Local clinical audit: handbook for physicians
August 2010

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GLOSSARY AND ABBREVIATIONS

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I am delighted to support the “Local clinical audit: handbook for Physicians”. The Royal College of Physicians in its Charter of 1518 was bound to “uphold standards ... both for their own honour and for public benefit”. The College seeks to fulfil that requirement as strenuously now as at any time. Clinical audit is an established and crucial tool for upholding standards and achieving improved care.

Local clinical audit has enormous clinical potential which to date has been, to a large extent, untapped. This handbook provides a stimulus and a means whereby physicians, both in training and in consultant posts, can maximise the full benefits of audit. While all are familiar with data collection, the other critical phases of the audit cycle are equally important. We need to enthuse and enable physicians to reflect on audit findings, inter-relate with patients and managers in devising methods for improving care, take a lead role in driving improvements and ensure repeat data collection to demonstrate change.

In these ways patient care can be improved, the quality of care can be assured and clinicians, both individually, as Societies and as a College, can truly meet their professional aspirations. This handbook should help us along the way.

Dr Michael Cheshire
Clinical Vice President
Royal College of Physicians, London

April 2010
INTRODUCTION

Welcome to a great new resource for physicians. This handbook is intended to give you all you need to know to do effective, robust and worthwhile clinical audit in your own organisation. It has been created, specifically for the busy physician, by people who are passionate, experienced and knowledgeable about the subject.

The authors have produced this handbook so that it can be useful and used! Useful in that it includes real examples from real audits and can be used:

• by the physician working in a multi-professional local clinical team
• by junior doctors to maximise benefit from local clinical audit
• for improving the quality of care at the local level
• in professional development.

The authors have specifically addressed the handbook towards the needs of physicians, both in consultant posts and in training. Many of the messages, however, will be relevant to all members of multi-professional clinical teams.

The relevance to consultant physicians and doctors in training is intimately intertwined. Junior doctors are required to carry out clinical audit as part of their training. They should use this requirement to maximise their insight and understanding of quality improvement from many perspective e.g. their personal clinical perspective, that of patients, of managers and other members of the multi-disciplinary team.

Consultant physicians can use the book to ensure they maximise the opportunities offered by clinical audit not only to improve care for patients and training for junior doctors, but also to develop professional skills such as clinical leadership, negotiation, presentation, motivation and an understanding of complex health systems.

Clinical audit is very much about working as teams – both clinical and managerial - to drive change. We very much hope this handbook will be used by clinicians and managers, working together, to maximise the benefit of clinical audit.

The first sections provide context for local clinical audit, emphasising why it is important for physicians, how it fits within the national agenda for quality of care in the NHS and how it relates to other forms of data collection and use. The subsequent sections address the practical issues of carrying out effective local clinical audit.

Some of the key points are:

• Consultant physicians can use the requirement to carry out clinical audit as a way of improving the quality of care provided for patients
• Junior doctors can use the opportunity provided by clinical audit to gain knowledge of all stages of quality improvement
• Clinical audit staff in trusts can provide expert advice and support. Make friends with them. They seldom bite.
1.1 What is clinical audit?

Clinical audit is an approach to quality improvement based on clinical data collected by clinicians, to support their work in improving the quality of care for patients.

Clinical audit is, first and foremost, a professional and clinical tool, not a management or regulatory tool. The General Medical Council [GMC] guidance requires all doctors to seek to improve the quality of care. Clinical audit provides a method for achieving such improvement.

Clinical audit has many definitions. One definition, internationally recognised and endorsed by the Healthcare Quality Improvement Partnership [HQIP], comes from the “Principles of Best Practice in Clinical Audit”

http://www.hqip.org.uk/nice-guidance/#principles

“Clinical audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, process and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery”.

The basis for carrying out clinical audit is outlined in the HQIP document “Criteria and indicators of best practice in clinical audit”


In simple terms clinical audit is a cycle as shown below:

In more detail the key stages are:

1. Identify a topic that it is important to audit.
2. Establish the authoritative standards against which to audit.
3. Develop audit criteria that will measure performance against the agreed standard.
4. Collect and analyse data and report results.
5. Reflect on results and agree and improvement plan.
6. Implement the improvement plan.
7. Repeat the data collection to measure improvement.

1. “Clinician” refers to all health professionals
'Principles of best practice in Clinical Audit' represents the audit process as below:


INFO: FURTHER INFORMATION
- What is Clinical Audit? (7pgs.) University Hospitals Bristol FT has developed a series of short articles about audit which provide a succinct explanation for students and junior doctors new to audit. http://www.uhbristol.nhs.uk/healthcare-professionals/clinical-audit/how-to-guides.html
1.2 Why is it important?

The NHS is more focused on “quality” now than at any time since its inception. Lord Darzi’s White Paper ‘High Quality Care for All’ calls for quality to be a core and an accountable element of clinical practice and service delivery. The report defines three components of quality:

Patient safety
Clinical effectiveness
Patient experience

The report emphasised the need to:

- Measure quality
  “In order to work out how to improve we need to measure and understand exactly what we do.”

- Publish quality performance
  “Making data on how well we are doing widely available to staff, patients and the public will help us understand variation and best practice ….”

- Improve practice
  “Making data on how well we are doing widely available to staff, patients and the public will help us … focus on improvement”


Clinical audit provides a methodology to deliver the quality improvement components of the Darzi agenda.

1.3 Why is it important for physicians?

First and foremost, clinical audit is a tool to assist clinicians to improve the quality of care they provide to patients. There are other benefits. The reasons why clinical audit is important for physicians are outlined below.

1.3.1 Doctor’s role in improving the quality of care for patients

The primary aim of a committed physician is to provide the best possible care for patients. As part of this professionalism doctors will seek to not only deliver high quality care but also ensure improvements in care. (See example 1).

Doctors can achieve change and improvement in services through locally conducted audit in several ways such as:

- providing leadership and being a local clinical champion
- actually collecting relevant and accurate data about their service provision
- providing strategic clinical expertise in working collaboratively with management and commissioners

1.EXAMPLE: CLINICAL AUDIT ASSOCIATED WITH IMPROVED PATIENT CARE

Clinical audit of Rapid Access Chest Pain Clinic (RACPC) triage of patients with chest pain at the Borders General Hospital demonstrated that RACPC assessment facilitates correct identification of patients for investigation by angiography.

POINT FOR CLINICAL BENEFIT:

Initial measurement against standards:

We successfully achieve national waiting time aims for: time between RACPC assessment and diagnostic angiography; time between diagnostic angiography and PCI and time between GP referral and PCI. However our waiting times: from referral by GP to RACPC assessment; from diagnostic angiography to CABG; and from GP referral to CABG exceed national waiting time aims and fall short of the standards of best practice set.

Change implemented:

We implemented changes to reduce waiting time from GP referral to RACPC assessment. These changes include GP referral direct to cardiac specialist nurse via bleep contact and direct booking of RACPC appointment by the cardiac specialist nurse.

Patient benefit:

Our changes have resulted in us achieving the local one week waiting time aim in the majority of patient referrals by January 2008.

Alison Sears, FY2 doctor
Supervisor: Paul Neary, Cardiology Consultant
• reflecting on their own and their teams results in practice

• implementing improvements in the work place recommended by the audit action plan.

1.3.1.1 Clinical champion

Change will not occur unless there is a champion. It is often a doctor who will fulfil this role. Clinical leadership is an important key skill needed by effective doctors. Engaging with clinical leadership, especially at a time when the health service needs to improve quality in the face of economic restraint, guards against clinically inappropriate prioritorisation.

1.3.1.2 Use of data

Making a case for change and improvement requires data. Measuring progress in making improvements also requires data.

Doctors are in a position to know the strengths and weaknesses, as well as the acceptability and validity of data. Getting involved with data collection improves the accuracy of the material collected and encourages acceptance and ownership and responsibility for the results obtained.

1.3.1.3 Working with managers and commissioners

To enable change clinicians need to work closely with managers and commissioners. The full implications of change have to be communicated to and appreciated by managers and commissioners especially to be clear about predicted impacts on other services. Services improvements are most readily achieved with the active collaboration between doctors as clinical leaders, and managers and commissioners.

Clinical audit can support clinicians in contributing to Trust strategic plans for service development by providing invaluable data for business plans in order to develop and enhance services.

In carrying out clinical audit, clinicians need to consider the cost implications associated with service delivery and service change. It is important at all times to recognise that there is a finite sum of money for health care delivery and clinicians need to understand the cost implications of changes they wish to implement.

Commissioners and managers will look with particular interest at projects that deliver cost effective as well as clinically effective care. There are often innovations possible that will provide good or better care in a more cost effective way. Such proposed changes are likely to attract support and are more likely to be easier to implement than those that are more costly. In the current times of severe economic constraint, clinicians need to be aware and work within the requirements of the QIPP agenda which requires health services to consider productivity in service development (see section 2.3.1).

Managers and commissioners will increasingly expect to see audit as part of clinical work to assure them of the quality of care provided.

1.3.1.4 Reflection on practice

Much benefit can be obtained by all clinicians reflecting on their practice. However doctors, as potentially independent and autonomous practitioners, need to be constantly aware of changes in the evidence base that might influence standards of practice.

1.3.1.5 Change methodology

A key phase of the audit cycle is “Doing something to make things better”. This change management phase provides an excellent opportunity for physicians to gather skills in leading and inspiring change. Leading on audits and taking responsibility for driving forward changes in practice helps develop leadership skills and management abilities.

These skills in change management significantly improve the effectiveness of the doctor in service developments and improvements. Acquisition of these skills can be obtained by professional development and incorporated into daily professional practice.

There is a well developed science related to change management which has been borrowed from other industries and adapted for the NHS. This knowledge needs to be incorporated into routine clinical practice.

http://www.institute.nhs.uk/

1.3.2 GMC professional requirement

The GMC Guidance on “Good Medical Practice” for professional standards includes the need to improve quality of care and to assess this via clinical audit.
1.3.3 Appraisal and Revalidation
[re-licensing and re-certification]

1.3.3.1 Appraisal

Clinical audit is already a part of the appraisal process for junior and senior doctors. However, currently much local audit is of poor quality and is limited to a single round of data collection to fit the brief time a junior doctor spends within a department resulting in no improvements. As the appraisal process matures increasingly the quality of the audits conducted will be measured against the standards for good quality audit defined by HQIP.


As a result it is likely that junior doctors during their shorter contract times will contribute to just one element of a well planned and ongoing departmental audit, for example:

1. The initial design stage identifying relevant standards and defining audit criteria.
2. Carrying out a single phase of data collection.
3. Contributing to the reflection and planning of change management following phase one.

Ideally each medical participant will be involved in a complete cycle of audit to experience/witness the improvement audit generates.

1.3.3.2 Revalidation

With the arrival of revalidation the part played by clinical audit will be enhanced further. The Bristol Enquiry initiated the process for establishing revalidation and one of the key recommendations was the inclusion of clinical audit as part of the evidence required for securing successful revalidation.

A key component of the revalidation process will be that doctors can provide evidence that they have contributed to quality improvement activity. An example of this will be participation in well constructed clinical audit which has included reflection on the findings and demonstrable efforts to improve care.
1.3.3.3 Revalidation (re-licensing and recertification)

The GMC working framework for appraisal and assessment includes four components:

- **Domain 1**: Knowledge, Skills and Performance
- **Domain 2**: Safety and Quality
- **Domain 3**: Communication, Partnership and Teamwork
- **Domain 4**: Maintaining Trust

Clinical audit is a tool that can be used to assess Domain 1 and Domain 2.

http://www.gmc-uk.org/doctors/licensing/revalidation_gmp_framework.asp

1.3.4 Audit as part of Continuing Professional Development (CPD)

As revalidation approaches it will become important that clinicians are well trained and versed in the methods of clinical audit and associated change management techniques.

