Chapter 21: Introduction

The Inquiry's Task

1 The final part of the Inquiry's Terms of Reference asked the Panel, in the light of findings from Bristol, to *'make recommendations which could help to secure high quality care across the NHS.'*[1] It was the philosopher George Santayana who remarked that 'those who cannot remember the past are condemned to repeat it.' The aim of this section of our Report, therefore, must be to build a bridge between the lessons of the past and the NHS of the future and, in so doing, our aspiration is that Bristol will be remembered not merely as a synonym for tragedy but also as a turning point for the NHS.

2 This is a daunting and a challenging task. A good deal has changed in the NHS since 1995, the cut-off point for our examination of the events in Bristol, not least the very significant improvements in paediatric cardiac surgical services in Bristol itself. The quality of healthcare is currently high on the agenda of healthcare professionals, the wider public and government. It is central to *'The NHS Plan'*[2] and to the purpose of such recently created bodies as the Commission for Health Improvement (CHI) and the National Institute for Clinical Excellence (NICE). In responding to our Terms of Reference, we have taken account of these initiatives aimed at improving the quality of healthcare. We have not seen it as our role to overturn them. Where recent changes are likely to help address the messages from Bristol we shall say so. But we believe that the lessons of Bristol must be applied at a more fundamental level. The question which we seek to address is this: what needs to be done, in terms of the needs of patients, the culture of healthcare, the role of healthcare professionals and the role of the NHS locally and nationally for the quality of care to improve, and to keep improving? Or, to put it another way, what was it that was absent from the healthcare system as a whole during the 'Bristol years', and is still absent today? For, despite the recent changes and initiatives, it is not necessarily the case that all of the lessons of Bristol have been learned. Even today, it is still not possible to say, categorically, that events similar to those which happened at Bristol could not happen again in the UK: indeed, are not happening at this moment.

3 Clearly, the Inquiry's brief is extremely broad. In addressing it, we wish to make one prior point of the utmost importance. It is inevitable that in this Inquiry the emphasis has been on failures and shortcomings in the NHS. This should not cause us to lose a sense of proportion. Every day the NHS provides a service to hundreds of thousands of patients, with which patients are satisfied and of which healthcare professionals can justifiably be proud. This must never be forgotten or overlooked, and it forms the essential backdrop to all that we say in this section of the Report.

4 While the events in Bristol are our starting point, we do not confine ourselves to recommendations relating only to paediatric cardiac services or to services in Bristol.

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[1] We take our Terms of Reference as applying to the NHS in England

[2] *'The NHS Plan'*, London: Department of Health, July 2000

As the evidence in Phase One made clear, while some problems were specific to Bristol, in many ways the Bristol experience exemplified what were and are national issues within the NHS. Thus, in considering our recommendations for the future, we look across the spectrum of the NHS: at its resources; at its culture; at the professionals who deliver healthcare (which we take to include doctors, nurses, other healthcare professionals *and* managers).[3] We also look at the systems and organisations which support healthcare, as well as at the external environment of policy, governance and regulation. Given the context of the Inquiry, the focus is necessarily on acute and children's hospitals.[4] It may well be, however, that many of the recommendations can be applied more widely to other parts of the NHS. We do not lose sight of the fact that it was a concern for the care of children which led to the Inquiry. Thus we also address the particular needs of children and their families in the NHS. We ask whether any further recommendations are called for to meet these particular needs and, if so, what they should be.

5 We believe that there is an enormous desire across the country, amongst the public, patients and healthcare professionals, to renew our commitment to the NHS and make it work for everyone. The recent injection of substantially increased funding into the NHS means that, for the first time in many years, there is now the opportunity to broaden the debate about what needs to change in the health service. We can begin to move beyond an exclusive focus on the level of funding, to embrace more fundamental issues about the culture of healthcare, the safety of medicine, and how to improve the quality of care for patients. That said, the recent injection of funding does not mean we can be complacent about resources: healthcare of good quality comes at a price. Increases in funding need to be sustained. Furthermore, if we are to continue to have a state-funded system of healthcare, the government must care about and take care of the NHS.

