Clinical Governance: in the new NHS

To: Health Authorities - Chief Executives
NHS Trusts - Chief Executives

Cc: Health Authorities - Chairmen
NHS Trusts - Chairmen
Health Authorities - Directors of Public Health
NHS Trusts - Medical Directors
NHS Trusts - Directors of Nursing
Special Health Authorities - Chief Executive
Community Health Councils - Chief Officers
Local Authorities - London Boroughs Chief Executives
Local Authorities - Metropolitan Districts Chief Executives
Local Authorities - Non-Metropolitan Districts Chief Executives
Social Services Directors - England
Local Dental Committees
Local Medical Committees
Local Optical Committees
Local Pharmaceutical Committees
Medical Schools - Deans
Schools of Nursing - Deans
Professional Bodies
Representative Bodies for Health services
Patient Representative Bodies
Consortia Chairs, for distribution to members
Dental Postgraduate Deans
Further details from: Julian Brookes
606 Richmond house
79 Whitehall
London
SW1A 2NS
0171-210-5455

Additional copies of this document can be obtained from:

Department of Health
PO Box 410
Wetherby
LS23 7LN

Fax 0990 210 266

It is also available on the Department of Health website at
http://tap.ccta.gov.uk/doh/coin4.nsf

© Crown copyright 1999
Clinical Governance: Quality in the new NHS

Summary

1. Following the publication of A First Class Service: Quality in the new NHS, and drawing on responses to that document, this circular covers more detailed guidance on the implementation of clinical governance in 1999/2000 and beyond. This HSC should be read in conjunction with attached guidance.

Background

2. The consultation document A First Class Service: Quality in the new NHS set out a framework for quality improvement and fair access in the NHS, the main components of which were:

   - clear national standards for services and treatments, through National Service Frameworks and a new National Institute for Clinical Excellence
   - local delivery of high quality health care, through clinical governance underpinned by modernised professional self-regulation and extended lifelong learning
   - effective monitoring of progress through a new Commission for Health Improvement, a Framework for Assessing Performance in the NHS and a new national survey of patient and user experience.

3. Clinical governance is central to this strategy. It provides a framework within which local organisations can work to improve and assure the quality of clinical services for patients. The commitment in A First Class Service to further guidance on its implementation was widely welcomed, and initial guidance on the development of clinical governance within Primary Care Groups (PCGs) has already been issued in HSC 1998/139 (LAC 98/21) and HSC 1998/228 (LAC 98/32).

4. HSC1999(33), covering publication of A First Class Service, tasked NHS Trusts and Health authorities with undertaking preparatory work on clinical governance. It also asked them to consider, in advance of further guidance, how they could use the proposals set out in that document to take forward work on quality improvement locally.

5. The attached document provides further guidance on the implementation of clinical governance in 1999/2000 and beyond. It identifies linkages with other parts of the modernisation agenda, and sets out a vision of clinical governance for the next five years and highlights key tasks for the first year of implementation.
Action

6. NHS Trusts, Health Authorities and PCGs should use this guidance to inform their work on implementing clinical governance.

7. In the first year of implementation NHS Trusts, Health Authorities and PCGs should as a minimum:

   By April 1999, identify lead clinicians for clinical governance and set up appropriate structures (including, for NHS Trusts, Board sub-committees) for overseeing clinical governance within their organisation;

   Agree with the relevant NHS Executive Regional Office (for NHS Trusts and Health Authorities) or Health Authorities (for PCGs and in due course PCTs) a process and timescale for conducting a baseline assessment of capability and capacity for implementing clinical governance;

   Formulate an action plan in the light of this assessment;


8. The implementation of clinical governance in NHS Trusts and Health Authorities will be monitored by Regional Offices of the NHS Executive. Implementation in Primary Care Groups (and in due course Primary Care Trusts) will be monitored by Health Authorities. In addition, the Commission for Health Improvement will, subject to legislation, provide an external assurance on implementation of clinical governance by visiting each local health system every 3-4 years.

This circular has been issued by:
The Chief Medical Officer
Clinical Governance
Quality in The New NHS
INTRODUCTION (Paragraph 1) Page 4
This section sets out what the Government’s programme of Modernisation of the NHS will achieve.

AIM (Paragraphs 2 – 4) Page 4
This section identifies quality as the driving force for the development of health services and explains why clinical governance is central to the quality agenda. It sets out the principles and processes that will develop clinical governance.

KEY POLICY PRINCIPLES (Paragraphs 5 – 13) Page 5
This section identifies the key elements of the strategy for Improving quality in the NHS. It sets clinical governance in the context of the wider quality agenda.

THE VISION FOR THE NEXT 5 YEARS (Paragraphs 14 – 17) Page 7
This section identifies the changes and developments that the NHS organisation must aspire to in the medium term if clinical governance is to be successful. With Annex 1 it sets out the areas of benefit that change will bring.

CLINICAL GOVERNANCE: ITS PLACE IN THE WIDER PICTURE (Paragraphs 18 – 20) Page 8
This section identifies how quality planning through clinical governance is integral to the Government’s policies for modernising and improving the NHS. It covers issues such as integrated planning; staff support and development; workforce solutions; adopting good practice; learning from experience; and addressing poor clinical performance. It also sets clinical governance in the wider context of controls assurance.
THE FOCUS OF CLINICAL GOVERNANCE: TEAMWORK, PARTNERSHIP, COMMUNICATION (Paragraphs 21 – 25)

This section sets out the focus of clinical governance as a multi-disciplinary and multi-agency activity aimed at delivering seamless care. With Annex 2 it sets out the main components of clinical governance.

ROLES AND RELATIONSHIPS (Paragraphs 26 – 27)

This section sets out the key roles and respective responsibilities of Health Authorities, Primary Care Groups, Primary Care Trusts, NHS Trusts, Regional Offices of the NHS Executive and the Commission for Health Improvement.

CLINICAL GOVERNANCE IN ACTION – YEAR 1 (Paragraphs 28 – 37)

This section identifies the key steps to be undertaken in the first year of clinical governance. These focus on establishing accountability and leadership arrangements; assessing the organisation’s baseline position; agreeing an action plan for the year; and implementing that plan.

