



Clinical governance and quality

This chapter aims to develop an understanding of the role of clinical governance in delivering quality in healthcare services. It also explores risk management, clinical audit, evidence-based practice and some of the NHS quality initiatives.

In essence, clinical governance is the method by which a systemic approach to the maintenance and improvement of a quality service and patient care is managed. The most widely cited formal definition describes it as:

A framework through which NHS organisations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish. (Sally and Donaldson 1998)

This definition is intended to embody three main attributes: recognisably high standards of care; transparent responsibility and accountability for those standards; and a constant dynamic pathway to improvement.

Clinical governance should consist of a framework which pulls together all the initiatives within a healthcare provider associated with quality assurance. It is easy to over-complicate the definition of clinical governance in the attempt to explain the phrase in words, for the precise characterisation of quality is elusive both as a concept and within the day-to-day workings of healthcare provision. In its simplest form it can be described as 'doing the **right thing** at the **right time** to the **right person** in the **right way**'. It is 'doing anything and everything required to maximise quality'. There also has to be a balance between cost-effectiveness and quality, because there can be a tendency to throw money at quality in the attempt to be seen to be taking it seriously but not to adequately measure the outcomes. In short, the concept of governance and quality is tricky to quantify and hence several national systems have been put in place to ensure its presence within all

hospitals and other healthcare providers, with its ultimate goal to make certain the culture of healthcare provision contains quality improvement as a routine element of clinical practice. Governance and quality are synonymous and good governance evidences a quality service.

The NHS Act (1999) placed a duty of quality on NHS organisations. The Act introduced corporate accountability for clinical quality and performance. Clinical governance also means that healthcare providers have a statutory duty to:

Continually improve the overall standard of clinical care, whilst reducing variation 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. (NHSE 1999: 5)

As an intrinsic part of the above, there has to be an increased focus on risk management, which can be defined as a means of reducing the risks of adverse events in organisations by systematically assessing, reviewing and identifying possible risks in processes, environments, staff roles and so on, and then seeking ways to prevent their occurrence (adapted from NHSE 1999).

Prior to 1999 trust boards had no statutory duty to ensure any particular level of quality. Their principal statutory responsibilities were to ensure proper financial management of the organisation and an acceptable level of patient safety. Maintaining and improving the quality of care was understood to be the responsibility of the clinical professions. This changed from 1999 when trust boards assumed the legal responsibility for quality of care in equal measure to their other statutory duties. Clinical governance is the mechanism by which this responsibility is discharged.

The elements of clinical governance

Clinical governance includes the following elements.

- **Risk management** – as well as the definition above, risk management describes the systems used to understand, monitor and minimise the risks to patients and staff, and to learn from mistakes. Risk management has to consider risks to patients (compliance with statutory regulations, critical event learning), and risks to practitioners (ensuring that clinicians are immunised against infectious diseases and work in a safe environment). Systems can include risk registers, risk assessments and incident reporting. Risk management also has to include the identification of business risk and risks to the organisation, risks from the environment or from pandemic illness, from catastrophic events, from personnel management and HR. The appropriate response to complaints, then learning from them, can be a key element in risk management. These are a few examples within a very wide field of potential risk. (There is more information about risk management later in the chapter.)
- **Clinical effectiveness** – the extent to which clinical interventions maintain and improve health and secure the greatest possible health gain from available

sources. This may include the implementation of NICE guidelines, clinical audit and staff reviews.

- **Education, training and continuing professional development (CPD)** – often referred to as Life Long Learning – this covers the support available to enable staff to be competent in doing their jobs as well as developing their skills. It reflects the importance of staff having up-to-date skills and knowledge through continuous learning and development.
- **Use of information** – describes the systems in place to collect and interpret clinical information and use it to monitor, plan and improve the quality of patient care. This should also stress the importance of **openness** – open proceedings and discussion about clinical governance issues should be a feature of the framework. Information which can be open to public scrutiny, while respecting individual patient and practitioner confidentiality, is again essential to quality assurance.
- **Staffing and staff management** – the recruitment, management and development of staff, promoting good working conditions, family-friendly policies, effective methods of working, absence management, annual leave allocations and so on – elements of this section can also be referred to as workforce planning.
- **Clinical audit** – systematic and critical analysis of clinical performance and the measurement of performance against agreed standards. This includes the procedures for diagnosis, treatment and care, the associated use of resources and the resulting outcomes in respect of quality of life for patients. It also encompasses the refining of clinical practice from results from audit – and results in a cyclical process for the improvement of patient care.
- **Patient/service user and public involvement** – patient/user satisfaction surveys, patient organisations – these describe how patients and users can have a say in their own treatment and how services are provided.
- **Research and development, research-based management and evidence-based practice** – good professional practice has always sought to change in the light of evidence from research. The time lag between obtaining research-based information and introducing the required change from this can be very long, so a governance framework needs to include emphasis not only on carrying out research but also on using and implementing the results of such research. Techniques such as critical appraisal of literature, project management and the development of protocols and guidelines are all tools for promoting the implementation of research practice. There is further explanation of evidence-based practice later in this chapter (*see* p. 89).

