

Nigel Starey

BSc MB BS MRCP
Director, Centre
for Primary Care,
University of
Derby

What is clinical governance?

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- **Clinical governance** is a system for improving the standard of clinical practice.
- Clinical governance was first described in a government white paper as ‘a new system in NHS Trusts and primary care to ensure that clinical standards are met, and that processes are in place to ensure continuous improvement, backed by a new statutory duty for quality in NHS Trusts’.¹
- The new framework is rapidly evolving, with the expectation that quality will improve incrementally in the future. This framework challenges clinicians’ traditional autonomy and will only succeed to the extent that they find it supportive and helpful.
- Existing activities such as **clinical audit, education and training, research and development**, and **risk management** (including complaints) will become part of clinical governance, and it is their resources that will fund it (Table 1, Figure 1).
- The approach will become systemic – with a senior clinician responsible for clinical governance throughout each organisation, and with important links to planning processes such as **Health Improvement Programmes (HIMPs), accountability agreements** and **personal development planning** (Figure 2).
- The chief executive of an NHS Trust or a Health Authority, as the accountable officer, will have responsibility for **quality**, including clinical governance.
- The system will be open to **public scrutiny** – it will be reported on at board meetings and subject to an annual reporting cycle.
- Further development of the system is likely to occur as it is implemented. Changes to **funding streams** and governance of teams, units, practices and working groups can also be anticipated, and relationships with **accreditation processes** and **partnership working** will evolve.

What is clinical governance?

*'Clinical governance is a powerful, new and comprehensive mechanism for ensuring that high standards of clinical care are maintained throughout the NHS and the quality of service is continuously improved.'*²

The elements of clinical governance

Clinical governance is composed of the following elements (see Figure 1):

- Education.
- Clinical audit.
- Clinical effectiveness.
- Risk management.
- Research and development.
- Openness.

Education

In the modern health service, it is no longer acceptable for any clinician to abstain from **continuing education** after qualification – too much of what is learnt during training becomes outdated too quickly. Different

systems have emerged to support continuing professional development by different practitioners – Post Registration Education and Practice (PREP) for nurses, Postgraduate Education Allowance (PGEA) for GPs, continuous professional development (CPD) for hospital doctors, for instance – and some practitioners have become trained educators to support such approaches (for example, GP tutors). In addition, some specialities have a requirement for considerable periods of postgraduate study before accreditation – medical specialities and specialist nursing, for example. For other practitioner groups, such as pharmacists, physiotherapists and occupational therapists, education has been the responsibility of the employer and the relevant professional body.

Most of this education activity has been focused on the individual practitioner and his or her own practice; the need to educate groups of practitioners together for the roles they fulfil together has not been well addressed. One of the reasons has been the way education has been funded. Medical and dental education is the responsibility of the dean and his or her staff using centrally allocated funds – **the MADEL funding stream**. Non-medical education has been the responsibility of Health Authorities through the non-medical education and training consortia – **the NMET stream**.

In NHS Trusts, the continuing professional development of clinicians has been the responsibility of the Trust. It has also been the professional duty of clinicians to remain up to date. The situation has been more complicated in primary care:

- There have been financial inducements to encourage GPs to undertake continuing professional development (PGEA scheme).
- Health Authorities have supported and provided training for members of the primary care team.
- There has been a professional requirement for continuing professional development for nurses and other clinicians working in primary care.

Figure 1. The elements of clinical governance



Table 1. The clinical governance system

Element	Previous	New
Education and training	PGEA, PREP, PRP Tutors, VTS	PPDP CG
Clinical audit	MAAG/audit group	NSFs/NICE CG
Clinical effectiveness	Public health	NICE/NSFs CG
Research and development	Networks	CG
Openness	Rare – CHC	Board
Risk management	Data protection COSHH Insurance Complaints	CG

PGEA = Postgraduate Education Allowance, PREP = Post Registration Education and Practice, PRP = Practice Receptionist Programme, VTS = Vocational Training Scheme, PPDP = Practice Professional Development Plan, CG = clinical governance, MAAG = Medical Audit Advisory Group, NSFs = National Service Frameworks, NICE = National Institute for Clinical Excellence, CHC = Community Health Council, COSHH = Control of Substances Hazardous to Health

In general, the schemes for supporting continuing professional development of practitioners have been effective; however, they are cumbersome to administer and fail to address adequately the health needs of the community and the requirements of the NHS.