Phase Two of the Inquiry

6 Phase One focused on the evidence of what happened in Bristol. It served to identify problems that need to be addressed. After hearing the Bristol evidence, we turned to Phase Two of the Inquiry. In response to the requirement in the Inquiry's Terms of Reference to make recommendations to *'help to secure high quality care across the NHS',* we asked questions as to what was currently working well within the NHS and what was working less well and why. We decided to seek an answer to the deceptively simple problem: what are the determining factors which enable a large complex organisation to meet its objectives? We sought ideas, submissions and argument on seven topics from over 150 experts and more than 50 organisations. We chose the

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[3] We concentrate throughout on those who provide and manage care and treatment. By so doing we do not ignore the contribution to healthcare made by others who work in the NHS

[4] We recognise, of course, that there is more to health than acute healthcare in hospitals, not least health promotion, preventative care and other social strategies

seven topics because the evidence we heard during Phase One suggested that they were of central relevance to the quality of healthcare. The seminar topics were as follows:

- what factors influence an organisation's performance, and what factors influence the performance of the NHS;
- the culture of the NHS;
- leadership;
- people: education, training, development and regulation of professionals;
- systems: safety, risk and information;
- empowering the public and patients; and
- children and children's healthcare services.

7 On each topic, the Inquiry's Panel sought written submissions from a wide range of interested organisations and subsequently held a seminar, in public, with 20 or so invited participants. All of the written contributions, plus an account of each seminar, were published on the Inquiry's website during the course of spring and summer 2000.[5] We heard from people working within or close to the NHS, as well as from those who hold senior positions in entirely different walks of life, elsewhere in the public sector, and in the private sector. Other large organisations, both public and private, face challenges similar to those confronted by the NHS, in terms of pursuing quality and safety, leading and managing a workforce of professionals, working within tight financial constraints, while subject to a variety of regulatory frameworks. We were struck by how frequently it was asserted in the Inquiry's seminars that the NHS is unique and yet how often, on examination, the similarities to other organisations became apparent.

8 To illustrate the point, there are many other organisations which employ professionally qualified people who give a service direct to the public. We heard from schools and local authorities, and from law and accountancy firms. Other industries face issues of quality and safety, not least the nuclear, chemical and airline industries. We invited contributions from participants from these sectors also. On the issue of safety, we were very struck by the way in which the airline industry has been active over the years in improving safety. By way of illustration, in a recent pilot study, Professor Charles Vincent and colleagues wrote that: 'Although we cannot extrapolate with any precision, our findings strongly suggest that adverse events are a serious problem in the NHS, as they are in the United States and Australia. We estimate that around 5% of the 8.5 million patients admitted to hospitals in England and Wales

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[5] See Annex B for a summary report of each seminar. See Inquiry website www.bristol-inquiry.org.uk for the discussion points and the position papers submitted by individuals and by organisations to each seminar

each year experience *preventable* [our emphasis] adverse events …'[6] Professor Vincent was not able to say, at this stage, what proportion of these preventable adverse events result in death. Studies in the USA suggest that the numbers are high. Estimates vary, but it is said that between 44,000 and 98,000 Americans die in hospitals each year as a result of preventable medical errors, some of which are due to accidents, others to negligence.[7] If the rate were similar in the UK, then as many as 25,000 people could be dying each year from preventable adverse events. Whether the result of accident or negligence, all are, by definition, avoidable. This scale of human loss is the equivalent of the avoidable crashing of one jumbo jet a week. If air travel were so unsafe, it is unlikely that airlines would survive more than two or three weeks. Something would be done. Of course, air travel is an extremely safe form of transport. Systems and procedures have been put in place to ensure this. The question which demands an answer is why, in the face of the evidence of avoidable deaths (and ignoring for the moment the undoubtedly larger incidence of avoidable injury), this is not so in the case of the NHS. One of the challenges for the future becomes, therefore, what can the NHS learn from other large organisations which have confronted and addressed issues such as safety which are of major concern to the NHS.

Guiding principles underlying our approach and recommendations

9 We take some principles as given, in so far as they are central to the NHS and served as the guiding principles in its creation. They are reasserted in *'The NHS Plan'*. They include that the NHS be a publicly-funded service, free at the point of delivery, that it provide a comprehensive service and that there be equity in people's access to its services. To these we add certain principles which have guided us in our Inquiry and which underpin our recommendations. Whatever the uncertainties of the future, they are the underlying conditions which are essential to ensure that the quality of care is improved and sustained over time. The principles are as follows:

- The complexity of the NHS as an organisation must be recognised.

