NHS
Clinical Governance Support Team

A Practical Handbook for Clinical Audit

Guidance published by the
Clinical Governance Support Team

Graham Copeland, *Clinical Audit Development Director*

March 2005

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Introduction

This handbook has been developed with the intention of improving clinical audit at a local level and is designed for use in acute trusts, primary care trusts (PCTs), ambulance trusts and mental health trusts. There are many different models for clinical audit which work well at a local level and the handbook documents the range of models which are applicable and where possible gives examples of good practice. The handbook is designed to give advice and guidance to those organisations where local clinical audit is proving difficult to embed within the trust and to improve its integration into clinical governance.

This is an evolutionary document and updates, in particular examples of good practice with contact details, will be added regularly to the web site.

The handbook has been endorsed by the Healthcare Commission, National Institute for Clinical Excellence (NICE), the Clinical Governance Support Team (CGST) and the National Audit and Governance Group (NAGG).

I am indebted to all those who have assisted in the development of this handbook in particular Martin Ferris, Emma Challans, Stephen Ashmore, Tracy Johnson, Richard Kuczyc and Jane Hartley from the National Audit and Governance Group (NAGG), Mark Noterman form the Department of Health, Andrew Singfield from the Clinical Governance Support Team (CGST) and Claire Morrell from the Royal College of Nursing.

My particular thanks to all members of NAGG who have given their time and enthusiasm during the evolution of this document.

Graham Copeland -- Clinical Audit Development Director

Contents

1. Background

1.1 Clinical audit has been variously defined. The standard definition, and certainly the one endorsed by both NICE and the Healthcare Commission is that ‘Clinical audit is a quality improvement process that seeks to improve the patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structures, processes 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’.

1.2 Audit is not a new process. As early as 1750 BC, King Hammurabi of Babylon instigated audit for clinicians with regard to outcome, sometimes with serious consequences for the clinician both financially, and with regard to life and limb, in the event of poor performance.

1.3 Clinical audit has moved on from these early beginnings, but it was only between 1989 and 1990, that monies were first made available to finance the development of audit activity throughout the NHS. Initially medical audit, it soon evolved to encompass all aspects of patient care, and with the involvement of all clinical staff became clinical audit. With the introduction of clinical governance into NHS organisations following the publication of the governments White Paper ‘The New NHS Modern Dependable’, there was a statutory duty of quality upon all NHS bodies . Clinical audit is a key and essential component of clinical governance.

1.4 Although clinical audit is an essential and integral part of clinical governance at a local level, it has often struggled to attain its rightful position within clinical governance. This is due in part to a lack of definition and guidance as to what is ‘good clinical audit’, combined with a failure to set priorities for clinical audit, and in many Trusts poorly defined responsibilities for clinical audit activity.

1.5 Although an excellent start has been made with the publication of ‘Principles for Best Practice in Clinical Audit’1 there is still a need to assist in the implementation of these ideals at a local level.

1.6 This handbook aims to provide this assistance, by providing a practical guide to the structures and processes necessary to deliver clinical audit at the local Trust level.

2. Strategic Health Authorities and Trust Responsibilities for Clinical Audit

2.1 Within Strategic Health Authorities the clinical governance lead is responsible for assuring that there is a clinical audit programme within local trusts, and that this reflects national audit priorities.

2.2 For clinical audit to function at a local level there is a need to define responsibilities for clinical audit to individuals within a Trust.

2.3 The chief executive and medical director are responsible for the quality of care delivered by their organisation. In some ambulance trusts and primary care trusts, where there is no medical director, the chief executive officer retains sole responsibility for the quality of care delivered by the organisation. The chief executive and/or the medical director may choice to appoint a clinical governance lead to assist in the coordination of governance activity, including clinical audit within that organisation.

2.4 The clinical governance lead need not be a clinician but within acute trusts there are advantages if an experienced clinician adopts this role.

2.5 The clinical governance lead ultimately retains accountability for clinical audit, but may choose to delegate this role to another, the clinical audit lead. At a local level this individual will then be responsible for creating a clinical audit strategy, setting audit priorities, agreeing the audit programme, implementing the strategy and implementing the audit programme.

2.6 The clinical governance lead however retains responsibility for ensuring that these tasks are completed and that clinical audit remains integrated with the other aspects of clinical governance

3. The Clinical Audit Lead

3.1 The clinical audit lead has a clear role in creating the strategy for embedding clinical audit within the organisation, but the individual chosen must have more than just a nominal strategic role. The clinical audit lead should have a high profile within the organisation, and must champion clinical audit both to colleagues and management alike.

3.2 The clinical audit lead need not be a clinician although there are advantages in acute trusts if a clinician with appropriate skills and training adopts this role In PCTs and ambulance trusts the lead and manager may be one and the same or the clinical audit lead may have other responsibilities within the organisation. Whatever model is adopted the lead officer should have this role clearly defined within their job plan have the necessary skills and training to fulfil this function

3.3 The clinical audit lead should build up a network of champions within specialities. This often leads to the formation of a Clinical Audit/Effectiveness Committee to oversee and disseminate results of audits performed.

3.4 The clinical audit lead should be actively involved in linkages to the other aspects of clinical governance to allow for the dissemination of clinical audit information and the setting of local clinical audit priorities.

3.5 The clinical audit lead should have adequate dedicated time and remuneration to achieve these tasks. In an average sized acute trust where the lead is a clinician and there is a clinical audit coordinator or manager this should be at least the equivalent of one PA per week and may require more if the Trust is large or multi-sited. In an ambulance trust or PCT the time spent by the lead will depend on the number of services provided by the trust and the number of additional roles adopted by the individual. Where the lead and manager roles are combined this will almost certainly be a full time appointment.

4. The Clinical Audit Manager

4.1 There has been a trend over the past few years for clinical audit staff to move from being clerks to facilitators and this trend should be encouraged. However, this trend requires a central coordinating focus. The appointment of a central clinical audit manager is essential if audit is to become integrated into clinical governance.

4.2 In acute trusts this will almost certainly be a defined role with a full time appointee. Within PCTs, ambulance trusts and Mental Health trusts it may be a dual role as clinical audit and effectiveness manager.

4.3 In acute trusts there are two main types of audit department in existence. In many Trusts there is a centralised audit department where the manager, facilitators and clerks are sited within one location. This model was the one recommended by the Bristol Royal Infirmary Inquiry (Department of Health 2001)3,4. Alternatively there may be a central office but the facilitators are devolved to directorates. This latter model is often to be found in larger or multi-site trusts. Both have there own advantages and disadvantages. It is often claimed that in the devolved example the facilitators build up closer working relationships with those involved in delivery of care, but the major disadvantage is that they can be diverted to research and simple data collection tasks. A central office has the advantage of avoiding such abuses and can allow a more profitable and flexible use of clinical audit staff expertise, resources and time.

4.4 An added advantage in adopting the model of a centrally managed clinical audit team is that the clinical audit manager can ensure that personal development occurs, skill sharing happens, and opportunities arise for audit staff to share learning from audits with each other. Although both models are possible, it is essential that the clinical audit manager retains overall responsibility for the management of the staffing resource and the allocation of staff. With these factors in mind there are major advantages to the development of a centralised resource.

4.5 In PCTs , ambulance trusts and Mental Health Trusts again there are two main models. The individual trust may have its own manager and/or lead for clinical audit or trusts may link together to develop a centralised resource. In larger organisations the former may be applicable but in smaller organisations there are major advantages in developing a unified resource. Some areas have developed this concept further by having a multi-trust clinical audit department involving both primary and secondary care and mental health services (Barnsley and North Stafford).

4.6 Clinical audit managers should develop links to sources of intelligence on the quality of care such as complaints, litigation, critical incident reporting and risk management so that lessons can be learnt quickly and audit activity can be fine tuned. In some Trusts this has led to mergers between departments resulting in Audit and Effectiveness Units or Clinical Governance Units. This can have advantages, but only with the proviso that the manager protects the time of facilitators to do clinical audit work alongside other pieces of work.

4. The Clinical Audit Manager (cont.)

4.7 Although the Clinical Audit Committee is responsible for developing the Trust's audit programme the manager should project manage the resources to deliver the programme within the desired time-frame.

4.8 The clinical audit manager should decide on the use of facilitators in the creation of data collection tools, in monitoring such data collection (in the main this should be performed by the clinicians involved in the delivery of care), the analysis of data and using the results of the clinical audit to develop and implement action plans to improve patient care and service delivery.