We can anticipate NHS Trusts and Primary Care Groups (PCGs) providing education programmes for staff, using funds from both NMET and MADEL sources, and requiring their staff to maintain standards through a process of professional and practice development planning. Primary Care Trusts (PCTs) can expect to be held to account by Health Authorities and the Commission for Health Improvement (CHI) in this area, and the Workforce Confederations can be expected to co-ordinate the delivery of education across traditional professional boundaries.

Clinical audit

Clinical audit is the review of clinical performance, the refining of clinical practice as a result and the measurement of performance against agreed standards – a cyclical process of **improving the quality of clinical care**. In one form or another, audit has been part of good clinical practice for generations. Participation in audit has been a

requirement of NHS Trust employees, including doctors, and protected time has been provided. However, participation has only been **encouraged** in primary care, where audit time has had to compete with other priorities.

Audit has been facilitated by trained staff and committees in NHS Trusts, and through Medical Audit Advisory Groups (MAAGs) in primary care. Although initially regarded as a medical prerogative, in recent years audit activity has spread to include other members of the clinical team as well as patients and managers where appropriate. Many audit protocols are available 'off-the-shelf' for commonly performed projects, and the data collection and analysis requirements are handled by administrative staff. Funding for clinical audit has varied from place to place, depending on the priority Health Authorities and NHS Trusts have given it. Management cost pressures have made it difficult to sustain a comprehensive programme of clinical audit activity, particularly in primary care where audit has not been underpinned by contractual arrangements.

Medical audit has moved to become **clinical audit** as other practitioner groups' perspectives have been noted as essential to quality improvement. In primary care, clinical

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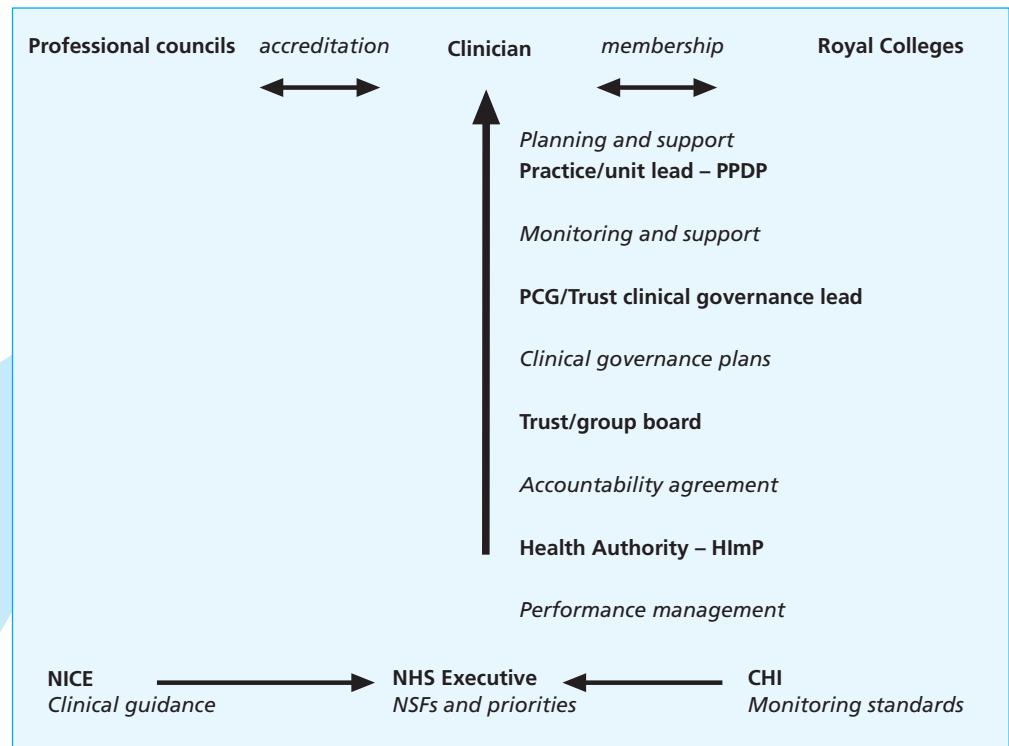


Figure 2. Managing clinical governance – who does what?