MONITORING PERFORMANCE (Paragraphs 38-40)

This section sets out the arrangements for monitoring clinical governance. It identifies the key roles and responsibilities of Regional Offices of the NHS Executive, Health Authorities and the Commission for Health Improvement.

ANNEX 1

Benefits arising from clinical governance.

ANNEX 2

Main components of clinical governance.

ANNEX 3

Minimum expectations for Annual Reports in 1999/2000
INTRODUCTION

1. The Government’s aim is to build a modern and dependable health service, providing a fast, responsive, high quality service consistently in all parts of the country. A substantial programme of modernisation is being introduced to:

- Improve people’s health – and that of the worst off in particular – by tackling the causes of ill-health nationally and locally;
- Make services quick and convenient for people to use;
- Improve the consistency of services so that people can be sure of a high quality service whenever they use the NHS;
- Break down the barriers between different parts of the health and social care system so that people’s needs are dealt with as a whole and without being passed from pillar to post;
- Modernise the NHS by investing in staff, buildings, equipment and information systems.

AIM

2. The new NHS White Paper and the consultation document A First Class Service set out the Government’s strategy for ensuring that quality of care becomes the driving force for the development of health services in England. Clinical governance is the linchpin of this strategy. It applies to all sectors of the NHS.

3. Clinical governance establishes the need to focus on the activities involved in delivering high-quality care to patients. It will mean the creation of a systematic set of mechanisms that will support staff and develop all health organisations to deliver a new approach to quality.

4. This guidance is intended to be developmental. In other words, its aim is to promote the measures, which will help health organisations develop good clinical governance. The guidance is not prescriptive as to the exact methods to be used. This is for health organisations and their staff to work out in the light of their knowledge of local services. However, the guidance does set out a clear framework for action. It emphasises the need for a fundamental shift in the culture of many NHS organisations. Its implementation needs to be consistent, with key principles and processes necessary to develop clinical governance. This guidance has been strongly influenced in its scope, content and overall approach by responses to consultation on A First Class Service.
KEY POLICY PRINCIPLES

5. *The New NHS Modern Dependable* sets out a ten-year modernisation strategy for the NHS. The consultation document *A First Class Service* focused on improving the quality of care, proposing a new model that brought together responsibility for quality at local level with clear national standards. The aim is to provide an NHS that continually improves the overall standard of clinical care, whilst reducing variations in outcomes of, and access to, services as well as ensuring that clinical decisions are based on the most up-to-date evidence of what is known to be effective.

There are three main elements of this strategy for improving quality in the NHS:

- **arrangements for setting clear national quality standards**, through National Service Frameworks and the National Institute for Clinical Excellence.
- **mechanisms for ensuring local delivery** of high-quality clinical services, through clinical governance reinforced by a new statutory duty of quality and supported by programmes of lifelong learning and local delivery of professional self-regulation; and
- **effective systems for monitoring delivery** of quality standards, in the form of a new statutory Commission for Health Improvement and an NHS Performance Assessment Framework, together with the first national survey of patient and user experience.
6. The new concept of clinical governance is central to this strategy. It sits in the centre of the quality agenda (see above). Its successful development and delivery is crucial to the overall success of the agenda. It is defined as:

“A framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.”

7. The challenge posed by the new statutory duty of quality in the NHS is to transform the delivery of primary, hospital and community care so that consistently better outcomes are produced for patients. Despite the overall high standard of care that the NHS produces, at any one time health organisations and the services they provide will show variation in their performance – some demonstrating excellence on a par with the best in the world, others experiencing serious problems which they are not able to resolve. The majority of local health services will fall somewhere around the middle of the “quality curve”; many things will be done well but managers, clinicians and patients will see other areas where they want to improve quality.

8. Clinical governance involves above all shifting the level of quality provided by the majority of health organisations – those in the middle range of performance – closer to the performance of the exemplar services in the NHS. It will also involve effective learning from leading edge services, something which the NHS has not done well in the past. The public also expects that clinical governance will be able to prevent the kinds of incidents, crises and serious failures in standards of care which, although not common, have been a very visible feature of the past. In other words, there will be high expectations that health organisations throughout the country will become good at learning from experience (both of success and of failure).

9. A First Class Service sets out the main components of clinical governance. Having considered carefully the responses to consultation, and further discussion with those actively involved in local clinical governance, these components have been refined in the Guidance (Annex 2). The initial emphasis on NHS Trusts has been broadened to show the relevance to primary care and the NHS as a whole.

10. Many health organisations in England are already working to achieve this end. What clinical governance does is to bring together the diversity of existing approaches into a systematic programme to establish continuous quality improvement in every health organisation.

11. Clinical governance will apply to all Health Authorities, Primary Care Groups, Primary Care Trusts, and to NHS Trusts. It will also apply to Special Health Authorities which provide services direct to patients (e.g. the three Special Health Authorities that provide high security psychiatric services). For the purposes of this guidance, these Special Health Authorities (SHAs) should follow as closely as possible the arrangements set out for NHS Trusts. Approaches need to be tailored to meet local needs and will depend on the individual organisation, the service and their current structure, but the basic principles are the same. Clinical governance also applies to clinical practitioners working outside these organisations (i.e. General Dental Practitioners, Optometrists and Community Pharmacists) – they will be covered in future guidance. All approaches need to form a coherent strategy across a local health service. It will be the responsibility of the Health Authority to ensure that this happens, and to ensure that the local clinical governance programme links to Health Improvement Programmes (HImPs).
12. Clinical governance cannot be implemented overnight. It will take time for the culture of quality improvement to become established and for the necessary supporting systems to be developed and work well. There are, however, some key changes, which will demonstrate – in short to medium-term - that clinical governance is being successfully implemented.

13. Clinical governance will be underpinned by a new statutory duty on NHS Trusts and Primary Care Trusts which will (subject to legislation) require them to put and keep in place arrangements for monitoring and improving the quality of the health care that they provide. This guidance, which will be complemented, by further guidance in the future, begins to set out the detail of what is required.