Clinical governance requires change and innovation at three levels: by individual healthcare professionals; by teams; and by organisations. Individual healthcare workers have to look at what needs changing by thinking about what they do and placing patient need at the centre of their thinking. Teams need to become true multidisciplinary groups. Understanding roles, sharing information and knowledge, and supporting each other should be part of everyday practice. General practices and primary care trusts need to have systems and local arrangements to support the teams and to ensure the provision of good-quality care. Commitment

and leadership from the PCTs and from general practices is crucial to the development of quality improvements.

In the 1950s and 1960s it was often assumed that more spending on health-care would lead to better health. Increased awareness of other determinants of health, such as housing, employment, family, education and social class positioning, has resulted in a more political approach. Other factors such as the oil crisis of the 1970s, the emergence of previously non-industrial countries as key players in the world economy, the increasing availability of new health technologies and the ever growing proportion of the aged population have led to increased pressure to contain costs. In addition, the advent of the Internet has led to the population being increasingly aware of treatment options, leading to higher expectations from the medical profession and the ability to 'check things out'. Health professionals can no longer expect the population to accept what is told them without questioning, and often have done their research before seeing a doctor. The creation of the NHS internal market as part of the reforms in the late 1980s and 1990s was accompanied by a plethora of initiatives aimed at improving quality. Quality then became focused on the twin concepts of clinical effectiveness and evidence-based medicine. Quality, and evidencing ongoing improvement, was the focus of Lord Darzi's High Quality Care for All published in 2008 (Darzi 2008), the final report in his series of NHS Next Stage Review documents, which responded to the 10 SHAs' strategic visions and set out the holistic vision for an NHS with quality at its heart.

In addition, there is considerable information out in the public domain giving comparative data about the way healthcare organisations perform. Access to websites such as the Doctor Foster Hospital Guide and the fact that patients can get into these types of sites on their telephones while sitting in a waiting room waiting to see a doctor has to be considered. Doctors have to be prepared for the patients asking far more questions based on being extremely well informed. Also, it has to be remembered that whereas patients may be able to obtain all this data, it does not necessarily mean that they understand it.

The service provided by a healthcare organisation may be excellent but will not be considered successful unless valued by the patient. The delivery process also has to be excellent. This is difficult in a health service where the expectations and requirements of the diverse numbers of parties involved may be very different. The first real acceptance of this ethos was in 1989 when the White Paper *Working for Patients* was published (DoH 1989). This proposed a set of seven patient-focused factors:

- appropriateness of treatment and care
- achievement of optimum clinical outcome
- clinical-recognised procedures to minimise complications and similar preventable events
- attitude which treats patients with dignity and as individuals
- environment conducive to patients' safety, reassurance and contentment
- speed of response to patients' needs and at minimum inconvenience to them (and their relatives or carers)
- involvement of patients in their own care.

These factors still provide a relevant way of determining a quality service for patients and you can see how the elements of clinical governance structures and the contribution of the nationwide organisations (see later) all contribute to these ideals.

There have been many methodologies introduced over the past 20 years or so pertaining to the management of quality and if you undertook a search on a website there are a large number of 'buzzwords' associated with quality in healthcare organisations. However, if quality initiatives are driven based on the elements of clinical governance, this will result in a quality-led organisation which can categorically evidence patient-focused care, which in turn is reviewed in line with patient, staff and doctors' feedback. Woe betide a management team that neglects to take notice of these latter three key parties. Quality and governance has to be embedded in the culture of the organisation and it calls for commitment at all levels.

Implementing clinical governance

The following systems and mechanisms contribute to clinical governance:

- clinical audit
- risk management
- health needs assessment
- evidence-based clinical practice
- patient feedback
- continuing professional development
- accreditation of healthcare organisations or providers
- development of clinical leadership skills
- effective management of poorly performing colleagues
- systems to ensure critical incidents are openly investigated and lessons learnt are implemented.

The requirements placed on healthcare organisations include:

- developing leadership skills among clinicians
- developing mechanisms to ensure that change in clinical practice occurs as a result of audit, risk management and complaints findings thus closing the 'audit loop'
- developing appropriate accountability structures
- working more collaboratively and effectively between primary and secondary care
- developing more effective multidisciplinary working
- building continuing medical education and continuing professional development into quality improvement programmes
- improving the information infrastructure of the NHS.

Thus, at trust level, the main principles of clinical governance are:

- clear lines of responsibility and accountability for the overall quality of clinical care
- a comprehensive programme of quality improvement systems (including

- clinical audit, supporting and applying evidence-based practice, implementing clinical standards and guidelines, workforce planning and development)
- educational and training plans
- clear policies aimed at managing risk
- integrated procedures for all professional groups to identify and remedy poor performance.

Trust chief executives are ultimately responsible to their boards for assuring the quality of services provided. Trusts usually have clinical governance committees, chaired by a clinical professional. Monthly reports are presented to trust boards and they are obliged to publish annual clinical governance reports. The **Clinical Governance Support Team** (www.cgsupport.nhs.uk) is a body which supports clinical governance developments.

An action list may be used to check that clinical governance is an active element within a healthcare provider.

- Are there quality improvement programmes (e.g. clinical audit)?
- Are leadership skills developed at clinical team level?
- Is evidence-based practice in everyday use?
- Is good practice and innovation disseminated within and outside the organisation?
- Are there clinical risk-reduction programmes?
- Are adverse events detected, openly investigated and lessons learned applied?
- Are lessons learned from complaints made by patients?
- Are problems of poor clinical performance recognised early and dealt with to prevent harm to patients?
- Do all professional development programmes reflect the principles of clinical governance?
- Is the quality of data collected to monitor clinical care consistently of a high standard?