4.9 The manager is responsible for overseeing their staff's training and development.

5. Clinical Audit Facilitators

5.1 Clinical audit facilitators should be managed by the clinical audit manager.

5.2 Clinical audit facilitators should as a minimum understand the principles of the clinical audit process and should have sufficient training to allow them to formulate ideas for a particular project and assist or project manage a small project under the direction of the coordinator.

5.3 At a higher level a clinical audit facilitator should have a comprehensive theoretical understanding of the context and process of clinical audit and be able to project manage large speciality based audit projects from inception to completion.

5.4 At the highest level a clinical audit facilitator should have an understanding of national clinical audit priorities and be able to plan and implement large national and multi-agency clinical audits and advise on the design of re-audit to address changes brought about by action plans.

5.5 Many PCTs, ambulance trusts and Mental Health trusts may not require facilitators but larger multi-trusts probably will, dependent upon their workload.

5.6 Whatever the model ready access to IT support and the training necessary for its application is essential if full and cost effective use is to be made of clinical audit time.

6. Clinical Audit Programme

6.1 The clinical audit lead is responsible for the development of the clinical audit programme in collaboration with the clinical governance lead and clinical audit coordinator.

6.2 This should initially reflect the National Clinical Audit Programme sponsored by the Healthcare Commission, NICE guidance and NSFs and then target local areas of clinical priority and interest. Each audit should reflect ‘Criteria for good audit’ (See appendix 1).

6.3 There is a tendency in many units to decide on audit topics at a late stage and then perform an often hasty and retrospective audit trawl through case notes or old data. The audit programme should decide in advance the audits necessary for the forthcoming year, the time frame for data collection and the design and format of the necessary data collection tools.

6.4 Prospective clinical audit allows for accurate real time accrual of data which reflects current rather than historical practice. Data collection should therefore be 100% accurate both in volume and detail. Case notes or data will be readily available and there is the added advantage that data which never makes it into the notes will be accessible.

6.5 Prospective audit has the further advantage that valuable clinical audit staff time can be allocated in a more fruitful way for the subsequent data analysis and presentation rather than in data collection which should remain the responsibility of clinical staff that have the specialist skills necessary for accurate data collection.

6.6 Retrospective clinical audit can however act as a historical benchmark but is of most use if a critical incident arises (be this complaint, litigation, adverse evident or serious adverse outcome) and a review of practice is required urgently. In the development stage of a clinical audit programme retrospective audit may have a role but attempts should be made to rapidly adopt a greater percentage of prospective audit.

6.7 In addition to national clinical audit topics the choice of further topics should be based on the classic criteria of high volume, high risk, high profile and high cost. Areas where care is recognised to be weak should be targeted as an audit where care is known to be 100% compliant with standards is clearly of little use. This will result in high interest and maximum staff and patient involvement.

6.8 To engage the interest of all members of multidisciplinary teams, clinical audit selection should be targeted on those areas which can maximise the involvement of as many members of the teams delivering care as possible. As a minimum 10% of audits should be across service providers, 30% of audit should be multi-service and 50% should be multi-professional. (see self assessment tool appendix 5)

6. Clinical Audit Programme (cont.)

6.9 Patients, the recipients of care, should not be forgotten is this regard, and should be involved in the preparation of the clinical audit programme, and the design and implementation of the individual audits. Many groups have actively involved patients in the audit process with excellent results (eg Sheffield South West PCT and Bristol).6.10 For each national clinical audit undertaken there should be an identified lead responsible for ensuring data collection, dissemination of findings and agreeing local action for performance development. If the data collection is onerous the clinical audit lead should seek on that individual's behalf contractual time for such work.

6.11 Each local clinical audit should have an identified lead responsible for ensuring data collection, dissemination of findings and agreeing local action for performance development. If the data collection is onerous the clinical audit lead should seek on that individual's behalf contractual time for such work.

7. Resources for Clinical Audit

7.1 The Trust should ensure that there is an identifiable budget for clinical audit including the necessary staff costs. Although this may not be essential for PCTs if clinical audit is not to lose its identity within the organisation it is highly desirable.

7.2 These budgets should be refined as requirements for national clinical audit increase.

7.3 The time necessary to perform good clinical audit is also a funding issue. Medical staff are often allocated time within their contracts for audit activity (commonly between 2 and 4hr per week). Some Trusts have similar time expectations factored into contracts for other non-medical clinicians. It is clearly desirable that time be factored into the contracts of all clinicians required by their Trust to engage in audit activity as recommended by the Bristol Royal Infirmary Enquiry (Department of Health 2001)3,4.

7.4 All staff involved in the delivery of clinical care should participate in clinical audit and should be allowed the appropriate time and facilities to complete this contractual requirement.

7.5 Many Trusts allocate time for audit presentation and discussion. The time spent and scheduling of such time will depend on the organisation itself. This time should be allocated to all members of the relevant multidisciplinary teams. Within PCTs, ambulance trusts and Mental Health trusts there should be protected time set aside for clinical audit issues.

7.6 Those involved in appraisal should assure themselves that this notional time is made available and used appropriately. Registrars of attendance and participation in clinical audit are essential as part of this process and records should be held within the clinical audit department. As a minimum clinicians should be expected to attend 70% of audit meetings and presentations. In some settings contribution to audit has become part of the contracting process. The pharmacy contract requires contribution to one multi-professional audit per year, and general practitioners are required to achieve quality standards as part of the QOF.

7.7 Managers should be actively encouraged to attend audit meetings as they share responsibility for overall quality of care and have a key role to play in helping clinicians to improve services by the development of action plans.

8. Developing a Local Audit Topic

8.1 There is a tendency to set up large multidisciplinary teams and working groups to develop audit proformas and audit tools. Often such exercises are detailed, lengthy and slow to fruition. These techniques may have a role in the development stage of national clinical audit topics, but at a local level they may delay audit, and render any audit tools developed outdated before they are applied.(See Appendix 2 for an Example form to assess the applicability of a particular audit and appendix 3 a tool to score the quality of an audit project).

8.2 Each audit should have a lead, who is responsible for the liaison with colleagues to assure that the audit design is appropriate to the topic and applicable. A short development time will usually maintain interest and enthusiasm.

8.3 There are many sources of established guidelines and protocols which can be readily transformed into audit proformas and these should be used in the development of clinical audit studies. In the future NICE intend to publish master templates for each published guideline to enable a speedier implementation process. It is often more useful to apply a tool first and then further adapt it later than to spend large amounts of time and other resources trying to cover all eventualities.

8.4 Clinical audit staff should be prepared to give advice on the potential sources of data and information and the use of guidelines and protocols in the development of audit tools.

8.5 Clinical audit is not research (See appendix 4 for definitions). Although research may direct audit and audit may lead to the development of a hypothesis which is tested by research they are not mutually inclusive.

8.6 The sample chosen for audit should be small enough to allow for rapid data acquisition but large enough to be representative. In some audits the sample will be time driven and in others it will be numerical. If the data acquisition time is too long interest will be lost and data completeness will often suffer.

8.7 In numerical audits the number of cases selected should reflect the commonness of the condition or therapy, but should be of reasonable number to draw subsequent conclusions.

8.8 In time based audits of common conditions one to three months should be adequate for the majority of audits.

8.9 The IT department of a Trust or central information from the Information Centre should be able to provide an estimate of the volume of a particular clinical condition or treatment to allow the sample size to be determined. The sample size, however, must be statistically sound if the results are to be credible.

8. Developing a Local Audit Topic (cont.)

8.10 As a general rule surgical audits are usually best suited to numerical samples although medical audits function well with both numerical and time related samples. It should be remembered particularly with regard to time related audits that seasons can have a dramatic effect on such samples. In primary care and the acute sector, process audit often shows deterioration in the winter and this should be factored into audit design.

8.11 Too often clinical audit is merely an assessment of process and structures with little thought to outcomes. However determination of outcome is essential if services to patients are to be improved. Audit design must include goals and outcomes. Some goals can be derived from established sources of guideline information such as the Healthcare Commission's national audits, NICE and the Department of Health, but in other cases no such goal exists. In this case a local ideal should be set following consultation with members of the multidisciplinary team. As far as possible all possible sources of evidence should be obtained to make these local goals as effective as possible.