While doctors tend at present to focus CPD on clinical aspects of care, the need for training in quality improvement, including clinical audit, will increase.

There are many opportunities for increasing professional knowledge of quality improvement including:

- lectures, seminars and workshops in quality improvement
  http://www.rcplondon.ac.uk/clinical-standards/ceeu/Pages/Clinical-Effectiveness-Evaluations.aspx
- the clinical effectiveness forum of the Royal College of Physicians
  http://www.rcplondon.ac.uk/clinical-standards/organisation/partnership/Pages/joint-specialty-clinical-effectiveness-forum.aspx
- masterclasses and training in clinical leadership
  http://masterclasses.bmj.com/physicians
  http://www.rcplondon.ac.uk/education/education/Pages/education.aspx
- fellowships e.g. the Health Foundation, NHS Institute for Innovation and Improvement, “Darzi” Fellowships.
  http://www.ihi.org/ihi/programs
  http://www.ihi.org/ihi/programs
- fellowships e.g. the Health Foundation, NHS Institute for Innovation and Improvement, “Darzi” Fellowships.

INFO: REVALIDATION - GMC APPRAISAL FRAMEWORK

The White Paper assigns significant roles to the GMC in setting standards for revalidation.

The White Paper confirms that relicensing will be based on agreed generic standards of practice set by the GMC, a revised system of NHS appraisal for doctors and any concerns known to the doctor’s medical director (or responsible officer).

The White Paper also proposes that, to support relicensing, the GMC should translate Good Medical Practice into a framework against which individual doctors’ practice can be appraised and objectively assessed. Our role is to provide the core content of revalidation, and for other organisations to embed these in the context of appraisal systems or assessment for recertification.

With this in mind, we have reviewed Good Medical Practice, and derived from it attributes that cover the core requirements of good practice. Those attributes are elaborated in a framework, which shows suggested generic standards, again taken from Good Medical Practice, and possible sources of evidence.

The framework provides a foundation for the development of the appraisal and assessment systems that will form a key part of revalidation. We, therefore, regard it as important that this framework has the confidence and support of all our key interest groups.
1.3.5 Audit as part of training and education

Clinical audit and associated change management techniques will become an increasingly important part of medical practice and medical training. Consultants will need to be able to contribute to the training of junior doctors in this area.

Doctors in training are already required to demonstrate their knowledge with regard to clinical audit and quality improvement through their appraisal process. Clinical audit at a local level can provide creative and constructive learning as an example of this. (See examples 2 & 3).

1.3.6 Audit and research

Clinical audit in principle cannot be considered research because it is not designed to lead to new knowledge or to test hypotheses.

However there is potential to carry out research as a spin-off from the clinical audit process and for audit to indicate research questions that need to be answered.

Some clinical audit is based on continuous data collection building up very substantial databases of accurate and high quality information. National examples include; the myocardial infarction national audit project (MINAP).

2. EXAMPLE: RECURRENT AUDIT CYCLES
LEARNING TO AUDIT AND LEARNING FROM AUDIT

Audit of cardio-pulmonary resuscitation in the hospice environment.

Decisions relating to cardiopulmonary resuscitation have been audited in the hospice environment four times since the introduction and implementation of a new policy in May 2003 (entitled Policy on cardiopulmonary resuscitation (CPR) Do not resuscitate (DNR orders) - CP6) to comply with the joint guidelines issued by the UK Resuscitation Council, the BMA and the RCN.

The audit has highlighted the challenges in applying the local recommendations for making DNR decisions and has helped refine local practice.

In the 2006 audit it was recommended that formal, compulsory training on CPR become part of the FY2 induction programme. This was further emphasised in 2008 with the suggestion that role play and communication skills tasks could be used. The 2009 audit reinforces these findings and makes recommendations for further improvement.

Carol Rodgers on behalf of Dr Dane Rayment, FY2 in Palliative Medicine
Dr Pamela Choudhury, Consultant, St. Giles Hospice. carol.rogers@st-giles-hospice.org.uk

3. EXAMPLE: TRAINING FOR JUNIOR DOCTORS
A JUNIOR DOCTOR’S REFLECTIONS ON AUDIT FINDINGS

Assessing patient knowledge about their Urgent Cancer Referrals (UCR).

I contributed to an audit to assess if:

• patients were told that their UCR was due to a suspicion of cancer
• patients were seen within the national target of 14 days
• a local UCR proforma was used.

I am now able to understand the patient journey from referral in a primary care setting to the secondary care setting. I believe this is important to know as it would enable me to understand my patients better in clinical practice. It was also an important learning curve on how nurses handle the patients and the patient notes before seeing a physician/surgeon.

As referrals for cancer suspicions impact on nearly all the specialties, the learning from the audit is relevant for other specialties.

Nikky Kanti Chauhan, University of Leicester Medical School. nk7@le.ac.uk or nikkychauhan@hotmail.com
and the national lung cancer audit

These databases collect data which allow an assessment of how care is being delivered at a local level. The very large numbers of cases collected, now running in excess of 500,000, does allow research questions to be posed which can be addressed through the databases.

1.3.7 Audit and Clinical Excellence Awards – points mean prizes

The White Paper ‘High Quality Care for All’ proposed that Clinical Excellence Award criteria should be adjusted so that greater emphasis was placed on service development to enhance the quality of care. The report tasked the National Quality Board and the National Leadership Council with providing advice to the Advisory Committee on Clinical Excellence Awards (ACCEA) on how to strengthen the quality and leadership aspects of the awards scheme.

Strengthening clinical excellence awards: advice from the National Quality Board and the National Leadership Council.

INFO: MINAP RESEARCH PAPERS

Early impact of insulin treatment on mortality for hyperglycaemic patients without known diabetes who present with an acute coronary syndrome.
Weston C, Walker L and J Birkhead JS.
Heart 2007;93 1542-1546

The impact of pre-hospital thrombolytic treatment on re-infarction rates: analysis of the Myocardial Infarction National Audit Project (MINAP).
Horne S, Weston C, Quinn T, Hicks A, Walker L, Chen R, and Birkhead JS.
Heart, Oct 2007; doi:10.1136/hrt.2007.126821

4. EXAMPLE: HEALTH SERVICES RESEARCH

National COPD Resources and Outcome Project [NCROP] peer review

Based on a national audit of COPD management in hospital, the NCROP project researched the role of reciprocal peer review as a quality improvement intervention. The qualitative component of the study demonstrated the ways in which change management at a local level can be facilitated by peer review.

http://www.rcplondon.ac.uk/clinical-standards/ceeu/Current-work/ncrop/Pages/audit.aspx

There are also opportunities for health services research into differing methods of change management to assess which approaches work most effectively in the reality of hospital life. (See example 4).

http://www.nihr.ac.uk/research/Pages/default.aspx

1.4 Why is it important for specialist societies?

The societies can provide a role in actively coordinating local clinical audit to greatly improve the benefit and increase the potential for benchmarking. For example societies can and do:

• Provide a forum for specialists to define a strategy for service development.

• Work to develop guidelines.

• Produce audit criteria to standardise local audit and permit comparison.

• Coordinate local or regional audit activity – often on a regional basis.

• Provide customised data collection systems to facilitate data collection, aggregation, analysis and reporting.
• Use data from local and regional audit to promote change and development within the specialty.

• Producing guidelines.

• Conducting clinical audit.

Smart use of the aggregated local data collection by societies, feeding into the national quality framework, can greatly assist specialist societies promote their clinical cause.

Clinical specialties have had variable involvement in addressing clinical effectiveness. Input has mainly been along two lines:

1.4.1 Guideline production - setting standards

Many specialties have a well established and often a highly developed commitment to the production of guidelines. These can be used to provide standards against which to audit.

1.4.2 Audit

Specialties are increasingly developing their capacity for local, multi-site or national audit. Clinical effectiveness teams within specialties have developed criteria for audit and carried out audits of varying complexity. Many societies are now looking to develop their own web based data collection systems to run alongside suites of audit criteria. Such approaches will assist local teams in carrying out well developed audits and provide the opportunity to generate accurate, high quality and comparable data.

Examples of audits that have been carried out through the British Thoracic Society include:

• Asthma
• Community acquired pneumonia
• COPD.

1.5 Why is it important for Royal Colleges?

Colleges have a remit to maintain and improve standards of care.

INFO: ROYAL COLLEGE OF PHYSICIANS, LONDON

Charter 1569
To uphold standards for their own good and for the public benefit.

Our mission
The Royal College of Physicians is a registered charity that aims to ensure high quality care for patients by promoting the highest standards of medical practice. It provides and sets standards in clinical practice and education and training, conducts assessments and examinations, quality assures external audit programmes, supports doctors in their practice of medicine, and advises the Government, public and the profession on health care issues.

http://www.rcplondon.ac.uk/About-the-college/mission/Pages/Overview.aspx
Standards can be improved through many methods including:

**Professional representation:** Colleges can develop and promote health care issues to push at a national level for change. Examples from the Royal College of Physicians include smoking, alcohol and obesity. Arguments for change and development can be supported by the findings from clinical audit.

**Education and Training:** A critical component of ensuring high quality and improving care is the learning and education of doctors, not only when in training but also post qualification and as part of continued professional development. Such learning needs to include not only the clinical aspects of care, but also personal develop such as clinical leadership, change management and effective function with the organisation.

**Clinical Standards:** Colleges often provide the focus for gathering national comparative data relating to clinical care which can be feed back to clinicians for use in driving improvements in clinical standards at a local level. Furthermore, Colleges have a responsibility to ensure effective methods of re-validation for doctors and clinical audit will be an important tool that Colleges can use to ensure that clinicians are assessing, reflecting and seeking to improve the quality of care they provide.
2.1 Framework for quality improvement - where to pitch your audit so “they” will listen

In the Government White Paper ‘High Quality Care for All’, 2008, Lord Darzi places quality at the centre of practice.


The NHS Quality Improvement Scotland provides a framework for quality improvement as below:

http://www.nhshealthquality.org/nhsqis/37.140.141.html

At a national level there are many processes and bodies involved in delivering the “quality agenda”. For example in the UK:

- Department of Health (DH) - Standards For Better Health

- National Institute for Health and Clinical Excellence (NICE).
  http://www.nice.org.uk/

- The Care Quality Commission (CQC).
  http://www.cqc.org.uk/

2.2 Advice, guidance and standards - where do they come from? Some of the terms, teams and targets

2.2.1 The National Quality Board (NQB)

The NQB is a committee within the DH, whose remit is to drive forward the vision of ‘High Quality Care for All’. It will provide strategic oversight and leadership in promoting quality across the NHS and in joining up health and social care. It will define which quality indicators should be used locally and nationally, to support development of new quality standards, and to support SHAs where the development of national systems would be of benefit.

Key functions of the Board are to:

- ensure the various national quality initiatives are aligned
- deliver on specific technical responsibilities including those set out in the ‘Next Stage Review’, namely to oversee the work to improve quality indicators, advise the Secretary of State on the priorities for clinical standards set by NICE and make an annual report to the Secretary of State on the state of quality in England using internationally agreed comparable measures
- assume a wider leadership responsibility for driving the quality agenda and acting as a powerhouse for change.

It has professional and lay representation as well as including many key players in the DH.


2.2.2 NICE guidance

NICE has been established for over 10 years. It produces a wide range of clinical guidelines and technology appraisals which set the standards for clinical practice.

NICE guidance is:

- designed to promote good health and prevent ill health
- produced by the people affected by our work, including health and social care professionals,
patients and the public

- based on the best evidence
- transparent in its development, consistent, reliable and based on a rigorous development process
- good value for money, weighing up the cost and benefits of treatments
- internationally recognised for its excellence
- constructed so as to provide audit criteria for its clinical guidelines.