Benchmarking

The NHS Benchmarking Network was established in 1996 in order that NHS organisations could contribute to a structure which would enable them to share best practice and to learn from each other. Subscribers come from primary care trusts, strategic health authorities and NHS trusts in England plus other equivalent organisations within healthcare systems in the UK.

The vision statement on the website www.nhsbenchmarking.nhs.uk explains that the network's purpose is: 'Supporting NHS organisations to improve the effectiveness, patient experience, productivity and value for money of services by using benchmarking and knowledge exchange to identify, share and promote excellent and innovative practice.'

Its objectives, again quoted from the site, are to:

- promote the use of benchmarking among members
- act as a network hub and learning zone for members in a safe and protected environment
- test out new ideas

- carry out excellent benchmarking projects with members which achieve results that can be implemented
- identify and share good practice in a ‘practical’ form, e.g. use of matrices, reports
- help members implement change.

Risk management

The New NHS (DoH 1997) and *Clinical Governance: quality in the new NHS* (DoH 1999) placed clinical risk management as a key component of clinical governance. This was further elaborated on when Lord Darzi (2008) defined quality of care as clinically effective, personal and safe. This means protecting patient safety by eradicating such avoidable problems such as healthcare-acquired infections and foreseeable accidents. Clear policies aimed at managing risk and supporting staff in identifying and tackling poor performance must therefore be in place.

Effective risk management at trust level demands clear unequivocal systems that are embedded in each area of healthcare provision. Most healthcare providers have committee structures with lines of responsibility for defined areas of risk, such as clinical risk, infection control and medicines management. Named individuals are given the task to facilitate risk management throughout the organisation. There is usually a multidisciplinary group given the autonomy to drive the process – a Quality and Risk Management Committee.

Risk assessment is an integral element. Risk assessments are normally undertaken using a risk rating scale/score. First, the risk is identified and the likelihood of it occurring is assessed on a scale of 1 to 5, 1 being rare and 5 being almost certain. Second, the consequences or impact of the risk occurring is assessed on a scale of 1 to 5, 1 being negligible and 5 being extreme. The scores are multiplied, giving a risk rating number between 1 and 25 – and responses can be determined based on the calculated rating. Many models for risk assessment are available and these can be viewed on the web.

An element of any risk-management process is the reporting mechanism for adverse incidents, which are completed by any member of staff. These are usually entered into a software tool developed to provide reports broken down into types of incident, grading the severity of impact, the incidence of harm to patients or identification of ‘near miss’ scenarios. The detection of trends is vital so that interventions can be initiated to prevent recurrence. These of course do not necessarily have to be clinical issues, but also include non-clinical such as manual handling, bullying and stress claims.

Trusts are normally insured against risk through the Clinical Negligence Scheme for Trusts. This scheme rewards trusts for compliance with its standards by discounting fees. The scheme is administered by the NHS Litigation Authority (www.nhsla.com), an authority with the responsibility for handling negligence claims made against NHS bodies in England. The NHSLA manage their risk-management programme by providing a range of NHSLA standards and assessments. Healthcare organisations are regularly assessed against these risk-management standards, which have been specifically developed to reflect

issues that have arisen in negligence claims reported to the NHSLA. There is a set of standards for each type of healthcare organisation incorporating organisational, clinical, and health and safety risks:

- NHSLA Acute, PCT and Independent Sector Standards 2009/10
- NHSLA Mental Health and Learning Disability Standards 2009/10
- NHSLA Ambulance Standards 2009/10.

In addition, there is a separate set of clinical risk management standards for NHS maternity standards:

- NHSLA Maternity Standards 2009/10.

All the standards are divided into three levels of compliance. Organisations that are graded at level 1 receive a 10% discount on their CNST contributions, at level 2: 20% and at level 3: 30%.

Organisations that achieve level 1 are assessed against the relevant standards once every two years, but the frequency of assessment can reduce at higher levels to at least once in any three-year period. If an organisation fails to comply, they have to be assessed on an annual basis until they have achieved compliance. Assessments take place over two days and are carried out by an external company who are responsible for much of the day-to-day administration of the risk-management processes.

In order to facilitate the assessments, evidence templates have been produced which must be completed and submitted. Self-assessments may be conducted using the templates and these may be used by assessors to record their scores and findings, which in turn enable the organisation to prepare an action plan.

Clinical audit

Medical audit was formally introduced into the NHS in 1989, changing its name to clinical audit in 1993 to reflect a more multidisciplinary approach. Clinical audit is a quality-improvement service that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Indicated changes are implemented at an individual, team or service level and further monitoring is conducted to confirm improvement in healthcare delivery (NICE 2002).

Types of audit may include standards-based audit, adverse occurrence screening and critical incident monitoring, peer review or patient surveys and focus groups, obtaining users views about the quality of the care they have received.

The audit process

In all types of audit, the audit process applies Figure 2.1. It is a cyclical movement, each cycle aspiring to a higher level of quality.

- 1 Identify a problem or issue (centre of the circle).
- 2 Set the criteria and the standards against which to audit.
- 3 Observe practice/collect the data.
- 4 Compare performance with criteria and standards.