THE VISION FOR THE NEXT 5 YEARS

14. For clinical governance to be successful, all health organisations must demonstrate features such as:

- An open and participative culture in which education, research and the sharing of good practice are valued and expected.
- A commitment to quality that is shared by staff and managers, and supported by clearly identified local resources, both human and financial.
- A tradition of active working with the public, users of services and their carers.
- An ethos of multi-disciplinary team working at all levels in the organisation.
- Regular Board-level discussion of all major quality issues for the organisation and strong leadership from the top.
- Good use of information to plan and to assess progress.

Annex 1 describes the areas of change and the benefits that change will bring.

A new culture in NHS organisations

15. Above all clinical governance is about changing organisational culture in a systematic and demonstrable way, moving away from a culture of “blame” to one of learning so that quality infuses all aspects of the organisation’s work.

16. Few would argue that the way an organisation is led, the extent to which staff are involved in planning its development, the willingness to embrace constructive criticism and new ideas, as well as a determination to break down barriers between professional groups, are hallmarks of an organisation in which quality is likely to thrive.

17. In so far as these characteristics can be measured, it is clear that some health organisations do indeed have a “culture” in which clinical excellence and high service quality are apparent, whilst a small number are quite dysfunctional. The majority lie somewhere in the middle, where many services are delivered well but others require improvement.
CLINICAL GOVERNANCE: ITS PLACE IN THE WIDER PICTURE

18. The Government has introduced a wide range of policies to modernise and improve the NHS. As these policies begin to be implemented it is important that everyone involved understands the way in which they are connected to and support clinical governance.

19. Clinical governance predominantly operates at local service level. It must be seen as a systematic approach to quality assurance and improvement either within a health organisation, within a clinical service delivered by a health organisation, or within a service provided by a number of local organisations or agencies working in partnership.

20. Once it is recognised that this local organisational or service focus is central to developing clinical governance then it will be clear that many other initiatives and mechanisms must be connected so that the local drive to develop clinical governance is empowered and supported.

(a) Integrated planning for quality

Creating plans to address deficiencies in a service or bring about an improvement in it will be a vital part of the clinical governance process in hospitals, community health services and primary care settings. If clinical governance works well, this will result in a myriad of “steps up” in the quality of care provided right across the country. It is important that nothing stifles this process of quality planning at local service level. Harnessing the knowledge and expertise of staff providing the service in assessing its strengths and weaknesses will be one of the cornerstones of quality improvement through clinical governance.

There are three main reasons why the process of quality planning at local service level must connect to the planning processes that are part of Health Improvement Programmes (HImPs):

- The needs assessment phase of the HImP may detect opportunities for quality improvement which have not been recognised by individual health organisations.

- Quality improvements proposed to the HImP by the local service may have a much wider applicability for other local services.

(b) When quality improvement depends on workforce solutions

Plans and initiatives to improve quality taken under clinical governance will seek, for example, to remedy deficiencies in a service, to achieve a standard of excellence comparable to a flagship service elsewhere in the country or to reorganise the service to make it more effective. Closing the gap between the present service and the desired new level of quality will often not be possible without addressing workforce issues such as:

- Enhancing the skills of existing staff through training or professional development.

- Developing a new group of staff with a set of skills and competencies to fit the new circumstances.
It is important to have the right number of people, with the right skills, to deliver the quality agenda. Important in this regard are the Regional Education and Development Groups, Education and Training Consortia, Postgraduate Deans and Local Medical Workforce Advisory Groups working within a clinical governance context. Continuing Professional Development (CPD) will also be key to delivery, ensuring that professional staff continue to improve their skills and knowledge. Making connections between local plans for quality improvement and workforce, education, training and professional development planning and resourcing mechanisms is crucial. In the past, they have too often proceeded on separate tracks. Certain individuals will be very important in ensuring that expertise in workforce solutions genuinely supports local quality improvement endeavours. They include Postgraduate Deans, Clinical Tutors, Royal College Tutors, Regional Directors of Education and Training. Linkages will also need to be made to library services to support local implementation of clinical governance.

An effective local human resources strategy will help to make many of these key connections. It will give structure to the training and educational needs of staff – both clinical and managerial. It will also enable clear, measurable objectives to be put in place (i.e. in the case of clinical governance, each local employer to have in place training and development plans for the majority of health professionals by April 2000). The recent Human Resource Strategy, The new NHS – Working Together: Securing a Quality Workforce for the NHS, further supports the process.

(c) Clinical governance needs good information to assess the quality and performance of services

The availability of good information is essential to any programme of quality improvement. Such information is necessary, for example, to:

- Identify the scope for improvement within available resources (a baseline assessment).
- Ensure that a planned quality improvement or an investment in developing a service has in fact resulted in the desired change (monitoring progress).
- Make comparisons between a local service and its counterparts elsewhere to identify scope for improvement (benchmarking).
- Provide information to the public about the quality of services provided by a health organisation (openness and public accountability).
- Monitor adverse outcomes of care (early warning of serious service failures).

Present NHS information systems are not of an adequate standard to meet these needs for information on quality. In small-scale initiatives within a service, data might be gathered specially to throw light on the quality of a service. Nevertheless, the clinical governance programme must be supported by good information, which is comprehensive, routinely available, relevant, up-to-date and accurate and which is capable of comparison with national data.

Over time, local NHS organisations will need to ensure that their clinical governance plans are underpinned by comprehensive information on quality. Health Authorities, Primary Care Groups, Primary Care Trusts and NHS Trusts must reassess their informatics needs and identify how they will develop the information and information technology infrastructure to support clinical governance. These plans should form part of the Local Implementation Strategy for Information Management and Technology.
The forthcoming NHS Performance Assessment Framework and associated set of High Level Performance Indicators (HLPIs) will also provide useful comparative information on performance relative to similar organisations. The set of HLPIs will include a selection of the clinical indicators which are being published later in the year. These initial clinical indicators will focus on a range of procedures, including mortality and readmission rates following heart attack and hip replacement on a hospital by hospital basis. In the future, clinical indicators will be developed to cover a wider range of procedures. The HLPIs and clinical indicators will be powerful tools in driving forward quality improvements. They will help to identify where questions need to be asked about a range of performance issues.

