National Clinical Audit Advisory Group

Annual Report 2009-10

Executive Summary

During our second year we have successfully consolidated and enhanced our working arrangements. We have pursued four principal strategies:

- clarifying the role and contribution of ‘clinical audit’
- expanding and improving national clinical audits (NCAs)
- assessing the value of accreditation of clinical audit
- establishing and promoting clinical audit in Quality Accounts

To achieve these we have made recommendations to the DH as regards:

- a definition of ‘clinical audit’
- a typology of NCAs
- a sustainable funding mechanisms for NCAs
- an annual commissioning cycle for new NCAs and renewals
- criteria for prioritising topics for national audits
- the use of multi-site audits
- innovations to extend national clinical audits to encompass primary care and social care
- the requirements for an improved NCA contract
- the value of accreditation of clinical audit
- the contribution of clinical audit to Quality Accounts

In 2010-11, in addition to maintaining and improving NCAs in England (regardless of funding source), we plan to:

- explore ways to facilitate links between NCAs and Hospital Episode Statistics
- establish policies on defining outlier providers and managing such information
- assist in establishing improved contracts for NCAs
- support the NPSA in establishing a National Childbirth Audit
- advise on the contribution of clinical audit in Quality Accounts for 2011
- explore with the Foundation Programme Office policies to improve doctors’ participation in audit.
Background

History
The establishment of the National Clinical Audit Advisory Group in April 2008 marked the creation of a voice for clinical audit in the Department of Health and at the centre of the NHS. Unlike the two other core professional activities aiming to enhance health care quality, namely education and research, clinical audit had lacked a national strategy and a coherent programme of activities. NCAAG endeavours to meet that challenge by enhancing the existing programme of national clinical audits and seeking to support the many NHS staff involved in local audits in their own Trusts. It also seeks to improve connections - between the centre and the periphery; between national clinical audits, regardless of their source of funding; between audit and quality improvement initiatives such as revalidation, regulation and commissioning; and between clinical audit and other routine data collection in the NHS.

Responsibilities
NCAAG's responsibilities are:

• to drive the reinvigoration of clinical audit, both nationally and locally, yielding new publicly available information to support improvements to clinical practice and service delivery

• to provide strategic advice and guidance to the Department of Health on the National Clinical Audit & Patient Outcomes Programme (NCAPOP), and in particular on proposals for new national clinical audits and for discontinuing existing ones

• to advise on issues as requested by the Department of Health

The National Clinical Audit & Patients' Outcomes Programme (NCAPOP) is administered by the Healthcare Quality Improvement Partnership (HQIP) - a consortium comprised of the Royal College of Nursing, Academy of Medical Royal Colleges and National Voices.

Membership
To achieve these goals, the members of NCAAG (unchanged from 2008-9) reflect the diverse range of backgrounds, skills and interests that are needed to understand the challenges and devise appropriate policies:

Nick Black (Chair)  Professor of Health Services Research, London School of Hygiene & Tropical Medicine
Boo Armstrong  Managing Director, Get Well UK
Martin Ferris  Head, Clinical Audit and Effectiveness, Sheffield PCT
Mick Peake  Consultant in Respiratory Medicine, University Hospitals of Leicester NHS Trust
Pauline Ong  Professor of Health Services Research, Keele University; Chair, Central and Eastern Cheshire PCT
Andrew Middleton  Ex-CEO Stamford College of Further Education; Non-Executive Director, Lincolnshire PCT; Lay Member, Nursing & Midwifery Council
Geraldine Walters  Director of Clinical Nursing, King’s College Hospital NHS FT.
The Group recognises that success will only be achieved by listening to and working with all those already engaged in clinical audit both locally and nationally. Together, clinical audit can be invigorated and enhanced so that it takes its rightful place at the centre of health care delivery and policy.

