Executive Summary

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

- expanding the portfolio of national clinical audits (NCAs)
- enhancing the capability of NCAs
- increasing Trust participation in NCAs

To achieve these we have advised the DH as regards:

- increasing the availability of uncommitted NCAPOP funds
- improving the application and review forms for NCAs
- funding of NCAs by other DH and NHS bodies
- commissioning two new NCAs
- guidance to NCA suppliers on data linkage
- guidance on the detection and management of outliers
- increasing the participation of high quality methodologists
- continuing funding of existing NCAs
- the pros and cons of making NCAs mandatory
- improving the reporting of NCAs in Quality Accounts

Over the next three years we plan to pursue policies that:

- support the development of NCAs that bridge health and social care.
- help bring assessments of the three dimensions of quality (effectiveness, safety, experience) together
- encourage the use of audit data by new commissioning bodies
- encourage the development of audits that embrace complete care pathways
- enhance the quality of NCAs
- develop the methodology of clinical audit
- support and encourage links between national and local audit
- enhance the position of local clinical audit staff
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 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 (member until December 2010)
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
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,
Mark Gritten       Ex-CEO NHS acute Trusts
Jan van der Meulen Professor of Clinical Epidemiology, London School of Hygiene & Tropical Medicine; Director, Clinical Effectiveness Unit, RCS
Danny Keenan  Consultant Cardiothoracic Surgeon, Manchester Royal Infirmary; National Clinical Advisor, Care Quality Commission

Terry Butler  Ex-Director of Social Services, Hampshire; Non-Executive Director, NHS South Central; General Social Care Council member

Sarah Schofield  General Practitioner, Southampton; Clinical Director, Hampshire PCT (member until June 2010)

Two members resigned during the year, Sarah Schofield (due to new work commitments) and Boo Armstrong (for health reasons). Four members were re-appointed by the Audit Commission for a second four-year term (Andrew Middleton, Mark Gritten, Danny Keenan and Jan van der Meulen). Two new members have been appointed (from April 2011): Steven Berg, a general practitioner, and Katherine Birch, a Trust clinical audit manager.

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 undertake aspects of the 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 ITTs and tenders for new NCAs

- **NCA Renewals Sub-Group**: chaired by Mark Gritten; responsible for assessing ITTs and 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 have been appointed:

**New Audits Sub-Group**

Elizabeth Draper, University of Leicester
Fiona Lecky, University of Manchester
Paul Roderick, University of Southampton

**Renewals Sub-Group**

Robert Grant, St Georges Hospital Medical School
Kathy Rowan, Intensive Care National Audit & Research Centre
Kate Tilling, University of Bristol
Communication
A website (www.dh.gov.uk/ncaag/ab/DH_097286) 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 2010-11

1. Expanding the portfolio of NCAs

Developments in the management and regulation of the NHS depend increasingly on high quality data from national clinical audits (NCAs). In addition, the demand from clinicians for additional NCAs needs to be met. There is, therefore, a need to expand the current portfolio of around 60 NCAs to widen the area of health care that is covered. NCAAG has pursued a number of policies to bring this about.

Increase in available DH NCAPOP funds
NCAAG supported the DH in requests for additional funds from the Comprehensive Spending Review 2011. Despite widespread reductions in funding throughout government and the public sector, an additional £1.2m was made available for new NCAs for 2011-12. Clinicians, national policy leads and professional organisations will be invited to suggest new topics which will be prioritised by NCAAG using the published DH criteria, before invitations to tender are issued.

The policy of shifting some well-established NCAs in the NCAPOP from central funds to subscription funds from Trusts proposed by NCAAG in 2009 will be instituted in 2011-12. It is important that the subscription costs to Trusts should not adversely affect local clinical audit budgets (eg by reducing staffing levels). During 2011-12, nine audits in the DH NCAPOP will be funded by subscriptions (collected by HQIP). These include four cancer audits, four cardiovascular audits and the neo-natal audit. Arrangements are currently being drawn up and Trusts informed. HQIP will issue one annual invoice to trusts covering the NCAs they participate in. The introduction of subscription funding will increase the amount of uncommitted funding available for new NCAs (in addition to the CSR increase).

Improved application and review forms
To clarify applications to tender for new audits and for continued funding, NCAAG recommended revising the existing version of the NCA application form (Service Specification Questionnaire) in the light of experience. We sought to simplify, avoid duplication and create a more logical sequence of areas to be covered, including specifying word limits for each section. This will also facilitate reviewing applications.