This process is set to be developed with the introduction of NICE quality standards.

http://www.nice.org.uk/guidance/index.jsp

### 2.2.3 NICE quality standards

Following the Darzi White Paper NICE has been commissioned by the DH to develop ‘quality standards’ over the next six years. These standards are often derived from audit standards. Some topics have already been developed with a total of 150 topic areas being covered and will all be found on the NICE website.

A quality standard is ‘a set of specific, concise statements that act as markers of high quality, cost-effective patient care across a pathway or clinical area’. They ‘are derived from the best available evidence’. They will contain ‘a descriptive statement of key infrastructural and clinical requirements for high-quality care as well as the desirable, or expected outcomes’.

The NQB will advise on topics for standards and will set the sequence for these standards depending on priority. The importance of which pathways/clinical areas are selected cannot be underestimated by the profession.

These standards are often derived from audit standards. In turn, the quality standards can be assessed using audit methods.

http://www.nice.org.uk/aboutnice/qualitystandards/qualitystandards.jsp

### 2.2.4 Indicators for Quality Improvement (IQI)

In 2008 the NHS Information Centre performed a ‘Clinical Quality Indicators Survey’ in partnership with the Royal Colleges and the Cardiovascular Society. The survey identified existing Indicators for Quality Improvement (IQI) to give a currency to Darzi’s vision. IQIs are intended to give ‘local clinical teams a set of robust indicators from which they can select as the basis for local quality improvement’ and to give ‘a source of indicators for benchmarking’.

There are over 200 indicators in the initial release (from the 440 that were offered in the survey) and they are grouped according to Darzi’s framework. None of these are new and thus the indicators are using data that should already be collected by providers. However, this process is in early development and new, perhaps more relevant, indicators need to be developed.

A detailed review of the list of IQIs reveals that many refer to patients in primary care (and already form part of the Quality Outcomes Framework). IQIs that apply to adult medical hospital patients currently only focus on patients with ischaemic heart disease and stroke with respect to effectiveness. The role of IQIs in assessing and monitoring the quality of hospital care has yet to be established.

Further information available at : DH Indicators for Quality Improvement (IQI).

https://mqi.ic.nhs.uk/ 

### 2.2.5 Local and regional metrics

‘Quality metrics’ is a new term to describe measures like those described in the IQIs as well as other measures that healthcare providers have developed following ‘High Quality Care for All’. These metrics have been defined by local providers as well as at the regional level, and there is huge variation across England. Differences between the regional quality metrics developed by SHAs arise from the perceived local needs of their population as well as the vision outlined in the SHA response to Darzi’s original call.

http://www.ournhs.nhs.uk/?tag=strategic-health-authorities

### 2.2.6 Patient Reported Outcome Measures (PROMs)

Patient Reported Outcome Measures (PROMs) are used to describe any metric which assesses patient quality of life following a healthcare intervention. However, in the context of the current quality initiative,
PROMs refers to the IQIs which have been developed to assess the effect of four surgical procedures (knee replacement, hip replacement, varicose vein ligation and hernia repair) on quality of life. These measures are delivered both locally and regionally, but are analysed nationally and will be linked to HES data to supply quality information at a hospital and consultant level.

It seems likely that other PROMs will be developed for other surgical (e.g. cataract surgery) and even non-surgical procedures. However, there is concern that over reliance on PROMs will lead providers to avoid performing procedures on patients who are likely to have a poor outcome (e.g. revision hip replacements), although the ‘quality’ of the quality data has yet to be seen.

Further information available at:
http://phi.uhce.ox.ac.uk/home.php

2.2.7 Patient Reported Experience Measures (PREMs)

Patient Reported Experience Measures (PREMs) permit an evaluation of the clinical process of care and are particularly helpful in auditing chronic conditions where outcomes are variable. The patient experience can be assessed against the clinical pathway or guideline standards that would be expected.

2.3 Implementation and improvement support

2.3.1 QIPP (Quality Innovation Productivity and Prevention)

The Department of Health has indicated that the drive towards quality improvement must be associated with increased productivity and innovation coupled with prevention. This approach is encapsulated in the QIPP agenda and will be a dominant feature of all NHS service development over the next few years. It will be increasingly important to be able to demonstrate that any changes in practice to improve care will be associated with cost savings.

Clinicians should be open to innovative ways of working that would deliver high or improved quality of care in a more cost effective way. This may mean, for instance, considering more community based provision of care, adopting new technologies or utilising skills of other professions.

Further information available at:

2.3.2 Commissioning

2.3.2.1 Commissioning for Quality and Innovation (CQUIN)

Commissioning for Quality and Innovation (CQUIN) is a payment framework that requires agreement between commissioners and providers to embed quality measures in the local healthcare plans. For hospitals, the quality measures include many of the IQIs, PROMs SHA regional metrics, and more specific measures applicable to a particular primary care trust.

CQUIN schemes must assess the three domains of quality (effectiveness, safety and experience) as well as innovation. 0.5% of annual contract income (tariff) is linked to achieving this quality framework and providers must demonstrate they have fulfilled their CQUIN contract to receive payment. While 0.5% is not an insignificant amount of money for many trusts, the plan is for this proportion to increase with time, further strengthening the importance of quality within the patient pathway. The expected increase for 2010/11 will be 1.5% of the total budget incorporating national, regional and local targets.

Further information available at:

2.3.2.2 Best Practice Tariff

Commissioning has moved from block contracts to “Payment by results”. Activity is defined in terms of HRGs [Health Resource Groups]. A sum is attached to each HRG [[the average cost nationally for the HRG]. Providers are paid the tariff x the amount of activity.

Efforts are under way to refine HRGs so that they represent the variation in workload that can be associated within one condition. A further development is the concept of “best practice tariff”.

Further information available at:
As well as payments based on the HRG, providers will receive an additional sum if they can demonstrate that they have matched specific “quality” metrics. The principle is that best quality care is cheaper care and therefore initial up front costs will soon be offset by much greater subsequent savings.

Stroke and Ortho-geriatric care are being used as pilots for the process.

Further information available at:
http://www.nhsconfed.org/Networks/PrimaryCareTrust/OurWorkProgramme/strengthening/Pages/Standard-NHS-Contracts-and-Payment-by-Result.aspx

2.3.2.3 The Quality Account

‘High Quality Care For All’ states that healthcare providers will have to report their performance and improvements with regard to quality, and this reporting takes the form of a ‘Quality Account’. These are now a legal requirement for provider units and the private health sector as of 2010 following the Health Act 2009. GPs and other independent contractors (Pharmacists, Dentists and Optometrists) will be required to produce Quality Accounts after registering with the Care Quality Commission. Part of the content of the Quality Account will be defined by the DH. The first quality accounts were finalised in April 2010 for the year 2009–10, with a requirement to report them at the end of June 2010. The aim of these accounts is threefold: to make provider boards focus on quality as a priority; to allow the public to hold providers to account for quality; to allow informed choice by patients.

Quality Accounts must be truthful, fair, and easily accessible to users, include relevant data, be comparable to other providers and produced in a timely fashion. Part of the content of a provider’s quality account is at the discretion of that provider, some compulsory parts of the account are backed by legislation. The Quality Account has mandatory content on clinical audit.

Further information available at:

2.4 Quality Assurance

2.4.1 The Care Quality Commission (CQC)

The CQC took over from the Healthcare Commission (HC) in April 2009. It is the regulator of all health and adult social care services in England, including mental health services and ensures that essential common quality standards are met and monitors improvements. Hospitals and other health providers have to be registered with the CQC to demonstrate they meet these quality standards (e.g. rates of healthcare associated infections).

The CQC has statutory powers to fine or suspend healthcare providers whom it finds are not meeting the essential standards. It has the power to investigate any provider it feels necessary and will use patient and other user input to this process. The CQC website sums up their priority thus: ‘CQC’s priority is to improve the public’s experience of health and social care and to improve outcomes – what happens to people as a result of the care they receive’.

  http://www.cqc.org.uk/publications.cfm?fde_id=13070
- National minimum standards for providing social care.
  http://www.cqc.org.uk/guidanceforprofessionals/socialcare/careproviders/nationalminimumstandards.cfm

2.4.2 Monitor

Monitor regulates NHS Foundation Trusts by identifying actual and potential financial and non-financial problems, and dealing with them effectively.

When a Foundation Trust is established it is authorised to operate within a detailed set of requirements which include:

- the general requirement to operate effectively, efficiently and economically
- requirements to meet healthcare targets and national standards
- the requirement to cooperate with other NHS organisations.
Monitor requires each foundation trust board to submit an annual plan and quarterly and ad hoc reports. Performance is monitored against these plans to identify where potential and actual problems might arise. Monitor publishes quarterly and annual reports on these submissions and assigns each foundation trust with an annual and quarterly risk rating. These risk ratings are designed to indicate the risk of a failure to comply with the terms of authorisation. There are three risk ratings for each NHS foundation trust relating to:

- governance (rated red, amber or green)
- finance (rated 1-5, where 1 represents the highest risk and 5 the lowest)
- mandatory goods and services (rated red, amber or green) - mandatory goods and services are defined in a foundation trust’s terms of authorisation. These are the services the trust is contracted to supply to its commissioners.

Monitor is developing its approach further, look out for changes on their website.

http://www.monitor-nhsft.gov.uk/

### 2.4.3 Strategic Health Authorities

Strategic Health Authorities, acting as regional arms of the Department of Health, monitor and performance manage quality improvement through local commissioning. Monitoring is managed through “Quality Observatories” established within SHAs. Measurement of performance within the SHA will be an important component of the process, while they exist.

http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets@dh/@en/documents/digitalasset/dh_4137227.pdf

### 2.4.4 Trust Boards

Trusts boards now have a statutory responsibility to define, report on and ensure explicit quality standards of care. The importance of these responsibilities has been highlighted by recent examples where the standards of care have been lacking e.g. the Mid Staffordshire NHS Foundation Trust and the Maidstone and Tunbridge Wells Trust.

To meet these responsibilities boards have well established quality assurance systems based on internal audit, specific departments committed to quality assurance and integrated governance throughout the organisation.


### 2.5 Revitalisation of clinical audit.

#### 2.5.1 Healthcare Quality Improvement Partnership [HQIP]

As part of the national strategy to ensure that the potential of clinical audit is maximised the Department of Health launched a new initiative for clinical audit in 2008. The approach was designed to re-invigorate local clinical audit and to support, maintain and develop the national clinical audit programme. The contract to deliver the new approach was won by the Healthcare Quality Improvement Partnership [HQIP] a collaboration between the Academy of Royal Medical Colleges, the Royal College of Nursing and National Voices, representing the patient perspective. A key principle of the HQIP collaboration is that it ensures that patients and clinicians remain at the very heart of national and local clinical audit. It seeks to ensure that clinical leadership remains the driving force for clinical audit.

HQIP commissions and performance manages national clinical audits funded by the Department of Health; it is working with a wide range of stakeholders to develop the national clinical audit programme to ensure it provides a fit for purpose portfolio of work targeted to achieve the greatest possible benefits for the NHS.

HQIP has been actively pursuing its work with great support from local clinical audit departments, working on many fronts to support and develop the contribution that such departments make.

http://www.hqip.org.uk/

#### 2.5.2 National Clinical Audit Advisory Group [NCAAG]

The NCAAG was established at the same time as HQIP. Its role is to provide policy advice to the Department of Health related to the national clinical audit programme.

http://www.dh.gov.uk/ab/NCAAG/index.htm
SECTION 3: WHAT AUDIT IS AND WHAT IT IS NOT

What clinical audit is:

“Clinical audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, process and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery.”

http://www.hqip.org.uk/nice-guidance/#principles

What clinical audit is not:

Clinical audit is commonly confused with other forms of data collection. This is particularly true in submissions to specialist society scientific meetings. Many societies have developed their own guidelines to differentiate clinical audit from these other activities. (See example 5).