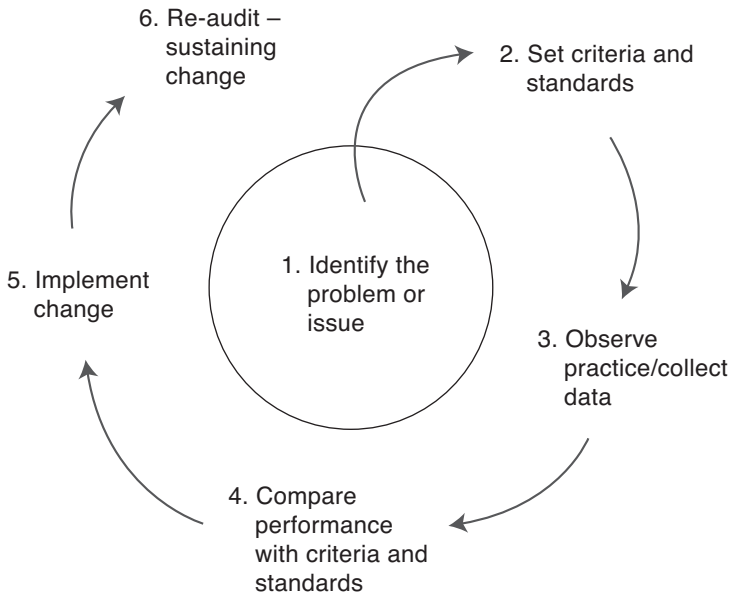


FIGURE 2.1 The audit process

- 5 Implement change.
- 6 Re-audit in order to sustain change, reset the criteria and return to Stage 2 in the audit cycle.

Stage 1: Identifying the problem or issue

This is likely to involve comparison with healthcare processes that have been shown to produce best outcomes for patients – and can be influenced by factors including a search for national standards or examples of clinical practice, problems that have been encountered in practice, problems raised by colleagues, patients or relatives, potential for improving service delivery or recommendations by national bodies such as the CQC or NICE.

Stage 2: Criteria

Criteria are explicit statements that define what is being measured and that can be measured objectively. They cannot include statements which rely on personal opinions or values.

A criterion is a measurable outcome of care, aspect of practice or capacity.

A standard is the threshold of the expected compliance for each criterion (these may be expressed as a percentage).

Stage 3: Data collection

Details of what is to be audited must be established from the outset. These include the user group to be included with any exceptions noted, the healthcare professionals involved in the care, and the period over which the criteria apply.

Consideration must be given to what data will be collected and how (electronic or manual), where it will be found and who will collect it.

Ethical issues must also be considered – data must relate only to the objectives of the audit. Staff and patient confidentiality must be respected, and identifiable information must never be used. Any potentially sensitive topics should be discussed with the local research ethics committee.

Stage 4: Comparison of performance with criteria and standards

The final stage of analysis is to conclude how well the standards were met, and identify the reasons for failure to meet them. Where a standard is not met, there may be the potential for improvement in care. However, if it is very close to being met, it may be decided to leave this particular event as it is and concentrate on something that needs further attention. In life and death situations it would be crucial to achieve 100% in an audit, but in other circumstances a lower score would be acceptable.

Stage 5: Implementing change

Once the results have been published and discussed then agreement must be reached about the recommendations for change. An action plan can be created, recording who is going to do what and by when.

Stage 6: Re-audit and sustaining improvement

This is often termed ‘closing the loop’. Re-audit should demonstrate any impact created by the changes. This stage is critical to the successful outcome of an audit process as it verifies whether the changes implemented had an effect and whether further improvements are required to achieve the standards set in Stage 2.

The differences between clinical research and audit are as follows.

- Research is often deductive and concerned with critical testing.
- Research is more likely to use control groups and validating measures.
- The scope of research is likely to be wider and will reach a greater audience in terms of publication of results in journals, etc.
- Research can provide answers in areas that audit could not tackle, and will challenge the efficacy of a particular therapy.
- Research raises questions about purposes – and the means of achieving them.
- Audit is often concerned with small-scale problems requiring local solutions.
- Audit evaluates what exists and takes purposes for granted.
- Audit ascertains whether the inputs and processes achieve the outcome desired.
- Audit can give rise to research questions – if the outcomes of audit are not what was intended or raise unexpected queries, research can ask why.
- Audit and research can feed into each other.

Research is finding the right thing to do . . . and audit is about ensuring you are doing the right thing right!

Clinical audit, education and professional development

Clinical audit is a professional development activity that highlights education needs through audit methods and data analysis. By generating new knowledge, clinical audit can contribute to the postgraduate and undergraduate curricula in the healthcare professions. The providers of education can use this new knowledge to modify curricula, while providing healthcare professionals with advice on research methods.

Clinical audit can be seen as a means to broaden the team by the development of reflective practice. The potential for learning that takes place through participation in the audit process can be recognised and accredited as part of an individual's continuing professional development. Records can be kept in a revalidation folder as evidence of involvement in continuing learning.

Evidence-based clinical practice

'Evidenced-based clinical practice is an approach to decision making in which the clinician uses the best evidence available, in consultation with the patient, to decide upon the option which suits that patient best' (Muir Gray 1997). However, a true quality service exists when this is combined with the doctor's education and experience and their insight into and knowledge of a patient. It is the opposite of conjecture-based decision making. There are many organisations, journals, Internet sites and electronic databases which are dedicated to the pursuit of evidenced-based clinical practice and encouraging its growth within all healthcare professions in the NHS and other healthcare providers. A few of these are described below.