8.12 Outcomes may be measures of access to care (ie time or who should see the patient) or results from care (ie blood pressure reduction in response to therapy). They may also be more direct measures such as death, complication or survival. Survival can be a particularly difficult outcome measure as it requires both case mix adjustment and often long follow up.

8.13 However in many clinical specialities outcome may be difficult to discern and in these cases it may be more useful to use process or even structures as a surrogate outcome measure (ie in stroke audit the presence of a stroke unit and team has been used as a measure on the assumption that this will improve outcome)5.

8.14 Contribution to Confidential Enquires is a statuary requirement for trusts but other types of audit i.e. Note keeping audit can have a direct affect on CNST assessment.

9. Completing the Audit Cycle (Action Planning and Re-Audit)

9.1 Audit should be a quality improvement process and therefore having identified problems or deficiencies in structures or processes or poor outcomes an action plan should be developed to improve either the structures or process of care as this should lead to an improvement in outcome.

9.2 In many instances process improvement alone may have to be used as a surrogate measure for outcome improvement particularly in those areas where the projected outcome improvements are either small or of long duration (ie improvements in thrombolysis times should improve mortality from myocardial infarction)6.

9.3 In surgical specialities outcomes may be more obvious (eg provision and appropriate use of high dependency facilities will reduce cardiovascular, renal and respiratory complications and reduce the risk of death)7. However even with true outcome audit the investigator will still need to know what parts of the process may have contributed to poor outcome. This will either come from published research or local expert knowledge.

9.4 Action plan development may involve refinement of the audit tool particularly if measures used are found to be inappropriate or incorrectly assessed. In other instances new process or outcome measures may be needed or involve linkages to other departments or individuals. Too often audit results in criticism of other organisations, departments or individuals without their knowledge or involvement. Joint audit is far more profitable in this situation and should be encouraged by the Clinical Audit lead and manager. (see targets in section 6.8).

9.5 The action plan must include a review date and identify the individual or individuals responsible for their implementation. 90% of audits with an action plan should be re-audited. (See self assessment tool appendix 5).

9.6 It is to be hoped that re-audit would then demonstrate improvements. If this is sustained some form of monitoring should replace a full audit which could be re-activated should performance deteriorate. This will retain enthusiasm in the audit process and allow a more enervative approach to patient care.

9.7 Results of good audit should be disseminated both locally via the Strategic Health Authorities and nationally where possible and the development of web based tools (in progress at the present time) may assist this process. (see appendix 6 for a assessment tool to monitor NICE guidance and technology appraisals).

10. References

1. NICE. *Principles for Best Practice in Clinical Audit*. Oxford, Ratcliffe Medical Press, 2002

2. Department of Health. *The New NHS: Modern, Dependable*. London. The Stationery Office, 1997.

3. Department of Health. *Learning from Bristol: the Report of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary 1984-1995*. Command paper CM 5207. London: The Stationery Office, 2001.

4. Department of Health. *Learning form Bristol: the Department of Health's Response to the Report of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary 1984-1995*. Command Paper CM 5363. London: The Stationery Office, 2002.

5. The Intercollegiate Stroke Working Party. *National Clinical Guidelines for Stroke. 2nd Edition*. Royal College of Physicians, 2004.

6. The Task Force on the Management of Acute Myocardial Infarction of the European Society of Cardiology. *Management of Acute Myocardial Infarction in Patients Presenting with ST-Segment Elevation*. European Heart Journal 2003;24:28-66.

7. Copeland GP. *The POSSUM system of surgical audit*. Arch Surg 2002:137;15-19

Appendix 1

Local Clinical Audit Criteria
The Top Dozen: Criteria for 'Good Local Clinical Audit'

1. Should be part of a structured programme.
2. Topics chosen should in the main be high risk, high volume or high cost or reflect National Clinical Audits, NSFs or NICE guidance.
3. Service users should be part of the clinical audit process
4. Should be multidisciplinary in nature.
5. Clinical audit should include assessment of process and outcome of care
6. Standards should be derived from good quality guidelines
7. The sample size chosen should be adequate to produce credible results.
8. Managers should be actively involved in audit and in particular in the development of action plans from audit enquiry.
9. Action plans should address the local barriers to change and identify those responsible for service improvement.
10. Re-audit should be applied to ascertain whether improvements in care have been implemented as a result of clinical audit.
11. Systems, structures and specific mechanisms should be made available to monitor service improvements once the audit cycle has been completed.
12. Each audit should have a local lead

Appendix 2

Clinical Audit Project Design Tool
Designed by Anita Green, Sheffield Children's Hospital

Project Title:

Directorate/Dept/Ward/Specialty etc:

Primary Contact(s): principal contact (state name/s and profession/s)	Contact address & contact number:

Lead for this clinical audit : Bleep number/e-mail address:

Context:- **Multidisciplinary –**				
Medical	PAMs	Pts rep	Manager	other
Please name other groups				

Multisectoral/Interface –			
Other Acute	Community	Mental Health	GP
Social services	Education	Public Health	Other
Multi- speciality – please state			

Commissioned	Trust issue	Service dev	Risk or IR	Complaint

Project team members: This team should be multi-professional where possible
(Please state names, professions and contact numbers) (a) Hands on Stakeholders participating in the audit
(b) Clinical Governance Stakeholders not participating in project, but whose support you will need in order to implement change e.g. Clinical manager
Reason for project: e.g. is there a perceived problem; are there new guidelines/evidence based criteria/standards available (e.g. NICE, NSF); is it considered nationally or locally important; is it a high risk/volume aspect of care?

Evidence: what is the quality of evidence on which the criteria/standards are based?	(Please tick)
Ia Meta analysis of RCTs	
Ib At least one RCT	
IIa At least one well designed controlled study without randomisation	
IIb At least one other type of well designed quasi-experimental study	
III Well designed non-experimental descriptive studies such as comparative studies or case studies	
IV Expert committee reports or opinions &/or clinical experiences of respected authorities	
V Other, eg. Previous audit report, hospital documents, other studies	

Main aim of project: what do you hope to achieve? What is the anticipated impact on clinical care, and potential benefit to patients/staff?

Evidence based criteria/standards: Do you have specific statements supported by evidence that describe the objectives of the service and professionally agreed level of performance? These will be measured in the audit.

[*Please attach a full copy of the criteria/standards*]

Where did you find the evidence?	(Please Tick)	
Literature search/research findings		
National guidelines		
Local guidelines (Trust/Directorate/Dept/Ward)		
NICE		
NSF		
Professional body ?		
Other (specify).		
[*Please attach copies of your evidence*]		

Methodology: You will need to think about the following issues; then arrange to come to the Clinical Audit & Effectiveness Unit to develop/confirm the audit method.	
	(Fill in with audit staff support)
Sampling criteria * Population (target group from which sample will come). * Method of sample selection e.g. random. * Estimate of sample size * Level of confidence/convenience sample.	
Method(s) of data collection * Examination of clinical records. . * Observation of practice . . . * Questionnaire * Concurrent/Retrospective/Prospective.	
Data analysis * How will the data be analysed? . .	

Audit resources: Please detail resources you think you will require from the Clinical Audit & Effectiveness Unit /other relevant departments.			
Case note retrieval		Database design	
X-ray retrieval		Data analysis	
Patient Identification/information		Action planning	
Advice on literature review		Advice on report writing	
Developing criteria/standards		Presentation support	
Data capture tool design		Management of change	
Other			

Other Clinical Audit Issues: Please discuss all of these issues with audit staff: (tick the appropriate box when discussions completed)		
	Discussed	State relevancy to your project
Funding (e.g. for the audit process or change management)		
Confidentiality in relation to data collection		
Access to data		
Disclosure of audit results:		
--> *Internal (e.g. Directorate/Trust)*		
--> *External (e.g. Patients/publication)*		
Patient involvement in planning the audit process		
Patient participation in the audit process (e.g. patient questionnaire)		
Ethics/questionnaire committee approval (e.g. dealing with sensitive issues)		
Re-audit		
[*Please add any further comments as a supplementary sheet*]		

Results: you are required to send the following to the Clinical Audit and Effectiveness Unit so they can be entered onto the Trust Clinical Audit Database:		
Audit Results*	Month_____	Year_____
Recommendations *	Month_____	Year_____
Action Plan*	Month_____	Year_____
	Timescale: anticipated date above will be available to Audit Dept	
***A formal report is required for commissioned and trust audits**		

Dissemination: how will you share your findings?	(Please Tick)
Report	
Presentation	
Publication *	
***** All publications, where appropriate, must include all relevant clinical and audit staff in the authorship**	
Presentation: please state presentation date if planned.	**Date:**

Agreement: this section should be signed when the details in this proposal have been agreed, on the understanding that this agreement includes the full audit process (e.g. change management)	
Project Lead: Date:	
Clinical Audit & Effectiveness Unit Lead: Date:	

When it has been signed by all parties, make a photocopy of this form for your own records and send the original to the appropriate Clinical Audit & Effectiveness Unit

Kindly note that no clinical audit project may commence until the Clinical Audit & Effectiveness Lead has signed this form. All projects will be recorded on the Trust project database and given a project identification number.