3.1 Differences between audit and other processes involving data collection

http://www.bgs.org.uk/Research/abstract_submission.htm

It is important to recognise that gathering data is only one component of the process of clinical audit. Clinical audit must include reflection on the data collected, a plan for improving care and, if necessary further rounds of data collection to ensure standards are improving.

5. EXAMPLE: BRITISH GERIATRICS SOCIETY – DISTINCTION BETWEEN AUDIT, RESEARCH AND SURVEYS

Both research and clinical audit may involve measurement of patient outcomes, however the purpose is different. Be clear about your objectives, and concentrate on these 3 key questions:

1. Is the purpose of your project to try and improve the quality of patient care?
2. Will the project involve measuring current practice against standards?
3. Does the project include anything being done to patients beyond their routine clinical management?

If your answers are ‘yes’ to the first 2 questions and ‘no’ to the third, your project is very likely to fall within the remit of clinical audit.

The following table gives further details regarding differences between research, audit and surveys

<table>
<thead>
<tr>
<th>Purpose</th>
<th>Research</th>
<th>Audit</th>
<th>Survey</th>
</tr>
</thead>
<tbody>
<tr>
<td>To provide new knowledge e.g. to set or change clinical standards</td>
<td>Tests practice against evidence-based standards</td>
<td>Inform specific questions on a theme relating to practice or policy</td>
<td></td>
</tr>
<tr>
<td>Methods</td>
<td>Pre-specified research designs with hypotheses</td>
<td>No allocation to treatment groups</td>
<td>Clear sampling methods, with reasonable response rate (&gt;40%)</td>
</tr>
<tr>
<td>Data analysis</td>
<td>Requires data analysis (quantitative or qualitative) to make inferences</td>
<td>Simple statistics (e.g. means, frequencies) to compare audit cycles</td>
<td>Simple descriptive statistics</td>
</tr>
<tr>
<td>Ethical approval</td>
<td>Required</td>
<td>Not required</td>
<td>Not required unless e.g. patient questionnaires considered outside routine management</td>
</tr>
<tr>
<td>Sample size</td>
<td>Statistically powered calculation</td>
<td>Sufficient number of cases to influence practice based on findings</td>
<td>Sufficient size to avoid sampling bias, and for survey to have wider generalisable message</td>
</tr>
<tr>
<td>Outcome</td>
<td>Improved knowledge</td>
<td>Strategies in place to improve clinical practice</td>
<td>Lead to clinical effectiveness strategy (e.g. guidance or audit)</td>
</tr>
</tbody>
</table>
3.1.1 Research

In simple terms research implies any form of data collection that results in new knowledge. Clinical audit does not seek new knowledge; it seeks to evaluate performance against explicit standards.

Research requires ethical approval and local R&D approval. Audit is a routine part of NHS practice and does not require such approval.

If there is any doubt as to whether a project, or an element of a project, might be regarded as research and so might require ethics approval, seek further guidance:


3.1.2 Surveys

Surveys gather information to establish baseline facts. These are not however related to specific standards and are not measuring performance against these standards. Surveys may be associated with changes in practice.

Ethical approval may well be required for surveys.

A brief overview of Research Ethic Committees - when to apply, Caldicott principles, Data Protection Act, patient confidentiality and how to apply is available at:

http://www.hqip.org.uk/clinical-audit-resources-3/

3.1.3 Patient registry

A patient registry gathers data on patients in a systematic way. Such registries can be very helpful in understanding the levels of service provision and can have a place in research and audit. Unless, however, the data collected allows measurement of performance against explicit standards it is not a form of clinical audit.

3.1.4 Patient outcome programmes

Outcome measurement is an important component of clinical audit assessment of quality. Outcomes can be hard to measure in clinical medicine especially in chronic conditions. However if clinical outcomes have been defined that assist in assessing the quality of care against a standard, then patient outcome programmes can contribute to audit.

Currently patient reported outcome measures have been developed mainly for elective surgical procedures. Patient reported outcome measures for chronic conditions such as diabetes or chronic obstructive pulmonary disease still need to be developed.

3.1.5 Patient (satisfaction) survey

Patient satisfaction is an important component of measuring quality. However it cannot be regarded as clinical audit unless the patients’ feedback obtained relates specifically to the processes of care received against standards of care.

3.1.6 Service evaluations

Evaluations usually assess the details of the service provided. Unless the evaluation assesses the service against explicit criteria it cannot be regarded as clinical audit. Also, by definition, an evaluation is a point measurement and so does not include comparison of performance following implementation of an improvement plan.

A brief overview of what is and isn’t audit is available at:


3.2 Regional/ Multi-site and Local audit

3.2.1 Regional audit

There are many examples of regional or multi-site audit. Such audits can be achieved at a low cost, provide opportunities for benchmarking that is very useful and provide opportunities for training and experience in quality improvement for doctors in training.

The British Society of Rheumatology has a method for audit that works well at a regional level. The method enables doctors in training to participate in a well planned systematic coordinated audit. (See example 6).

Another example comes from Genitourinary Medicine. The British Association Sexual Health & HIV [BASHH] carry out national audit and provide regional aggregates of performance to regional audit chairs. Local departments can carry out local audit which enables them to compare with regional and national performance. (See example 7).
3.2.2 Confidential enquiries

Confidential enquiries have proved a powerful tool for evaluating care and driving change. While NCEPOD (National Confidential Enquiry into Patient Outcomes and Death) is best known at a national level, a regional confidential enquiry, such as the Eastern region confidential enquiry into asthma deaths, provides the opportunity to improve care at a local and regional level. (See example 8).

3.2.3 Local audit

Local audit is primarily designed to see how a local service is performing against externally agreed standards. However it is possible, if established audit criteria are used, to compare performance with other sites.

The HQIP provides many support tools for local audit and it is worth visiting the website when planning an audit:

http://www.hqip.org.uk/local-audit-support

Some societies have established audit criteria for specific clinical conditions or settings. It is worth reviewing whether examples exist on the appropriate website.

Some societies have developed standardised data collection tools including web based data collection systems. The British Thoracic Society has an established web based audit tool that allows sites to audit their performance against standards e.g. community acquired pneumonia, COPD and asthma. As data are entered into the web tool real time feedback is provided as to performance against other sites that have also entered data.

6. EXAMPLE: BRITISH SOCIETY OF RHEUMATOLOGY


Audits of the prevention and treatment of corticosteroid-induced osteoporosis in outpatients with rheumatic diseases in the West Midlands.

Paskins Z, Potter T, Erb N, Obrenovic K, Rowe IF; West Midlands Rheumatology Services and Training Committee.

Department of Rheumatology, University Hospitals Coventry and Warwickshire NHS Trust, Coventry.

The management of corticosteroid-induced osteoporosis in rheumatology outpatients in the West Midlands was audited in relation to the 2002 Royal College of Physicians (RCP) Guidelines and re-audited in relation to the 1998 National Osteoporosis Society (NOS) Guidance. Practice was assessed from prospective data on all follow-up patients over a 2-week period in 13 rheumatology units. Data were analysed on 2,609 patients. Of the 626 patients fulfilling criteria for assessment against the RCP Guidelines, 351 (56.1%) were treated appropriately. The results do not allow for availability of, or wait for, DEXA scanning. Of 197 patients fulfilling the criteria for assessment against the NOS Guidance, 137 (69.5%) were treated appropriately, compared to 63% in a similar audit undertaken in 2000. Regional audit may facilitate clinical governance. These audits will inform discussion on both improving local practice and strengthening cases for improved osteoporosis services.

7. EXAMPLE: MULTI-SITE AUDIT, GENITOURINARY MEDICINE

CONTRACT TRACING IN GENITOURINARY MEDICINE

A regional audit of contact tracing for genital chlamydial infection against national standards, showed that one clinic had outstandingly good performance. The health advisers from this clinic presented their clinic processes for contact tracing to a regional audit group meeting. An important feature in their practice was that the health advisers had a dominant position in organising patient flow through clinics, so that patients were very unlikely to slip through the net of not seeing a health adviser when this was needed. Also, the health advisers had dedicated time to contact and follow-up patients, and were not expected to fit this in whilst, at the same time, seeing patients during clinics.

Dr Hugo McClean FRCP, Chair British Association Sexual Health & HIV National Audit Group
Hugo.mcclean@chcphull.nhs.uk
Further information is available at:

http://www.brit-thoracic.org.uk/

3.2.4 Audit across the interface of primary and secondary care

Increasingly, to evaluate the pathway of care for an individual patient, it will be important to audit care across the interface between primary, intermediate and secondary care. There are significant challenges in measuring care across the interface. Problems relate to differing records systems, extraction of data, sharing data across clinical teams and differing requirements to carry out clinical audit, as outlined below:

1. The use of an NHS number for patients is not yet fully established. A patient will have different numbers in different hospitals and in the community. It is therefore impossible to track a patient without using patient identifiable information e.g. name, address and date of birth.

It is therefore necessary to share patient identifiable data across healthcare sectors. While this is routinely done in clinical care – a discharge letter provides patient identifiable data between secondary care and primary care - there is often concern about requests to share such data for clinical audit. There is an important need to obtain National Information Governance approval that routine sharing of patient identifiable data for this purpose is acceptable as part of routine practice.

2. Data are recorded and stored in many different systems in many different ways. Most professional groups have their own records and their own way of storing information. The validity of the data is dependent on the care that is taken to enter data into the records. Thus in primary care there are very good electronic data systems for records and indeed most practices are now paperless. However the usefulness of the data recorded is dependent on the care with which it is coded and entered. GPs are very busy and each consultation is often not enough time to ensure accurate and specific coding of data and full data entry.

3. General Practices will usually require reimbursement for the time taken for data extraction. In the near future this problem may be resolved by improved methods of electronic extraction of data using such systems as "PRIMIS" [Primary Care Information Services] and "SystemOne". These approaches enable data extraction irrespective of the IT system used within the practice. While this may simplify data extraction, it does remove the practitioner further from the audit process and tends to reduce the benefit of audit as a clinical tool for clinicians to evaluate and improve their practice.

While careful consideration is needed at a local level to decide whether it is feasible to carry out audit in primary care, there are successful examples (See example 9).

In care homes there are further specific challenges including that: data are often stored in various health records as patients are seen by clinicians of differing professions; the staff often have limited experience of audit; there is very little time to carry out audit and that there are issues with access to web data entry systems. (See example 10).

For more information see the following HQIP guidance:

3.2.5 Audit for small clinical specialties

Audit for small specialist societies presents specific challenges. The small number of specialists on a national basis means that the same people are required to take the lead on many aspects of specialty development e.g. teaching, training, research, audit and CPD.

The numbers of patients presenting with rare conditions is limited and therefore patient identification is a challenge as is the building up of sufficient numbers to carry out meaningful audit.

HQIP multi-site funding provides an opportunity to address this issue:

http://www.hqip.org.uk/multi-site-clinical-audit-funding-2/

9. EXAMPLE: AUDIT ACROSS THE PATHWAY OF CARE

AUDITING STANDARDS IN OSTEOPOROSIS AND FALLS PREVENTION IN PRIMARY CARE

Over 12 years a Primary Care based audit team has worked with local general practitioners and a health care organisation to carry out clinical audit aligned to NSF strategy and leading to changes in line with current Department of Health Policy Priorities.