PubMed

PubMed is a service of the United States National Library of Medicine and it includes multi-million citations for MEDLINE and other life science journals for biomedical articles back to the 1950s. PubMed includes links to full-text articles and to other related resources. The website address is www.ncbi.nlm.gov/pubmed.

The Cochrane Library

This site contains high-quality, independent evidence to inform healthcare decision making. It includes reliable evidence from Cochrane and other systematic reviews, clinical trials and more. Cochrane reviews bring the combined results of the world's best medical research studies and are recognised as the gold standard in evidence-based healthcare.

The website address is www.wiley.com/Cochrane.

The UK Cochrane Centre was established at the end of 1992 by the NHS Research and Development Programme and is part of the National Institute for Health Research. The website address is www.cochrane.co.uk.

Bandolier

The first issue of *Bandolier*, an independent journal of evidenced-based healthcare written by Oxford scientists, was published in February 1994. It has appeared

monthly ever since and have become the most recognised source of evidence-based healthcare information in the UK and worldwide for all healthcare professionals and consumers. The paper version was discontinued in 2007, but the Internet version is updated at more or less regular intervals.

The website address is www.medicine.ox.ac.uk/bandolier.

Ovid's evidenced-based medicine reviews

Ovid is a definitive resource for electronic information which combines seven of the most trusted evidenced-based medicine resources into a single database that is easily searchable. The website address is www.ovid.com/site/catalog/DataBase/904.jsp.

Department of Primary Health Care

This is based at Oxford University. Together with the Department of Public Health the Division of Public Health and Primary Health Care is part of the university's Medical Science Division. The Division aims for excellence in teaching and research and the department is one of the five founding members of the National Institute for Health Research School for Primary Care Research. Primary research focus is based on the prevention, early diagnosis and management of common illnesses in general practice.

UCL Institute of Child Health

This institute is based at Great Ormond Street Hospital for Children NHS Trust and together they form an international centre of excellence for treating sick children and teaching and training children's specialists. It is the largest centre of research into childhood illness outside the US and promotes evidenced-based medicine in relation to children.

The website address is www.ich.ucl.ac.uk.

Institute of Public Health

Based at Cambridge University, this institute aims to improve the health of the population by understanding the cause and natural history of disease, and to identify and evaluate new possibilities for both primary and secondary care intervention and prevention. The website address is www.iph.cam.ac.uk.

Centres for Evidenced Based Mental Health

The Centres for Evidenced Based Mental Health and the Department of Psychiatry at Oxford University provide information, and promote and support evidence-based healthcare in mental healthcare. The website addresses are www.cebmh.com and www.psych.ox.ac.uk.

NHS quality initiatives

The following organisations and initiatives exist to contribute to the maintenance and improvement of quality in healthcare. They are numerous and diverse, each providing a specific function within the structure of quality and governance.

Care Quality Commission

The Care Quality Commission is the independent regulator of health and social care in England. The aim is to make sure that better care is provided for everyone whether in hospital, in care homes, in people's own homes or elsewhere. The CQC regulates health and adult social care services whether provided by the NHS, local authorities, private companies or voluntary organisations. It also protects the rights of people detained under the Mental Health Act. The website address is www.cqc.org.uk.

Until March 2009 regulation of health and social adult care was carried out by the Healthcare Commission and the Commission for Social Care Inspectorate. The Mental Health Act Commission had monitoring functions with regard to the operation of the Mental Health Act 1983. The Health and Social Care Act 2008 established a single, integrated regulator of health and adult social care – The Care Quality Commission which replaced the three previous bodies.

The Act set the CQC's functions in terms of assuring safety and quality, assessing the performance of commissioners and providers, monitoring the operation of the Mental Health Act and ensuring that regulation and inspection activity across health and adult social care is managed and co-ordinated effectively. This joined-up approach should help to ensure better outcomes for the people who use the service.

All providers of health and social care – including, for the first time, NHS providers – will be required to register with CQC. Regulation requirements are consistent across all groups, and the regulatory system provides clear expectations of the requirements needed to provide services. It is a risk-based approach which means that regulation activity is targeted where action is required.

The CQC has a wide range of enforcement powers along with flexibility as to how and when to use them. The regulator will have greater powers to achieve compliance with registration requirements. In order to be granted registration, care providers will have to demonstrate that they can meet, or are already meeting, the requirements; and to maintain registration, they will need to demonstrate an ongoing ability to continue to comply with requirements.

NHS providers will have to achieve registration by the end of April 2010 and independent sector providers by October 2010. For the NHS, the registration criteria will replace Standards for Better Health.

Assessment of providers will be based on completion of a self-assessment process which will require the submission of verifiable evidence pertaining to each stated requirement.

In Scotland and Wales regulation of healthcare comes under different legislative bodies. The Scottish Commission for the Regulation of Care website is www.carecommission.com and information regarding the Health Care Inspectorate in Wales can be found at www.hiw.org.uk. Scotland and Wales have specific areas on the NHS website: www.scotland.nhs.uk and www.wales.nhs.uk.

Quality indicators

The Department of Health and the NHS Information Centre published a set of National Indicators for Quality Improvement. NHS clinical teams are able to view a list of more than 230 existing quality indicators on the NHS Information

Centre website. The Indicators for Quality Improvement will allow clinical teams to measure the quality of care they deliver to patients against local and national benchmarks. They will also support providers and commissioners of NHS services.