Although not part of the Service Specification Questionnaire, NCAAG recommended that the level of detail of costs requested from bidders was insufficient to make informed judgments. We proposed that greater detail, including information on the role and tasks for each post requested, was needed. In addition, a Review Form for NCAAG Sub-Groups to use for the initial assessment of bids was developed. It will be used for initial filtering and comparison purposes.
Both recommended forms were accepted by the DH who instructed HQIP to adopt them.

New topics commissioned
Two new NCAs were successfully commissioned during 2010-11:

- National Paediatric Diabetes Audit: supplied by Royal College of Paediatrics & Child Health.
- National Adult Diabetes Audit: supplied by NHS Information Centre and Diabetes UK

It is anticipated that the adult audit will provide a template for other audits of long-term conditions centred on primary care. This is a high priority for NCAAG but we recognise the formidable methodological and practical challenges that undertaking a high quality audit of a common condition in primary care represents. Careful monitoring will be carried out to ensure lessons are learnt for future audits of long term conditions which we hope can be established in the next year or so.

A development project, commissioned from King’s College London, to determine the feasibility and design of a national audit of nutrition in the elderly in hospitals, nursing homes and residential social care will report in autumn 2011 and the possibility of procurement of an audit will be considered by NCAAG.

Advising other funders
NCAAG advised the National Patient Safety Agency on the redesign and subsequent procurement of their Clinical Outcome Review Programme (CORP). This programme has traditionally focussed on the safety of care, using national confidential enquiries (retrospective case note review). NPSA’s decision to extend their approach in the field of childbirth to include a national clinical audit led to them seeking advice so as to ensure it was consistent with NCAAG’s criteria of a good quality NCA and that it complemented the existing National Neonatal Audit (funded by the DH through NCAPOP). The National Childbirth Audit was subsequently commissioned from the National Perinatal Epidemiology Unit, University of Oxford to commence in 2011-12.

2. Enhancing the capability of national clinical audits

Guidance on data linkage
Following the difficulties that NCA suppliers (such as Royal Colleges, professional associations) have experienced linking their data to other databases and, in particular, to Hospital Episode Statistics (HES), NCAAG felt it would be useful to provide standard, user-friendly guidance. We organised a meeting with representatives of all the relevant bodies who actively contributed their perspectives, concerns and requirements: Department of Health, NHS Information Centre, Office of National Statistics, NIGB Ethics and Confidentiality Committee. Roles and responsibilities were clarified and a consensus as to the processes involved emerged from the discussion. Following several iterations, including translating legal into plain English, NCAAG produced ‘Guidance on Data Linkage’ which has been distributed to NCA suppliers.
Detection and management of outliers
NCAAG devised guidance for NCA suppliers on the detection and management of health care providers whose performance lie more than two and more than three standard deviations from the mean for England. This advice has been endorsed and issued as DH guidance. It has been sent to NCA suppliers and made available on the DH NCAAG website. We are keen to evaluate it in summer 2012 to determine the views of NCA suppliers and, if necessary, suggest any necessary modifications in the light of experiences.

Increasing participation of top quality methodologists
NCAAG recognises that to establish rigorous, high quality NCAs requires the involvement of excellent methodologists with skills that include epidemiology, statistics and outcome measurement. We are concerned that the current contractual arrangements in the NCAPOP between HQIP and NCA suppliers precludes the latter retaining any intellectual property rights. Clearly the interests of suppliers need to be balanced by the DH’s needs to protect the public interest. NCAAG identified five objectives that need to be met in an ideal contract:

- 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 supplier (without cost) to maintain continuity of analysis and reporting and enable temporal trends to be observed.
- Respect the intellectual property rights of NCA suppliers: 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 suppliers 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.

During 2011-12 NCAAG is seeking to explore possible solutions with the Procurement Team at the DH.

Reviewing existing NCAs funded by DH NCAPOP
NCAAG has sought to improve the quality of NCAs funded by the DH NCAPOP by rigorously reviewing them when they seek renewed funding. This process leads to one of four recommendations to the DH: approval of further funding; approval subject to revision, including merger with another NCA; competitive retendering; or no further funding.

Approval of further funding
National Lung Cancer Audit – until March 2012; then retender
Head & Neck Cancer Audit – until March 2012; then retender
National Bowel Cancer Audit – until March 2012; then retender
National Oesophago-gastric Cancer Audit – until March 2014
National Neonatal Audit – until March 2014

Approval subject to revision
National Sentinel Stroke Audit – until March 2012; then merger with SINAP
National Dementia Audit – core component only, until December 2012; then retender with expanded remit
National Audit of Falls and Bone Health in Older People – until March 2012; then merger with NHFD

Competitive retendering
Carotid Interventions Audit (CIA)

No further funding
Kidney Care Services (patient transport)
Kidney Care Services (vascular access) explore incorporation in Renal Registry

