Clinical Governance in Primary Care

Second Edition

Edited by **Tim van Zwanenberg** and **Jamie Harrison**

FOREWORD BY **SIR MICHAEL RAWLINS**

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Foreword

Clinical governance is about trying to ensure that NHS patients receive the highest attainable standards of clinical care. It is a philosophy that places a responsibility on health professionals to seek ever greater improvements to the individual, collective and institutional care that patients receive from the NHS.

However, the philosophy is uncomfortable. For it implicitly accepts that we do not invariably provide our patients with the quality of care they deserve – and that although we want to do our 'best' for our patients, we sometimes depart from 'best practice'. It is also implicit that clinical governance, and the commitment it demands, can never be wholly satisfied. Yet it is in the striving, asymptotically, for the goals we seek that we are most likely to achieve them. For as we get close to utopia, the goal posts will change and more will be required of us.

This second edition of *Clinical Governance in Primary Care* extends and amplifies the principles outlined in the first edition. It explains and explores clinical governance in all of its multifaceted dimensions. It will instruct and enthuse all those involved in delivering care to patients, and will bring clinical governance alive.

Sir Michael Rawlins
Chairman, National Institute for Clinical Excellence
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September 2003

Preface

So what is clinical governance?

> A man that looks on glass, on it may stay his eye; or if he pleaseth, through it pass, and then the heaven espy.
>
> George Herbert

How comprehensive is our gaze? How willing are we to explore the world, and let it survey us? Even before the current power of globalisation, it had become clear to many that clinicians could no longer live in isolation, from either themselves, their colleagues or their clients (patients). The arrival of clinical governance is a public recognition of that fact.

The themes of clinical governance are those of quality, accountability, transparency and continuous improvement. It is said that such concerns can only flourish in a context of co-operation, teamwork and support. Much is made of the need to develop a 'no-blame' culture, yet ultimately someone or some group must take responsibility, and someone must lead.

In the light of such a discussion, many differing pictures of clinical governance have emerged, each with its own interest group. It is interesting to speculate on how to complete the sentence beginning 'Clinical governance is…'.

A window

The verse from George Herbert's hymn reminds us that to look upon a window offers us two choices. We can focus on the glass itself (near focus) or look beyond it (distant focus). The near focus will hold us to a near, familiar view of our world – a limited horizon, where familiarity may breed complacency.

Better to look through the window, to gain the broader horizon and the challenge of the bigger picture. With that may come a glimpse of heaven, but equally an inkling of the road that must be travelled to get there. In this sense, clinical governance is the means by which organisations begin to see what their true objectives are.

A mirror

Windows also reflect light, as mirrors on the world. Some of the components of clinical governance can act like that, feeding back information, as they do, on what we are like, how we are doing. There are those who avoid the presence of mirrors.

Mirrors are valuable tools – ask any dentist, ENT surgeon, shaver or beautician. The reflections of the mirrors within clinical governance inform the thinking of teams and practitioners in the health service. They cannot, of course, ensure that any action is taken as a result. They are merely inert commentators, companions on the journey.

A system

System development, or systemisation, would be seen, by many, as the answer to difficulties in primary care. The problem is not, they would argue, the individuals concerned, but the context in which such individuals work together.

Certainly, teaching about how to initiate and develop systems in primary care has been slow for clinicians. Better management has, however, begun to rectify this. Clinical governance allows this process to accelerate, as the need for both good management systems and care pathways is highlighted.

A culture

To bring about cultural change is always difficult. Such change must be accompanied by a clearly articulated vision of what is envisaged, be realistic and well supported – financially and with human resources – and be seen as beneficial to all stakeholders. Otherwise, the change will only be superficial and cosmetic.

Clinical governance encourages a culture of excellence, partnership and accountability. As such, it must also find the resources to sustain its high ideals and maintain its vision across all the players in primary care.

An education

Some would wish to see clinical governance as purely an educational exercise. Clearly, the need for education about clinical governance, in addition to the clear role for continuing professional development within clinical governance itself, is self-evident.