PPDP = Practice Professional Development Plan, HImP = Health Improvement Programmes, NICE = National Institute for Clinical Excellence, NSFs = National Service Frameworks, CHI = Commission for Health Improvement

audit has frequently also involved the users' perspective, and Health Authorities have supported this process and encouraged NHS Trusts to adopt a similar approach.

Health Authorities have sought to use clinical audit as a tool for coordinating and promoting action on **clinical effectiveness**. Agreeing audit plans and encouraging cooperation between NHS Trusts and PCGs can be seen as an early example of integrated clinical governance. Box 1 gives an example of a successful audit.

Conducting a formal audit programme is a cyclical process which starts with selecting a topic and moves on to agreeing standards, measuring performance against those

standards, reviewing standards in the light of performance and adapting the system before repeating the cycle. Much audit activity over the past few years has not adopted these formal steps, but has nevertheless provided useful information about current practice and stimulated change in the light of evidence and an agreed need for change in practice.

The clinical governance framework will need to build on the previous experience of audit activity and ensure that it becomes an effective contributor to quality improvement programmes. With the development of clinical governance, including clinical audit, we can expect closer monitoring of audit activity and more integration of the audit agenda with the needs of the community and the advance of clinical practice.

Box 1. A successful audit

Sixteen practices participated in a MAAG-facilitated audit of the care provided for people with asthma. The practices identified 1,346 patients with asthma, and a questionnaire looking at the patients' experience of their asthma achieved a 79% completion rate. The audit also included looking at the drugs used in the management of the patients' asthma and the use of guidelines for the management of asthma. As a result of the audit, the practices reviewed the standard of care that patients with asthma received.

Clinical effectiveness

Clinical effectiveness is a measure of the extent to which a particular intervention works. The measure on its own is useful, but it is enhanced by considering whether the intervention is appropriate and whether it represents value for money. In the modern health service, clinical practice needs to be refined in the light of emerging evidence of

Box 2. An example of clinical effectiveness

In patients who have had a total hip replacement, the use of low molecular weight heparins as thromboprophylaxis, in comparison with standard heparins, resulted in a reduction of total deep vein thrombosis (DVT) from 149 of 685 patients (22%) to 117 of 735 patients (16%) and of proximal DVT from 86 of 685 patients (13%) to 40 of 735 (5%) patients.^{3,4} Therefore, in order to prevent one episode of proximal DVT, 14 patients would need to be treated with low molecular weight heparin instead of standard heparin.

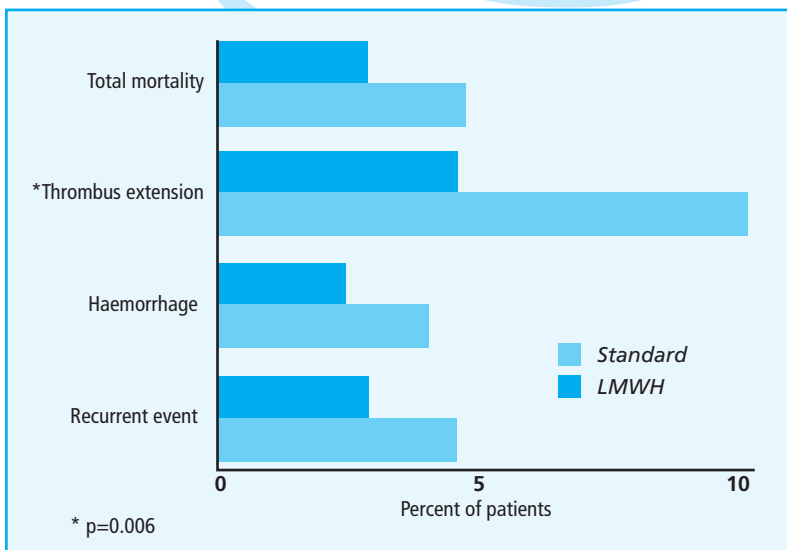
Among patients with established DVT, treatment with low molecular weight heparins was associated with non-significant reductions in total mortality, recurrent thromboembolic events and major bleeding, and significantly reduced thrombus extension (Figure 3).^{3,5} Nineteen patients with established DVT would need to be treated with low molecular weight heparin rather than standard heparin to prevent one instance of thrombus extension (that is, an NNT of 19).