For Clinical Audit & Effectiveness Department office use only.

Project Ref No:	Priority:	Commissioned	Supported	Trust Programme
Date First Received:		Non-commissioned	Unsupported	Directorate Programme

Audit Proposal Approved	Yes / No	Ref No_____	Date_____
Audit Proposal Priority, *please specify*		(Further Description)	
1 Commissioned – External "must do's"	Yes / No		
2 Trust – Internal "must do's"	Yes / No		
3 Directorate – Ext' & Int' "should do's"	Yes / No		
4 Clinician Interest	Yes / No		
Entered onto database	Yes / No		
Facilitation support level ?	Yes / No		
Agreed start date	**Date:**		

Audit Proposal Rejected	Yes / No
Why? Please specify	

Referred to Research Department ?	Yes / No
Outcome	

Requires further clarification	Yes / No
What clarification, please specify	

Funding issues	Yes / No
Funding contact details	

Comments

Appendix 3

Audit Project Assessment Tool

Criteria	Score	Comment
Topic appropriateness		Maximum score allowed 5
- High volume, high risk, high cost. - As a result of litigation or patient compliant, adverse incident. - National Clinical Audit or NHS Standard	Score 2 Score 2 Score 2	
Standards (evidence based)		Maximum score allowed 5
- Based on nationally agreed best practice eg NICE/NSF - If none available then standards based on SIGN or College guidelines. - Alternatively literature search undertaken, supporting information with regard to the level of evidence identified and the method of consensus. - Patient perspective considered.	Score 3 Score 2 Score 1 Score 2	
Methodology		Maximum score allowed 5
- Multidisciplinary design with service users. - Outcome and process built into design. - Lead responsible clinician identified - Data sources for prospective data collection identified - Adequate audit tool and sample size - Case mix adjustment for outcome assessment	Score 2 Score 2 Score 1 Score 1 Score 1 Score 1	
Intended dissemination of results		Maximum score allowed 5
- Distributed to all stakeholders and service users. - Presented to directorate including managerial team. - Local team presentation - Presentation to regional or national meeting or publication	Score 2 Score 2 Score 1 Score 1	
Potential for change consideration		Maximum score allowed 5
- Lead clinician responsible for action planning identified. - Managerial input into action planning identified. - Potential barriers to change identified. - Potential financial implications and risks identified and prioritised. - Re-audit planned with tool adjustments if necessary - Service monitoring criteria considered.	Score 1 Score 1 Score 2 Score 2 Score 1 Score 1	Some criteria may not be achievable pre-audit
Total (max 25)		Maximum score allowed 25

A score greater than 16 would be regarded as a good clinical audit project.

Appendix 4

Definitions of Audit vs Research
Produced by the Research and Development Forum

Guidance on defining research within the Research Governance Framework for Health and Social Care

Background

This guidance has been collated by the NHS Research and Development Forum as an aid to researchers and NHS R&D staff in determining whether projects should be managed within the Research Governance Framework.

"1.1 Research can be defined as the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods. This document sets out the responsibilities and standards that apply to work managed within the formal research context. Other documents on clinical governance and on quality in the NHS and social care set out standards and systems for assuring the quality of innovative work in non-research contexts."

Research Governance Framework for Health and Social Care, draft second edition, Autumn 2003
http://www.dh.gov.uk/assetRoot/04/02/08/96/04020896.doc

It is clear from the above extract from the Framework that although the NHS has a responsibility for assuring the quality of all work undertaken within the service, not all innovative work should be defined and managed as research. The increasing amount of evaluation, practice development, audit and research within the NHS has resulted in a number of grey areas where it is not easy to distinguish research from other forms of innovative work. Some NHS R&D departments may wish to treat all grey areas as research to avoid the risk of any research not being managed correctly. However, this would result in an unnecessary administrative burden to the people undertaking the work, and an unnecessary management burden and cost to the R&D department. Projects that are not defined as research should therefore be managed within the other appropriate systems in the NHS.

NHS R&D departments are encouraged to develop appropriate links with other relevant departments such as clinical governance and data protection so that procedures are in place to manage the legal and ethical aspects of all types of projects.

Where a proposed project seems difficult to categorise, the aims of the project should be assessed. The project should then be designed to match the purpose.

Ethical review of research

Ethical review by an NHS Research Ethics Committee is required in the circumstances set out below:

"3.1 Ethical advice from the appropriate NHS REC is required for any research proposal involving:
a) Patients and users of the NHS. This includes all potential research participants recruited by virtue of the patient or user's past or present treatment by, or use of, the NHS. It includes NHS patients treated under contracts with private sector institutions.
b) Individuals identified as potential research participants because of their status as relatives of carers of patients and users of the NHS, as defined above
c) Access to data, organs or other bodily material of past or present NHS patients
d) Fetal material and IVF involving NHS patients
e) The recently dead in NHS premises
f) The use of, or potential access to, NHS premises or facilities
g) NHS staff – recruited as research participants by virtue of their professional role"

Governance Arrangements for NHS Research Ethics Committees, July 2001
http://www.dh.gov.uk/assetRoot/04/05/86/09/04058609.pdf

In addition, the Medicines for Human Use (Clinical Trials) Regulations 2004 require that all clinical trials of investigational medicinal products falling within the remit of the regulations should receive a favourable opinion from an appropriate ethics committee.

Medicines for Human Use (Clinical Trials) Regulations 2004
http://www.hmso.gov.uk/si/si2004/20041031.htm

Research meeting the above criteria requires ethical review by an NHS Research Ethics Committee. However, ethical issues are raised in other forms of innovative work, particularly where direct interaction with patients, service users or carers will take place. Where clinical or university ethics committees are not available this work may be referred to an NHS Research Ethics Committee, who may undertake to review the project. Review of these projects within the NHS Research Ethics Committee system does not mean that the project is required to follow the NHS permission process for research as set out in the Research Governance Framework.

For further information on projects that do not require approval by an NHS Research Ethics Committee see sections 1.65 – 1.68 of the Standard Operating Procedures for Research Ethics Committees in the United Kingdom http://www.corec.org.uk/recs/help/docs/SOPs.doc

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Research

"*Research can be defined as the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods.*"
Research Governance Framework for Health and Social Care, draft second edition, Autumn 2003
http://www.dh.gov.uk/assetRoot/04/02/08/96/04020896.doc

Research generates evidence to refute or support or develop a hypothesis. Research aims to investigate what happens if we add or change (manipulate) clinical or service practice in some way, or investigate in a systematic way the views/ opinions/ experiences of stakeholders. It may also require only observation, without any intervention, and may be prospective or retrospective. It may be qualitative or quantitative in approach. Research is designed so that it can be replicated.

Research is likely to involve one or more of the following:
• Usually involves well-defined, often strict selection criteria for the sample selected
• In quantitative research, the sample size is usually defined by statistical methods. In qualitative research, statistical sample calculations and statistical sampling methods may not be applicable. There should however be a clear description of how the sample will be obtained and the selection criteria to be used.
• Usually involves statistical analysis to extrapolate from the sample to a wider population. This includes studies where only simple descriptive statistics such as percentages are appropriate.
• May test a new practice, therapy or drug
• May involve contact with participants
• May involve experiments on human subjects, whether patients, patients as volunteers, or healthy volunteers
• May be invasive
• May involve collecting data from medical records
• May solely involve collecting data from medical records
• May involve examining tissue or body samples
• May involve extra disturbance or work beyond that required for normal clinical management
• May use interviews or questionnaires
• Participants may be randomised
• It is intended to publish and disseminate the results beyond the organisation, generally at conferences or in academic journals.
• The results may change practice if new interventions, tests, etc are shown to be effective.