**Working arrangements**

NCAAG meets quarterly to discuss policy and strategy for clinical audit and to make recommendations to the DH. In addition, three sub-groups have been established to undertake aspects of strategic management of national clinical audits (NCAs) and make recommendations to the full Group:

- **New NCAs Sub-Group:** chaired by Pauline Ong; responsible for considering and assessing tenders for new NCAs in both the centrally commissioned scheme and the responsive scheme

- **NCA Renewals Sub-Group:** chaired by Mark Gritten; responsible for assessing tenders for renewals of NCAs

- **NCA Advisory Sub-Group:** chaired by Jan van der Meulen; responsible for providing comments and advice on NCAs being funded by the Department of Health but not part of the NCAPOP

To enhance the methodological strengths of two of the sub-groups, additional members were appointed:

**Renewals Sub-Group**
- Ben Bridgewater, NICOR, UCL
- Elizabeth Draper, University of Leicester
- Fiona Lecky, University of Manchester

**New Audits Sub-Group**
- Paul Roderick, University of Southampton
- Kathy Rowan, Intensive Care National Audit & Research Centre
- Kate Tilling, University of Bristol

**Communication**

A website (www.advisorybodies.doh.gov.uk/ncaag/) provides information on the work of NCAAG including the agenda and minutes of its quarterly meetings, policy papers and annual reports. In addition, members describe the work of NCAAG at national and regional meetings.
Policy developments 2009-10

1. Defining 'clinical audit'
NCAAG continued its consideration, started in 2008-9, of the most widely used definition of clinical audit which was developed about ten years ago by a consortium of the National Institute for Clinical Excellence, the Commission for Health Improvement and the Royal College of Nursing:

*Clinical audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change.*

Inevitably, given the significant changes that have and are taking place in policies and mechanisms for assuring quality in the NHS, NCAAG felt there was a need to clarify the definition to reflect this changing world. In particular NCAAG had three concerns:

- The focus on assessing the processes of care and not encompassing outcome assessment
- The lack of recognition of the wider quality framework and the key role of clinical audit data in underpinning quality improvement carried out by other players (eg regulators, commissioners etc)
- The requirement that those undertaking clinical audit should not just stimulate quality improvement but should implement change (a complex task that requires different skills to those for assessing quality).

To address these concerns, NCAAG suggested revising the definition of clinical audit:

*Clinical audit is the assessment of the process (using evidence-based criteria) and/or the outcome of care (by comparison with others). Its aim is to stimulate and support national and local quality improvement interventions and, through re-auditing, to assess the impact of such interventions.*

Discussions that NCAAG held in September 2009 revealed considerable opposition to any change in the definition from local audit staff, while those managing national audits were divided with most opposed but some welcoming the proposed new definition.

While NCAAG remains concerned about the existing definition, it has not recommended that the Department of Health adopt the proposed new one as this risks the co-existence of two definitions which would prove counterproductive to the key task of reinvigorating clinical audit.

Instead, NCAAG recommended that the existing definition is seen as *permissive rather than prescriptive.* This will enable those involved in clinical audit, whether local or national clinical audit, to continue to limit their involvement to assessing quality, disseminating findings, stimulating improvement and, by re-assessing quality, determining the impact of any improvement interventions. Meanwhile those who also wish to engage locally in implementing change to improve quality can continue to do
so. We will continue to monitor opinions and may re-engage with this issue in the future.

2. Improving national clinical audits

Establishing a typology
Given the variety of forms that national clinical audits take, NCAAG established a simple typology to aid discussion and strategic development. It is based on two criteria:

- whether patient recruitment is continuous (all patients) or intermittent (a sample of patients)
- whether the process or the outcome (or both) of care are assessed.

Some examples include:

- Continuous; processes of care (eg National Diabetes Audit)
- Continuous; outcomes of care (eg ICNARC Case Mix Programme)
- Continuous; processes and outcomes of care (eg Renal Registry)
- Sample; processes of care (eg National Sentinel Stroke Audit)

We also recognise a version of the last category in which the audit topic varies over time (eg the British Thoracic Society and the College of Emergency Medicine audits). A review of the 30-40 existing NCAs revealed that most are ‘continuous’. Of those that involve sampling, most are conducted by the Royal College of Physicians.