(d) Health professionals need knowledge from research to support their clinical decisions

Without the knowledge which flows from a comprehensive and sound research and development programme, the first building block in evidence-based clinical decision making will be missing. When such knowledge is generated it must be converted into information which is tailored to the needs of health professionals taking clinical decisions. This means focusing on the means by which evidence is made accessible and equipping staff with the skills to know how to evaluate and apply it in individual clinical situations. The NHS Research and Development Programme ensures that relevant primary research is carried out to generate new knowledge. The production of evidence is, however, not enough. It must be easily available to clinicians and its use encouraged to support high quality clinical decision-making. There needs to be a systematic approach to the collection and dissemination of evidence, within an organisation, to ensure that clinicians are able to access the most up-to-date information deriving from research. Libraries have an important function in facilitating this, but should not be exclusively relied upon to provide information for clinicians. Bulletins, newsletters and computer based information systems should also be encouraged as part of the infrastructure of local clinical governance.

Some existing sources are well known:

- **The Cochrane Library.** This is designed to provide the evidence that is needed to make informed health care decisions. It contains four databases: the Cochrane Database of Systematic Reviews, the Database of Abstracts of Reviews of Effectiveness, the Cochrane Controlled Trials Register, and the Cochrane Reviews Methodology Database.

- **The NHS Centre for Review and Dissemination (CRD).** This commissions and supports reviewers to undertake reviews on areas of importance to the NHS. It also publishes the Effective Health Care Bulletins and Effectiveness Matters which produce accessible summaries of research evidence which are topic based.

- **The National Research Register,** which gives information on research under way in the NHS

Two major new initiatives are being implemented that over time will, in future make a significant difference to the consistency and authority of guidance, and to the accessibility of information.

- **The National Institute for Clinical Excellence (NICE),** which is being established to promote clinical and cost-effectiveness. It will produce and disseminate high quality, evidence-based guidance to support front line staff, including guidelines for the management of diseases and the use of significant new and existing interventions.
The National Electronic Library for Health which was announced in the NHS information strategy, will be organised so as to make information about the state of scientific knowledge readily accessible to decision makers in the NHS via the Information Management and Technology network. It will include outputs ranging from summaries of primary and secondary research evidence (including systematic reviews) to evidence based guidance to support clinical practice and evidence-based learning.

Health Authorities, Primary Care Trusts, Primary Care Groups and NHS Trusts will need to monitor their professional staff to ensure that they are gaining access to the knowledge and evidence that they need to improve the quality of their work.

(e) Poor Performance

Weaknesses in the quality of care provided by a local health service can result from poor performance by individual health professionals. Although such occurrences are small in proportion to the high standards maintained by the majority of practitioners, they have a disproportionate impact. They can have serious repercussions for individual patients and their families, but they can also lead to a more general loss of public confidence in a local service. Recent experience has shown that the present mixture of professional self-regulation and NHS procedures has not been successful in preventing, recognising and dealing effectively with the problem of poor clinical performance. In medicine, important new proposals have been made by the General Medical Council, to strengthen procedures for professional self-regulation through revalidation. If the proposals are implemented, a doctor’s right to remain on the medical register would have to be affirmed every five years. A range of other bodies, including professional organisations such as the medical Royal Colleges, have begun to identify their potential contribution.

All these initiatives will have an important part to play in dealing with poor practitioner performance. However, they must be closely aligned with the mechanisms of clinical governance. To this end, a consultation document will shortly be issued which will address these issues, initially for medical practice. It will explain how professional self-regulation and clinical governance relate to each other and propose changes to enable an integrated approach to deal with poor clinical performance within an NHS setting.

(f) Learning From Experience

A crucial element of clinical governance, and indeed of any good quality improvement system, is the ability to detect, analyse and learn from relevant experiences, including adverse events and service failures. We cannot pretend that, in a system as complex as the NHS, things will never go wrong, but it is important to ensure that where adverse events do happen the lessons are learned and put into practice to help prevent recurrence. In implementing clinical governance, local health organisations should give early attention to this area, concentrating on what can be learned from complaints, adverse incidents and enquiries into their services.

Historically, this is not an area where the NHS has always been strong. An expert advisory group, chaired by the Chief Medical Officer, has therefore been convened to look at ways in which the NHS can most effectively learn from service failures and adverse events, drawing on existing good practice in the NHS and other sectors.
(g) Adopting good practice

The NHS is a national service. If patients in one part of the country are benefiting from best practice – say as a result of innovation in a local service – then patients in the rest of the country should also enjoy the benefits of the enhanced quality. As an organisation, the NHS in the past has not been able to ensure that demonstrated good practice in the service is systematically adopted more widely. The lost opportunities to improve quality because of this weakness are enormous. We need to move to a situation in which health organisations and services delivering clinical governance can:

- Have access to service-specific information on good practice
- Be prompted to look critically at their own services by the same service in other organisations/regions
- Ensure that good practice is evidence-based

Many NHS organisations have established their own networks or have worked with external organisations such as the King’s Fund and the British Association of Medical Managers (BAMM) to provide them with relevant good practice. It is important that NHS organisations continue to develop their own networks to learn from and share good practice from other similar organisations. There are a variety of ways in which this is done at present – benchmarking clubs, twinning, exchange visits, master classes. The impetus to search for good practice must come from within the organisation and be part of its culture. National initiatives support and enhance this process. An NHS Web Site is being launched simultaneously with the issuing of this guidance. The intention is that the site will enable local services and interested staff to interact with one another, sharing good practice and accessing information from other web sites. The site can be accessed via:

www.doh.nhsweb.nhs.uk/nhs/clingov.htm

Over the last year, the NHS Chief Executive has been leading work on good practice. As a result:

- NHSWeb. It will house a database, called the database of Service delivery and practice (SDP). NHS staff will be able to enter details of activities designed to improve services for patients, for example implementing clinical governance, managing emergency pressures, managing waiting lists. NHS staff will also be able to search the database for relevant examples of good practice in other parts of the country. The Learning Zone will also contain an NHS Trust Benchmarking Database – to allow comparisons of cost and outcomes by NHS Trust. High level indicators of performance by NHS Trusts will be put on to this database at a later date.

