ACADEMY OF
MEDICAL ROYAL
COLLEGES

CLINICAL AUDIT AND REVALIDATION

REPORT AND RECOMMENDATIONS

THE ACADEMY CLINICAL AUDIT WORKING GROUP
DECEMBER 2009

Designed and Typeset by
Millbank Media Ltd

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1. INTRODUCTION

Revalidation is the process by which doctors will have to demonstrate to the General Medical Council (GMC) that they are up to date, are fit to practise and are complying with the relevant professional standards.

The information that doctors will need to provide for revalidation will be drawn largely from their actual practice. The information required will include evidence of participation in clinical audit and evidence that the doctor has both reflected and acted on the results of clinical audit. This information will be considered at a doctor's annual appraisal. The outputs of appraisal and other collated information will lead to a revalidation recommendation about the doctor to the GMC from a responsible officer. This single recommendation will cover both relicensing and, for doctors on the GP register or the specialist register, recertification. The revalidation cycle is likely to be every five years.

2. THE ACADEMY CLINICAL AUDIT WORKING GROUP

2.1 Aims and objectives of the working group

It was agreed that the objectives of the Academy Clinical Audit working group (the working group) were to discuss and define:

- What activities can be considered clinical audit
- Principles for the use of clinical audit in revalidation
- Criteria and key indicators for demonstrating involvement by a doctor in the process of clinical audit
- Criteria and key indicators for demonstrating reflection and action in response to the results of clinical audit
- Agree the criteria and indicators of a good clinical audit project previously developed by Healthcare Quality Improvement Partnership (HQIP).

2.2 Membership

The working group contained representatives from HQIP, GMC and a number of Colleges and Faculties, including individuals associated with the development of national and local clinical audits. The group participated in two workshops, one in June and one in July 2009.

Chair	
Paul Lelliott	**Chair, HQIP and Royal College of Psychiatrists**
Robin Burgess	HQIP
Malcolm Braithwaite	Faculty of Occupational Medicine
Fiona Browne	General Medical Council
Jo Cripps	Royal College of Surgeons of England
Charnjit Dhillon	Royal College of Obstetricians and Gynaecologists
Anna Henderson	Royal College of General Practitioners
Jane Ingham	Royal College of Physicians London
John Kemm	Faculty of Public Health
Stella Macaskill	Royal College of Pathologists
Louise Povey	General Medical Council
Kashif Quereshi	Royal College of Ophthalmologists
Rita Ranmal	Royal College of Paediatrics and Child Health
Eve Riley	HQIP
Kirstyn Shaw	AoMRC Revalidation Project Manager
John Sparrow	Royal College of Ophthalmologists
Elaine Tait	Royal College of Physicians Edinburgh
Elaine Young	HQIP

3. PRINCIPLES AND CRITERIA DOCUMENT

One of the primary objectives of the working group was to draft a series of principles, criteria and key indicators for the use of clinical audit in revalidation. A copy of this document is provided in Appendix A.
The content of this document was based as far as possible on existing research and evidence about clinical audit. However, in those areas where evidence was limited, the working group used a consensus approach. The criteria and key indicators document contains an appendix outlining indicators of best practice in clinical audit which were developed independently by HQIP as part of their work in support of reinvigorating local and national clinical audit.

4. STAKEHOLDER ENGAGEMENT EXERCISE

After completing an initial draft, the Principles and Criteria document was circulated as part of a stakeholder engagement exercise to gather feedback on its structure and content. The document was sent to a number of key stakeholders including the Medical Royal Colleges and Faculties, General Medical Council, British Medical Association, Department of Health and the Revalidation Support Team. A total of 24 organisations were contacted and 15 provided feedback giving a 63% response rate. Of those who responded:

- 10 Colleges and Faculties
- One Department of Health
- Four Stakeholder organisations.

The stakeholder engagement exercise ran for a period of three weeks in September 2009. Respondents were universally positive about the language, tone, format, clarity, scope and usefulness of the document. Some felt the document was too long and at times repetitive with the indicators appendix being aspirational rather than reflecting current practice. A number or respondents suggested that doctors would benefit from more detail around the type of information they could collect and present at appraisal to demonstrate their involvement in clinical audit, with the majority indicating that they would find it difficult to collect supporting information. Finally, half of the respondents indicated that the document should refer to other quality improvement activities undertaken by doctors including outcomes data and registries.