The audit of osteoporosis and falls addresses a relatively neglected clinical area with huge health, health economic and social care burdens. It demonstrates how a sustained clinician led audit programme over many years can lead to important and measurable changes in patient care and transcend many upheavals in primary care organisational structures and variable engagement with the clinical focus at an executive and directorate level. It can involve high levels of participation by general practices if appropriate informatics solutions are developed and good use is made of the rich resource of clinical data on primary care information systems. The approach can be dove-tailed with quality improvement initiatives and up-scaled from a single general practice, through localities, trusts to national level audit that informs strategic health care planning. It demonstrates the value of partnership with an academic institution in ensuring dissemination of findings at scientific conventions.

Jonathan Bayly MB BS MRCGP, University of Derby on behalf of Gloucestershire Primary and Community Care Audit Group jonathan@bayly.org

10. EXAMPLE: CLINICAL AUDIT IN CARE HOMES

AN AUDIT OF CONTINENCE CARE

An audit of continence care might wish to assess care in care homes. The individual whose care is being audited may have had a hospital admission or attendance for assessment, assessment by their general practitioner, review by the continence nurse specialist, district nurse, and allied health professionals such as an occupational therapist. Each will have their own records and they will not be kept in the Care Homes.

Trying to track down all these record sources is very difficult.
4.1 Topic selection

4.1.1 What to audit: How to identify an appropriate topic.

In order to ensure the audit is meaningful to the clinicians involved it is important to ensure an appropriate topic is selected. (See examples 11 & 12).

It helps if:

- It is of interest and importance to the clinicians of all professions within the area of treatment.
- It is of relevance to the department and the way the department delivers care.
- It is important and relevant to the Trust management. In reality it is going to be hard to influence how care is delivered unless the management within the department is interested. The role of the local management team should be carefully considered from the outset. They should be aware the audit is taking place and should be copied in to all papers even if they do not attend steering group meetings. Results should be communicated to them as the process passes through its various stages.
- There are established standards against which to audit. These must be authoritative and accepted by all. NICE guidelines often produce the basis for standards. Many Society guidelines are also well formulated and a good basis for audit.
- Audits are carried out in areas of care where service improvements can be achieved. Audit is time consuming and there is no point in auditing something that is already very well performed. While in some situations it might be felt that standards of care are sub-optimal but the possibility for improving practice are poor. Such limitations should not prevent an audit being carried out. It is possible by the use of various “levers” that change might be achieved.
- The population to be audited should be clearly defined, the data required readily and reliably accessible and the measures to be assessed meaningful.

4.2 Engagement of key participants and stakeholders

4.2.1 Physicians

Physicians have many reasons to contribute actively and enthusiastically to local clinical audit as outlined in Section 1. Well planned audit provides the opportunity for improving patient care as well as assisting with junior doctor training.

In terms of training, the physician should see clinical audit as a quality improvement tool and should therefore give attention to all phases of the audit cycle. Any one audit project will run much longer than the time committed to a department by junior doctors in training. The physician should, therefore, encourage junior doctors to contribute to different phases of the audit process depending on the stage of the audit when the junior doctor is in the department. For example, the junior doctor might contribute to:

- A literature search to define standards against which to audit.
- The first round of data collection.
- The analysis and reflection on the data leading to an action plan.
- Developing methods for change to ensure things are done better.
- Further rounds of data collection to determine whether improvement has been achieved.

11. EXAMPLE: IMPORTANT TO CLINICIANS & MANAGERS

AUDIT OF ANTIBIOTIC PRESCRIBING

We have a new antibiotic husbandry setup which restricts antibiotic use in clinical conditions. I raised concerns that although we are actively looking at C Difficile and MRSA incidence which it’s designed to combat no-one had thought to see if it’s actually still treating patients adequately e.g. with pneumonia (new BTS guidelines give different advice but acknowledge need to consider these issues). A local clinical audit has shown no immediate cause for concern (small sigh of relief!) - though further more detailed work is planned.

John White, York NHS  John.White@York.NHS.UK
In this way a senior doctor can ensure a much wider experience for junior doctors providing them with insight and skills in literature searching, data gathering, leadership and change management. It will provide junior doctors some insight into the patient perspective on quality care, the opportunities of working within multi-disciplinary teams and with relating to management.

In such a way, clinical audit will become a much more meaningful and beneficial part of junior training.

In order to provide such an experience, physicians will need, themselves, to be well versed in the competencies required to conduct effective clinical audit so as to provide the appropriate leadership to junior staff. Physicians should look to benefit from CPD opportunities to enhance their knowledge of clinical audit including the aspects of leadership and change management.

4.2.2 Junior medical staff

Junior doctors need to ensure that the clinical audit they carry out maximises their opportunity for learning. As indicated above such learning can relate to much more than improving the technical skill with which care is provided to patients. It can include a better understanding of healthcare from the patient and managerial perspective as well as learning skills related to change management. Such knowledge will be invaluable to junior doctors later in their careers.

Junior doctors should seek to participate in all phases of the audit cycle. In so doing they can enhance their prospects of audit data being used not only locally but also disseminated more widely. One of the criteria that most specialist societies use for the presentation or publication of clinical audit work is that the audit cycle should be complete i.e. that a second round of data collection has occurred to demonstrate change. Junior doctors should therefore be encouraged to contribute to an audit project within a department for which one round of data collection has already occurred.

Similarly, junior doctors should be aware that knowledge of all phases of the audit cycle will enhance their position in applying for posts. They should promote that fact that they have an understanding of the methodology behind clinical audit and how it can be used to work with patients and managers to achieve change.

See HQIP guidance:

4.2.3 Local clinical audit staff expertise

Ensure the project is agreed and supported by the local clinical audit team. Their expertise can be invaluable in ensuring the methodology is robust. Most departments will have a check-list to ensure that the audit methodology is sound.

They may be able to help with the setting up and running of the project depending on time availability and the rest of the clinical audit demands.

They can ensure that the audit is recognized within the Trust Clinical Governance programme if appropriate. This will help maximize the impact of the audit and increase the opportunities for driving changes in practice.

The clinical audit team will be able to provide advice on the presentation of results and the methods that can be used to develop an action plan and promote change.

4.2.4 Multi-professional team

Most physicians work within multi-disciplinary teams. Ensure that all relevant professional groups are signed up to the audit and are involved and supportive of the project. This means ensuring that they agree the standards and questions to be asked.

In this way they will have “ownership” of the results and will be encouraged to promote change within their own professional group. (See example 13 & 14).

4.2.5 Management

Think how the local management team, especially at the departmental level, can be involved in the audit. At the very least they should be aware that the audit is being carried out and they should be included in communication loops as the audit progresses. There is clear evidence that change in practice is greatly facilitated when clinicians and managers work together.

INFO: SUPPORT AVAILABLE FROM CLINICAL AUDIT DEPARTMENT

Every trust has a clinical audit department that comprises staff who are very familiar with clinical audit and its conduct. They are in post to facilitate clinical audit and to ensure that a robust process is followed. Often, audit departments have excellent networks with other trusts that can be used to support individual audits. This should ensure that the outcome of the audit is an improvement in patient care. Skills and knowledge in a typical audit department are outlined below.

<table>
<thead>
<tr>
<th>Topic selection</th>
<th>Proposed audits have often been done before, either in the trust or elsewhere. The audit department can advise on the best way forward.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Setting standards</td>
<td>As audits are standards based, the audit department can provide advice to ensure that this is robustly done.</td>
</tr>
<tr>
<td>Project registration</td>
<td>Most audit departments have some form of project registration procedure. Following this will strengthen the audit process.</td>
</tr>
<tr>
<td>Data collection</td>
<td>It is usually the responsibility of the clinical lead to take responsibility for this. Some audit departments may offer resources, but this number is decreasing.</td>
</tr>
<tr>
<td>Data processing</td>
<td>Audit departments have usually developed systems and processes, often with sophisticated software, to assist in the processing and analysis of data.</td>
</tr>
<tr>
<td>Reporting</td>
<td>Most trusts have a template for the production of audit reports. Using this will prompt the author to include all relevant aspects of the process and results.</td>
</tr>
<tr>
<td>Presentation</td>
<td>Audit departments are very familiar with the use of PowerPoint and similar presentation software. They can provide advice on the best way to present results to different audiences.</td>
</tr>
<tr>
<td>Action Plans</td>
<td>It is rare for an audit to be done without a need identified to change practice. The audit department can provide advice and support in the creation of action plans that address issues raised.</td>
</tr>
<tr>
<td>Change management</td>
<td>Most audit departments have a lot of experience on issues relating to change management and tools that could be used.</td>
</tr>
<tr>
<td>Publication/</td>
<td>Audit staff are generally aware of opportunities for publication in journals, other than those that specialise in clinical management. Staff are also aware of regional and national conference where successful audits may be presented.</td>
</tr>
<tr>
<td>conferences</td>
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</tbody>
</table>
Their involvement and commitment will greatly help at the end if changes in practice are to be sought. In many cases change will require support and assistance from the management team. It is much better if they are in from the beginning rather than being faced with demands for changes at the end of the process. They have many other considerations and priorities and so forewarning them of potential changes that might be required and attract a new cost pressure in the future helps with their business planning processes if nothing else.

13. EXAMPLE: MULTI-PROFESSIONAL AUDIT
AUDIT TO ASSESS COMPLIANCE WITH LOCAL POLICIES FOR THE HANDLING OF HISTOPATHOLOGY SAMPLES

This was a trust-wide multi-disciplinary retrospective audit, including several departments across the Trust (Histopathology, Mortuary, Early Pregnancy Unit, Patient Affairs and the Clinical Audit Team). Following a brainstorming exercise, a multi-disciplinary team (stakeholders) were requested to consult on the initial design of the proforma to ensure compliance towards the local policy could be assessed. The audit department facilitated the stakeholders throughout the entire project, this work included identifying the target population and subsequent sampling method. The audit team also identified, located and delivered the relevant medical records although all data collection from the medical records was undertaken by clinical and managerial stakeholders. This methodology was chosen to encourage ownership and accountability of subsequent audit results.

Trust-wide multi-disciplinary audits are extremely difficult to undertake, but as teams do not work in isolation they are extremely valuable to ensuring improvements in the overall care provided to patients. Having the correct stakeholders involved from the beginning of the project has been invaluable. The facilitation by the audit department has brought together a piece of work which could not have been achieved by individual teams within the Trust.

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14. EXAMPLE: MULTI-PROFESSIONAL TEAMWORK
A MULTI-DISCIPLINARY AUDIT OF STROKE

An effective multi-professional audit of stroke care was carried out which was followed by a series of actions. Keys to the success of the project included clinical commitment and leadership, close working with the clinical audit team and engagement from commissioners on the project team. A member of the clinical audit team worked very closely with the clinicians, designing a stroke care proforma – based on the RCP stroke audit - to go in the notes, carrying out the analysis and producing the reports.

The audit was followed by a series of actions and audits implemented by a “multi-disciplinary professional development group” (MPDG). Actions included the development of a patient leaflet, in consultation with the patients and carers in the local “stroke group”. A carer support group was also established. Members of the audit team worked with the MPDG.

Richard Hancock (PhD), Hancock RJT, Oddy M, Saweirs WM, Court B. The RCP stroke audit package in practice. Journal of the Royal College of Physicians (London) 1997; 31, 74-78. richard.hancock@nhs.net

See the HQIP website for guidance for NHS Boards:

4.2.6 Commissioners

It may be appropriate to consider involving commissioners. The more that providers and commissioners communicate the better. It will provide an understanding of the challenges faced by all parties.