- Patients must be at the centre of the NHS, and thus the patient's perspective must be included in the policy, planning and delivery of services at every level.

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[6] Vincent C, Neale G, Woloshynowch M. 'Adverse events in British hospitals: preliminary retrospective overview.' *'BMJ'* 2001; **322**: 517 – 519. www.bmj.com Professor Vincent defines an adverse event as: '... unintended injuries caused by medical management rather than the disease process'

[7] Kohn L. et al., eds. *'To Err is Human: Building a Safer Health System'*, Washington DC: National Academy Press, 1999; p. 26 gives details of two studies, one in New York state and the other in the states of Utah and Colorado, where the percentages of adverse events resulting in death were, respectively, 13.6% and 8.8%

- The dedication and commitment of NHS staff is and must remain at the core of the service.
- The quality of healthcare must include all aspects of care: clinical and non-clinical.
- Patients' safety must be the foundation of quality.
- Systems of care, and facilities, as well as individuals, affect the quality of healthcare.
- Learning from error and mistakes, rather than seeking someone to blame, must be the priority in order to improve safety and quality.
- Openness and transparency are as crucial to the development of trust between healthcare professional and patient, as they are to the trust between the NHS and the public.
- The particular needs of children's healthcare services must be addressed.

Recognising the complexity of the NHS

10 One of the key messages from Bristol which has guided us is the profoundly complex nature of healthcare and of hospitals, and the unbalancing effect of adopting at any given time an approach to improvement which concentrates on one specific, single issue. Not only is the NHS highly complex in its processes and its organisation, but healthcare and medicine are constantly changing, as are patients' needs and expectations. It follows that this Inquiry's Panel cannot anticipate all the challenges which the NHS may face ten or even five years from now. Therefore, our recommendations are intended to be realistic and workable in the near to medium term.

11 There is no 'quick fix' to the challenges which we identify. Change needs time and patience. In an organisation as large and complex as the NHS, which has deeply entrenched patterns of behaviour, forged over the 50-plus years of its existence, sustained change for the better will take years, not months. This calls for political nerve. It calls for consistency of direction. It calls not for one-off injections of funds but a significant and sustained increase in resources. It calls for sympathetic understanding, since little of lasting value can be achieved without consent and co-operation. And it calls for a reaffirmation of the values and mission which are ultimately what the NHS is about. Thus we are wary of suggesting what may be seen as grand or iconic gestures whereby the pressure for change can be bought off, but little of substance actually changes. Our approach is more to work with the grain, and to make proposals which are likely to be capable of implementation. Thus our recommendations are a mixture of longer-term 'directions of travel' and a series of particular measures which are 'bite-size' in nature. Taken together, over time, they can begin the process of reshaping the NHS in the manner which, we are convinced, all those who use and who work in the service would wish.

Patients must be at the centre of the NHS

12 The NHS exists as a service to patients. Those whom it exists to serve are all of us, since we are all patients at some point in our lives. The legitimate needs of patients must be at the centre of the NHS and thus they are at the centre of our recommendations. There may have been times when it has appeared that the NHS was organised more in the interests of those who work in it than of those for whom it exists. It was the General Medical Council (GMC), in its contribution to Phase Two, which described the NHS as 'too heavily provider-oriented and too unresponsive to the people it serves.'[8] This approach must be consigned to history. It is not the way forward. But a patient-centred service does not mean, and should not be taken to mean, a patient-dominated service, in which doctors, nurses, managers and other healthcare workers are regarded merely as functionaries. This would be to devalue, indeed ignore, the professionalism of those who work in the NHS. This professionalism must be respected and given its proper place.