5. RECOMMENDATIONS AND FURTHER WORK

The working group acknowledges that the recommendations set out in this document may evolve as the processes and implementation of revalidation are more clearly defined. Following their deliberation, the Group have the following recommendations:

- *Guidance for appraisers on how to review clinical audit in appraisal should be developed by HQIP in collaboration with other key stakeholders.*
- *Further clarification is needed about how clinical audit might relate to other quality improvement activities undertaken by doctors and used as supporting information for revalidation*
- *The resource implications of increased clinical audit activity by doctors in response to revalidation should be further investigated.*

APPENDIX A: CLINICAL AUDIT AND REVALIDATION REPORT

1 Introduction

This document sets out the principles and criteria for the use of information about a doctor's involvement in clinical audit in revalidation. It provides guidance for doctors, for the appraisers (with whom they will discuss clinical audit in the context of appraisal) and for responsible officers. They are also intended to help those involved in designing and supporting local and non-local clinical audit projects.

2 The Definition of Clinical Audit

For the purpose of revalidation, the GMC will use the definition of clinical audit proposed by the National Institute for Health and Clinical Excellence (NICE).[1]

"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 review of change. Aspects of the structure, process and outcome 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."
(NICE, 2002)

Clinical audit can be conducted at all levels of healthcare. These include:

- the practice of an individual doctor
- the care provided by a clinical team of which a doctor is a member
- the care provided by a directorate or a whole provider service
- care provided by many separate clinical providers across a region or a country.

For the purpose of revalidation, clinical audit activity will be categorised as either "local"[2] or "non-local" . Local clinical audit focuses on aspects of care that have been identified as a priority by the individual clinician, clinical team or provider service. Non-local clinical audit focuses on aspects of care that have been identified as a priority at a regional, national or specialty level and involves clinicians and clinical teams from a number of provider services.

[1] Some doctors, such as medical managers and those working in public health and pharmaceutical medicine do not provide direct clinical care to patients. These doctors will have to demonstrate that they engage in quality improvement activities that are relevant to their work. These activities should be systematic and will be expected to have similar attributes to the indicators listed in section 3.2.

[2] "Non-local audit" includes multi-site, regional, national, international and specialty clinical audit initiatives.

Doctors participate in a range of other regional, national and specialty quality improvement activities that gather information about the quality or outcomes of clinical care. These include contributing data to:

- National registries
- National outcomes projects
- Confidential inquiries
- National and regional observatories
- Professionally led quality improvement and service accreditation programmes.

For the purpose of revalidation, a doctor should provide any relevant information about their involvement in clinical audit and/or any of these related quality improvement activities as evidence to demonstrate their practice for revalidation.

3 Principles, criteria and key indicators for clinical audit and revalidation

3.1 Principles

The following principles are broad contextual statements that outline the fundamental requirements about clinical audit and revalidation. The criteria should be considered in the context of the revalidation cycle and in accordance with any relevant specialist revalidation guidance.

- Doctors undertaking clinical activities must participate actively in high quality clinical audit. This should include local clinical audit and non-local clinical audit that relates to the doctor's specialty. Doctors, including those whose work is not amenable to clinical audit, should also participate in other systematic quality improvement activities that are relevant to their work
- A doctor must reflect on the results of local and non-local clinical audit that relate to the doctor's practice or to the care provided by the doctor's clinical team
- Participation in clinical audit includes the taking of appropriate action in response to the results of local and non-local clinical audit that relate to the doctor's practice or to the care provided by the doctor's clinical team.

3.2 Criteria and Key Indicators

A doctor's involvement in clinical audit must meet the following criteria to be acceptable to the GMC for revalidation.

	CRITERIA	KEY INDICATORS
Principle 1: Participation in High Quality Clinical Audit		
1	The doctor participates actively in local clinical audit	1.1 The doctor is involved in selecting the audit topic, designing the audit or assisting with data collection, analysis and presentation 1.2 The doctor attends meetings at which the design and/or results of clinical audit are discussed
2	The doctor participates actively in non-local clinical audit, or related quality improvement initiatives that are relevant to their specialty	2.1 Data about the doctor's clinical activities, or data about the clinical activities of the team of which the doctor is a member, are submitted to those managing national clinical audits, or related quality improvement initiatives, that are relevant to the doctor's specialty
3	Clinical audit projects that the doctor participates in are designed to address the criteria and indicators of a high quality clinical audit	3.1 Appendix 1 sets out the criteria and indicators of a high quality clinical audit. This document outlines the ideal or gold standard qualities that clinical audit projects should strive to achieve