Yet there is a danger that the educational element could take over the whole agenda. It must see itself in partnership with the drive to better systems in primary care, and in the evolution of the culture of mutuality, trust and excellence which is already present in much of primary care.

A stained glass window

Returning to George Herbert, we may wish to finish with another type of window. A stained glass window comprises many differently coloured panes of glass, each set in place to form a coherent whole. Individually, each pane may be monochrome, uninspiring. Put all the panes together and a totally different effect emerges – a story told or an image expressed.

The components of clinical governance considered individually may not add up to much. Each is rather a building block, or a coloured pane, in the construction of a larger and more significant work of art. Only when viewed in its entirety can such a work be judged. Lose one component and the story is incomplete, the image marred. Each component on its own is not enough.

Tim van Zwanenberg
Jamie Harrison
September 2003

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About this book

Who is it for?

We hope everyone involved in primary care will find useful information in this book. Clinical governance is after all 'everybody's business'. Primarily we have aimed to meet the needs of those charged with leading the development of clinical governance at the level of primary care trust and primary care team. The contents should be of interest and relevance to all professional groups, although we recognise that much of the material is drawn from general practice and community nursing, with less reference to the other allied professions.

For simplicity we have used the term *primary care trust* throughout, recognising that this is the organisational arrangement in England. There are equivalent primary care organisations, with different names, in the other parts of the United Kingdom. The issue of clinical governance is generic to them all.

What does it contain?

The book is intended to provide a description of the principles of clinical governance in primary care, and practical information about many of its component processes. In general, definitions, evidence and practical experience have been emphasised. Many of the chapters point to other sources of information. We have made no attempt at a detailed description of the supporting structures and processes which are being developed on a national basis to support clinical governance – in England, the National Institute for Clinical Excellence, the National Clinical Assessment Authority, the Commission for Health Audit and Inspection, the National Patient Safety Agency and National Service Frameworks. Moreover, we have tried to provide information that might be useful to primary care staff in implementing, for example, national guidelines.

How to use it?

The book is divided into three parts. The first part (Chapters 1–4) sets the scene. The conceptual and political origins of clinical governance are traced, and the significance of organisational culture is emphasised. The importance of patients, healthcare staff and processes is highlighted. Examples are given of clinical governance in action in a primary care trust and a primary care team. The second part (Chapters 5–17) is arranged around four domains of clinical governance, namely humane care, clinical effectiveness, risk management, and personal and professional development. It describes a range of practical processes that support the development of clinical governance. The third part (Chapters 18–20) looks ahead, offering a critique of how professionalism might develop in the future against a background of increasing expectation.

Readers will have different interests and can use the book accordingly.

- You may wish to read the book from page 1 to the end.
- You may have a specific interest in clinical audit (Chapters 8–10) or complaints (Chapter 13).
- You may need to understand the pressure for accountability in the NHS (Chapters 1, 5 and 19).
- You may want to consider the implications for education and training (Chapters 15–17).
- You may keep hearing about ‘poor performance’ and want to know more (Chapters 1 and 14).

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To our children
Saffron and Luke van Zwanenberg
and
Sarah, Timothy and Nicola Harrison

Clinical governance is a system 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.

Gabriel Scally and Liam Donaldson

Clinical governance is a framework for the improvement of patient care through commitment to high standards, reflective practice, risk management, and personal and team development.

Royal College of General Practitioners

Primary care is first contact, continuous, comprehensive and co-ordinated care provided to individuals and populations undifferentiated by age, gender, disease or organ system.

Barbara Starfield

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PART 1

Setting the scene

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CHAPTER 1

Clinical governance: a quality concept

Sir Liam Donaldson

If you always do what you always did, you always get what you always got.

Granny Donaldson

This chapter defines clinical governance and describes its origins. Clinical governance involves ensuring that quality assurance, quality improvement and patient safety are part of the everyday routines and practices of every healthcare organisation and every clinical team. Recognising the importance of organisational culture to the success of clinical governance in the new primary care trusts is vital.