The National Patient Safety Agency

The NPSA has a wide-ranging quality role within the NHS. It has been estimated that around 10% of patients admitted to the NHS each year are unintentionally harmed in some way and that half of these incidents may be preventable (Vincent *et al.* 2001). Since April 2005 the NPSA has been responsible for the co-ordination of organisations and individuals in healthcare to investigate and learn from patient safety incidents occurring within healthcare providers. The website address is www.npsa.nhs.uk.

The NPSA also encompasses work within the safety aspects of hospital design, cleanliness and food and nutrition. It ensures that research work is carried out safely and ethically through its responsibility for the Central Office for Research Ethics Committees (COREC).

The NPSA manages the contracts with the three confidential inquirers: the National Confidential Enquiry into Patient Outcome and Death (NCEPOD), the Confidential Enquiry into Maternal and Child Health (CEMACH) and the National Confidential Inquiry into Suicide and Homicide by People with Mental Illness (NCISH).

The NPSA seeks to ensure that all incidents are reported, and promotes an open and fair culture in hospitals and across health services. Doctors and staff are encouraged to report incidents and 'near misses'. It is vital to encourage staff to report incidents without fear of personal reprimand. It is not responsible for investigation of complaints or issues concerning individuals.

The NPSA has set up a national reporting structure, which is aimed at collecting and analysing information from all staff and patients, and it produces publications including case studies with expert advice.

The National Clinical Assessment Service

The NPSA incorporates the National Clinical Assessment Service (www.ncas.nhs.uk). This was set up to promote public confidence in doctors and dentists by giving confidential advice and support to NHS organisations on how to manage doctors and dentists whose performance was giving cause for concern. Contact to NCAS can be made by an employer, contracting body or a single practitioner. The aim of NCAS is to work with all parties to clarify the concerns and make recommendations, with the ultimate aim being to help the practitioner deliver a high-quality and safe service for patients. It is an advisory body and the referrer retains responsibility for handling the case throughout the process.

NCAS also helps NHS organisations improve local management of performance concerns so that difficulties are recognised and addressed before they become serious.

NCAS has working arrangements with a number of partners including the General Medical Council (GMC), the General Dental Council, the Care Quality Commission and the Academy of Medical Royal Colleges.

The Institute for Innovation and Improvement

This was created in 2005 and it superseded the Modernisation Agency, the NHSU and the NHS Leadership Centre. Its mission is to support the NHS in accelerating the delivery of world-class healthcare for patients and public by encouraging innovation and developing capability at the frontline. The website address is www.institute.nhs.uk.

The institute has expertise in service transformation, technology and product innovation and incorporates the National Innovation Centre, which is based at the University of Warwick. This provides an entry point for industry and the NHS to explore and adopt new concepts, and to develop specific products for particular needs.

The institute seeks to lead and commission development and research to build an evidence base of new and best practice in service transformation.

It also works to promote a culture of lifelong learning for all NHS staff by working with NHS organisations to develop learning systems to accelerate organisational growth and individual core learning materials to enhance personal development. Many of the learning programmes and outputs of the previous organisations are still available (www.nhsu.nhs.uk and www.wise.nhs.uk) – the series of Improvement Leaders' Guides represent the best known in NHS improvement practice.

The National Confidential Enquiry into Patient Outcome and Death (NCEPOD)

NCEPOD was originally the Confidential Enquiry into Perioperative Deaths but expanded its remit to cover a far greater number of studies than just death within 30 days of surgery. Its purpose now is to assist in improving the standards of medical and surgical care by reviewing the management of patients by undertaking confidential surveys and research into a varied number of conditions and patient groups – a recent example of this in 2009 being death within seven days of surgery in the patient aged over 80. The results of the surveys are published; its work does not involve new treatments or therapies, but a review of outcomes of current practice. Individuals or organisations may initiate studies by submitting a proposal to NCEPOD that should be relevant to the current clinical environment.

NCEPOD staff may be invited to visit hospitals and give presentations as part of multidisciplinary meetings such as audit days. NCEPOD also holds conferences where they present the results of their surveys.

The website address is www.ncepod.org.uk.

National Institute for Health and Clinical Excellence

NICE's role was identified in the White Paper *Choosing Health: making healthier choices easier* (DoH 2004). Within this the government set out key principles for informing people so that they may make healthier and more informed choices about their health, and the DoH required NICE to bring together knowledge and guidance of ways of promoting good health and treating ill health.

NICE is an independent organisation, and produces national guidance in three areas of health, as follows.

- Public health – guidance on the promotion of good health and the prevention of ill health for those working in the NMHD, local authorities and the wider public and voluntary sector.
- Health technologies – guidance on the use of new and existing medicines, treatments and procedures within the NHS.
- Clinical practice – guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS.

Each guidance area is the responsibility of one of the three centres of excellence.

- The Centre for Public Health Excellence.
- The Centre for Health Technology Evaluation – technology appraisals are recommendations for the use of new and existing medicines and treatments within the NHS. Interventional procedure guidance evaluates the safety and efficacy of the procedures where they are used for diagnosis or for treatment
- The Centre for Clinical Practice which develops and produces clinical guidelines – these are recommendations on the treatment of people with specific diseases and illnesses based on the best available evidence.