- areas of service: waiting lists and times; primary care; mental health; cancer services; health improvement; and staff development. A beacon is a service within the NHS which has been selected as a particularly good example of what it does. Beacons will be given financial support to enable to disseminate learning about their good practices to other NHS organisations.
(h) **Linking clinical governance and wider controls assurance**

In the past two years the NHS has adopted a policy of controls assurance – organisational risk management, to ensure that its organisations are well managed. The management of organisational risk underpins the delivery of high-quality clinical care. The task of delivering quality care to patients is made easier if organisations have in place sound financial systems and complementary arrangements for assessing and managing organisational (non-financial and non-clinical) risks - such as those which impact on the health and safety of staff and patients.

---

**THE FOCUS OF CLINICAL GOVERNANCE: TEAM WORK, PARTNERSHIP, COMMUNICATION**

21. The primary focus of clinical governance is the delivery of care to patients: in Primary Care Groups; Primary Care Trusts; NHS Trusts. Later sections of this guidance set out the steps which all health organisations can take to establish good clinical governance.

22. It must be recognised, however, that the practice of clinical governance at service level – clinical teams analysing and assessing the quality of their services and seeking ways to improve them – will be a multi-disciplinary and often also a multi-agency activity.

23. Today, many patients’ needs derive from chronic diseases, which require care from a range of health professionals working in different organisations in a locality. Obvious examples in which there is an integrated approach between primary and secondary care are diseases like diabetes mellitus, asthma and epilepsy. High quality care should be characterised by multi-sectoral, multi-professional care delivered in a way which is seamless, as far as the patient is concerned. Judgements about quality and how to improve it, as well as arrangements to address these issues must also have the same service focus – with accountability linking back to the organisations.

24. The focus of clinical governance will be different for smaller clinical specialities where lead professionals delivering them may have no local counterparts with whom to make comparisons and assessments of quality. They must therefore share clinical governance arrangements with similar sub-specialists in other hospitals either regionally (e.g. renal services) or nationally (e.g. clinical genetic services).

25. Thus, clinical governance must have a service as well as an organisational focus. Although health organisations remain accountable for the quality of their services, they must recognise that many services are multi-professional, multi-disciplinary and multi-agency. The main components of clinical governance are also summarised in Annex 2.
ROLES AND RELATIONSHIPS

26. NHS organisations will need to ensure that they can demonstrate that they are implementing clinical governance – both in the short term and long term. Development at local level will vary from organisation to organisation, but there is a range of key tasks and responsibilities that all NHS organisations will need to be able to demonstrate progress against. These are:

- The four key steps outlined in the next section of this guidance.
- The vision for the medium term in Annex 1.
- The main components of clinical governance as outlined in Annex 2.

27. There are also some specific key roles and responsibilities which apply to particular types of NHS organisations.

a) Health Authorities

The main aspects of Health Authorities’ roles and responsibilities on clinical governance are:

- Identifying the priorities for quality improvement in the locality through the needs assessment phase of the Health Improvement Programme, drawing on individual health organisation’s action plans and other sources of information.
- Deciding on investments and action required in the HIImP to bring about agreed improvements in quality.
- Recognising and promoting good practice through experience of working with individual health organisations on their quality plans.
- Supporting and facilitating the development of clinical governance amongst all local NHS organisations, but particularly in Primary Care Groups (PCGs) and amongst those contractor professionals (who are not encompassed by PCG arrangements).
- Identifying those specialities or services which, because of their specialist nature, have insufficient ‘critical mass’ to undertake clinical governance on a purely local basis, and ensuring adequate arrangements.
- Ensuring good clinical governance of Health Authority functions, such as public health including communicable disease control, obtaining appropriate clinical advice and health needs assessment.
(b) **Primary Care Groups**

Primary Care Groups have responsibility for:

- Undertaking the four key implementation steps (establishing leadership and accountability arrangements, baseline assessment, action plan, reporting arrangements) for clinical governance; see next section of this guidance.

- Integrating clinical governance into the development of Primary Care Groups – as laid out in PCG guidance, and further developing the programme in accordance with this and future guidance, which may be issued from time to time.

- Assuming joint accountability for clinical governance of services which are delivered on a multi-sector, multi-agency basis.

- Making sure that clinical governance principles are applied to services delivered by other providers on their behalf through Long Term Service Agreements and through contracts with non-NHS providers.

- Developing a coherent cross-organisational approach to clinical governance, by working effectively with other agencies, including NHS bodies.

- Supporting their member practitioners in applying clinical governance to the delivery of the general medical service and personal medical services in the Primary Care Act pilots.

(c) **Primary Care Trusts**

Primary Care Trusts will have responsibility for:

- Undertaking the four key implementation steps (establishing leadership and accountability arrangements, baseline assessment, action plan, reporting arrangements) for clinical governance; see next section of guidance.

- Further developing the programme of clinical governance in accordance with the principles outlined in this guidance and taking account of further guidance which may be issued from time to time.

- Making sure that clinical governance principles are developed and applied which cover the full range of services they provide, and those that are delivered by other providers on their behalf.

- Assuming joint accountability for clinical governance of services which are delivered on a multi-sector, multi-agency basis.

- Establishing an open, learning relationship with bodies which may make judgements about the quality of their services or their programme of clinical governance (particularly the Commission for Health Improvement).

- Making sure that clinical governance principles are applied to services delivered by other providers on their behalf through Long Term Service Agreements and through contracts with non-NHS providers.
• Supporting their member practitioners in applying clinical governance to the delivery of the general medical service and personal medical services in the Primary Care Act pilots.

