Clinical governance and revalidation: the role of clinical audit

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This is the first in a series of articles outlining the role of clinical audit in supporting the requirements of clinical governance and revalidation. The Professional Standards Unit is responsible for providing guidance for pathologists to produce evidence on the quality of care and service they provide, as well as their own performance.

This will enable:

- pathologists to use audit processes to gather evidence that the quality requirements are being met
- Members and Fellows to identify those clinical audits that meet the needs of governance and contribute to a personal portfolio containing evidence in support of revalidation.

The PSU guidance will:

- explain the meaning of clinical governance and the duty of quality
- emphasise that the requirements of clinical governance are imposed by an Act of Parliament, with legal sanctions for non-compliance
- suggest areas of practice that can be subjected to clinical audit and provide evidence on quality and clinical performance
- highlight those audits relevant to governance
- show how key evidence to support revalidation of an individual doctor can be drawn from audit information assembled for clinical governance.

Background to statutory and professional regulation

The 1989 NHS reforms required all doctors to adopt medical audit in their clinical practice.[1] It was stipulated that time was to be allocated for audit work within each consultant's job plan.[2] In 1993, the term 'medical audit' was replaced by 'clinical audit', covering audit activity carried out by all healthcare professionals, including doctors.[3] In 1997, the Royal College of Pathologists published guidelines entitled *Clinical Audit in Pathology.*[4]

The 1998 NHS reforms introduced clinical governance. This provided the framework through which "NHS organisations are accountable for continuously improving the quality of their services and for safeguarding high standards of care".[5] The main goal of the governance initiative was to create an environment in which excellence in clinical care would flourish. Two new bodies were created in order to achieve this: the National Institute for Clinical Effectiveness (NICE) and the Commission for Health Improvement (CHI). In effect, governance introduced the concept of corporate accountability for clinical performance.

In 1999, the General Medical Council (GMC), independently of these NHS initiatives but responding to public concerns, stated that in order to maintain their registration, "*all doctors must be able to demonstrate that they can continue to be fit to practise in their chosen field*".[6]

In June 1999, the Health Act received Royal Assent and statutory duty of quality for all those working in the NHS became law.

Thus the Government's clinical governance initiative and the embryonic GMC revalidation arrangements were moving from conception to implementation. It became clear that both had one fundamental requirement in common: the provision of evidence. Evidence would be needed to demonstrate that the corporate accountability for quality was being met (i.e. governance). Evidence would also need to be provided by each individual doctor as he/she demonstrated his/her fitness to practise. In both cases, a large part of the evidence would be provided by formal review of practices and clinical performance; the tool for producing that evidence would be clinical audit.[7]

In late 1999, the Chief Medical Officer produced a consultation document, entitled *Supporting Doctors, Protecting Patients*, which made suggestions in relation to the requirements of governance and to the methods that would address poor performance of doctors.[8]

In June 2000, the GMC produced a consultation document, *Revalidating doctors: ensuring standards, securing the future*, which outlined the principles of revalidation and proposals for its implementation.[9] The current timetable for the introduction of revalidation is April 2002, pending the passing of an Act of Parliament.

The role of The Royal College of Pathologists

The College intends to make the relationship between clinical governance and clinical audit easy to understand by providing a selection of audits to help individual pathologists and pathology departments meet their statutory duty of quality.

The College has asked its Specialty Advisory Committees (SACs) to describe those audits necessary for governance that overlap with revalidation and that will help an individual member when he/she puts together a folder and profile of performance for revalidation. Detailed outlines of key audit projects relating to clinical governance will follow in future issues of *Education in Pathology*.

What is clinical governance?

Govern v. to regulate proceedings of (corporation, etc.)
Governance n. the act or manner of government

Many doctors find the term 'clinical governance' puzzling. It originated from the concept of corporate governance, used in the commercial world for over a decade and introduced into the health sector by Nolan in 1994.[10] 'Corporate governance' specifies arrangements that ensure that directors and senior managers of a public company exercise their power responsibly (i.e. running the company in the interests of not only the shareholders, but also the broader community). The arrangements incorporate checks and balances upon the power of the chief executive, for example, by splitting the roles of the chairman and the managing director. The aim of corporate governance is to ensure that public service values are placed at the heart of the NHS.[11] Clinical governance was introduced to ensure that each NHS organisation was made accountable for continuously improving the quality of its clinical services and for safeguarding high standards of care.