Recognising the dedication of NHS staff

13 Whatever the changes in the NHS in the course of its history, there have been certain constants. Principal among these is the dedication and commitment of those who work in and for the NHS. We acknowledge and wish to harness these qualities. What we are seeking is an NHS which will marshal these qualities fully in the service of the public and of patients: to create a partnership in which all respect the needs and claims of others. The changes which we recommend, therefore, are intended both to be in tune with the values of public service and to allow professionals in the NHS the opportunity, the time and the space to fulfil the commitment they have chosen to undertake. Furthermore, the changes must be backed in large part by incentives, since, in our view, the carrot always works better than the stick. Of course *incentives* in the public sector are not easy to fashion. But as soon as incentives are understood as not being confined solely to financial rewards for individuals, creative approaches can be adopted. We have sought to reflect this need for incentives in all that we propose.

A comprehensive approach to quality with safety as the foundation

14 We are convinced that the only definition of quality in the context of healthcare which can be of real value has to be one which is all-embracing. A first condition for achieving quality in healthcare is that the service is safe. Once safety, as a fundamental prerequisite, has been addressed, attention must turn to the pursuit of

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[8] Seminar 3. General Medical Council. Position Paper

quality. In essence, this involves identifying what will enable the NHS to meet its own high objectives and values. For us, this translates into the following concrete requirements. The quality of healthcare can only meet levels of which the NHS can be proud, if healthcare first encompasses the notions of respect for and honesty towards patients. It must recognise the emotional as well as the physical needs of patients (and their families). It must be delivered by competent staff who have suitable facilities and are always striving for improvement. It must be informed by up-to-date medical knowledge, including mechanisms for assessing the effectiveness and value of treatment. It must be safe, avoiding error and accident as far as is possible. It must be appropriate for and responsive to the needs of the patient, including being available when needed, in good time and accessible. Finally, responsiblity for the quality of healthcare services must rest with some identifiable person. That person now is the chief executive of each trust.[9]

15 A particular feature in our approach should be noted. Traditionally, analyses of the quality of healthcare have concentrated largely on the skills of the healthcare professionals who work in the NHS. More recently, attention has turned to the systems by which healthcare is delivered, focusing on such systems as those concerned with safety, standards, and the 'pathway'of patients' care as they move between GP and hospital. We go further. We are also concerned with the *attitudes* which those in the NHS bring to their work: how they relate to and respect the interests of patients. We are saying, in effect, that to secure care of high quality across the NHS, we can no longer overlook those elements of the service which go beyond technical skills and competence and beyond the systems in which they are practised. We have to care about attitudes, about respect and honesty, indeed about a partnership between patients and professionals.

Systems affect the quality of healthcare

16 The skills of healthcare professionals are only one component of the quality of care. As we learned from Bristol, an individual clinician's effectiveness is significantly influenced by other matters, such as the physical arrangements for healthcare, the availability of equipment, the members of the team, whether there are standards and protocols for practice and the extent to which these are followed and monitored.

17 As we set out in the introduction to Section One of our Report, throughout the Inquiry, both in its conduct and in framing our recommendations, we have been convinced of the value of what is known as the 'human factors' approach to understanding how people behave and function in complex systems. According to this approach, the performance of an organisation must be understood in terms of the complex interaction of factors which, only when taken together, explain success or failure. Thus, whatever the temptation to focus on the actions of individuals and to seek to blame someone when things go wrong, it is as important to pay attention to the system(s) in which those individuals find themselves.

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[9] Throughout we use the word 'trust' to refer to an NHS acute hospital or healthcare trust. We do not intend it to refer to any other type of trust. Whenever we wish also to include primary care trusts we specifically say so

18 The human factors approach suggests that, in any particular example of failure, there will have been a set of underlying factors which set the scene for the failure, as well as the more obvious direct factors which were the immediate cause. Thus, for example, if we are *to learn* how to avoid repeating it in the future, a surgeon's error must be understood not as a single, isolated occurrence, but as part of a system in which a host of other factors may well have played a part. These may be more or less visible, ranging from the surgeon's own skills to, for example, the training and competence of the theatre nurses, the quality of the equipment, the morale of the unit, or even of the hospital, and the pressures of time and resources. Using this example, to concentrate on the surgeon's error *in isolation* is to misdiagnose the problem and thus run the risk of it being repeated on another patient.