It may well be that, if the audit demonstrates inadequacies in care, there may be better and often more efficient ways to provide a service. Commissioners will be interested in any proposals that will enhance and develop care especially if there can be an efficiency in the system. This may require hospital based services considering alternative methods of service delivery i.e. more community based delivery of care. If this is going to ensure a higher standard of overall care is provided such alternatives need to be considered.
Although unusual with local audit projects, commissioners can in some cases be the commissioners or instigators of the audit. It may well be helpful to work with commissioners to identify aspects of service that would benefit from audit to assess whether different models of delivery might be appropriate.

Clinical audit is increasingly important to commissioners as a vehicle for monitoring that a high quality service is being delivered. Audit criteria are being used within commissioning contracts to ensure the delivery of a quality service.

4.2.7 Patients

Consider carefully how patients or service users can or could be involved. Clinical audit is about the evaluating the quality of care provided and this encompasses patient safety, clinical effectiveness and patient experience.

While patient involvement has not featured significantly in local clinical audit to date – physicians should make efforts to address this. Local audit will be more meaningful and powerful if patient involvement is seriously taken on board.

Such involvement might include participation in:

• Topic selection

While clinical audit questions might be derived from clinical guidelines, the priority for patients might be different from clinicians’ or managers’ priorities. For example communication may be the most important concern for patients, while appropriate clinical assessment and management might be the priority for doctors.

• Governance

There may well be local patient groups related to specific conditions that would provide patient representation on a local clinical audit project.

• Data collection

As well as seeking to include patients in the process of clinical audit, physicians should ensure that clinical audit measures, not only the technical quality of care delivered but also the experience from the patient perspective.

• Interpretation of results

Patient involvement in the interpretation of results might throw up interesting insights given that their priorities might differ from those of clinicians and managers.

• Dissemination

Local patient groups offer channels of communication for the dissemination of results. The local patient networks will be very interested in issues related to local service delivery.

• Looking at ways to make things better

Patients have the greatest motivation to see services delivered to the highest possible standard. Their involvement in the interpretation and use of clinical audit data is likely to be very powerful in driving change.

Clearly there will be challenges in finding ways to effectively include patient input but this should not deter physicians from trying.

For further advice see:


4.3 Project management

A carefully worked out plan will help ensure that everyone is working to the same agenda and that the expectations are recognised up front.

The project plan should include:

• statement of the background to the issue and why it is important for clinical audit

• the aims and objectives

• the standards to be used

• the audit criteria

• the patient population and how they will be defined

• who to involve – identify stakeholders: anyone who may need to make a change.

The project team should include the following representation;
• Medical
• Nursing
• Allied Health Professions
• Clinical governance/effectiveness/audit
• Managers
• Patients/users.

Get them involved from the start; agreeing the standards and audit criteria. Consider how the audit will relate to Trust governance. When it comes to implementing change as a result of the audit data, support and involvement from the governance team will greatly help.

4.4 Other Governance issues

4.4.1 Is it ethical?

Clinical audit does not need research ethics approval and does not need to be cleared by the local R&D governance processes. It is an accepted part of clinical practice. Therefore, as long as the project accords with the definition of clinical audit, no approval is required i.e.

• there are defined standards
• the audit evaluates practice against these standards
• the results are reflected on
• a process for change is established
• there is a commitment to re-evaluate.

It is important to consider if there are any ethical issues; guidance can be obtained from the HQIP website.


4.4.2 Patient identifiable information - Data Protection Act and Caldicott principles

As a general rule it is best and simplest if clinical audit is carried out using at least pseudo-anonymised patient data i.e. no patient identifiable data is stored.

Patient identifiable information includes;

• Name
• Date of birth
• Address
• Post code (although the first three figures are acceptable as these allow some analysis of socio-economic grouping).

Patient identifiable data will be required if linked data from different data sources is to be used. This is not usually necessary for local clinical audit. If such patient identifiable data is required specific approval from the National Information Governance Board is required.

The issue of patient identifiable information is potentially complex and if there are any doubts about patient anonymity within a project they should be discussed with the local information governance lead i.e. with your hospital Caldicott Guardian or data protection officer.

4.4.3 Patient consent

Explicit patient consent is not required for clinical audit. In many audits it would be hard to achieve as numbers are high and retrospectively it would be hard to track down all patients.

There should however be an explicit statement in information to patients that the hospital carries out clinical audit as a routine part of the service delivered and if any one wishes to specifically opt out they have the right to do so.

Data Protection Act 1998


Data handling requirements


HQIP’s Information governance guide for clinical audit

http://www.hqip.org.uk/information-governance-guide-for-clinical-audit
4.5 Resources

Local clinical audit should be carried out within the resources committed to it by the Trust. Each doctor both at a senior and junior level has time built into their job plan for supporting activities which include audit. Both have clinical audit as part of their appraisal. In the near future clinical audit and the reflection and change management associated with it will become part of revalidation.

Similarly, clinicians are fortunate in the hospital setting to have hospital audit departments with committed and experienced teams ready to provide support and advice for audits.

NHS Information Governance


Further information available at:

• http://www.gmc-uk.org/guidance/ethical_guidance/confidentiality.asp
• http://www.gmc-uk.org/guidance/ethical_guidance/confidentiality.asp
• http://www.clinicalgovernance.scot.nhs.uk/section1/systemsandstructures.asp
5.1 Introduction

5.1.1 The audit cycle is like any other cycle – don’t re-invent it

There are useful resources for advice on audit methods. Find out if someone else has carried out a similar audit. Try your specialist society web site or the HQIP web site including the National Clinical Audit Forum [NCAF] web page. Ask your local clinical audit department – they will have good networks with neighbouring hospitals and with regional clinical audit groups.

You may find someone else has identified standards and audit criteria that can be used. This will potentially save a lot of work and in addition will provide results you can benchmark against.

5.1.2 Is there method in your madness?

Is the method sound?

If you have not done audit before, are you happy with the method you have developed to carry out the audit? Have you looked at the HQIP best practice guidelines?


Liaise with your local audit department. They will have invaluable advice which will help ensure the audit is productive. Look at the HQIP website which has many useful local audit tools.

5.1.3 The four stages of audit.

In the first edition of the ‘Principles of Best Practice Guide’, the audit process was broken into five stages with re-audit comprising the fifth stage. In their publications, HQIP have simplified this model to four stages, with re-audit being part of the last stage. The process is still a cycle in which measurement is followed by action and then re-measurement. Whatever way you look at it, you need to have:

- Identified authoritative standards.
- Measured performance against those standards.
- Reflected on the findings.
- Initiated processes to improve practice.
- Re-measured performance to record progress.

5.2 Setting the standard

The first essential of an audit is to identify the standards against which the audit will be conducted. Unless the standards are expressly stated and audited against it will not be possible to identify areas for change and improvement.

Standards should be “robust” and evidence based. Useful sources include NICE, Specialist Society Guidelines and SIGN. NICE guidelines are accompanied by audit criteria and audit guidance documents that may be used as a starting point for developing a clinical audit. NHS Evidence is now developing within NICE and provides another route to identify standards. NICE is beginning a process of developing Quality Standards which will contribute to the audit spectrum. These standards will contain a small selection of overall standards which could, alongside other methods of performance

15. EXAMPLE: ASSESSING AGAINST NICE GUIDELINES

ASSESSING PATIENT KNOWLEDGE ABOUT THEIR URGENT CANCER REFERRALS

NICE guideline of Urgent Cancer Referrals [UCR] indicates that adult patients should normally be told that they have been put on a cancer service due to suspicion of cancer. Local experience indicated that patients were not always aware of the possibility of cancer resulting in feelings of anger and anxiety.

Audit conducted to assess if:

- Patients were told that their urgent referral was due to a suspicion of cancer.
- Patients were seen within the national target of 14 days.
- A local UCR proforma was used.

This audit demonstrated that not all patients were aware of the nature of the referral. Implementation phase is raising awareness of GPs to conform with the NICE guideline.

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management, form the basis of clinical audit activity, enhanced with more standards as required. (See example 15).

Specialist societies provide another source of guidelines:

British Thoracic Society

British Society of Haematology
http://www.bcshguidelines.com/guidelinesMENU.asp

If there is no evidence base, then consensus standards have to be agreed and documented. These should have been derived by an appropriate consensus methodology (Delphi, Nominal Group approach etc.) The standards have to be sufficiently authoritative that, if deviation from the standards is found, clinicians and management can be persuaded that change is needed.

5.3 Establishing the criteria - measuring care against the standards

5.3.1 Don’t forget Donabedian

The great guru of quality measurement in healthcare was Avedis Donabedian\(^2\). He defined two types of quality in healthcare: technical quality and interpersonal quality. In order to measure quality he believed it was possible to consider:

The structure of care: \textit{How is care delivered}

The process of care: \textit{What care was delivered}

The outcome of care: \textit{What was the result of the care delivered}

5.3.1.1 Structure – like the facilities available, the numbers and skills of staff in post, the facilities for training and education

2. In 2000 Avedis Donabedian’s concise book, Introduction to quality assurance in healthcare, was published posthumously which summarised his theories. A review of this book by Sir Muir Gray can be read on http://www.healthcarecultureprogramme.org/podcasts/1

5.3.1.2 Process - measures the care people receive

The assumption is that if people receive care that accords with best practice then the outcomes will be good. Assessing processes of care requires abstracting data from patient case records. Such work can be time consuming and is open to problems of interpretation and poor record keeping. However in complex chronic conditions it is often easier to obtain process data than outcome data.

5.3.1.3 Outcomes

Outcomes measured might be defined by the clinical team, by patients (PROMs) or management (which might relate to cost effectiveness). (See example 17).

5.3.1.3.1 Clinical outcome measures

Whilst outcomes are the ideal measure for assessing the quality of care, they can be difficult to assess.

The outcome measure will be dependent on knowing both numerator and denominator, i.e. has the mortality rate for a malignancy dropped as a result of adherence to best practice? To determine the rate it is necessary to know the number of deaths (the numerator). Is it possible to determine the number of deaths? Deaths in hospital may be easy to identify, but deaths outside will require recourse to national statistics the ONS (the Office of National Statistics). Are you interested in all deaths or only those that appear to relate to the condition being audited? In order to determine the percentage the denominator is

16. EXAMPLE

In the National Audit of Falls and Bone Health, 74% of Trusts reported having an integrated falls service. The clinical audit demonstrated that only 27% of patients received the coordinated, multidisciplinary assessment and intervention expected of an integrated falls service.

Structures are relatively easy to measure. They do not require the identification of patients’ case records. However, teams and management often have a rosy view of the organisational structures in place which is not born out by evaluations of the care people receive.

(See example 16).

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(See example 16).
Outcome measures can be difficult to compare between healthcare settings unless case mix is allowed for. One hospital may serve a population with greater healthcare needs and hence will be likely to have less good outcomes than another with a healthier population. Case mix issues that will influence comparison of outcomes include: age, gender, ethnicity, co-morbidities. Achieving reliable case-mix adjustment is a major challenge and is potentially a significant limitation in the use of outcome data.

5.3.1.3.2 Patient reported outcome measures

It is increasingly important to consider how to measure the patient experience of care. Patient experience of care is one of the three measures of quality highlighted in the Darzi report. Patient experience can be measured in various ways including: "patient reported outcome measures" and "patient reported experience measures". Well validated patient reported outcome measures have been developed for certain surgical procedures and provide an important measure of care. Currently however such validated measures are not available for chronic – more medical – conditions. (see also section 2.2.6).

5.3.1.3.3 Cost outcomes

While rarely done at present there will be increasing pressure and advantage in considering the cost implications associated with change within the audit cycle. Trusts are under great pressure to reduce costs and will want a clear view as to the implications of any proposed changes. The national QIPP agenda [see section 2.3.1] means that all service development will be scrutinised to evaluate whether improved care can be delivered at reduced cost.