NICE has staff based in London and Manchester who deliver the institute’s work. The guidance is developed by a number of independent advisory groups who consist of health professionals, staff from the NHS, patients, their relatives or carers and the public. There is a Board and Senior Management team who set the strategic direction and oversee the delivery, provide stewardship and ensure corporate governance. In addition NICE produces a wide range of resources to help practitioners implement the guidance into their practice. Details of these can be found on the website at www.nice.org.uk.

Once NICE guidelines are available, organisations who employ health professionals as well as the healthcare professionals themselves are expected to take them into account when deciding which treatments to give to patients. However, the guidance does not replace the skills or knowledge of the individual professionals – treatment still remains their ultimate decision about particular patients, always in consultation with the patient themselves and relatives/carers.

What health professionals are expected to do depends on the type of NICE guidance.

- *Public health guidance:* Take into account when developing local area agreements.
- *Clinical guidelines:* Review the current management of the conditions then consider the resources and time needed to implement the guidelines.
- *Technology appraisals:* Fund and resource medicines and treatments recommended. Three months is the usual time between guidance and implementation.
- *Interventional procedures:* Practitioners should always check whether NICE has issued guidance before carrying out a new procedure. If there is no guidance, a practitioner must seek approval from their NHS trust clinical governance committee – and ensure that the patient has given informed consent before carrying it out.

Medicines and Healthcare Products Regulatory Agency

This government agency is responsible for ensuring that medicines and medical devices work and are acceptably safe. It acknowledges that no product is risk free – but robust and fact-based judgements are gathered to ensure that the benefits to patients and the public justify the risks. The MHRA observe medicines and devices and take any necessary action very promptly to protect the public if there is a problem. MHRA Alerts are issued to all healthcare providers and it should be an active part of the governance structure that prompt action is taken to disseminate the alerts throughout the healthcare organisation, and that relevant action is identified, implemented and documented. As much information as is possible is made publicly available. The MHRA encourages everyone – the public, healthcare professionals as well as industry – to report problems with a medicine or a medical device. Investigation is prompt and necessary action is communicated through the alert system.

National Service Frameworks (NSFs)

These are policies set by the NHS in the UK to define standards of care for major medical conditions such as cancer, coronary heart disease, mental health and diabetes. Frameworks are also defined for some patient groups including children and older people. The main purposes of NSFs are:

- to set defined quality requirements for care based on best available evidence of what treatments and services work most effectively for patients
- to offer strategies and support to help organisations achieve these.

One of the main strengths of each NSF is that they are inclusive, in that they have been constructed in partnership with health professionals, health service managers, patients, carers, voluntary agencies and other experts as relevant to each one. They are intended to be long term; they set national standards with measurable goals within set time frames. Individual frameworks can be reviewed on the website at www.nhs.uk/nhsengland/NSF/pages/Nationalserviceframeworks.aspx.

Critical Appraisals Skills Programme (CASP)

Since its birth in 1993, the Critical Appraisal Skills Programme has helped to develop an evidence-based approach in health and social care, working with local, national and international groups. It is a programme within learning and development at the Public Health Resource Unit.

CASP aims to enable individuals to develop the skills to find and make sense of research evidence, and helps them to put knowledge into practice.

The website address is www.phru.nhs.uk/pages/PHD/CASP.htm.

The NHS Information Centre (NHS IMC)

This centre is a central and authoritative source of health and social care information. Information is sourced to aid local decision makers to improve the quality and efficiency of frontline care. The Information Centre acts as a hub for high-quality, national and comparative data.

The website address is www.ic.nhs.uk.

The National Audit Office (NAO)

This body scrutinises public spending on behalf of Parliament. Currently a review is taking place of the implementation of clinical governance in PCTs – recommendations are published upon the completion of their reports.

The website address is www.nao.org.uk.

The Audit Commission (AC)

This is another independent public body responsible for ensuring that public money is spent economically, efficiently and effectively in health and other areas. Their mission is to be a driving force in the improvement of public services, promoting good practice and helping to achieve better outcomes.

The website address is www.audit-commission.gov.uk.

Good Medical Practice guide

The General Medical Council regularly reviews their *Good Medical Practice* guide, the latest being November 2006 (GMC 2006). The booklet is designed to strengthen the process of professional self-regulation. It forms the basis of the GMC's medical appraisal scheme and provides advice on how to maintain good practice and what to do in cases of poor practice, the procedures involved and whom to contact.

The website address is www.gmc.co.uk.

Continuing medical education (CME) and continuing professional development (CPD)

Lifelong learning and continuing education is a component part of the maintenance of professional registration. CPD has to be evidenced at performance review and as part of a revalidation programme. NHS organisations are expected to provide programmes for education and training, personnel and organisations, particularly around clinical governance.

Safeguarding Patients

The document *Safeguarding Patients: lessons from the past, proposals for the future*, published in February 2007 (DoH 2007), brings together all the initiatives in this area that have occurred in the last decade. The government published *Safeguarding Patients* as a response to the recommendations of the Shipman Enquiry's fifth report and to the recommendations of the Ayling, Neale and Kerr/Haslam Inquiries in February 2007. (Dr Harold Shipman, a GP from Hyde, murdered around 250 of his patients over a 20-year period). Each of the five inquiries made recommendations to balance the need for additional safeguards for patients with the need to avoid placing unnecessary obstacles in the way of the normal processes of patient care. The embedding of clinical governance within the NHS to promote continuous quality improvement has been driven since the publication of the Shipman Reports, for it is widely accepted that had the systems that have now been introduced been in place at the time of Shipman's crimes, then it would have been highly unlikely that those abuses could have continued for such a long period of time.