Introduction

Clinical governance was one of the central ideas in a range of proposals to modernise the National Health Service (NHS) contained in a White Paper produced by the incoming Labour government in the late 1990s.[1]

From the post-war years at the beginning of the NHS, through the 1960s, to the periods of cost containment in the 1970s and 1980s, and into the era of health system reform of the early 1990s, concepts and methods of quality in healthcare underwent a quiet revolution.

In the early years of the NHS, quality was implied, assured by the training, skill and professional ethos of its staff. Standards of care were undoubtedly high for their time, and the nationalisation of health services and facilities brought about by the creation of the NHS undoubtedly improved many past inequalities in access and provision. However, quality was essentially viewed through paternalistic eyes, with the patient a passive recipient of care. The 1960s saw a growth in thinking about concepts of quality, much of it emanating from North America, notably Donabedian's quality triad (structures, processes and outcomes),[2] which has endured over more than 30 years. Despite these more sophisticated notions of quality emanating from academics and health service researchers, the vision was seldom realised in practice.

By the 1980s, management was beginning to become established within the health systems of many parts of the world. In the NHS, accountability for the performance of a health organisation came as career general managers replaced health service administrators.[3] Initially resented by many professional staff, management gradually extended to the running of clinical services with the creation of clinical directorates and budgets.

The desire to build on these trends led, in the late 1980s and early 1990s, to attempts to design incentives for efficiency and quality into the NHS system itself. The resulting internal market for public healthcare in the UK split responsibility for the purchasing and provision of healthcare between health authorities and general practice fundholders (which were allocated budgets to purchase) and NHS trusts (which competed to provide services and gained a share of these budgets).[4] The theory was that the internal market would simulate the behaviour of a real market and drive up quality while reducing costs. This concept of quality improvement remained controversial, and many professional staff working within the NHS were not confident that it could or did work.

During the 1990s, a series of high-profile instances of failed care among NHS service providers caused widespread public and professional consternation and sustained media criticism. During this time, incidents and events within local health services became public in a way that would not have been conceivable in the early years of the NHS. Traditional deferential attitudes towards doctors and others in positions of authority were changing as UK society became more consumer orientated. This was reflected in the way in which the media challenged and accused health service providers that had been responsible for incidents involving poor standards of care in which patients had been harmed or had died. Many such events in the past would not have seen the light of day at all, or if they did would have been explained away in general terms and quickly forgotten.

In the media climate of the late twentieth century, patients' deaths were no longer mishaps or unfortunate accidents. They were scandals in which, although the plight of the victim was highlighted, as much emphasis was placed on identifying those perceived as responsible.

The watershed in public and professional attitudes towards serious failures in the standards of healthcare was undoubtedly the events which took place in the Bristol children's heart surgery service during the late 1980s and early 1990s. Bristol appeared to be a statistical outlier for mortality after surgery, particularly in relation to one type of operative procedure. Despite concerns within the hospital, attempts to address and resolve the problems of clinical performance were inadequate. It was left to a 'whistleblower' – an anaesthetist – to bring the matter to external attention. At one point the surgeons were asked not to proceed with a heart operation on a particular child, but they judged the risks to be acceptable and proceeded, only for the child to die post-operatively.

What led to particular outrage when these events became public through disciplinary hearings and media reports[5] was the extent to which clinical decisions were being made on behalf of parents rather than with them. A major public inquiry into the Bristol affair[6] drew attention to a 'club culture' which was detrimental to high-quality care.

This and other cases of failed care[7,8] gave the impression of an NHS culture which at times subordinated patient safety to other considerations, such as professional loyalty, an unwillingness to challenge traditional practices and a fear of media

exposure. However, they did pave the way to major reform in the way in which quality and safety were managed within the NHS.

Organisations and people

The NHS underwent a major process of reform, beginning in 1998,[1] which focused on developing primary care as the organisational locus for assessing and meeting local health needs and for commissioning and funding health services for their populations.[9]

NHS reform has also placed an emphasis on modernisation – of facilities and infrastructure, of professional practice, of organisational systems and ways of working and of attitudes towards the patient as a consumer of care.

