetings are held in each speciality on a bi-monthly basis, this provides the forum for dissemination of audit findings and consideration of potential research opportunities.

**Use of Information Technology**

**Clinical Audit**

- The Trust will continue to develop the Clinical Audit Database
- Information Requests will continue to be gathered from Trust Patient Administration System (PAS)
- The Trust will continue to enter data on to the National Databases

**Research**

- The current Research information management system is outdated and the Trust plans to transfer to the National Institute of Health Research
system for monitoring research and accrual as this is rolled out nationally.
- The Trust will continue to alert staff that patients are enrolled into a clinical trial via the Trust Patient Administration System (PAS)
- The Patient Administration System will be used to determine study feasibility.
- The Research Department will interrogate national information systems to:
  - Identify potential NIHR studies for further collaboration
  - Access associated documentation
  - Verify accrual data reported via the national portal
- The use of externally created electronic case report forms is expected to increase over the next few years as methods of safe data transfer are developed

Data Collection Methodologies

Data Collection can be in many formats for both Clinical Audit and Research:

- Staff/Patient Questionnaires
- Staff/Patient Interviews and focus groups
- Data Collection Tool (Paper/Electronic)

All methods of data collection and use of data within research will continue to be approved on a study by study basis by the research ethics committee and locally vetted to ensure data management arrangements are in line with the requirements of the Data Protection Act 1998.

TRAINING AND EDUCATION

Membership of the library and knowledge service should be taken up by all staff and all new staff will be encouraged to join at induction. The Hanley Library at Southport is staffed between 8.30 a.m. to 4.30 p.m. 24 access is available to all staff and students by arrangement with the library staff. There is also a Library Resource room located within the Education Centre on the Ormskirk site.

The Clinical Effectiveness Team and the Research Team are committed to providing training on clinical effectiveness techniques throughout the Trust on a rolling basis. This training will be available to both clinical and non clinical staff. The core work of the team is clinical projects; however, support, advice and training are available to non clinical staff such as those in the corporate services.

The Research team already delivers a number of research related workshops to promote good clinical practice in research. However, a programme of training and education is being established to further develop the Research Capability and Capacity of Trust staff. The team of clinical research facilitators employed to support principal investigators in managing NIHR studies undergo a comprehensive programme of workshops and on-the-job
training and supervision. In addition, the Research Department is actively collaborating with the Local Research Networks to develop and deliver a region-wide training programme to ensure all clinical research facilitators are working to the same competent standards.

The Trust will continue to use the services of the Regional Research Design Service to assist researchers in developing grant writing skills.

SUMMARY

Over the next 2 years the Trust will engage in a variety of national and regional clinical effectiveness/research initiatives to meet the requirements of relevant regulatory and review bodies. We will aim to meet performance targets and improve systems and processes to continually assess, monitor and improve the care and service delivery for Southport & Ormskirk NHS Trust patients. The objectives of this Strategy and the associated work plan which demonstrates how those objectives will be met are attached in appendix 1.

REFERENCES

NHS Research Governance Framework for Health and social Care, Second Edition April 2005

Best Research for Best health: A new national health research strategy, Department of Health, Jan 2006

The Data Protection Act 1998

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The Handbook to the NHS Constitution for England January 2009

The Operating Framework for the NHS in England 2009/10 High Quality Care for All

Principles for Best Practice in Clinical Audit 2002

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