3. Increasing Trust participation in NCAs

Mandation
NCAAG considered the option that participation in NCAs should be made mandatory for health care providers involved in NHS-funded care. We did not support such a proposal because we perceive it to be unnecessary, costly to institute and maintain, and goes against the voluntary ethos of clinical audit. In addition, given the existing variation in the quality of NCAs, it would be necessary to establish a mechanism for determining which ones were to be mandated (otherwise there is the danger of mandating NCAs that are considered in need of improvement). Also decisions not to mandate a NCA could be result in an appeal by the supplier. NCAAG therefore advised against mandation and instead encouraged the use of other incentives to encourage (eg Quality Accounts, revalidation, CQUIN)

In their considerations, the DH decided to mandate, from April 2011, those NCAs that they fund through NCAPOP (Standard terms and conditions for acute hospital services - Gateway Ref 15458). One repercussion for suppliers of NCAPOP audits will be the need to obtain approval from the Review of Central Returns (ROCR). The impact of mandation on those NCAs that remain voluntary will need to be monitored.

Quality Accounts
Clinical audit is a key component of QAs. A review of the reporting of NCAs by acute trusts in 2010 QAs reported:

- Overall participation in NCAs was 69% but varied between acute Trusts from less than 40% to 100%.
- Participation levels was unrelated to whether or not a Trust had Foundation status, was associated with a university or the region of the country.
- Despite guidance, there was considerable variation in the way NCAs were reported, in particular the patient recruitment rates.
In the light of these findings, NCAAG provided advice to the DH as to how 2011 Quality Accounts could be improved by: ensuring concordance with the requirements for data for quality measures for other bodies, such as CQC: clarifying the guidance provided; providing Trusts with earlier notification as to which NCAs will be included each year; and providing more central support as regards information to help complete their QA.

We helped redraft the guidance for QA 2011 and suggested the following modifications to the DH: the requirement to report on all 54 NCAs approved for inclusion so as to avoid variability in the denominator each Trust reported; improvements in the accuracy of recruitment rates, particularly for NCAs that are based on samples of consecutive patients and thus vulnerable to selection bias; the provision of a list of all NCAs that had published a report during 2010 to stimulate Trusts to report local quality improvement interventions that had resulted; that requirement for Trusts to report examples of QI interventions be a specified number (three).

To meet one of these objectives, in March 2011 NCAAG provided the list of NCAs for inclusion in QA 2012 to ensure Trusts had this information before the start of the financial year in question.

**Plans for 2011-14**

Having reviewed our achievements over the first three years, we have identified several areas that need addressing over the next two to three years. Some of these are a continuation of existing themes whilst others are new areas.

1. National policies

   **Social care**

   Despite identifying the need to promote national audits that encompass social as well as health care, little progress has so far been made. We are aware of the considerable experience of audit of those working in social care and the need to enhance their engagement through collaboration. Both sectors probably have much to learn from one another. Differences in the governance of social care and of health care plus methodological differences present challenges that need to be addressed. We will endeavour to support the development of NCAs that bridge health and social care.

   **Links between dimensions of quality**

   Clinical audit tends to focus on clinical effectiveness (though some audits also encompass aspects of safety and experience). Responsibility for assessing safety and patient experience is largely separate at national level. Despite widespread agreement of the need to bring consideration of these different dimensions together, little progress has been made. We will seek to achieve this through closer working at national policy level.
Use of audit by commissioners
Encouragement of the use of audit outputs has been focused on clinicians, provider managers and national bodies (regulators, performance management, finance). The establishment of new local commissioning bodies provides an opportunity to ensure that clinical audit output (both from national and local audits) is considered and used by commissioners. We will seek to ensure that the National Commissioning Board is aware of the potential benefits of clinical audit and that national policies facilitate the use of audit data.

Audit of care pathways
Many existing clinical audits focus on single points in a patient’s care pathway. Increasingly we need to encourage the development of audits that embrace a complete pathway. This is clearly much more demanding both methodologically and practically but needs to start being addressed.

2. National clinical audits

Enhance quality of NCAs
We now have about 60 national clinical audits in England. With even the best there is scope for improvement and enhancement. The scope for improvement includes greater methodological rigour, increased participation, better outputs, and more effective stimulation of quality improvement locally. In addition, we are aware of the lack of support in all these areas that clinicians who want to develop new NCAs face. To realise significant improvements in the quality of NCAs, suppliers of existing and of new NCAs need to be supported and helped in several ways. To achieve this we recommend the establishment of a NCA Support Unit (similar to the way Clinical Trial Support Units have transformed the quality of RCTs in the NHS). This could also undertake some of the methodological developments that are needed (see next section). We outline the functions that need to be undertaken in the Appendix to this report.