At the heart of the process of reform has been the establishment and implementation of a clear framework for quality. This has involved setting clear standards for the NHS as a whole, formulated through a variety of mechanisms, but most importantly a National Institute for Clinical Excellence (NICE)[10] and a series of National Service Frameworks covering priority areas of care (e.g. coronary heart disease and mental health).[11–13]

It has created robust mechanisms of inspection. The Commission for Health Improvement (or, from 2003, the Commission for Health Audit and Inspection) visits local NHS organisations, reviews quality and makes public reports.[14,15]

The quality framework also requires healthcare organisations to fulfil a statutory duty of quality.[16] This means implementing satisfactory 'clinical governance' arrangements. The concept of clinical governance[17,18] has been the driving force behind improvement in local NHS services. It seeks to establish in every healthcare organisation the culture, leadership, systems and infrastructure to ensure that quality assurance, quality improvement and patient safety activities are part of the everyday routines of every clinical team. A national clinical governance development team has undertaken a major programme of change management to fulfil this aim.[19,20]

Clinical governance is essentially an organisational concept. This is made clear by the way in which it was first 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'.[16]

The elements of accountability, of ensuring that positive outcomes are delivered and of creating the right environment for good practice to flourish are all organisational features. Organisational culture – what it constitutes, what determines whether it is beneficial and how to change it – has not on the whole been studied systematically in the healthcare field, although it features extensively in the management sciences research literature.[21] However, there are a number of generic features which many health service managers and professionals would recognise from their good and bad experiences during the progression of their careers (*see* Table 1.1). Yet achieving the right culture is seen as the most important element in implementing the clinical governance programme within the NHS.[22]

Much of the past work on improving quality through organisational development within the NHS has been directed at hospital or community health services rather than at primary care. Although a general practice, with its extended primary

Table 1.1 Ten key features of a positive culture within a health organisation

- Good leadership at all levels
- Open and participative style
- Good internal communication
- Education and research valued
- Patient and user focus
- Feedback on performance routine
- Good use of information
- Systematic learning from good practice and failure
- Strong external partnerships
- Produces leaders of other health organisations

care team, was certainly an organisation, it was small in scale; the framework of accountability was diffuse and devolved, and the element of management was firmly in support of clinical activities rather than leading and placing responsibilities on the health professionals within the practice.

The creation of 300 primary care trusts in England (*see* Figure 1.1) changed all of this.[23] Primary care trusts serve average populations of around 170 000 and contain as many as 50 general practitioners. They have boards and chief executives.

The new primary care structures are thus substantial new organisations which are creating their own cultures. Individual general practitioners and other health professionals will become committed to success at the corporate level, as well as at the level of their own clinical teams. In setting out the agenda for the new NHS, and in particular the primary care organisations, the UK government has described this as a long-term agenda for development.

Well into the twenty-first century, primary care trusts are developing as organisations, leaving behind the small-practice ethos of the early years of the NHS. This organisational development task includes building into the new organisations a working model of clinical governance.

The first stages of implementation of clinical governance involve four key steps.[22]

1 Establish leadership, accountability and working arrangements.
2 Carry out a baseline assessment of capacity and capability.
3 Formulate and agree a development plan in the light of this assessment.
4 Clarify reporting arrangements for clinical governance within board and annual reports.

One possible model (*see* Figure 1.2) would see different members of the team taking responsibility for key functions, such as ensuring that different aspects of the quality improvement programme are ‘joined together’, that the important information and information technology needs of the programme are being met, that an overview of progress is taken and that communication is effective.

Whatever the leadership arrangements, essential elements are that the whole organisation is involved in a way that promotes inclusivity, and that there is clear leadership and communication from the top (*see* Table 1.2).

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Fund and commission services — **302 primary care trusts**

318 hospital NHS trusts

PATIENTS AND PUBLIC

Figure 1.1 NHS organisational structures. Note that public health regions and care trusts are not shown. *Source*: Donaldson LJ and Donaldson RJ (2003) *Essential Public Health* (2e). Petroc Press, London.