Clinical governance is…

- 'a system through which NHS organisations are accountable for continuously improving the quality of services' (Professor Aidan Halligan)
- 'a corporate accountability for clinical performance' (Mr Sam Galbraith MP)
- 'a duty of quality' (Health Act 1999).

The quality of service provided to patients is not confined to doctors' clinical activity. Doctors cannot avoid responsibility for the use of resources or other aspects of patient care that impact on quality of care or the service provided, and they have a duty to highlight inadequate resources in this respect.

Clinical audit performed against relevant, definable and defendable standards is the process by which doctors can gather the evidence to improve patient care. Doctors have always had a duty to patients, but the Health Act (1999) now makes that duty a legal obligation.

The principles of clinical governance are:

- clean lines of accountability within Trusts
- a comprehensive programme of quality improvement systems (including clinical audit, supporting and applying evidence-based practice, implementing clinical standards and guidelines, workforce planning and development)

- clear policies aimed at managing risk, the identification and remedy of poor professional performance, and clinical care monitoring integrated with a quality assurance programme.

Six pillars of clinical governance are:
- clinical effectiveness
- continuing professional development
- clinical risk management
- departmental organisation
- investigative protocols
- service quality.

The Professional Standards Unit will provide examples of audits relating to the key areas to help individual pathologists and pathology departments to meet quality standards required.

All core audits for clinical governance should address:
- the patient user view
- critical incident reporting
- the perceived quality of help and advice to other doctors.

Additional audits

Area	Example
Clinical effectiveness	Do surgical pathology reports provide the necessary clinical diagnostic information? Are datasets used?
Continuing professional development	Consultant audit involvement in his/her own area of high activity or risk.
Consultant appraisal	Assessment of personal achievement during the year (this is now a contractual obligation).
Clinical risk management	Monitoring of adverse events.
Departmental organisation	Pathologists' workload compared with national standards; clarity of lines of responsibility and accountability in the pathology department; communications within the department.
Investigative protocols	Availability of and adherence to agreed protocols for investigations of common conditions, e.g. diabetes mellitus.
Service quality	Turnaround time; complaints analysis with lessons learnt and action taken; availability of out-of-hours service.

Governance: monitoring

The organisation and effectiveness of local governance arrangements will be recorded, monitored and assessed as follows:
- NHS Trusts must report on their clinical governance arrangements in their annual reports
- NHS Trusts will be monitored by the regional offices of the NHS Executive
- in England and Wales, CHI will assess and review local arrangements when visiting each local health system every 3–4 years.

CHI has been identified as a key organisation in the drive to improve quality in England and Wales. In Scotland, the Clinical Standards Board (CSBS) and Health Technology Board operate similarly to CHI.

The Commission for Health Improvement (CHI)

Origin An independent body established on 1 November 1999.
Remit To provide external scrutiny of the quality of clinical care provided to NHS patients in England and Wales.

Key functions

1. To provide national leadership to develop clinical governance.
2. To conduct national reviews on the implementation of National Service Frameworks and to review the implementation of the guidance provided by NICE.
3. To check, through a rolling review programme, the local arrangements to improve quality.
4. To highlight best practice and to suggest (at the reviews) improvements where and when are found to be necessary.
5. To help the NHS identify and tackle serious or persistent clinical problems, for example: where an NHS organisation experiences serious service problems, it can invite CHI to advise and help identify solutions or where serious problems are not responding to local solutions, the Secretary of State for Health can send CHI in to that institution.
6. To identify excellence and to celebrate and share good practice, thus producing benchmarks.

The relationship between clinical audit and clinical governance

Accountability n. the condition of being accountable, liable or responsible
Accountable adj. liable to be called to account; responsible for

'Corporate accountability for clinical performance' defines clinical governance. How will CHI evaluate whether a Trust's statutory obligation is being met? How will Trust managers determine whether individual departments and individual specialists are meeting the standards, and confirm that the duty of quality has been achieved? Evidence will be required. Most of the evidence will be provided by regular, careful, systematic and formal clinical audit.

The relationship between clinical audit and clinical governance

Clinical governance
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How well are we doing?
Service quality
Clinical activity
Investigative protocols
CPD
Departmental organisation
Clinical risk management

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