In patients at high risk of thromboembolism, the evidence concerning the effectiveness of using low molecular weight heparin versus standard heparin, in prophylaxis or treatment, should determine clinical practice.

effectiveness but also has to consider aspects of **efficiency** and **safety** from the perspective of the individual patient and carers in the wider community.

Clinical effectiveness also struggles to measure some of the qualitative aspects of care that a broader definition of care needs to encompass. These include issues such as continuity of care, care which is sensitive to the personal needs of the patient and care which is based on a holistic analysis of the individual patient's needs, rather than the effectiveness of any

Figure 3. Comparison of low molecular weight and standard heparin in treatment of deep vein thrombosis³



particular intervention.

Clinical effectiveness has been promoted through the development of guidelines and protocols for particular diseases. These are based on evidence of effectiveness as assessed following randomised controlled trials, meta-analyses and systematic reviews, and made more understandable by the use of terminology such as '**numbers needed to treat**' (NNTs).

The development of National Service Frameworks (NSFs) and the formation of the National Institute for Clinical Excellence (NICE) and the Commission for Health Improvement (CHI) are further attempts to improve the responsiveness of the service to evidence of effectiveness. Dissemination through paper and electronic media under titles such as *Bandolier*, *Effectiveness Matters*, and *Therapeutics Bulletin* has been helpful in ensuring uptake in clinical practice.

Those responsible for clinical governance are likely to encourage the development of clinical practice in the light of clear evidence of effectiveness; an example is provided in Box 2.

The **medicolegal implications** of the adoption of effective practice should not be forgotten. Practitioners are increasingly being asked to justify their clinical practice, and the clinical governance framework is likely to make this process of justification more explicit. Practitioners who do not follow recommendations will have to document their reasons.

Risk management

Providing health care is a risky business. There are risks to the patient, risks to the practitioner and risks to the provider organisation. These risks all need to be minimised as part of any quality assurance programme.

● **Risks to patients:** compliance with statutory regulations can help to minimise risks to patients. Examples are the Data Protection Act, the Control of Substances Hazardous to Health (COSHH) regulations, Medicines Control Agency approval, indemnity insurance and so on. In addition, patient risks can be minimised by ensuring that systems are regularly reviewed and

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questioned – for example, by **critical event audit** and learning from complaints.

● **Risks to practitioners:** ensuring that clinicians are immunised against infectious diseases, work in a safe environment (eg, COSHH) and are helped to keep up to date are important parts of quality assurance. In the past, the levers to ensure good practice have been stronger in NHS Trusts than in primary care, and it is anticipated that the clinical governance framework will encourage wider dissemination of good practice.

● **Risks to the organisation:** poor quality is a threat to any organisation. In addition to reducing risks to patients and practitioners, organisations need to reduce their own risks by ensuring high quality employment practice (including locum procedures and reviews of individual and team performance), a safe environment (including estates and privacy), and well designed policies on public involvement.

Associated organisations, such as GP co-operatives, community pharmacists and residential care homes, should be covered by the clinical governance framework by agreeing to comply with the standards of the organisations that they are associated with.

The contracting framework of the internal market encouraged Trusts to comply with the above elements. The development of PCGs and PCTs should produce a more systematic response to these issues in primary care.

Research and development

Good professional practice has always sought to change in the light of evidence from research. The time lag for introducing such change can be very long – for example, the use of thrombolytic agents in acute myocardial infarction took more than 20 years from the first evidence of effectiveness to becoming established medical practice. Reducing time lag and associated morbidity requires emphasis not only on carrying out research, but also on using and implementing research.