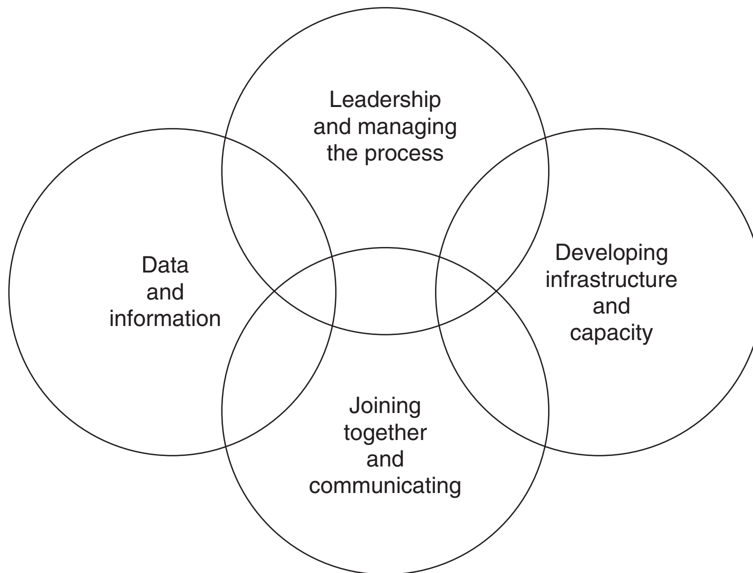

Figure 1.2 Developing clinical governance: leading change.

Table 1.2 Clinical governance: key elements of leadership arrangements

- *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.

A thorough analysis of the organisation's services from a quality perspective to identify their strengths and weaknesses establishes the baseline from which a development plan can be drawn up.

In closing the gap between the current position and the desired future state of improved quality, a number of questions need to be addressed (*see* Table 1.3).

Table 1.3 Closing the quality gap in a service: some important questions

- Is the solution a workforce one (more staff, different skills)?
- Is the solution an education and training one (development of existing staff)?
- Is the solution a realignment with patients' perspectives on quality (greater involvement of service users and carers in planning the improvements)?
- Is the solution an infrastructure one (new facilities or equipment)?
- Is the solution to remedy information deficits (better information, information technology, access to both)?
- Is the solution substantial investment of new resources (prioritisation through the local spending plans)?

Shifting the quality curve

A simple composite measure of quality, if one existed, would see healthcare organisations distributed along a curve (*see* Figure 1.3), with the worst performers at the left-hand tail and the leading-edge organisations at the right. The greatest impact on quality (i.e. the biggest move of the curve towards the right) will be achieved by shifting the mean – in other words, helping organisations whose performance is average (or just above or just below average) to achieve the levels of the best. However, the two tails of the distribution cannot be ignored. Poor organisational performance and serious service failure are phenomena which are probably uncommon in relation to the totality of healthcare provided in the NHS. Thus eliminating them would not cause the quality curve to shift a great deal overall. Nevertheless, such events have very serious, sometimes catastrophic repercussions for individual patients and their families. Specific incidents are often portrayed by

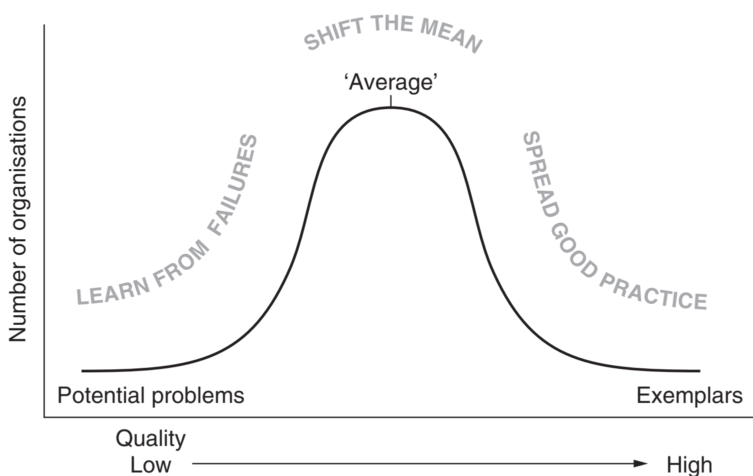

Figure 1.3 Variation in the quality of organisations. *Source*: Scally G and Donaldson LJ (1998) Clinical governance and the drive for quality improvement in the new NHS in England. *BMJ*. **317**: 61–5.

the media as if they were the tip of an iceberg of similar problems within health services. Thus their occurrence, and the media criticism which attends them, can damage public confidence in services.