Clinical Audit

"The overall aim of clinical audit is to improve patient outcomes by improving professional practice and the general quality of services delivered. This is achieved through a continuous process where healthcare professionals review patient care against agreed standards and make changes, where necessary, to meet those standards. The audit is then repeated to see if the changes have been made and the quality of patient care improved. "

Healthcare Commission, 2004
http://www.healthcarecommission.org.uk/InformationForServiceProviders/NationalClinicalAudit/AboutClinicalAudit/

Clinical Audit is directly related to improving services against a standard that has already been set by examining:
1. Whether or not what ought to be happening is happening
2. Whether current practice meets required standards
3. Whether current practice follows published guidelines
4. Whether clinical practice is applying the knowledge that has been gained through research
5. Whether current evidence is being applied in a given situation

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Clinical Audit:
• May or may not involve patient contact but generally does not involve disturbance beyond that required for normal clinical management
• Some audits can potentially require substantial patient/carer input and carry risks of distress and psychological harm
• Participants are never randomised. Participants may receive different treatments or services but allocation of participants to different groups is through normal clinical decision-making processes
• Results are not transferable to other settings
• May use research methodologies eg interviews, statistical analysis
• Standards of good practice are basis of measurement not hypotheses and/or theoretical constructs
• Clinical audit outcome is improved quality of practice; Clinical research outcome is improved knowledge.

Surveys should be designed in such a manner as to cause minimal possible disruption to patients. Where substantial patient/ carer input is necessary ethical approval may be required. Issues such as confidentiality, validity, questionnaire design and whether participants might be distressed or harmed by their involvement should be reviewed by the NHS organisation but not necessarily by the R&D Department. Information on confidentiality and consent issues relating to audit are available from the Healthcare Commission
http://www.healthcarecommission.org.uk/InformationForServiceProviders/NationalClinicalAudit/fs/en.

Service evaluation

"A set of procedures to judge a service's merit by providing a systematic assessment of its aims, objectives, activities, outputs, outcomes and costs"

NHS Executive, 1997 (Quoted in "*An introduction to service evaluation*", Royal College of Psychiatrists Research Unit, www.focusproject.org.uk)

Evaluation provides practical information to help decide whether a development or service should be continued or not. Evaluation also involves making judgements about the value of what is being evaluated.

Evaluation:

- Usually can be designed within an audit framework
- May provide cost and/or benefit information on a service
- Uses quantitative and qualitative data to explore activities and issues
- May identify strengths and weaknesses of services
- May include elements of research eg collecting additional data or changes to choices of treatment

If an evaluation study includes a research project, the research should be managed within the Research Governance Framework.

Consensus Methods

"The focus of consensus methods lies where unanimity of opinion does not exist owing to a lack of scientific evidence or where there is contradictory evidence on an issue. The methods attempt to assess the extent of agreement (consensus measurement) and to resolve disagreement (consensus development)."

J. Jones, D. Hunter; BMJ 1995;311:376-380
http://bmj.bmjjournals.com/cgi/content/full/311/7001/376

Consensus techniques and consensus workshops are a communication process used to inform decision-making where evidence is lacking or contradictory. Consensus methods may be used to agree guidelines, priorities, processes or policy. These include the Delphi method, the nominal group technique and consensus conferences.

Consensus methods:

- May involve interviews and/or questionnaires
- Those involved are partners rather than participants and their names are usually included in any report or publication
- May be used to design a research project
- May be used to decide where research is required

Consensus methods would not normally require ethical approval. Consensus methods may also form part of a research project and, if so, should be managed as research.

Clinical Investigation
Diagnostic tests may be the subject of a research study by a scientist within or outside the NHS. In situations where diagnosis of disease is difficult, NHS staff may request such a diagnostic test, in an attempt to obtain a diagnosis. Where the purpose of requesting the test is to obtain a diagnosis or to determine the appropriate care for a particular patient (or relatives, in the case of genetic disease), the request for the test should not be regarded as research. The person requesting the test does not need to be included in an ethics application and R&D approval from the NHS organisation of the person requesting the test is not required. Where the purpose for requesting the test is to help the scientist in developing a new diagnostic technique, and the aim is to develop the body of knowledge about the technique or the disease, the request for the test should be regarded as part of the research. For further discussion of this complex area see BMJ 2004;329:624
http://bmj.bmjjournals.com/cgi/content/full/329/7466/624
In international collaborations, other countries requirements for ethical approval for participating clinicians may be different.

Case Studies/ Case Reports
Case reports are usually anonymised and there are rarely ethical issues to be considered as long as consent is obtained. However, some journals may require ethical approval prior to publication.

Data management and analysis
Data collected in the course of normal administrative functions of the NHS may be analysed to provide management information to monitor current provision or to plan future developments of the service. Routine data management and analysis is not research. Issues about data protection and confidential information should be handled through normal NHS processes.

Student Research

Student projects should be assessed by the same criteria as above and managed as research, where it is research. Sometimes student projects are audits, and in these circumstances, the projects do not need to be managed as research and ethical approval is not required. Further guidance on student research is being developed by the Central Office for Research Ethics Committees (COREC).

Appendix 5

Self Assessment Tool for Clinical Audit Departments
Developed by Martin Ferris, South Yorkshire Strategic Health Authority

Ref No	Criterion	Data Source / Evidence	Target	Comment
1	The organisation has suitably qualified staff in post to support clinical audit	Human Resources	Staff / resources available to support the clinical audit programme. All staff should be suitably qualified or receiving appropriate training.	The staff in post may be employed by another NHS organisation provided that there is a written agreement, typically a Service Level Agreement, that specifies what level of service may be expected. The agreement should consider the audit criteria below.
2	There is a clinical audit budget that delivers the clinical audit strategy, programmes and associated activities	Audit dept / Finance	There is a budget allocated for clinical audit that will enable the organisation to fulfil its programme and supports audit training and staff development. There is evidence that the budget allocation has been linked to the business planning process of the Trust.	This may be encompassed within a joint clinical audit / effectiveness budget
3	The organisation has a steering committee or other formal group for clinical audit that meets at least quarterly	Organisational structure / Minutes of meetings	Committee/group in place and meeting at least quarterly	This could be encompassed within a joint audit and effectiveness group
4	There is a clinical audit strategy that has been approved by the steering committee and clinical governance committee	Copy of strategy / minutes of meetings	Strategy exists and has been communicated to all appropriate staff	For PCTs, this strategy should also be submitted to the PEC for approval. The strategy should be current.

5	The strategy has been implemented throughout the organisation	Various including staff newsletter / intranet / minutes of meetings	All services to be aware of and following the strategy	Some evidence should be available to demonstrate dissemination of the strategy to clinical audit leads and that it is being followed.
6	There is a up-to-date trust-wide database of clinical audit projects	Audit dept	Database in current use	This need not be an actual electronic database, but there needs to be a record of audits undertaken by the organisation. A paper list or spreadsheet could be acceptable.
7	An annual audit programme exists for the organisation that includes national priorities and is agreed with partner organisations and with trust staff, and has also been approved by the trust's audit committee or steering group.	Clinical audit committee minutes / Audit dept database	All national audits e.g. relevant NICE guidance (see right), NSFs, national sentinel audits, confidential enquiries and other identified priorities are considered for inclusion in the audit programme. Unnecessary, wasteful or inappropriate audits are not initiated with the reasons documented.	"Relevant" NICE guidance is not necessarily all that applies. If an organisation can demonstrate that it already complies with NICE guidance then audit is not necessary. It may also be that funding has not been secured to implement national guidance, in which case appropriate audit(s) may be deferred. However, it is imperative that such exclusions are fully documented, with reasons, in case of external review.
8	There is evidence that unnecessary, wasteful or inappropriate audits are not initiated with the reasons documented	Clinical audit committee minutes / Audit dept database	There should be no inappropriate audits in the annual programme	There is a massive demand for robust or national audits, with limited resources to carry them out.