Techniques such as **critical appraisal of the literature, project management** and the development of **guidelines, protocols** and **implementation strategies** are all tools for promoting implementation of research evidence. The development of

research practices and research networks in primary care, along with the national research and development programmes, such as the health technology assessment programme, and dedicated research support through Culyer funding, are promoting research in operational practice into areas of agreed national priority.

Openness

Poor performance and poor practice can too often thrive behind closed doors. Processes which are open to **public scrutiny**, while respecting individual patient and practitioner confidentiality, and which can be justified openly, are an essential part of quality assurance. Open proceedings and discussion about clinical governance issues should be a feature of the framework.

Corporate and clinical governance

The new statutory duty for quality described in the white paper required the clinical governance lead practitioner to be accountable to the chief executive (the accountable officer) of the Health Authority or NHS Trust. The line of accountability for clinical performance is therefore linked to the corporate governance accountability lines at this level. In addition, the processes for openness, learning from and review of performance, and accountability for the use of power and resources are all part of both clinical and corporate governance systems. In the future, it would seem logical for corporate and clinical governance to become even more closely integrated.

Next steps

All NHS organisations have nominated a clinician with lead responsibility for clinical governance, who reports to the chief executive and the board on all aspects of clinical quality. These clinicians will have assessed the state of readiness of the organisation for clinical governance, and will have worked with colleagues to produce a plan of action for implementing the local framework.

The plan is part of the corporate planning process and would be linked to the health

improvement programme, practice development planning, and organisational development plans and strategies, to promote quality improvement through the use of resources targeted by these planning processes. The full system of integrated planning and provision of clinical governance activity within, and between, NHS organisations had to be established by April 2000.

Practitioner re-accreditation, for example through the General Medical Council (GMC) or the United Kingdom Central Council for Nursing, Midwifery and Health Visiting (UKCC), is being implemented alongside clinical governance, and there will be important relationships between them. Poor quality practice should be uncovered through the clinical governance framework and be reported on regularly at board level. The cultural change required to promote 'whistle-blowing', complaints review, critical event audit and performance audit as integral parts of professional development will not be simple. Nevertheless, these processes are essential if quality is to improve, and will need to be actively supported by all NHS organisations.

The continuation of confidential screening and investigation by peers – for example, 'three wise men', or Health Authority and local medical committee groups – can be expected to continue with onward reporting to the GMC, for example, remaining as an option. In time, we can expect the relationship between clinical governance and professional accreditation to change and develop.

The Royal Colleges have played a vital part in promoting high standards of professional practice and will continue to do so through supervision of their members. The clinical governance framework introduces the view of

the community as an additional perspective to be taken into account in promoting quality in practitioner performance.

Current funding of clinical governance activity through the use of audit funds will need to be supplemented by the diversion of educational resources and management budgets to support relevant aspects of the framework. Changes to the funding and organisation of continuing professional development for all practitioners can be anticipated, with much more collaboration and synergy between the medical and non-medical approaches.

Any organisation providing high quality care has to show that it is meeting the needs of the population it serves. Health needs assessment and understanding the problems and aspirations of the community will require cooperation between NHS organisations, public health departments, local authorities and community health councils. Community involvement with the clinical governance processes will have to be ensured, and the roles and relationships between practitioners and the wider community will have to be reassessed, if quality is to be more broadly defined.

The system of clinical governance brings together all the elements which seek to promote quality of care, and the challenge to those responsible should not be underestimated. They will need to understand the cultures involved and will require great sensitivity if they are to help clinicians to review and justify their performance. Many clinicians are apprehensive about clinical governance and feel the changes involved could be an unnecessary intrusion. They will only be won over when they can see that it is in their interest, and that of their patients.

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What is clinical governance?