Relatively little research has been conducted to explore reasons why health organisations fail. Experience suggests that organisations which are poorly led, which are defensive to criticism, which have no ethos of teamwork and where there are weak management systems will be those that are prone to failure.[18]

Finding ways to learn lessons from service failure within primary care trusts is an important part of clinical governance, and is a manifestation of their becoming effective organisations.

The activities of sharing and adopting good practice concentrate attention on the right-hand tail of the quality curve in Figure 1.3. They will help to shift the overall curve to the right, but there are other reasons for concentrating on good practice. First, it is not something which the NHS has been good at in the past. Thus patients in one part of the country will have benefited from an innovation in service delivery, while those elsewhere will have been denied its benefit. This is surely inequitable. Secondly, sharing good practice encourages a learning approach to service development and is likely to have other quality spin-offs in the type of culture that it creates. Thirdly, an increasing amount of clinical decision making will be based on following good practice guidelines, so a similar ethos needs to be developed in service organisation and delivery – recognising models of service which can be transferred to other services to create improved quality.

The emergence of the evidence-based medicine movement, which started in Canada[24] and rapidly became international in its scope, has encouraged the adoption of more rigour in clinical decision making. Numerous examples[25] exist of research evidence having been slow (or having failed entirely) to enter routine practice, so that suboptimal care is delivered to patients. The philosophy of evidence-based medicine has provided the impetus for the standards-based approach to quality.

Addressing these issues in primary care trusts is perhaps not as straightforward as it is in specialist areas of hospital medicine. This is partly because of the degree of uncertainty in many patient encounters in primary care, and the absence of a diagnostic label on which there is a strong body of research evidence with regard to clinical effectiveness. Nevertheless, promoting an evidence-based culture means ensuring that all health professionals have been trained in the critical appraisal of research evidence. It means having available and knowing how to access specialist information resources (such as that provided by the Cochrane Collaboration[26]). It also means ensuring that health professionals in primary care are able to use evidence in the interest of clinical audit and other quality-improvement methodologies.

Less experience has been gained in evaluating service models than in evaluating clinical interventions. A ‘good’ service (say) for diabetic people will often gain its reputation by being valued by patients and referring practitioners, rather than by formal evaluation. If the NHS is to ensure that good practice is replicated, then ways will have to be found of identifying the organisational ingredients that amount to success.

Patient safety: a key strand of clinical governance

Policy in the UK has focused on two separate dimensions of patient safety, both of which are contained within the overall clinical governance framework.

The first addresses the problem of the poorly performing practitioner. Of course, it is important to recognise that the vast majority of adverse events are not indicative of, or attributable to, deep-seated problems of poor performance on the part of individual clinicians. The causes of error are manifold and complex, and can rarely be attributed solely to the actions of one individual. Nevertheless, there are some instances where the poorly performing practitioner is at the heart of the problem. Such situations were badly dealt with by the NHS in the past.[27]

Incompetence, misconduct and ill-health-impaired performance traditionally became visible late in the day with some kind of serious incident. Too often investigation revealed a problem practitioner who had been well known in the locality for years. The issue had not been confronted, and patient safety was compromised.

In a national healthcare system it is not acceptable for a local primary care service to withdraw the practising rights of an impaired physician, leaving him or her to disappear, only to become a problem elsewhere in the country.