(d) NHS Trusts

NHS Trusts have responsibility for:

• Undertaking the four key implementation steps (establishing leadership and accountability arrangements, baseline assessment, action plan, reporting arrangements) for clinical governance; see next section of this guidance.

• Making sure that clinical governance principles are applied to services delivered by other providers on their behalf and in private practice areas of their own facilities.

• Further developing the programme of clinical governance in accordance with the principles outlined in this guidance and taking account of further guidance which may be issued from time to time.

• Ensuring that all hospital doctors take part in national clinical audits and Confidential Inquiries.

• Assuming joint accountability for clinical governance of services which are delivered on a multi-sector, multi-agency basis.

• Establishing an open, learning relationship with bodies which may make judgements about the quality of their services or their programme of clinical governance, particularly the Commission for Health Improvement.

(e) Regional Offices of NHS Executive

Regional Offices of the NHS Executive have responsibility for:

• Ensuring that all guidance is implemented in a coherent manner.

• Assessing year-on-year progress against individual organisation’s objectives for the implementation of: the four key steps; the vision, (monitored against the sort of indicators outlined in Annex 1); and the main components of clinical governance outlined in Annex 2.

• Facilitating links between the Commission for Health Improvement (CHI) and NHS organisations. Helping NHS organisations to: make best use of CHI; and develop and implement effective action plans following CHI reviews or investigations.
Commission for Health Improvement

The Commission’s core functions were outlined in A First Class service. These are to:

- Provide national leadership to develop and disseminate clinical governance principles;
- Independently scrutinise local clinical governance arrangements to support, promote and deliver high quality services, through a rolling programme of local reviews of service providers;
- Undertake a programme of service reviews to monitor national implementation of National Service Frameworks, and review progress locally on implementation of these Frameworks and NICE Guidance;
- Help the NHS identify and tackle serious or persistent clinical problems. The Commission will have the capacity for rapid investigation and intervention to help put these right; and
- Over time, increasingly take on responsibility for overseeing and assisting with external incident inquiries.

The Commission will have the key role in providing the public and the Secretary of State with the assurance that clinical governance is being implemented appropriately at every level of the NHS.
The previous sections set out an ambitious vision. However, the initial task for NHS organisations is to take practical steps to ensure that the NHS implements clinical governance in a coherent manner. Organisations will be at very different stages of development, but there are four key steps which will need be taken in the first year.

**The 4 Key steps to be undertaken by Year 1 by April 2000**

- Establish leadership, accountability and working arrangements
- Carry out a baseline assessment of capacity and capability
- Formulate and agree a development plan in the light of this assessment
- Clarify reporting arrangements for clinical governance within Board and Annual Reports

**Step One: Establishing leadership, accountability and working arrangements**

29. The NHS Bill places a duty of quality on Primary Care Trusts and NHS Trusts. Chief Executives and the Board will be responsible for ensuring that this duty is discharged properly.

30. *A First Class Service* proposed that the Chief Executive should identify a lead clinician for clinical governance in their organisation. The leadership arrangements will differ according to local circumstances, but it is likely that the lead clinician will wish to assemble a team with each member having responsibility for different aspects of the programme (one possible model is illustrated in Figure 3).

Whatever leadership arrangements are decided upon it is important that they demonstrate:

- **Inclusivity**, ensuring that all key groups in the organisation are involved and kept fully informed about the purpose and progress of the clinical governance programme.

- **Commitment from the top**, reporting and having free access to the Chief Executive and the Board particularly when problems need to be resolved or barriers to progress have been identified.

- **Good external relationships**, forging strong, open working partnerships with health organisations and other agencies in the locality.

- **Constancy of purpose**, keeping the programme on course and not being deflected from the goals that the organisation has set itself.

- **Accounting for progress**, being able at all times to provide a comprehensive overview of progress with the clinical governance programme throughout the organisation.

- **Communicating**, to all staff in the organisation and to external partners on a regular basis.
31. All NHS organisations need to establish clear accountability and working arrangements for clinical governance. Most NHS Trusts have already established a quality or clinical governance committee of their Board; all should do so. These committees should represent an appropriate balance of skills and interests, and organisations should also give consideration to how they can best ensure public and user input into high-level discussions about the development of clinical governance.

<table>
<thead>
<tr>
<th>Action: Establishing leadership, accountability and working arrangements:</th>
</tr>
</thead>
<tbody>
<tr>
<td>By April 1999, Health Authorities, Primary Care Groups, Primary Care Trusts and NHS Trusts should have identified lead clinicians for clinical governance and set up appropriate structures. Arrangements should reflect this guidance. For NHS Trusts, arrangements should include Board Sub-Committees for overseeing clinical governance within their organisation.</td>
</tr>
</tbody>
</table>

Step two: The baseline assessment of capability and capacity

32. Implementation of clinical governance should start with a baseline assessment of the organisation’s position. Primary Care Groups may wish to discuss with Health Authorities how they access the skills needed to undertake the baseline assessment, and which form part of their development plan. This baseline will inform the first year’s plans. The timescale and process for completion should be agreed with Regional Offices (for Trusts and Health Authorities) or with Health Authorities (for Primary Care Groups, and Primary Care Trusts). The process should be organisation-wide and participative. It should, as a minimum, include:

- A searching and honest analysis of organisations’ strengths and weaknesses in relation to current performance on quality.
- The identification of any particularly problematic services (drawing where possible on objective data or feedback from users of services or referring agencies).
- An assessment of the extent to which data are in place for quality surveillance.
- Establishing whether there are deficits in key mechanisms (e.g. for risk management, multi-disciplinary clinical audit, supporting information management, patient participation).
- Making sure that there is integration of quality activities and systems.
- Establishing explicit links to Health Improvement Plans, National Service Frameworks – and for PCG/PCTs, locally identified priorities.
- Designing the ways in which underpinning strategies (ie information management and technology, human resources, Continuing Professional Development, and research and development) will support clinical governance within the organisation.

When a quality initiative has significant resource consequences, discussions should take place within the context of the HImP and the available resources. Decisions will have to be made about which improvements are feasible and which are not.
33. The baseline assessment should let the whole organisation see what it is good at, what it is less good at, and the areas needing to be developed. It should provide the basis for an action plan that includes clear milestones.