9	There is regular feedback from the clinical audit sub-group to the clinical governance committee	Clinical governance committee minutes / terms of reference for both groups	Each clinical governance meeting receives feedback from clinical audit and provides advice and direction as appropriate. The chair of the clinical audit sub-group or other nominated is a full member of the clinical governance committee.	
10	Board-approved trust-wide audit programme	Board minutes	Approved audit programme exists	This may be PEC-approved for PCTs.
11	There is a board member lead for clinical audit	Board minutes	Named board member exists	The lead may be for clinical governance, but is expected to be able to lead on issues relating to audit
12	Clinical audit training is available to all staff	Audit dept records	All staff are aware of and have access to training	There should be a range of training options available to all staff from a basic introduction to the opportunity for advanced accredited training for key individuals, including those working wholly within clinical audit
13	Each service has audit projects completed that comply with the definition in "Principles of Best Practice in Clinical Audit"	Audit dept database	At least two per service per year, but see comment (right) and footnote.	Where a management unit of the organisation e.g. directorate contains a number of separate "services", then this is an aggregate total of those services (see footnote).
14	All audits are standards based	Audit dept database	100%. The standards used are recorded when the audit is conducted	

15	There is evidence of multi-professional audit throughout the organisation	Audit dept database	50% of audits within the trust should be multi-professional	All audits should be multi-professional unless there are compelling and recorded reasons why this is not so. It is recognised that there are many opportunities to improve the quality of care by improved working between groups. It is also noted that Ambulance Trusts are essentially uni-professional and that this standard may need to be refined for their particular circumstances. It is expected that this target will be increased over time.
16	There is evidence of multi-service audit throughout the organisation	Audit dept database	30% of audits within the trust are across services	See above
17	There is evidence of audit with other local organisations	Audit dept database / audit committee minutes	10% of audits within the trust are with partner organisations	See above
18	There is evidence that audits have identified a need for a change in practice.	Audit dept database / spot check	90% - it is possible but rare for an audit to be done and no change in practice identified/documented	
19	There is evidence that that action plans have been generated as a result of audits	Audit dept database / spot check	All those that have identified a need for change should create an action plan.	Consideration should be given to random spot-checks of action plans to confirm changes identified

20	There is evidence that all audits which have generated an action plan are re-audited.	Audit dept database	90% of those that have an action plan. All audits that have generated an action plan should be audited, but it is unlikely that this will be 100% of this group, due to service changes, resource limitations etc.	It is recognised that some audits will not need to be repeated.
21	There is evidence that audits involve patients / carers where appropriate	Audit dept database	10% of audits have active patient involvement.	Active patient involvement requires patients etc to be included in the design, conduct and actions within an audit project – not just have audits done to them. N.B. Patients should not be involved in those audits in which they cannot have an impact. This requires careful consideration by staff. It is expected that the target percentage will rise over time.
22	There is evidence of audits which were initiated by other clinical governance areas e.g. risk, complaints	Clinical governance committee minutes	Connection is made between clinical audit and other pillars of clinical governance	No quantifiable target can be set, BUT scrutiny of the minutes of clinical governance meetings would show whether audits had been identified from other sources.

23	There is evidence of audits which feed into other clinical governance areas	Clinical governance committee minutes	Connection is made between clinical audit and other pillars of clinical governance	No quantifiable target can be set, BUT scrutiny of the minutes of clinical governance meetings would show whether audits had been identified from other sources. It is possible, but unlikely, that clinical audit has not interfaced with other clinical governance areas. If so, this should be documented.
24	All audit meetings are multi-professional and include representation from all professions who may be involved and / or affected by audits identified by or reported to the meeting	Audit dept records / Individual dept records	100%	All clinical audit meeting should be multi-professional. It is noted that Ambulance Trusts are essentially uni-professional and that this standard may need to be refined for their particular circumstances
25	All staff should attend service audit meetings and a record should be kept	Individual dept records	Each staff member should attend 70% of service meetings	Individual attendance is unlikely to reach 100% due to patient care / annual leave / other commitments, but every individual should attend most meetings. Where it is not possible for all staff to attend there needs to be some evidence that all staff have an input to and receive information from these meetings.
26	Each service should have an identified lead for clinical audit	Individual dept records / audit dept records	100% of services have an identified lead	

Appendix 6

Monitoring TOOL for NICE guidance and technology appraisals
Based on a design by Lisa Knight, Cheshire and Mersey SHA

Guidance	Applicable	Audit against Guidance		Guidance implemented		
		Yes	No	Fully	Partly	Not at all
BEHAVIOUR						
Technology Appraisals						
Methylphenidate for attention deficit hyperactivity disorder						
Nicotine replacement therapy (NRT) and bupropion for smoking cessation						
Zaleplon, Zolpidem and Zopiclone for the short-term						
CANCER						
Clinical Guideline						
Familial breast cancer: The classification and care of women at risk of familial breast cancer in primary, secondary and tertiary care						
Interventional Procedure						
Interstitial laser therapy for breast cancer						
Photodynamic therapy for advanced bronchial carcinoma						
Laparoscopic radical prostatectomy						
Radiofrequency abalation of hepatocellular carcinoma						
Technology Appraisals						
Capecitabine and tegafur with uracil for metastatic colorectal cancer						
Capecitabine for the treatment of locally advanced or metastatic breast cancer						
Docetaxel, paclitaxel, gemcitabine and vinorelbine for non-small cell lung cancer						
Fludarabine for chronic B-cell lymphocytic leukaemia						
Gemcitabine for pancreatic cancer						
Imatinib for the treatment of unresectable and/or metastatic gastro-intestinal stromal tumours						
Imatinib for chronic myeloid leukaemia						
Irinotecan, oxaliplatin and raltitrexed for advanced colorectal cancer						
Laparocopic surgery for colorectal cancer						

Guidance	Applicable	Audit against Guidance		Guidance implemented		
		Yes	No	Fully	Partly	Not at all
Liquid based cytology for cervical screening						
Paclitaxel in the treatment of ovarian cancer						
Pegylated liposomal doxorubicin hydrochloride (PLDH) for the treatment of advanced ovarian cancer						
Rituximab for aggressive non Hodgkin's lymphoma						
Rituximab for recurrent or refractory stage iii or iv follicular non-Hodgkin's lymphona						
Taxanes for breast cancer (review)						
Temozolomide for maliganant glioma (brain cancer)						
Topotecan for advanced ovarian cancer						
Trastuzumab for advanced breast cancer						
Vinorelbine for the treatment of advanced breast cancer						
CARDIOVASCULAR						
Clinical Guidelines						
Hypertension: management of hypertension in adults in primary care						
Chronic heart failure - Management of chronic heart failure in adults in primary and secondary care						
MI prophylaxis - drug treatment, cardiac rehabilitation and dietary manipulation						
Interventional Procedures						
Balloon angioplasty of pulmonary vein stenosis in infants						
Balloon angioplasty with or without stenting for coarctation or recoarctation of the aorta in adults and children						
Balloon dilatation of pulmonary valve stenosis						
Balloon dilatation of systematic to pulmonaryarterial shunts in children						
Balloon dilatation with or without stenting for pulmonary artery or non-valvar right ventricular outflow tract obstruction in children						
Balloon valvuloplasty for aortic valve stenosis in adults and children						
Endovascular atrial septostomy						

Guidance	Applicable	Audit against Guidance		Guidance implemented		
		Yes	No	Fully	Partly	Not at all
Endovascular closure of atrial septal defect						
Endovascular closure of patent ductus arteriosus						
High-flow interposition extracranial to intracranial bypass						
Intraoperative fluorescence angiography for the evaluation of coronary artery bypass graft patency						
Laser sheath removal of pacing leads						
Radiofrequency valvotomy for pulmonary atresia						
Stent placement for vena caval obstruction						
Subfascial endoscopic perforator vein surgery						
Thrombin injections for pseudoaneurysms						
Endovenous laser treatment of the long saphenous vein						
Non-surgical reduction of the myocardial septum						
Off-pump coronary artery bypass						
Partial left ventriculectomy (the Batista procedure)						
Radiofrequency ablation or varicose veins						
Stent-graft placement in abdominal aortic aneurysm						
Transilluminated powered phlebectomy for varicose veins						
Technology Appraisals						
Clopidogrel in the treatment of non-ST-segment-elevation acute coronary syndrome						
Coronary artery stents						
Early thrombolysis drugs for acute myocardial infarction						
Glycoprotein llb/llla inhibitors in the treatment of acute corary syndromes (review)						
Implantable cardioverter defibrillators for arrhythmias						
Myocardial perfusion scintigraphy for the diagnosis and management of angina and myocaridal infarction						
CENTRAL NERVOUS SYSTEM						
Clinical Guidelines						