Cost analysis is a complex science. However a basic assessment can be made. The base cost of delivering the care under review can be determined from the first round of audit. The impact of change on costs can then be evaluated taking into account issues such as savings from reduced length of stay, reduced hospital visits, and reduced costs of investigation. Of course costs may increase, at least in the short term.

Local clinical audit departments may well have a standardised method for addressing the issue of cost which will be pragmatic for a local audit.

Clinicians will have a primary concern to improve the clinical quality of care. However, they have to recognise

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17. EXAMPLE: OUTCOME BASED AUDIT

30 DAY MORTALITY ASSOCIATED WITH ANTI-CANCER THERAPY

An audit of 30 day mortality following systemic anti-cancer therapy was carried out initially in 2008 based on a NCEPOD study. The audit has provided important information and has been rolled out across all disease groups, supported by publication of reports from NCEPOD and NCAGG. Extensive consultation with consultants to develop a generic data collection tool took place.

The audit is strongly supported by the trust board of directors and the level of therapy related mortality is reported in quarterly board reports. It is also reported monthly in more detail to the chemotherapy advisory group. The rate of completion of audit proformas has increased by half over the last 12 months to 76% currently. Individual cases are increasingly (51%) discussed at mortality and morbidity meetings using a structured review sheet.

The audit results are presented regularly at grand round meetings and reviews are informing future decision making by identifying themes and pathway issues. Chemotherapy regimes contributing significantly to mortality are being reviewed and systems put in place to manage neutropenic admissions both here and in referring hospitals across the region. Results are to be benchmarked with similar tertiary cancer specialist trusts.

Resources were identified to cover 0.5 WTE clinical audit facilitator hours for two years. The facilitator meets monthly with the consultant audit lead to discuss data quality issues. The facilitator regularly advises consultants of outstanding proformas and prepares a monthly report for chairs to discuss at disease group meetings. This is raising the profile of clinical audit across the trust and has led to additional audits.

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required i.e. the population for whom the intervention is relevant. Can the catchment population of a hospital be accurately defined? Should it be based on the geographic boundaries, hospital catchment boundaries, PCT boundaries?
that they are operating within a cost constrained service, and therefore the impacts of increased cost in one area will result is less available in another.

5.3.2 Are the criteria robust and reliable?

Having identified the standards against which to audit, and the type of audit criteria to be used, the next step is to define the criteria that will assess the standards. Check that the questions being asked in the audit relates to the standard being assessed. Make sure you audit what you need to know not what would be nice to know.

In phrasing the questions bear in mind:

• Is it possible to understand precisely what information is required?
• Is it possible to obtain the information required to answer the question?
• Is the question specific enough that it will give an answer that is useful and meaningful?
• Is the question sensitive enough to relate solely to the standard being assessed?

Should the standard being measured be fully complied with? In many cases 100% compliance is not possible or desirable. In these cases, targets need to be set. (See example 18).

5.4 Audit population & sample size – the who and the how many

5.4.1 Who to audit: how to identify patient groups for audit & data collection

Think carefully about the group of patients you wish to audit. Can they be readily defined and will their records be readily obtained? Will they be the patient group that relates to the evidence base? It helps to select a population that is easily identified whose records and information can be easily accessed. (See example 19).

The patients may be identified by use of hospital coding. Is coding accurate for the group you wish to

18. EXAMPLE: AUDIT TARGET
SECONDARY PREVENTION FOLLOWING MYOCARDIAL INFARCTION

Myocardial infarction guidelines indicate that all patients where possible should have secondary protection with Aspirin, Beta blockers, ACE Inhibitors and Statins.

However there will be contra-indications for some patients e.g. patient with asthma should avoid beta blockers, patient with a recent severe GI bleed may need to avoid aspirin etc.

A target for secondary prevention may therefore be set at 90% rather than 100%.

19. EXAMPLE: DIFFICULTY IN PATIENT IDENTIFICATION
THE NATIONAL CLINICAL AUDIT OF FALLS AND BONE HEALTH SELECTED PATIENTS ATTENDING A&E WITH A FRAGILITY FRACTURE (HIP OR NON-HIP)

This group was selected for various reasons:

• There is an evidence base that indicates that this group benefit from multi-factorial assessment and targeted interventions.
• There is a NICE guideline that provides standards for assessment and intervention.
• A&E is a clearly defined site at which it is possible but, not easy to identify patients. Individuals experiencing falls and fractures in the community would be hard to identify.
• A manageable number would be identified. An audit of falls rather than falls and fractures would be overwhelming.

Despite seeking to audit this apparently well defined group, patient identification remained difficult because there is no code for falls in hospital routine data. Furthermore patients who attend A&E and are not admitted do not get a hospital code. Patients had therefore to be identified by a daily trawl of A&E records to identify the required number of patients to enter the audit.
study? You may wish to compare between hospital records and other data sources such as Hospital Episode Statistics (HES). It will be important to ensure that the group studied can be identified by HES.

Increasingly, the patient perspective is required to give further meaning to an evaluation of care. If this is the case, think carefully how patients would be identified, approached and included.

5.4.2 How many to audit?

The numbers of case notes required when process measures are used is not an exact science. It is not possible to do a power calculation to work it out. National audit studies have indicated that approximately 40 sets of notes are required to provide a view of the care within a healthcare setting. Ideally more should be assessed, but it is necessary to set a balance between the number required to provide an unbiased picture of care against the number it is possible to assess within time and staff constraints. For further advice see:


To establish the numbers needed for outcomes measures it is necessary to consider the frequency with which the outcome might be expected. Thus post operative mortality rates are low and a great number of cases would be needed if a significant change was to be sought between audit rounds. Post operative infections however would be much more common and fewer numbers would be needed in the audit.

In some larger audits, continuous data collection occurs e.g. for hip fracture, carcinoma of the lung, myocardial infarction. With continuous audit, many thousands of case can be built up and powerful outcome analysis is possible. Such data collections however, will be beyond the scope of local audit projects.

5.4.3 Looking forward or looking back - retrospective versus prospective data collection

Retrospective audit increases the possibility of identifying all patients meeting the inclusion criteria i.e. complete patient numbers. However it does depend on being able to identify patients through coding or other record systems who fit the inclusion criteria. (See example 20). Prospective audit increases the chance of good quality data collection, but there is a risk some patients – in particular patients who it might be important to audit – will be missed and there will be incomplete patient numbers. Furthermore there is a risk that, because teams are aware that an audit is on-going, clinical practice may alter. In some ways this is a good thing if it means patients get better care, but it may result in a false evaluation of routine care. (See example 21).

If outcomes at a time period after admission are needed further careful consideration is required.

Some outcomes can be obtained from other sources e.g. Mortality rate can be obtained from the Office

20. EXAMPLE: RETROSPECTIVE AUDIT

Hospital coding can result in some anomalies in patient inclusion.

One large scale local audit of diabetes care identified patients through coding and included two patients with diabetes insipidus as well as the required patients with diabetes mellitus.
of National Statistics [ONS]. However the process is complex and requires sharing of patient data between datasets. It is likely to be beyond the scope of a local clinical audit.

A retrospective audit of people who met the inclusion criteria might be possible. Patients could be identified who were admitted one year previously. Their care can be reviewed and the notes reviewed to assess whether there was evidence of outcomes such as re-admission, mortality or enhanced functional ability. Some patients may have died at home or had been admitted to another hospital – so it can be difficult to be sure the outcome for all patients has been assessed.

A prospective audit in this situation would require the audit to run for at least one year to allow sufficient time to assess outcomes – i.e. mortality at one year. This will often result in an unduly long audit process which is impractical.

In most local clinical audits the most practical solution is to carry out a retrospective audit and to focus on process measures (for example; did the patient get care that accorded with best evidence based practice?) rather than outcomes.

5.5 Piloting - Test the water

Piloting is essential. Test out the method for identifying patients, collecting the information from records, and entering the data onto a data collection tool, be it paper based or an electronic system.

Testing of a 10% sample will provide invaluable evidence as to whether the audit is feasible and will potentially save a great deal of time.

5.6 Data collection

Identify who will be collecting the data from the hospital record and other audit sources.

Ensure everyone is agreed about how terminology will be interpreted. (See example 22).

Give thought to how cases will be selected. Will a random selection of notes be looked at or a continuous sample? It is very easy to introduce bias unless great care is taken. (See example 23).

5.6.1 How will the data be collected?

Will the data be collected on a paper questionnaire? Are there electronic data capture tools? Is there a web based tool that will facilitate data collection?

Arrange data items to be collected within the audit proforma in a logical order for those doing the collection. They can be re-sequenced at a later date. Remember that for a single audit data may come from several sources.

22. EXAMPLE: DIFFERENCES IN DEFINITIONS
AN AUDIT OF STROKE UNIT CARE

Does the unit have a stroke unit?
How is a stroke unit defined?
Is it a ward or part of a ward with a sign up that says “Stroke Unit”?
Is it an area to which stroke patients go?
Is a unit which provides certain basic characteristics e.g. daily consultant led ward rounds, multi-disciplinary input, ability to continuously monitor patients?

23. EXAMPLE: HOW BIAS CAN CREEP IN AN AUDIT OF STROKE CARE

For an audit of stroke care, notes were requested for a consecutive series of admissions for patients coded as having had a stroke. The first 40 sets that were obtained were audited.

The results showed a very high mortality rate.

Review indicated that the easiest notes to obtain were those of patients that had died. Other sets of notes were out in the system for outpatient appointments, other wards etc. The selection process had therefore produced a biased sample that distorted the mortality rate.

When the consecutive sample was reviewed mortality rate was exactly in line with national norms.
There are now many software tools that allow electronic data capture. These can be helpful in assisting with data aggregation, analysis and reporting. Examples of tools used in audit projects include SNAP and Survey Monkey. These tools offer different levels of sophistication and consideration needs to be given to the specification needed for the audit. Check with your local audit office what might be in use in your trust.

This is an area where checking with your specialist society web site might indicate that others have done a similar audit and use can be made of their template.

Some specialist societies now facilitate multi-centre audit with web based data collection tools. Aligning the audit to be carried out with such tools will enable you to benchmark your care with other units. (See example 24).

http://www.snapsurveys.com/

http://www.surveymonkey.com/

24. EXAMPLE: CLINICAL AUDIT ASSOCIATED WITH IMPROVED PATIENT CARE

Clinical audit of Rapid Acces Chest Pain Clinic (RACPC) triage of patients with chest pain at the Borders General Hospital, demonstrated that RACPC assessment facilitates correct identification of patients for investigation by angiography.

POINT FOR JUNIOR DOCTOR LEARNING EXPERIENCE:

Tips for audit:
1. Avoid having to look back at medical notes more than once! Start with fixed objectives; think ahead, brainstorm with a supervisor to work out all the possible directions the audit might take – make a spreadsheet to collect all the information you need from medical notes before starting.
2. It is easier to collect, analyse and reassess quantitative than qualitative data.
3. Do not be so enthusiastic you take on too much and it never gets finished – take on a simple project with a well defined clinical question. From a personal perspective choose something that interests you and is clinically relevant/important. From a job application perspective choose something that is possible to re-audit in a relatively short timeframe; completion of the audit loop is essential, and can be difficult to achieve when moving sites between four month foundation year rotations.

Alison Sears, FY2 doctor  Supervisor: Paul Neary, Cardiology Consultant

5.7 Data analysis

Depending on the size of the local audit, help with data analysis may be required. This may be with regard to the database to be used for data storage and analysis e.g. Excel or Access, or may relate to statistical analysis. The local clinical audit department will have the expertise to advise.