Achieving sustainable funding
NCAAG rejected the idea of trying to limit the number of NCAs, for three principal reasons:

- feasibility: many NCAs are established outwith the NCAPOP so the DH has limited control on the total number
- desirability: DH policy is to encourage clinicians to undertake and engage in NCAs
- external requirements: increasingly clinicians will be required to participate in NCAs for revalidation, Trusts will be required by regulators (CQC, Monitor) etc

NCAAG recommended to the DH that the best use of the limited funds available in the NCPOP was:

- new audits should initially receive 3 years full funding to maximise the likelihood of establishing the audit.
- new audits would then receive tapered funding from year 4 to 6 (though they would be encouraged to start putting alternative funding in place during the preceding three years)
- funding for existing audits would be tapered over a three year period, following one additional year of full funding
• the pros and cons of a proportion of permanent funding from NCAPOP needed further consideration
• strict criteria for exceptional permanent full funding needed to be established

It was accepted that the principal alternative source of funds was the participating Trusts (or commissioners) through subscriptions. This approach had proved successful for UKTARN, Renal Registry and ICNARC CMP. NCAAG also recommended that NCAs maximise their income from contributions from charities and industry, acknowledging these contributions would be relatively small in terms of overall impact. In the case of industry, NCAs would need to ensure they maintained their actual and perceived independence.

Establishing an annual commissioning cycle
NCAAG recommended to the DH that an annual cycle should be adopted by HQIP to avoid the delays that had occurred in 2008 and 2009 which led to end of contract deadlines being missed. To minimise the length of the commissioning cycle, NCAAG recommended excluding the Expressions of Interest stage as unnecessary.

New Audits
• HQIP invite topic suggestions (January/February)
• NCAAG prioritise and select topics (March)
• HQIP issue ITT (May)
• Closing date for bids (mid-July)
• New Audits Sub-Group meeting to consider bids (September)
• NCAAG meeting to decide on recommendations to DH (September)

Renewal of Existing Audits
• HQIP prepare review of audits whose funding ends in 14 months time (January/February)
• NCAAG decide on whether to continue audit (March)
• HQIP issue ITT (May)
• Closing date for bids (mid-July)
• Renewals Sub-Group meeting to consider bids (September)
• NCAAG meeting to decide on recommendations to DH (September)

Improving NCA contracts
NCAAG perceive there is a need for greater clarity as to the ownership of NCA data, access to data and possession of intellectual property rights. Some of the confusion arises because insufficient distinction is made between these elements and between ‘raw’ patient identifiable data and aggregated or summary data.

While NCAAG’s immediate concern was the NCAs within the NCAPOP, it would be desirable that NCAs funded from other parts of the DH and other public sources adopted any proposal. An improved contract needs to achieve five objectives:

• Ensure availability of aggregated NCA data: an essential requirement is that NCAs provide data for several bodies engaged in improving the quality of services.
• Maintain continuity of NCA databases: on the occasions when the organisation contracted to manage a NCA changes, the existing historic raw data must transfer to the new contractor (without cost) to maintain continuity of analysis and reporting and enable temporal trends to be observed.
• Respect the intellectual property rights of NCA contractors: if responsibility for the establishment and management of NCAs is going to be taken on by the most able clinicians and methodologists, their intellectual property rights must be respected. This includes their right to ensure that the data are used in responsible and justifiable ways. The IPR is distinct from ‘ownership’ of the data.
• Ensure DH interests are respected: for NCAs funded by the DH (mostly through the NCAPOP but also through other schemes), NCA contractors should share in advance any output with the funder.
• Protect privacy and rights of patients: the privacy of patients must be protected by ensuring raw, patient-identifiable data are secure and remain confidential.

Given the complexity of the issues involved in drawing up a policy that meets all five objectives, NCAAG recommended to the DH that specialist advice is sought to draw up proposals both for future contracts for NCAs and for modifying existing contracts where necessary.

3. Assessing the value of accreditation of clinical audit

NCAAG advised the DH to be cautious as regards establishing accreditation of local (Trust) and national (Royal Colleges) audit departments, audit programmes, national clinical audits and audit education programmes. This was for several reasons, the most important being the lack of convincing evidence as to the effectiveness of accreditation as a means of improving quality. In addition we had the following concerns:

• Cost: not only the cost of establishing an accreditation process but also the costs incurred by the accrediting body and the organisations being accredited.
• Opportunity costs: as the accreditors need to include those most respected and experienced in clinical audit, the opportunity costs of their time need to be considered as such people might be more effectively employed in improving quality of care.
• Risk of error: accreditation carries the risk that if an organisation that has been accredited is found to be failing to provide a good service, the credibility of the whole accreditation system may be undermined.
• Overlap: the health care sector is awash with systems of external review so it is likely the introduction of additional accreditation would overlap with existing systems.
• Legal implications: organisations that fail to be accredited may take legal action to challenge the accrediting body.
• Feasibility of identifying an accrediting body with credibility in the world of clinical audit.
4. Establishing Quality Accounts