This aspect of patient safety has been addressed by creating a new national specialist service, the National Clinical Assessment Authority (NCAA), to which referrals of doctors with problems can be made. This service assesses the general practitioner or hospital specialist using expert advisers, and makes a recommendation for action, with an emphasis on retraining or rehabilitation where possible.[28]

The NHS now understands much more about poor practitioner performance, and has mechanisms to identify it early on, to assess it rigorously and to identify solutions. In this way patients are not exposed to unnecessary risk for long periods, and impaired performance is viewed as a problem to be fixed – not (as previously) as grounds for punishment.

For the individual practitioner it will mean keeping up to date, participating to the full in the clinical governance programme of the primary care trust, and recognising problems with his or her own performance and seeking help. Importantly, it will no longer be acceptable professional behaviour to fail to draw attention to concerns about serious problems with regard to a colleague's standard of practice.

The second dimension of patient safety, and the aspect that is now becoming very familiar to healthcare policy makers worldwide, is the risk associated with medical error occurring in unsafe systems. The whole field of medical error is becoming much more extensively researched (*see* Figure 1.4). The systems perspective is the key to understanding medical error and to improving safety.[29]

The turning point in the UK was the publication of the report *An Organisation With a Memory*.[30] This drew attention to the absence within the NHS of a reliable way of identifying serious lapses in standards of care (or medical errors), analysing them, systematically learning from them and introducing change (both locally and throughout the health service) to prevent similar events occurring again elsewhere. Drawing on research in England[31] which used similar methodologies to studies conducted in the USA[32] and Australia,[33] the report estimated that the problem in England was affecting about 10% of inpatient hospital admissions (*see* Box 1.1).

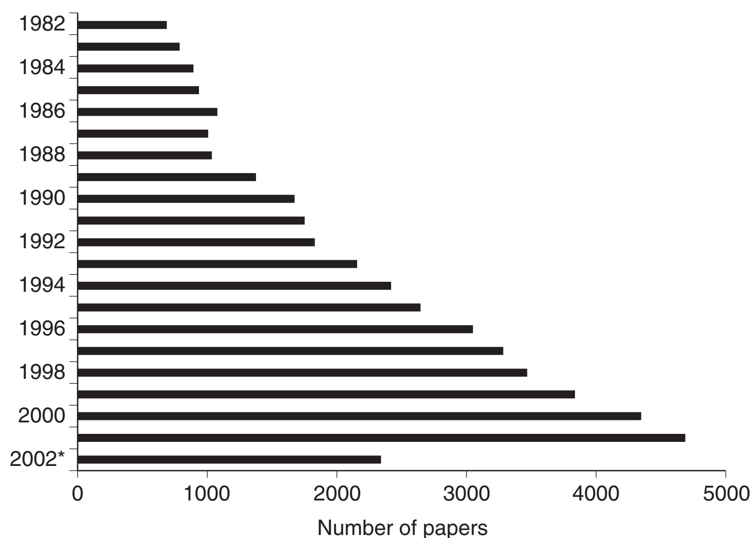

Figure 1.4 Papers in peer-reviewed journals on patient safety and medical error.
*Up to end of August 2002.

Box 1.1 Size of the problem of avoidable harm in the NHS: key facets

- An estimated 850 000 adverse events in NHS hospitals per annum
- Costs of £2 billion in additional bed days alone
- Costs of £400 million per annum in clinical negligence litigation settlements
- Nearly 7000 adverse events per annum involving medical devices
- Costs to the NHS of hospital-acquired infection estimated at £1 billion a year

Source: Department of Health (2000) *An Organisation With a Memory: Report of an Expert Group on Learning From Adverse Events in the NHS*. The Stationery Office, London.

Drawing on the experience of other industries with a more embedded safety culture, *An Organisation With a Memory* called for a similar approach in the NHS (*see* Box 1.2).[30]

Serious adverse events occurring across the NHS continue to reinforce the need for action with regard to the design and safety features of medical devices and the packaging and labelling of medicines. Recent high-profile cases include the death of another 18-year-old leukaemia patient from an intrathecal injection of vincristine (a drug for intravenous use only), the death of a small child who was given nitrous oxide instead of oxygen, deaths of babies from overdoses of digoxin, potassium chloride being mistaken for sodium chloride, and lignocaine being mistaken for water.