Guidance	Applicable	Audit against Guidance		Guidance implemented		
		Yes	No	Fully	Partly	Not at all
The epilepsies: the diagnosis and management of the epilepsies in adults and children in primary and secondary care						
Interventional Procedure						
Lumbar subcutaneous shunt						
Selective peripheral denervation for cervical dystonia						
Stereotactic radiosurgery for trigeminal neuralgia using the gamma knife						
Subthalamotomy for Parkinson's disease						
Supraorbital minicraniotomy for intracranial aneurysm						
Deep brain stimulation for Parkinson's disease						
Vagus nerve stimulation for refractory epilepsy in children						
Technology Appraisals						
Beta interferon and glatiramer acetate for multiple sclerosis						
Donepezil, rivastigmine and galantamine for Alzheimer's disease						
Multiple sclerosis - Management of multiple sclerosis in primary and secondary care						
Newer drugs for epilepsy in adults						
Newer drugs for epilepsy in children						
Riluzole (Rilutek) for motor neurone disease						
DENTAL, ORAL AND FACIAL						
Clinical Guidelines						
Dental recall: recall interval between routine dental examinations						
Interventional procedure						
Exposed customised titanium implants for orofacial reconstruction						
Stereotactic radiosurgery for trigeminal neuralgia using the gamma knife						
Technology Appraisal						
Wisdom teeth - appropriate removal						
EAR, NOSE AND THROAT						
Interventional Procedure						

Guidance	Applicable	Audit against Guidance		Guidance implemented		
		Yes	No	Fully	Partly	Not at all
Coblation tonsillectomy						
Cyanoacrylate instillation for occulsion of parotid sinuses						
Endoscopic stapling of pharyngeal pouch						
Radiofrequency volumetric tissue reduction of turbinate hypertrophy						
Technology Appraisal						
Hearing aid technology						
ENDOCRINE AND METABOLIC						
Clinical Guidelines						
Type 1 diabetes: diagnosis and management of type 1 diabetes in children, young people and adults						
Management of type 2 diabetes: management of blood glucose						
Management of type 2 diabetes: management of blood pressure and blood lipids						
Management of type 2 diabetes: renal disease - prevention and early management						
Management of type 2 diabetes: retinipathy - early management and screening						
Type 2 diabetes - Prevention and management of foot problems						
Interventional Procedure						
Endoscopic transsphenoidal pituitary adenoma resection						
Islet cell transplantation						
Technology Appraisals						
Continuous subcutaneous insulin infusion for diabetes						
Glitazones for the treatment of type 2 diabetes						
Human growth hormone (somatropin) in adults with growth hormone deficiency						
Human growth hormone (somatropin) in children with growth failure						
Long-acting insulin analogues for the treatment of diabetes - insulin glargine						
Patient-education models for diabetes						
EYE						

Guidance	Applicable	Audit against Guidance		Guidance implemented		
		Yes	No	Fully	Partly	Not at all
Interventional Procedures						
Arteriovenous sheathotomy for branch retinal vein occlusion						
Insertion of hydrogel keratoprosthesis						
Scleral expansion surgery for presbyopia						
Transpupillary thermotherapy for age-related macular degeneration						
Macular translocation for age-related macular degeneration						
Radiotherapy for age-related macular degeneration						
Technology Appraisal						
Photodynamic therapy for age-related macular degeneration						
GASTROINTESTINAL						
Clinical Guidelines						
Dyspepsia: management of dyspepsia in adults in primary care						
Interventional procedure						
Artificial anal sphincter implantation						
Photodynamic therapy for high-grade dysplasia in Barrett's oesophagus						
Radiofrequency ablation for the treatment of colorectal metastases in the liver						
Selective internal radiation therapy for colorectal metastases in the liver						
Circular stapled haemorrhoidectomy						
Complete cytoreduction for pseudomyxoma peritonei (Sugarbaker Technique)						
Endoscopic Injection of bulking agents for gastro-oesophageal reflux disease						
Extracorporeal albumin dialysis for acute-on-chronic liver failure						
Laparo-endogastric surgery						
Percutaneous pancreatic necrosectomy						
Sacral nerve stimulation for faecal incontinence						
Technology Appraisals						
Laparoscopic surgery for inguinal hernia repair						
Infliximab for Crohn's disease						

Guidance	Applicable	Audit against Guidance		Guidance implemented		
		Yes	No	Fully	Partly	Not at all
Laparoscopic surgery for ingyinal hernia						
Proton pump inhibitors for dyspepsia						
GYNAECOLOGY, PREGNANCY AND CHILDBIRTH						
Clinical Guidelines						
Antenatal Care: Routine care for the healthy pregnant woman						
Caesarean Section						
Electronic Fetal Monitoring						
Fertility: Assessment and Treatment for people with fertility problems						
Fluid-filled thermal balloon and mircrowave endometrial ablation techniques for heavy menstrual bleeding						
Induction of Labour						
Interventional Procedures						
Fallopian tube recanalisation by guidewire						
Falloposcopy with coaxial catheter						
Uterine artery embolisation for the treatment of fibroids						
Balloon thermal endometrial ablation						
Bone-anchored cystourethropexy						
Free fluid thermal endometrical ablation						
Hysteroscopic sterilisation by tubal cannulation and placement of intrafallopian implants						
Laparoscopic helium plasma coagulation of endometriosis						
Laparoscopic laser myomectomy						
Laparoscopic radical hysterectomy for early stage cervical cancer						
Magnetic resonance (MR) image-guided percutaneous laser ablation of uterine fibroids						
Microwave endometrial ablation						
Photodynamic endometrial ablation						
Uterine artery embolisation for fibroids						
Technology Appraisals						
Routine antenatal anti-D prophylaxis for RhD negative women						

Guidance	Applicable	Audit against Guidance		Guidance implemented		
		Yes	No	Fully	Partly	Not at all
Tension-free vaginal tape (Gynecare TVT) for stress incontinence						
INFECTIONS AND INFECTIOUS DISEASES						
Clinical Guidance						
Infection control - Prevention of healthcare-associated infection in primary and community care						
Technology Appraisals						
Interferon alfa (pegylated and non-pegylated) and ribavirin for the treatment of chronic hepatitis C						
Drotrecogin alfa (activated) for severe sepsis						
Oseltamivir and amantadine for the prophylaxis of influenza						
Zanamivir, oseltamivir and amantadine for the treatment of influenza						
INJURIES AND ACCIDENTS						
Clinical Guideline						
Pre-hospital initiation of fluid replacement therapy in trauma						
Triage, assessment, investigation and early management of head injury in infants, children and adults						
MENTAL HEALTH						
Clinical Guideline						
Self-harm: The short-term physical and psychological management and secondary prevention of self-harm in primary and secondary care						
Core interventions in the treatment and management of schizophrenia in primary and secondary care						
Eating disorders - Core interventions in the treatment and management of anorexia nervosa, bulimia nervosa and related eating disorders						
Technology Appraisals						
Computerise cognitive behavioural therapy for anxiety and depression						
Electroconvulsive therapy						

Guidance	Applicable	Audit against Guidance		Guidance implemented		
		Yes	No	Fully	Partly	Not at all
Newer (atypical) antipsychotic drugs for schizophrenia						
Olanzapine and valproate semisodium in the treatment of acute mania associated with bipolar I disorder						
MUSCULO-SKELETAL						
Interventional Procedure						
Endoscopic division of epidural adhesions						
Percutaneous endoscopic laser thoracic discectomy						
Percutaneous intradiscal electrothermal therapy for lower back pain						
Percutaneous intradiscal radiofrequency thermocoagulation for lower back pain						
Balloon kyphoplasty for vertebral compression fractures						
Computed tomography-guided thermocoagulation of osteoid osteoma						
Endoscopic laser foraminoplasty						
Extracorporeal shockwave lithotripsy for cacific tendonitis (tendinopathy) of the shoulder						
Laser lumbar discectomy						
Minimally invasive placement of pectus bar						
Needle fasciotomy for Dupuytren's contracture						
Percutaneous vertebroplasty						
Technology Appraisals						
Anakinra for rheumatoid arthritis						
Autologous cartilage transplantation for full thickness cartilage defects in knee joints						
Cyclo-oxygenase (Cox) II selective inhibitors, celocoxib, rofecoxib, meloxicam and etodolac for osteoarthritis and rheumatoid arthritis						
Etanercept and infliximab for rheumatoid arthritis						
Hip protheses for primary hip replacement						
Metal on metal hip resurfacing arthroplasty						
NUTRITIONAL DISORDERS AND WEIGHT CONTROL						