Abbreviated prescribing information: Clexane®

Presentation: Clear, colourless to pale yellow solution of 100mg enoxaparin sodium per 1mL (anti-factor Xa activity of 10,000IU/mL with reference to the WHO First International LMW Heparin Reference Standard). **Cartridges:** single dose prefilled syringes fitted into a cartridge containing either: 20mg enoxaparin sodium in 0.2mL (2,000IU) or 40mg enoxaparin sodium in 0.4mL (4,000IU) The cartridge is to be fitted into the Clexane® Auto-Injector. 100 mg/mL prefilled syringes: single dose prefilled syringes containing either: 20mg enoxaparin in 0.2mL (2,000IU) or 40mg enoxaparin in 0.4mL (4,000IU). **Indications:** Prophylaxis of thromboembolic disorders of venous origin, in particular those associated with orthopaedic or general surgery and in medical patients bedridden due to acute illness. **Dosage & Administration:** Patients with low to moderate risk of thromboembolism, eg general surgery, recommended dose of Clexane® is 20mg (2,000IU) once daily subcutaneously, the initial dose being given approximately 2 hours preoperatively. Patients with high risk of venous thromboembolism, eg orthopaedic surgery, the recommended dose is 40mg (4,000IU) once daily subcutaneously, the initial dose being given approximately 12 hours preoperatively. Clexane® should be continued for 7 to 10 days or until risk of thromboembolism has diminished. Medical patients bedridden due to acute illness, the recommended dose is 40mg (4,000IU) once daily for a minimum of 6 days until return to full ambulation, for a maximum of 14 days. **Elderly:** No dosage adjustment necessary. **Children:** Not recommended. **Contraindications:** Acute bacterial endocarditis, major bleeding disorders, thrombocytopenia in patients with positive *in-vitro* aggregation test in presence of Clexane®, active gastric/duodenal ulcer, hypersensitivity to enoxaparin, stroke (unless due to systemic emboli) and other patients with increased risk of haemorrhage. **Warning:** Clexane® must not be administered by the intramuscular route. **Precautions:** Clexane® should be used with care in hepatic insufficiency, history of thrombocytopenia, and conditions with increased bleeding potential. Different low molecular weight heparins may not be equivalent; alternative products should not be substituted during therapy. Heparins can suppress adrenal secretion of aldosterone leading to hyperkalaemia. **Pregnancy:** Clexane® should not be used during pregnancy unless no safer alternative is found. **Lactation:** Advise avoidance of breast-feeding. **Interactions:** Care in patients receiving agents affecting haemostasis, eg oral anticoagulants, thrombolytics, systemic glucocorticoids, NSAIDs, aspirin. **Adverse Reactions:** Bleeding in the presence of associated risk factors, rarely retroperitoneal and intracranial bleeding. Rarely thrombocytopenia, liver abnormalities (eg transaminases and alkaline phosphatase changes), allergic reactions. At site of injection: pain, haematoma, irritation, rarely hard inflammatory nodules and skin necrosis. Osteoporosis has not been reported with Clexane® but the risk cannot be excluded. Heparins can cause increase in plasma potassium, and rarely, clinically significant hyperkalaemia. Rare reports of intra-spinal haematoma when using spinal/epidural anaesthesia and post-operative indwelling catheter. **Pharmaceutical Precautions:** Do not mix with other injections or infusions. Clexane® cartridges: store at or below 25°C. Do not freeze cartridges. Prefilled syringes: do not store above 25°C. Do not refrigerate or freeze.

Legal Category: POM; Clexane® cartridges PL 0012/0336, Clexane® 100 mg/mL prefilled syringes PL 0012/0196. **Basic NHS cost for 10 cartridges:** 20mg - £47.90, 40mg - £60.79. **Basic NHS cost for 10 prefilled syringes:** 20mg - £33.89, 40mg - £45.16.

Full Prescribing Information and further information is available on request from Aventis Pharma, 50 Kings Hill Avenue, West Malling, Kent. ME19 4AH. **Date of preparation:** June 2000.

This publication, along with the others in the series, is available on the internet at www.evidence-based-medicine.co.uk



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Any enquiries please contact:

Team Assistant to the Health
Economics Unit
Aventis House
Kings Hill
West Malling
Kent
ME19 4AH
Tel: 01732 584 254
Fax: 01732 584 029

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