Action: The baseline assessment of capability and capacity

Baseline assessments should be carried out in accordance with the guidance and completed at the latest by the end of September 1999. NHS Trusts and Health Authorities should agree with their relevant NHS Executive Regional Office a process and timescale for conducting these baseline assessments. Primary Care Trusts and Primary Care groups should agree similar arrangements with their Health Authority.

Step three: Formulating and agreeing the development plan

34. On the basis of the baseline assessment, organisations can then put together a plan for developing clinical governance addressing issues such as:

- Closing gaps in present performance of the organisation (agree plan that will bring a particular service or part of the organisation, over time, up to the desired standard).
- Developing infrastructure (i.e. reporting structures, information management and technology, human resources, organisational structures, Continuing Professional Development cross linkages with other organisations and services).
- Identifying and responding to staff and Board development needs (i.e. education and training, Personal Development Plans, Board members induction, and continued training and management skills for general and clinical management).

Additionally, development planning and prioritisation should link closely to local Health Improvement Programmes (HImPS) and work to implement National Service Frameworks (NSFs).

Action: Formulating and agreeing the development plan

NHS organisations, in line with guidance should produce and begin to implement an agreed development plan for clinical governance locally. The plan should include the activities and timescale for closing gaps identified in performance, developing infrastructure, staff and Board development, planning and prioritisation, and where appropriate, milestones to assist in assessing achievement. For Trusts and Health Authorities, monitoring of the plan should form part of existing performance management processes. For PCGs and PCTs, a process for progress reporting should be agreed with the Health Authority.
Step four: Clarifying reporting arrangements

35. Reports to the Board will be an important part of the accountability mechanisms that underpin clinical governance. The nature, range and importance of the clinical governance issues which are taken to the Board will be crucial to the development of the whole programme within the organisation. The content of the Board’s agenda will send a powerful signal to the whole organisation, to the local media, the public, and to the health organisation’s partners. The more substantial and searching the issues the Board discusses, the more it will be concluded that the organisation has a clear sense of direction on clinical governance and is taking it very seriously.

36. There will, however, need to be a balance between ensuring openness of debate and enabling discussion of sensitive issues about both health services and individuals. Where boards agree that there is a need for a confidential discussion, closed sessions can be used. HSC 1998 207 gives detailed guidance on this issue and should be read in conjunction with this report.

37. Health Authorities and Primary Care Groups, Primary Care Trusts and NHS Trusts will be required to publish their first annual reports on clinical governance in 2000. The style and detailed content of Annual Reports will be a matter for local determination. However, consultation on A First Class Service revealed very strong support for a common set of core reporting requirements, to be included in the clinical governance report. The language and style of clinical governance reports should be accessible to lay readers, and reports should where possible include quantitative data as meaningful indicators of progress. The NHS Performance Assessment Framework and its associated High Level Performance Indicator Set will provide useful information for comparing performance with other similar organisations.

Clinical governance reports for all organisations should attempt to answer three broad sets of questions about clinical governance implementation:

- Where did we start? – the baseline position
- What progress have we made and how do we know? - the Action Plan for the year and the monitoring and evaluation undertaken.
- Where are we going next? – action plan for the coming year.

In due course, Trust reports should include comments on the findings of any Commission for Health Improvement (CHI) reviews.

On a more detailed level, clinical governance reports for 1999/2000 should as a minimum address the points made in Annex 3.

Action: Clarifying reporting arrangements

Organisations should ensure that they have appropriate mechanisms in place to deliver routine Board reports on progress made in implementing clinical governance. These reports should reflect guidance and look to both the short and medium term.

Health Authorities, Primary Care Groups, Primary Care Trusts and NHS Trusts should produce annual reports on what they are doing to improve and maintain clinical quality. These annual reports should, as a minimum, address the issues identified in the guidance, addressing the three broad questions and the template in the section above.
38. Monitoring of clinical governance will take several forms. Regional Offices of the NHS Executive will have primary responsibility for performance managing its implementation in NHS Trusts and Health Authorities, and monitoring improvements year-on-year. Health Authorities will provide the first line of external monitoring for its development in Primary Care Groups/Primary Care Trusts. The new NHS Performance Assessment Framework will complement the introduction of clinical governance by focusing on the quality and effectiveness of health care, as well as on efficiency.

39. The Commission for Health Improvement, which will be established – subject to legislation – later in 1999, will provide an external assurance of the development of clinical governance in NHS Trusts and Primary Care Trusts through a rolling programme of local reviews. It is anticipated that the Commission will visit each local health system every three to four years.

40. The statutory regulatory bodies for health professionals are an important part of the wider clinical governance framework. Arrangements for professional self-regulation and clinical governance will need to be closely aligned.
## Areas of Change

<table>
<thead>
<tr>
<th>Areas of Change</th>
<th>Benefits of Change</th>
</tr>
</thead>
</table>
| **A new culture in NHS organisation** | Open and participative, and can demonstrate this both internally and to external bodies such as the Regional Office of the NHS Executive and the Commission for Health Improvement.  
  Able to demonstrate a commitment to quality, shared by staff and managers, and supported by clearly identified resources, both human and financial. These resources are part of an agreed development and implementation plan and their use is reviewed by the Board as part of their discussions on Clinical Governance.  
  Working routinely with patients, users, carers and the public.  
  An ethos of multi-disciplinary team working at all levels of the organisation.  
  Informed and underpinned by education and research activities which are focused on the needs of the organisation and improving the quality of services.  
  Regular Board level discussion of the big quality issues for the organisation and strong leadership from the top.  
  Good use of information to plan and assess progress. |
| **Inequity and variability**     | Unjustifiable variations in the quality of care provided (including outcomes, access, and appropriateness) between services in different areas are reduced through quality improvement.  
  NHS organisations are working to ensure that they are making progress against recognised benchmarks. |
## Areas of Change

### Involving users and carers
- An organisation wide strategy for involving users, carers and the public, including strategic plans for communicating with users, carers and the public.
- Designated senior individual to oversee user, carer and public involvement strategy
- User representatives on clinical governance committee/groups
- Use of involvement methodologies e.g. patient panels, focus groups
- Training and education for all individuals on effective user, carer and public involvement.