Clinical audit is a key component of QAs. NCAAG helped the DH specify the requirements for Trusts to report on national and local clinical audit in their 2009-10 Quality Account due for release in June 2010. In particular, we advised on which national clinical audits should be included in the designated list. The criteria used to select audits were:

- Coverage: intention to achieve participation by all relevant providers in England.
- Data: collected on individual patients
- Comparisons of providers (processes and/or outcomes)
- Recruited patients during 2009-10

5. Commissioning new national clinical audits

**Criteria for prioritising topics**

NCAAG advised the DH as to the criteria against which proposed new topics for national audits funded in the NCAPOP should be judged:

- Meets remit of the DH National Clinical Audit & Patient Outcomes Programme
- Clinical/health and social policy importance of condition
- Evidence of need for improvement in quality of care
- Sufficient evidence to establish criteria of good quality (if it is an input or process rather than a outcome audit)
- Evidence that improvements in quality might be achievable
- Supports broader DH/NHS policy objectives

**Multi-site audits**

Following a recommendation by NCAAG in September 2008, the DH has provided modest resources (for three years) from NCAPOP to support groups of local Trusts that have a shared interest in an audit topic that is not covered by a national clinical audit. Such ‘multi-site audits’ allow participating Trusts to share and agree common methods which will facilitate comparisons of the quality of their services. Central aggregation or coordination enhances the value to each locality and acts as a foundation for wider uptake. HQIP have administered two rounds of applications for multi-site audit funding. It is recommended that the scheme be appraised in 2011.

**Innovations**

Although there have been unfortunate administrative delays, progress has finally been made with two innovations in national clinical audits. First, the aim of establishing a major audit of a long-term condition (adult diabetes) focused in primary rather than
secondary care was put out to tender and it is anticipated that preparatory work on the new audit will commence in October 2010 with full establishment from April 2011.

Second, the aim of establishing an audit that covers both health care and social care (nutrition in elderly inpatients/residents) has commenced with the funding of a one year development project that will report in summer 2011.

Advising other funders
NCAAG has been advising the NPSA on the redesign of their programmes so as to include a national clinical audit of childbirth (maternal and neonatal care) that is consistent with NCAAG’s criteria of a good quality NCA and complements the existing National Neonatal Audit (funded by the DH through NCAPOP).

Plans for 2010-11

While several of the activities established in 2009-10 will need to be continued and developed further, the following are the additional topics that NCAAG will be addressing in 2010-11.

1. NCA links to Hospital Episode Statistics
NCAAG has been encouraging all NCAs to exploit opportunities to link their data to other existing databases, most notably HES. Information governance concerns, such as data confidentiality, have caused NCA contractors considerable difficulties which are often time consuming and fruitless. NCAAG will be working with the DH to establish clear protocols for NCA contractors to facilitate such linkage by providing generic guidance on how to negotiate successful linkage.

2. Outliers in national clinical audits
NCAAG will develop recommendations for the DH on defining outlier providers and on best practice for managing the situation when an outlier is detected. As far as is feasible, generic advice will be produced.

3. NCA contracts
NCAAG is keen to collaborate with the DH in the drawing up of new standard contracts for NCAs that meet the five proposed criteria.

4. National Childbirth Audit
NCAAG will support the NPSA in establishing a National Childbirth Audit from April 2011. This will complement and collaborate with the National Neonatal Audit, subject to retendering during 2010-11.

5. Quality Accounts
NCAAG will advise the DH on the contribution of clinical audit in Quality Accounts for 2011 including the scope of NCAs covered, coverage of PCTs, and enhancements to the requirements for Trusts.

6. Foundation Programme doctors
The curriculum for 16 000 FP doctors includes the requirement that during their two-year programme they participate in audit. NCAAG plans to investigate, in
collaboration with the Foundation Programme Office, the experiences of FP doctors and their mentors with a view to devising new policies that might enhance the value of this activity for the doctors and for clinical audit.