Methodological development
While some of the methodological challenges of rigorous comparisons of health care providers have been addressed, there remain an array of issues that have either received no or insufficient attention. These include: definition of outliers; continuous monitoring; design of complex audits; presentation of output. We need to seek ways of supporting such methodological research for which there is currently no source of funding.

3. Local clinical audit

Increasing the links between national and local clinical audit
We recognise that there will inevitably be some tension between the needs of local and national clinical audits. Not only are both essential but also there are benefits to be gained by much closer links between the two. The relationship could be enhanced by NCA suppliers being more effective in the ways they communicate findings to providers (see above). In addition, there appears to be scope for local audit staff to promote the use of NCA findings locally to improve quality of care. We will explore
policies that will support and encourage the links between NCA suppliers and local audit staff.

*Enhancing the role of local clinical audit staff*

We are aware that the position of local staff in many Trusts needs strengthening and enhancing. We perceive that the role and responsibilities of staff in some Trusts focuses too much on undertaking audits rather than on providing leadership in audit, facilitating clinicians and others to carry out audits, and providing technical advice. We will seek ways assisting in enhancing the position of local staff.
Appendix

Enhancement of national clinical audit

The increasing roles for national clinical audits in quality management in the NHS (redesign, revalidation, quality regulation, commissioning, reimbursement, risk management etc) means that they must be of sufficient accuracy, rigour and clinical and patient relevance to meet these challenges. To achieve this, suppliers of existing and of new NCAs need to be supported and helped. The following functions at national level are needed:

1. Scoping reports for new audit topics
   Investigation of potential of new audit topics through clinical literature review, discussion with interested parties (clinicians, policy makers etc), review of existing data on quality of services. Preparation of rigorous reports on the feasibility and, if feasible, scope of a NCA.

2. Preparation of specification for new NCAs
   Provide methodological input to the preparation of specification of new audits for Invitations To Tender.

3. Improving the quality of bids for NCAs
   Provision of help and advice to those developing bids (both for new NCAs and renewals). This will encompass not only advice on audit design and scientific methodology but also on governance and identifying appropriate partners (eg patient organisations, methodologists).

4. Assessing the methodological quality of NCAs
   Explicit, rigorous assessment of the quality of all existing NCAs is needed. This needs to be based on explicit criteria that cover such aspects as: provider participation rates; patient recruitment rates; recruitment bias; extent of data on confounders; justification for process measures (scientific evidence base); appropriateness of outcome measures; validity and predictive power of risk adjustment; identification of outliers.

5. Improving the quality of NCAs
   Provision of advice to NCA suppliers as to how to improve the rigour and value of their audit.

6. Reviewing DH-funded NCA reports
   At present NCAs funded by the DH (in particular those included in the NCAPOP) publish reports (often seeking maximum publicity) without their methodological and clinical rigour having been reviewed by the DH. A rapid review process (within 28 days) is needed to provide the DH with information in advance of the NCA publication.

7. Enhancing NCAs’ stimulation of QI
   Enhancement of the role of NCA suppliers in stimulating local quality improvement in response to NCA findings. This would encompass identifying current good practice in terms of local use of data (‘drilling down’) and providing advice and support to NCA suppliers. This might be universal for all NCAs or specific, dependent on
characteristics of the NCA (eg process or outcome). It will also involve providing advice about dissemination and the range of local interventions that might be used to improve quality.

8. **Promoting the wider use of NCA databases**
Encouraging greater use and exploitation of NCA databases for research and informing policy.

9. **Supporting the development of a NCA suppliers’ network**
Development of a network of NCA suppliers; facilitating activities; sharing of ideas and initiatives; developing the methodological rigour of NCAs.

10. **Investigation of NCAs**
Undertake investigations of NCAs to establish best practice and to enhance their value and impact in a wide range of quality improvement approaches: Quality Accounts, NHS Outcomes Framework, revalidation, cost-effectiveness of different NCA methods (eg sampling versus census) etc.

11. **Undertake methodological research**
The development of many aspects of NCA requires a coordinated programme of research. At present developments largely depend on piecemeal work undertaken by a few individual NCA suppliers. Topics include risk modelling, handling skewed data, interpreting distributions of non-mortality outcomes etc.

**Recommendation**
While NCAAG can provide strategic vision and direction, it cannot undertake the operational implementation of these functions. This needs the establishment of a small NCA Support Unit. Staff would need to have skills and expertise in epidemiology, statistics, outcome measurement, data management, data presentation, stimulation of local QI and NCA governance. Such a unit would have to have scientific credibility with NCA suppliers and be able to provide practical expertise in management and governance issues.