### Sharing of good practice
- Evidence that individuals and organisations are actively learning from others, for example by actively seeking out and make use of examples of good practice and of the ways in which particular issues have been tackled elsewhere.
- Wasteful duplication of effort is minimised.
### Areas of Change

<table>
<thead>
<tr>
<th>Areas of Change</th>
<th>Benefits of Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detecting and dealing with poor performance and adverse events</td>
<td>Poor performance is the concern of all clinical and managerial staff. Clear mechanisms for the identification and management of poorly performing clinicians; routes for other clinicians to voice their concerns about performance of their colleagues (taking account of new national policies and procedures). Poor performance procedures aim to identify practice as it begins to slip, and to proactively support and develop clinical staff, enabling sustained improvements in the vast majority of cases without risk to the quality of patient care.</td>
</tr>
</tbody>
</table>
### Main Components of Clinical Governance

<p>| 1. Clear lines of responsibility and accountability for the overall quality of clinical care through: |
|---|---|---|---|
| - The NHS Trust Chief Executive carries the ultimate responsibility for assuring the quality of services provided by the Trust | ✓ | | ✓ |
| - A designated senior clinician responsible for ensuring that systems for clinical governance are in place and monitoring their continued effectiveness | ✓ | ✓ | ✓ | ✓ |
| - Formal arrangements for NHS Trust, PCT and PCG Boards to discharge their responsibilities for clinical quality, through a clinical governance committee | ✓ | | ✓ | ✓ |
| - Regular reports to NHS Boards on the quality of clinical care given the same importance as monthly financial reports | ✓ | ✓ | | ✓ |
| - An annual report on clinical governance | ✓ | ✓ | ✓ | ✓ |</p>
<table>
<thead>
<tr>
<th>Main Components of Clinical Governance</th>
<th>Trust</th>
<th>HA</th>
<th>PCG</th>
<th>PCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. A Comprehensive programme of quality improvement activities which includes:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Full participation by all hospital doctors in audit programmes, including speciality and sub-speciality national audit programmes endorsed by the Commission for Health Improvement</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Full participation in the current four National Confidential Enquiries</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Evidence-based practice is supported and applied routinely in everyday practice</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• Ensuring the clinical standards of National Service Frameworks and NICE recommendations are implemented</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• Workforce planning and development (i.e. recruitment and retention of appropriately trained workforce) is fully integrated within the NHS organisation’s service planning</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• Continuing Professional Development: programmes aimed at meeting the development needs of individual health professionals and the service needs of the organisation are in place and supported locally</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• Appropriate safeguards to govern access to and storage of confidential patient information as recommended in the Caldicott Report on the Review of Patient-Identifiable Information</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• Effective monitoring of clinical care with high quality systems for clinical record keeping and the collection of relevant information</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>• Processes for assuring the quality of clinical care are in place and integrated with the quality programme for the organisation as a whole</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• Participation in well designed, relevant R&amp;D activity is encouraged and supported as something, which can contribute to the development of a &quot;evaluation culture&quot;.</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>
### Main Components of Clinical Governance

<table>
<thead>
<tr>
<th>3. Clear policies aimed at managing risks:</th>
<th>Trust</th>
<th>HA</th>
<th>PCG</th>
<th>PCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Controls assurance which promote self-assessment to identify and manage risks</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• Clinical risk systematically assessed with programmes in place to reduce risk</td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4. Procedures for all professional groups to identify and remedy poor performance, for example:</th>
<th>Trust</th>
<th>HA</th>
<th>PCG</th>
<th>PCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Critical incident reporting ensures that adverse events are identified, openly investigated, lessons are learned and promptly applied</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• Complaints procedures, accessible to patients and their families and fair to staff. Lessons are learned and recurrence of similar problems avoided</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• Professional performance procedures which take effect at an early stage before patients are harmed and which help the individual to improve their performance whenever possible, are in place and understood by all staff</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• Staff supported in their duty to report any concerns about colleagues’ professional conduct and performance, with clear statements from the Board on what is expected of all staff. Clear procedures for reporting concerns so that early action can be taken to remedy the situation.</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>
# Minimum Expectations for Annual reports in 1999/2000

<table>
<thead>
<tr>
<th>Clinical Governance Reports – 1999/2000</th>
<th>Relevant to:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- An explanation of the leadership, accountability and working arrangements for implementing clinical governance.</td>
<td>All NHS organisations</td>
</tr>
<tr>
<td>- Work to ensure that clinical decision-making is increasingly evidence-based. This should include local action as well as progress on implementation of National Service Framework (NSFs) and NICE guidelines.</td>
<td>All NHS organisations</td>
</tr>
<tr>
<td>- Progress on integrated planning for quality including information establishing explicit links to HImPs and where appropriate, National Service Frameworks.</td>
<td>All NHS organisations</td>
</tr>
<tr>
<td>- Progress on Continuing Professional Development and lifelong learning, and on designing the ways in which staff development, educational and workforce solutions are being used to support clinical governance.</td>
<td>All NHS organisations</td>
</tr>
<tr>
<td>- Participation in and impact of multi-disciplinary clinical audit programmes – including national speciality and sub-speciality audits – and national confidential enquiries.</td>
<td>All NHS organisations</td>
</tr>
<tr>
<td>- The identification of particular services in which there are identified shortfalls in quality and of deficits in other clinical governance support mechanisms (e.g. risk management, clinical audit).</td>
<td>All NHS organisations</td>
</tr>
<tr>
<td>- Evidence of active working with the public, users of services and their carers.</td>
<td>All NHS organisations</td>
</tr>
<tr>
<td>- An account of the mechanisms that have been established to ensure that lessons are being learned from complaints, adverse incidents and enquiries into services.</td>
<td>All NHS organisations</td>
</tr>
</tbody>
</table>