5.8 Reporting – Feeding back - Getting the message across

- Be sure that patient inclusion and exclusion criteria are clearly stated.
- Ensure the standards against which the audit is carried out are clearly stated.
- Include the provenance of the standards (i.e. NICE SIGN etc.).
- Indicate the compliance expected with the standard (is 100% reasonable).
- Ensure audit questions are related to the relevant standards.
- Present the results in a readily understandable way.
- Where possible consider graphs – visual images convey messages more effectively than tables.
- Ensure results include denominators and numerators.
- Use text to provide context and comment.
- Compare with previous rounds ensuring that patient groups are strictly comparable.

If data are available from other units, benchmarking data for...
comparison can be helpful. This may become increasingly possible as specialist society web based data entry systems develop as well as libraries of audit criteria.

5.9 Maximising the impact of local audit

The impact will be maximized if:

• There is a committed lead clinician.
• The methodology is robust.
• The topic is relevant to the Trust and is amenable to improved care delivery.
• There is a committed and supportive multi-professional team involved.
• Management is involved.
• Results are presented in a clear manner.
• There are a limited number of recommendations that identify specific actions.
• There is a clear plan for improvement – “action plan”.

5.10 Dissemination of audit results

Consider how the results and messages can be presented at a local level. This includes:

• Through management, feed in to Trust governance systems.
• Use Trust newsletters or Bulletins, use the Intranet, establish Trust audit days.
• Through clinical channels.
• Present at clinical meetings, hold educational events, put posters in post-graduate centres and libraries.
• Consider patient group support.
• Patient and Public Involvement (PPI) Forum.
• Share with colleagues in other sectors.
• PCTs, both commissioners and providers, SHA Observatory, Public Health, general practice, PEC chairs.
• Feed into society audit systems.
• Feed into clinical audit networks at local regional and national level.

5.10.1 Clinical audit networks

There are increasing numbers of clinical audit networks at local level, regional level, society level and nationally. Use them.

To find out more about your local network see:

http://www.hqip.org.uk/local-clinical-audit-networking-groups/
6.1 Barriers to change

The greatest barrier to change is the attitude that nothing can be done. In the busy turmoil of hospital life, managing to effectively deliver care is a challenge enough. It is often perceived that development of the service or care provided is not possible.

Examples of barriers raised include:

- Lack of time.
- Lack of management interest.
- Not a high enough priority.
- Problem is to maintain services in the face of cuts rather than enhance services.
- Change impacts on other people’s budgets.
- Too difficult to get everyone on board to drive change.

However, many do manage to improve services. It is possible. It should be part of the professional practice of all doctors to be continually asking themselves: “How could we be doing this better?” Having asked the question, think carefully how things could be done differently and consider with colleagues how to improve care.

Changes in care are not always associated with increased costs. There may be significant efficiencies and cost saving as well as an improvement in quality.

6.2 Audit action planning

Having gathered data about performance and
reflected on service delivery, the next step is to develop an action plan of how things might be improved.

The action plan outlines the changes that need to be made, who will do what and by what time.

An example of an action plan is given within the Template clinical audit report on the HQIP website.

http://www.hqip.org.uk/template-clinical-audit-report

6.3 Mechanisms for change management

The rewarding part of clinical audit is driving change to achieve better patient care. Although challenging, it is often associated with a better working environment for the clinicians and an improvement in morale.

Having identified the changes that are needed through the data collection phase of clinical audit, a robust action plan needs to be developed – as indicated in Section 6.2. The action plan will need to determine the methods to be employed for driving change. Doctors should consider whether these changes might be achieved using the application of formal change management approaches.

There is an entire science related to change management which includes approaches such as: PDSA cycles, LEAN, 6 sigma, root cause analysis and process mapping. There is a wealth of information and experience available to assist and the NHS Institute for Innovation and Improvement is a good place to start.

http://www.institute.nhs.uk/organisation/about_nhsi/about_the_nhs_institute.html

All doctors, whether as part of their training or as part of continuing professional development, should have knowledge of these methods and should work with colleagues to utilise them.

6.4 Using audit alongside other improvement methodologies

Clinical audit is one of many methods that can be used to improve the quality of care. Other approaches should be considered in conjunction with clinical audit. Such approaches include critical incident review, national confidential enquiries, analysis of complaints, patient satisfaction feedback. (See example 25).

25. EXAMPLE:CRITICAL INCIDENT REPORTING

CRITICAL INCIDENT REPORTING IN ORTHOPAEDICS

An audit of critical incident reporting in Orthopaedics highlighted lack of awareness of both the need to report incidents and who needs to respond.

Findings

Current data shows:

• Lack of incident reporting therefore clinical problems are not identified.
• 22% of incidents were reported on time to CG but there was a delay in incident investigation.
• Lack of incident recognition – e.g. lack of consent.

Interviews show:

• Lack of knowledge of incident reporting among staff.
• Lack of any incident outcome an/or feedback to clinicians after incident report.

The possible causes were:

• Reporting to the wrong person or team.
• “Human factors”.
• Missing paper work.

Sadia Siddique Ealing Hospital NHS Trust on behalf of Shan Shan Jing FY2, who carried out the audit. Sadia.Siddique@eht.nhs.uk

6.5 Embedding clinical audit in Trust systems

Clinical audit should be part of a whole-team approach to changing practice, including nurses, support workers and managers. Change derived from clinical audit may often be slow as it has to compete with other management agendas. The critical point is to ensure that clinical audit is built into the Trust structure with appropriate support
and resources. Effective clinical audit will help demonstrate where changes can be made and in many cases changes can be associated with more cost effective ways of working.

If truly embedded within the Trust structure clinical audit can move from the laborious process of trawling through notes to the exciting and constructive process of driving up standards of care associated with opportunities for learning in presentational skills, negotiation, leadership, motivational skills and understanding of change within complex health systems.

You can find guidance for Trust Boards on the HQIP website:


6.6 Top tips for improving quality

The NHS Institute for Innovation and Improvement [NHSIII] provides a guide to tips for improving quality. The key ingredients are:

- A clinical champion (that's you).
- Good cooperation with management and commissioners.
- Good information (clinical audit information, clinical indicators).

6.6.1 Clinical performance indicators

A key part of achieving change is the ongoing collection of data to indicate whether progress is being made. This may be achieved using a "dashboard" of measures. They may be key indicators from a national audit. National audit is associated with carefully refined audit criteria for explicit standards of care.

It may often be helpful to use these criteria for local audit in between rounds of national audit. This will allow a local site to see how it is progressing in improving care following on from the national audit findings.

However, watch out that there is a risk that services will become very good at delivering the key indicator elements of care and overlook other important elements. Some variation in the audit criteria selected will protect against this happening.

<table>
<thead>
<tr>
<th>Trust Name (Site Name)</th>
<th>No of cases in the audit</th>
<th>Screening for Swallowing Disorder within 24 Hours of Admission</th>
<th>Brain Scan within 24 hours of Stroke</th>
<th>Physiotherapist assessment within 72 hours of Admission</th>
<th>OT assessment within 4 days of Admission</th>
<th>Patient Weighted during Admission</th>
<th>Rehabilitation Goals Agreed by Multi-disciplinary Team</th>
<th>Aspirin or Clopidogrel by 48 hours after Stroke</th>
<th>Patients spent at least 90% of Stay on A Stroke Unit</th>
<th>Percentage of eligible patients receiving all 9 indicators</th>
<th>Average of 9 Key Indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median All Hospital Sites</td>
<td>11369</td>
<td>73</td>
<td>57</td>
<td>88</td>
<td>69</td>
<td>76</td>
<td>68</td>
<td>92</td>
<td>88</td>
<td>56</td>
<td>17</td>
</tr>
</tbody>
</table>

**INFO: 9 KEY STROKE INDICATORS**

NATIONAL SENTINEL STROKE AUDIT 2008

CARDIAC AND STROKE NETWORK

*Stroke Key Indicators*
6.7 Re-audit – importance of completing the cycle

Re-audit is an essential component of the audit cycle and to determine whether improvement has been achieved.

In the local environment it is common for a one off data collection to occur, usually carried out by a junior doctor for their training log book. The results may be considered, and an action plan drawn up. Often however there is no drive for change or repeat audit to assess improvement.

A better approach is to involve juniors doctors in contributing to different stages of the audit cycle. During their four – six month commitment to a department they may contribute to:

- Identifying standards for an audit.
- Carrying out the data collection, reflection and developing an action plan.
- Working with senior colleagues to drive some change arising from the action plan.
- Carrying out a re-audit.

This leads to more coherent clinical effectiveness and thus a more rewarding experience for doctors.


6.8 Celebrating success (“success breeds success”)

The results and achievements of a clinical audit should be broadcast and recognised. Within the hospital setting this might be at departmental meetings, grand rounds and post –graduate events.

The findings and achievements could be acknowledged in news letters and on local intranets as well as in clinical governance and hospital trust annual reports. Trusts should have audit days and awards to showcase success. The more ways the successful clinical effectiveness project is communicated, the more widely the message will be received. (See example 26).

On a more regional basis there are specialist society regional meetings which often are short of topics for presentations. Well conducted clinical audit provides a ready source of relevant clinical material. Presentation can provide recognition for those that have carried out the audit and form the basis for discussion at meetings.

On a national basis there are annual society meetings as well as clinical audit related meetings. Presentations and posters at these meetings provides experience for junior doctors in preparing posters and talks, an opportunity to discuss findings with interested colleagues and an opportunity to network. Some societies award prizes for the best audit presented at their national meetings e.g. British Association of Dermatologists, British Geriatrics Society.

If the findings from the clinical audit are of general interest, the audit could be submitted for publication in a peer reviewed journal. Again this provides good experience and discipline for a doctor in training.

26. EXAMPLE: CELEBRATING SUCCESS

AUDIT TO ASSESS COMPLIANCE WITH LOCAL POLICIES FOR HANDLING OF HISTOPATHOLOGY SAMPLES

The audit was presented as a poster on the Trusts second Research and Audit Open Day. This allowed all members of staff to have the opportunity to see the positive achievements and well as the drawbacks in the system. A brief synopsis of the audit results were disseminated across the Trust by inclusion within the Monthly Newsletter (also available on the Clinical Audit web-page) which is included within the Clinical Matters Newsletter. Also a brief synopsis was also included within the Audit Summary which is sent on a monthly basis to all the relevant Business Unit Quality and Risk Meeting.

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ACKNOWLEDGEMENTS

The authors would like to thank the Healthcare Quality Improvement Partnership for funding the development of this book. Thanks also go to the members of the Clinical Effectiveness Forum of the Royal College of Physicians and the National Audit and Governance Group for providing advice and guidance on the content. Thanks go to all the individuals who so enthusiastically responded to our call for examples, good and bad, of audit practice. And finally a heartfelt thanks to Nancy Turnbull for her invaluable support in managing the project, for her advice and for the meticulous attention to the detail of the Handbook.

GLOSSARY

To avoid confusion and ‘re-inventing the wheel’, the authors have not written their own glossary of terms. Instead, you are referred to the HQIP glossary:


ABBREVIATIONS

ACCEA Advisory Committee on Clinical Excellence Awards
NCAAG National Clinical Audit Advisory Group
CPD Continuing Professional Development
NICE National Institute for Health and Clinical Excellence
CQC Care Quality Commission
NIHR National Institute for Health Research
CQUIN Commissioning for Quality and Innovation
NQB National Quality Board
GMC General Medical Council
ONS Office of National Statistics
HES Hospital Episode Statistics
PROMs Patient Related Outcome Measures
HQIP Healthcare Quality Improvement Partnership
QIPP Quality Innovation Productivity and Prevention
IQI Indicators for Quality Improvement
SHA Strategic Health Authority
MINAP Myocardial Infarction National Audit Project
SIGN Scottish Intercollegiate Guidelines Network
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