Principle 2: Reflection on the Results of Clinical Audit		
4	The doctor reflects on the results of clinical audit	4.1 The doctor has made reflective notes in their appraisal folder about the implications for them of the results of clinical audit 4.2 The doctor has discussed the results of clinical audit at peer-supervision, professional development and/or multidisciplinary team meetings

Principle 3: Taking Action on the Results of Clinical Audit		
5	The doctor acts in response to the results of local and non-local clinical audit	5.1 The doctor has developed, or participated in the development of, an action plan, based on the results of clinical audit 5.2 The doctor has informed colleagues, including non-clinical managers, of findings of clinical audit and of any action required 5.3 The doctor has considered the results of re-audit to assess whether improvement has occurred or good practice has been maintained
6	The doctor demonstrates at their appraisals that they have assured the quality of their practice through ongoing participation in local and non-local clinical audit	6.1 The doctor has presented evidence drawn from clinical audit and re-audit at appraisals that confirms improvement in practice has occurred or that good practice has been maintained
7	The doctor demonstrates at their appraisals that their participation in local and non-local clinical audit has contributed to their professional development	7.1 The doctor presents evidence that demonstrates reflection and change in their practice following participation in clinical audit; and this is represented in their personal development plan

APPENDIX TO THE CLINICAL AUDIT AND REVALIDATION REPORT: CRITERIA AND INDICATORS OF BEST PRACTICE IN CLINICAL AUDIT (HQIP 2009)

Definition of Clinical Audit

"Clinical audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care 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."

National Institute for Clinical Excellence, 2002

Introduction

The purpose of this guidance is to define the markers or indicators of good quality clinical audit, at both national and local level, conducted by both individuals and more commonly, by teams, taking into account the views of those active in audit at all levels – clinicians, managers and audit specialists.

The purpose of this activity was to set an agreed, definitive, widely consulted, consensus standard for audit quality which could then be used in other processes. These include; revalidation of individual professionals; the allocation of funding for audit; the offer of support, such as from audit departments, for audits proposed by provider teams; the accreditation or kite marking of audits and audit departments; the performance management of audit teams; the commissioning of services; and in regulation and performance management of healthcare.

The aims of the process were to be inclusive, by engaging people (including patients) from a range of disciplines, roles, and locations, as well as experience and orientation and use of audit; to draw from the history and experience of audit over the last forty years, starting work from accepted and agreed definitions instead of re-inventing terminology; and be thorough and extensive, by consulting widely and in phases at greater levels of detail, which allowed participants to reflect on their original views given the subsequent contributions of others, and re-contribute.

Process

This list of criteria has been derived from these stages:

a. An identification of a wide number of pre-existent but recent definitional lists of quality indicators for audit from the international literature
b. From these, a synthesis document which incorporated the common elements was compiled and used as the basis for consultation
c. A series of focus groups conducted after open invite with those who run national audits and work locally on audit including methodologists, clinicians, managers and audit staff, including representatives from professional bodies for several disciplines. These were held across England and involved 65 people
d. Further focus groups of patients with experience of involvement in audit on a range of conditions
e. Two workshops with attendees at the Healthcare Quality Improvement Partnership (HQIP) national conference of local audit practitioners (a further 60 people)
f. Wide email consultation with HQIP's list of contacts, which reflects the groups listed above; a total of 250 participants
g. Further consultation with the National Clinical Audit Advisory Group
h. Revalidation workshops that have discussed these criteria as a tool in the revalidation process, including members of the Academy of Royal Colleges
i. A final email consultation with all the above with the updated version.

Outcomes

These processes have led to the following key headings being identified below, with definitional expansion in each case as to what the heading means, derived from the views expressed in focus group work and the broader consultation.

The consistent consensus view was that good audit has to have four essential stages of activity to be considered a high quality audit:

Stage 1: Preparation and Planning
Stage 2: Measuring Performance
Stage 3: Implementing change
Stage 4: Sustaining Improvement

Quality in audit is then further defined by detailed indicators or markers under each heading, set out below. These stages, and the definitional markers of quality within them, are common to both national and local audit work, although some of the emphasis will as of necessity be different.

Following the Criteria

Given this diversity, not every criterion or indicator will apply to every clinical audit project undertaken by every speciality, nor will they be relevant for consideration of audit products in all of the processes outlined above. The list given here represents a ‘gold standard’ that would apply to an ideal clinical audit project. In the circumstance that a criterion or indicator cannot be applied, the reason should be followed and omissions made with exception and explanation.

The criteria have been designed to apply in principle to all types of audit – outcome, process and input, at the local, regional and national level, and against audits carried out by all professional disciplines; although inevitably some criteria are more applicable to one setting or another, or will need adaptation to specific settings.