The fifth inquiry report recognises that the NHS and the context in which it operates have changed radically since Shipman's crimes came to light.

The overall quality strategy, *A First Class Service* (DoH 1998) was set out in 1998 with explicit standards to be monitored by the then Healthcare Commission. This was preceded by *The New NHS: modern, dependable* in 1997 (DoH 1997). Developments in the regulations of healthcare organisations have continued to evolve, and the central role of clinical governance in assuring quality and promoting quality improvement has been totally embedded within the management structures of healthcare providers. New approaches to the handling of disciplinary and performance issues including the role of the NCAS in both primary and secondary care have been introduced. The patient safety agenda was further launched by *An Organisation with a Memory* in 2000 (DoH 2000).

Increasing recognition has been given to the role of patients' experience and involvement in shaping services, and providing feedback to improve service quality. There has been an increasing movement towards 'a patient-led NHS' and the wider health reform programme.

Recruitment and screening processes for employees in health organisations are now robust, following guidance issued by NHS Employers, a part of the NHS Confederation.

The White Paper from the Department of Health, *Our Health, Our Care, Our Say* (DoH 2006), launched a review of the complaints system. It has been recognised that complaints from patients or their representatives and concerns raised by fellow professionals can provide vital information in identifying potential risks to patient safety.

The safer management of controlled drugs was introduced in 2004, and *Good Doctors, Safer Patients* was published in July 2006 by the Department of Health (DoH 2006).

Licences issued to doctors by the GMC (*see also Chapter 2, The Doctor's Handbook, Part 1 – on Licensing and Revalidation*) are the beginning of a process to establish 'revalidation and recertification' initiated by the CMO's (DoH 2006) report mentioned above, *Good Doctors, Safer Patients*; followed by the White Paper *Trust, Assurance and Safety*, in February 2007 (DoH 2007); and the CMO's second report, *Medical Revalidations: principles and next steps*, in July 2008 (DoH 2008).

All doctors on the GMC register have been asked to declare whether or not they wish to have a Licence to Practice. In the future, all doctors who wish to perform the clinical functions of a medical practitioner, to write prescriptions, sign death certificates etc., now require a licence. Licences were due to be issued on 16 November 2009. When revalidation and recertification processes commence in 2010 there will be a process of review of appraisals, feedback, patient outcomes and the like by a designated 'Responsible officer', and if approved the doctor will have the licence renewed for a period of five years. The document, *Safeguarding Patients*, published in February 2007 (DoH 2007) brings together all the initiatives that have occurred in the last decade.

High Quality Care for All

In 2008 Lord Darzi published *High Quality Care for All* (Darzi 2008), co-produced with the NHS during a year-long process involving more than 2000 clinicians and 60 000 staff from the NHS, patients, members of the public and other stakeholders. In June 2009 Lord Darzi published a second report: *High Quality Care for All: our journey so far* (Darzi 2009). These are both available on the Department of Health website www.dh.gov.uk.

Over the last 10 years, the NHS providers have focused on the provision of capacity. This has needed a significant investment in resources (in 1996/7, the budget for the NHS in England was £33 billion and in 2008/09 it is £96 billion) and it is timely therefore to align the system to support the delivery of high-quality care by frontline staff. Care has to be effective, from the start of the intervention, to the clinical procedure the patient receives to their quality of life after their treatment. High-quality care is also about the patient's opinion of the entire experience of the NHS, including their need to be treated with compassion, dignity and respect in a clean, safe and well-managed environment.

The Quality Framework will support local clinical teams to improve the quality of care by:

- bringing clarity to quality – making it easy to access evidence about best practice by asking NICE to develop quality standards
- supporting clinicians to measure quality to support improvement
- requiring quality information to be published, making it available to the public and making it as important to NHS chief executives as it has always been for NHS staff
- rewarding the delivery of high-quality care
- safeguarding basic standards through a new independent regulator, the Care Quality Commission
- staying ahead by ensuring that innovation in medical advances and service design is fostered and promoted
- recognising the role of clinicians as leaders and giving them the freedom to drive improvements in quality of care.

A workforce strategy has been created to support Lord Darzi's report – many of the features described in the report already existed in the NHS but not in any definitive systems – this explains why freeing up staff is such a big theme within the workforce proposals – as it is by unlocking the talents of NHS staff that the *High Quality Care for All* visions can be provided across the board.

However, greater freedom will come with a new and enhanced accountability – for the expectation is to be far more open about the quality of outcomes that are achieved for patients. The workforce strategy also states that there will be strong leadership.

Staff pledges, underpinned by core NHS values and an NHS Constitution, will help to ensure the high-quality workplaces which will be required to deliver the high-quality services. Both the values and the constitution will stretch the system or promote greater engagement with staff and excellence in education and training – all supported by transparent funding and structured career pathways.

The workforce strategy expresses the importance of being responsive to what

staff need to succeed in a very important part of getting services to patients right. Workforce systems, including quality-assured, aligned workforce planning and education commissioning plus an increased transparency of reporting will help develop the system as a whole so it is fit to deliver all that is required. All the greater freedoms and accountabilities need to be translated into meaningful and significant outcomes for patients.

Related reading

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