Guidance	Applicable	Audit against Guidance		Guidance implemented		
		Yes	No	Fully	Partly	Not at all
Technology Appraisals						
Orlistat for obesity in adults						
Sibutramine for obesity in adults						
Surgery to aid weight reduction for people with morbid obesity						
RENAL AND URINARY						
Interventional Procedure						
Extracorporeal shockwave therapy for Peyronie's disease						
Holmium laser prostatectomy						
Laparoscopic cystectomy (of the urinary bladder)						
Laparoscopic pyeloplasty						
Laparoscopic live donor simple nephrectomy						
Percutaneous radio-frequency ablation of renal cancer						
Sacral nerve stimulation for urge incontinence and urgency-frequency						
Sacral nerve stimulation for urge incontinence						
Transurethral electrovapouisation of prostate (TEVAP)						
Transurethral radiofrequency needle ablation of prostate (TUNA)						
Technology Appraisals						
Immunosuppressive therapy for renal transplantation in adults						
Home compared with hospital haemodialysis for patients with end-stage renal failure						
RESPIRATORY						
Clinical Guideline						
Chronic obstructive pulmonary disease - Management of chronic obstructive pulmonary disease in adults in primary and secondary care						
Interventional Procedure						
Extracorporeal membrane oxygenation (ECMO) in adults						

Guidance	Applicable	Audit against Guidance		Guidance implemented		
		Yes	No	Fully	Partly	Not at all
Extracorporeal membrane oxygenation (ECMO) in postneonatal children						
Technology Appraisals						
Inhaler devices for chronic asthma in older children (aged 5-15)						
Inhaler systems for under-5s						
SKIN DISORDERS AND WOUNDS						
Clinical Guideline						
Pressure ulcer prevention - Pressure ulcer risk assessment and prevention, including the use of pressure-relieving devices (beds, mattresses and overlays) for the prevention of pressure ulcers in primary and secondary care						
Technology Appraisals						
Frequency of application of topical corticosteroids for atopic eczema						
Intralesional photocoagulation of subcutaneous congenital vascular disorders						
Tacrolimus and pimecrolimus for atopic eczema						
Debriding agents and specialist wound care clinics for difficult to heal surgical wounds						
MISCELLANEOUS						
Clinical Guideline						
Preoperative tests - The use of routine preoperative tests for elective surgery						
Technology Appraisals						
Ultrasound locating devices for placing central venous catheters						

Appendix 7

Clinical Audit Patient Panel (CAPP)

Why create a clinical audit patient panel?

Past CHI reviews indicate that primary care trusts demonstrate minimal patient involvement in how primary care services are delivered.

How do we know we are delivering the best care to a patient? There are evidence-based NICE technology appraisals and clinical guidelines as well as National Service Frameworks, but do we really know what the patient wants or expects from a service? If we are to improve services and ensure that patients feel that they have ownership of their care, what do we do to ensure that patients remain at the centre of the organisation and that they can be heard through active patient involvement?

When involving patients it must be clear from the very start why the patient is involved and how they are expected to assist the service. Balogh et al (1995) stated that users can be genuine collaborators, rather than merely sources of data. Clinical audit assists and develops services in improving patient care; therefore it appeared only logical to create a Clinical Audit Patient Panel (CAPP).

Involving patients is key to developing services. They can tell us a range of things: how to communicate, how we make them feel, how convenient the service is, how we respect them and their culture, whether we involve them in decisions and whether they trust us. When designing a patient questionnaire to find out how well patients think the service is, are we asking them the right questions, are we asking them things that are of no importance to them and what they actually feel is most relevant has never been asked? Would it be better for a member of staff to go through a patient questionnaire with a patient or for a patient to go through it with another patient? Recent projects indicate that a patient is more likely to tell another patient something that they would never mention to their health care provider.

Creating a panel

To date, very few audits involve patients and most of these have had only token patient input. A panel of trained patients can advise, support and improve clinical audit activity within a trust enabling service user's and carer's perspectives to be included in evaluating quality and to identify opportunities for improvement. Members can be actively involved in all phases of the project from initiation to completion.

To ensure active involvement it is essential that all panel members have a basic knowledge and understanding of clinical audit and therefore, basic clinical audit training should be given on how audits are done, why they are done and what audit can achieve if done properly. A clinical audit guide should also be provided for each panel member.

To ensure confidentiality, all trained patients wishing to become part of a panel must sign a confidentiality agreement approved by the Caldicott Guardian. Once members have received training and signed to be part of the panel they are then available to the organisation to assist in developing and improving services through clinical audit and patient questionnaires.

As part of the training the concerns and benefits of patient involvement from staff and patients should be discussed. Issues such as a patient feeling that their views are not taken seriously, that they will look foolish, won't understand issues and that what they say or do may affect their future care. Issues around staff feeling that they are being criticised, involvement undermines their role, it will affect a doctor / patient relationship and that it may result in loss of patient confidence. All of these should be discussed and reassured by the policy that patients will not work with their own GP practice or a service that they are currently accessing.

Sheffield South West PCT - Operational panel

A panel of 8 members are currently available to work with PCT services and independent contractors. All service areas have the opportunity to put forward audit projects with the possibility of involving a member of the panel. This concept has been accepted widely resulting in all of the panel members currently working with staff on audit projects. The audit projects currently in existence are as follows:

- Older People's National Service Framework - Standard 1, Age Discrimination
- DoH policy and guidance, Intermediate Care Services - Effectiveness of service, patients perception
- DoH initiative, Expert Patients Panel (EPP)
- Therapy Services - patient questionnaire redesigned and implemented
- COPD care pathway - 1-1 discovery interviews carried out between health care professional, panel member and patient
- DoH, Free Nursing Care policy and guidance - audit of new care records

The panel have been available to advise, support and improve clinical audit activity within the trust by supporting services and by enabling service user's and carer's perspectives to be included in evaluating quality and to identify opportunities for improvement. Each panel member has signed a confidentiality agreement, which has strengthened their accountability and reassured staff that all information is kept within highest confidence. Members of the panel have been able to get involved with services at the very beginning of the project to support and advise right through to the final report stage.

Where users are involved in audit projects, careful thought needs to be given to issues of access, preparation and support (Kelson, 1998). All panel members have received clinical audit training to gain a basic knowledge and understanding of clinical audit, how audits are done, why they are done and what audit can achieve if done properly. Since setting up the panel the process for identification of audit projects is that a member of staff identifies an audit and requests for a panel member to be involved. The Clinical Effectiveness Manager reviews the project criteria and makes the decision to involve a patient on the following; is it audit (not data collection), why a panel member should be involved, how a panel member should be involved and if acceptable identify a panel member to be part of the audit project. Once a panel member(s) has agreed to be involved in the project an initial meeting will be set up for the panel member to meet the project lead and any other relevant staff. The Clinical Effectiveness Manager attends the first meeting and others thereafter if the panel member or service request so.

As listed above, there are several audit projects currently running with panel member involvement. These projects may have one or more panel members working on the project, depending totally on the preference of the panel member. Some panel members prefer to work in pairs. It is expected that panel members will work in pairs until their confidence and experience has grown after which they will work alone with services where appropriate. Various presentations and information regarding the panel has been shared with including; Department of Health, Healthcare Commission, National Audit and Governance Group (NAGG) and with other colleagues via National Primary Care Trust and Development Programme (Natpact). Further presentations have been delivered at Clinical Audit 2005 (23-24 Feb) and a joint presentation with a panel member will be given at the Patient Involvement, Empowerment and Information conference (25-26 May).

Below, are comments made by both panel members and staff after working together on audit projects:

Staff

"Can see how patient involvement can really help"

"Will not hesitate in involving patients again"

"Feel very positive"

"Will not hesitate again in involving patients"

Panel members

"Really useful"

"Allows end users to have input into care"

"Feel like I'm making a difference"

"Member has seen possible drawbacks which we did not see"

In October 2004 the CAPP had its first general meeting where all members were able to meet each other. An agenda was prepared in advance with panel member input. Agenda items discussed included; terms of reference, operational issues, chair of the group and representation on the Trust Evidence Based Practice group. Standing agenda items were agreed for future meetings and these included feedback from each panel member relating to their audit project including experiences of what worked well and what did not and identifying areas of improvement. The group agreed to meet twice yearly.

7 more patients have expressed an interest in being part of the panel. A training and information event for new members will take place in March 2005.

Involving patients in clinical audit will help the trust take forward patient-driven services and to do this effectively we have taken the first steps in giving patients a real opportunity to help us rather than what has often been a mere token.

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