Additional guidance for those applying these criteria in some specific settings will be developed as part of further HQIP work streams.

CRITERIA	KEY INDICATORS	REMARKS
STAGE 1: PREPARATION AND PLANNING		
1 The topic for the audit is a priority	1.1 The audit topic reflects a local service, speciality or national priority which merits evaluation and where care could be improved or refined through audit	Some topics will be maintenance audits
	1.2 The key stakeholders, both clinical and non-clinical, agree that the audit topic is a priority	Stakeholders may include providers, commissioners, non-clinical managers, trust boards (or equivalents), clinicians, staff, patients/service users and national organisations representing both clinicians and patients/users
2 The audit measures against standards	2.1 The audit standards are based upon the best available evidence	For example; NICE guidelines (or equivalent), National Service Frameworks, national guidelines etc. A literature source to identify suitable standards may be appropriate. If there is no other evidence, the standards should be developed through an appropriate process; for example a properly designed consensus exercise. Some outcomes audit will have a role in defining or refining standards
	2.2 The audit standards are referenced back to their source and an explanation of this link is provided	

CRITERIA	KEY INDICATORS	REMARKS
	2.3 The audit standards are agreed and signed off by the clinical audit team and by those clinicians, clinical governance teams and patients to whose practice they relate	
	2.4 The audit standards are expressed in a form that enables measurement	For example, the standards are expressed as criteria that are "SMART-compatible"; that is - Specific, Measurable, Achievable, Relevant and Theoretically sound. ('T' can also refer to Timely, which is also appropriate but needs to be in keeping with a scientific process)
3 The organisation enables the conduct of the audit	3.1 A written plan describes the structures and processes necessary to support the audit	This includes a statement about who provides the leadership, the composition of the audit project team, the frequency of meetings, how commitment from the key clinical and non-clinical stakeholders will be secured and a communications plan which includes the production of a comprehensive audit report and to disseminate the findings

CRITERIA	KEY INDICATORS	REMARKS
	3.2 Staff have time to participate fully in the audit	As far as possible, audit work should be embedded into the routine work of clinicians. If clinicians will be required to give time over and above normal practice, this must be identified at the outset of the audit, and all relevant clinicians given protected time to participate
	3.3 The organisation provides the administrative and other practical support required to conduct the audit	When necessary this should be provided by experienced clinical audit support staff
	3.4 Any necessary training to conduct the audit is identified and provided	Managers need to accept reasonable training requirements to support effective delivery of audit programmes
	3.5 Any financial costs associated with running the audit are identified and met	
4 The audit engages with clinical and non-clinical stakeholders	4.1 Where possible, an audit should review the practice of all clinical disciplines in the service unit or team whose work is relevant to the audit topic area	Most healthcare practice happens in teams with various disciplines and the audit should cover the whole team rather than the practice of individual disciplines within the team
	4.2 Those clinicians with senior responsibility for the area of healthcare being audited show commitment to the audit and provide the necessary leadership	

CRITERIA	KEY INDICATORS	REMARKS
	4.3 There is ownership of audit findings at the most senior management level. Responsibility to enact change resulting from an audit is accepted by those with power to implement change	This commitment should be at Board level and, if appropriate, should involve commissioning organisations as well as providers
	4.4 The roles of stakeholders, and their accountability, are defined clearly from the outset and are in the audit plan	
	4.5 All relevant stakeholders are involved from the beginning of the audit cycle through to completion	
	4.6 Active communication with stakeholders is maintained throughout the audit process	
5 Patients or their representatives are involved in the audit if appropriate	5.1 The patient group to whom the audit standards apply is clearly defined	
	5.2 The audit standards take full account of patient priorities and patient-defined outcomes	For example, the audit incorporates Patient Related Outcome Measures (PROMS)

CRITERIA	KEY INDICATORS	REMARKS
	5.3 Patients/carers are recognised as key stakeholders in the audit process	If appropriate and feasible, patient representatives and relevant patient organisations are involved in audit governance, treated as stakeholders, and where appropriate, in all stages of the audit cycle as equal members of the audit team
	5.4 Patients who are members of the audit team are fully informed about what is expected from them in terms of participation, commitment and workload	Not all patients and/or patient organisations will be members of the audit team but as relevant stakeholders should still be kept informed and engaged
	5.5 If required, patients who are members of the audit team are given basic audit training to enable them to contribute effectively to the audit process	
	5.6 Patients are kept informed throughout the audit process about timescales, progress, results and actions	All communications should use plain English avoiding the use of jargon and acronyms
STAGE 2: MEASURING PERFORMANCE		
6 The audit method is described in a written protocol	6.1 The timetable for the audit is described; including timescales for completion and re-audit, where necessary	
	6.2 The protocol describes the methodology and data collection process in detail	

CRITERIA	KEY INDICATORS	REMARKS
	6.3 Systematic consideration is given to ethics, data confidentiality and consent issues, and Caldicott principles are applied	Audits should not require approval from a research ethics committee but still have ethical issues to address, for example maintaining confidentiality and obtaining process consent
	6.4 The methods used in the audit are recorded so that re-audit can be undertaken later in the audit cycle	
7 The target sample should be appropriate to generate meaningful results	7.1 If a sample of the population is to be audited then the method for sampling is that which is best suited to measuring performance against the standards and as best as possible, scientifically reliable	Those planning the audit should consider seeking statistical advice about how to ensure that the sample is adequately significant, representative, clinically relevant, unbiased etc
	7.2 The sample size is sufficient to generate meaningful results	Those planning the audit should consider seeking statistical advice about sample size relevant to a given topic
	7.3 When necessary, the sample allows for adjustment for case mix	Those planning the audit should consider seeking statistical advice about casemix adjustment

CRITERIA	KEY INDICATORS	REMARKS
8 The data collection process is robust	8.1 The audit utilises pre-existing data sets where possible	Those planning the audit should consult with appropriate advisors to identify any relevant data sets, but these should be used with caution dependent on their reliability
	8.2 The data collection tool(s) and process have been validated	This might include undertaking simple statistical tests on the data collection tools to examine their reliability and accuracy in practice, or by using data collection tools that have already been proven for this type of audit
	8.3 The data collection process aims to ensure complete capture of data	This should demonstrate full case ascertainment and full completion of each case within the audit. Any excluded data should be explained
9 The data are analysed and the results reported in a way that maximises the impact of the audit	9.1 Data are analysed, and feedback of the results is given, so that the momentum of the audit is maintained in line with the agreed timetable	
	9.2 Results of the audit are presented in the most appropriate manner for each potential audience to ensure the audit results stimulate and support action planning	For example; the use of accessible graphics
	9.3 The results are communicated effectively to all key stakeholders, including to patients	Through presentations at meetings; in written reports; posters etc, in such a form as to be easily understood
STAGE 3: IMPLEMENTING CHANGE		

CRITERIA	KEY INDICATORS	REMARKS
10 An action plan is developed and implemented to take forward any recommendations made	10.1 The audit results are channelled into a plan which both sets out the areas needing attention and where there is good compliance; recommends the actions required to address the identified issues and sets out how these will be carried through	Recommended actions should be targeted at service, team, managerial or organisational level, where possible. Local teams will need to devise their own action plans in relation to the results of national audits
	10.2 The action plan has the agreement of all or the majority of stakeholders involved in the audit process; including managers who may have to commit resources to the changes, and patients whose care they will affect	Any barriers to implementing change are identified in the plan and action taken to address them. A suitable risk management strategy will need to be incorporated into the plan
	10.3 The plan identifies who is responsible for taking which actions and by when, and when achievement of actions will be reviewed	
	10.4 The plan identifies any financial or other resource implications associated with the recommended actions	Managers need to be involved from the start to ensure that any resource requirements are anticipated
	10.5 The results and the following action plan is communicated and distributed widely and effectively, including to managers and patients	There should be a clear pathway through which the audit results are reviewed by the immediate clinical team and their patients, and by the senior management team responsible

CRITERIA	KEY INDICATORS	REMARKS
	10.6 Implementation of the action is closely monitored and progress regularly communicated to stakeholders. Those with responsibility oversee and drive the implementation of the action plan and its subsequent follow up	Timetables for implementation need to be set
STAGE 4: ACHIEVING AND SUSTAINING IMPROVEMENT		
11 The audit is a cyclical process that demonstrates that improvement has been achieved and sustained	11.1 The topic is re-audited to complete the audit cycle, where necessary	Re-audit can measure continuing compliance with the audit standards; confirm that recommendations arising from the initial audit have been implemented, or measure that good practice has been maintained. In some cases, re-audit may not be necessary or possible; for example if all standards are met in the first audit; or there has been a significant structural change
	11.2 Where recommended action has not been achieved in full the topic is re-audited at agreed intervals	
	11.3 The results of re-audit are recorded and disseminated appropriately, including to patients	Audits, which demonstrate both compliance and non-compliance, should be widely shared and made widely available

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