Learning from mistakes

19 The history of the NHS is littered with the reports of Inquiries and Commissions: most have soon been consigned to gather dust on shelves. There must be many reasons for this. Perhaps one significant reason is the prevailing culture of blame and stigma. A serious failure of some sort occurs somewhere in the NHS. An Inquiry is set up. Months, or years, later, a report is published. Almost always, the report singles out an individual, or group, who are held to have been responsible. The individual is condemned. The NHS proceeds on its way, assuming that the matter is resolved: until the next serious failure.

20 The flaw in this approach is obvious. While it may be appropriate to criticise some individual(s), it is often too easy a response to stop at that point. Crucially, it deflects attention from the context in which that individual was working. The individual may be replaced, but the underlying environment, which gave rise to the problem, goes unchanged. It will only be a matter of time, therefore, before the same, or a similar, set of problems arise again in the same place or elsewhere in the NHS.

21 Throughout our Inquiry we have adopted an approach which looks beyond individuals to the systems within which they work. We do not reject the concepts of blame, or of individual accountability. When individuals are held accountable and shown to be guilty of misconduct, blame is both necessary and appropriate. What we reject is recourse to blame as a necessary, almost a reflex action, as if it were a solution in itself. What we also reject is the assumption that if individuals have been blamed, this is proof that an organisation has been held to account. Accountability is a complex notion, calling for a variety of mechanisms, as much active as reactive. Singling out individuals for blame after the event is an entirely different exercise. Its contribution to the effective performance of an organisation is at best limited and it can sometimes be counterproductive. It certainly is not a proxy for a proper, rigorous process of accountability.

22 One important lesson from Bristol is how, by concentrating on this or that person, by seeing things simply in terms of people, even those in Bristol who wanted action left the larger issues unaddressed. This is crucially important. Our aim is to encourage change, with a view to empowering and assisting professionals within the NHS to serve those for whom it exists: the public. In doing so, criticisms may be made. But they are made constructively, to clear the air, to offer a prospect of healing divisions, of rebuilding trust and starting again.

Developing an open and transparent NHS

23 A further principle which has guided us is the need for an ethos of openness and transparency in the NHS of the future. The NHS must let in and work with the public: it must celebrate its successes and make known its shortcomings. Of all our guiding principles, this is perhaps the most significant and the most difficult to put into action. But, if it is not translated into practice, little progress can be made. Celebrating success appears unproblematic, even if there will always be sceptics (and rivals) who challenge the criteria. Admitting shortcomings, however, is a wholly different matter. It constitutes an immense challenge. Most important, it calls for maturity, and since we emphasise partnership between patient and healthcare professional, we point out that the maturity must come from both. Patients and the public must understand that not everyone can be the best and that data need careful understanding. Healthcare professionals must face up to possible underperformance and be prepared to demonstrate how they aim to improve it.

The need to address the particular requirements of children’s healthcare services

24 It has been clear for a long time that healthcare services for children need to be improved. What is shocking is how hard it seems to be to bring this about. Fundamentally, it has to be accepted that children have particular healthcare needs which are indisputably distinct from those of adults. While there are many examples of good healthcare services for children, there are still too many circumstances in which children have to make do with services designed for adults which are quite simply unsuitable and inappropriate for children. We cannot say too loudly that this is wrong. As a society we can do better for our children; we must do better. While we believe that children will benefit from the more general recommendations in this Report, more needs to be done, and done urgently, to address the particular needs of children. Thus we devote a separate chapter of the Report to this crucial area of healthcare.

The structure of the NHS: understanding management and regulation

25 We have said that our approach is patient-centred. The future of the NHS lies in a realignment of services so that they are organised around the patient. And it lies more fundamentally in an understanding of the distinct roles of regulation and of management. Regulation must ensure that the NHS works in patients' interests. Once it is grasped that it is the interests of patients which should determine the future form of the NHS, what we say here acquires its context. In approaching our task we have found it essential to address what may be described as the architecture of the NHS. In particular, we have asked ourselves what should be the role of government, principally through the Department of Health, and how should systems concerned with the safety and quality of healthcare be organised. We recognise that the NHS is a state-run organisation with a virtual monopoly in the provision of healthcare. As such, responsibility for the NHS can and will always be traced back to the Secretary of State for Health as the person responsible to Parliament. It is right that the Department of Health should be the headquarters for the NHS, at the apex of a hierarchical system of management. But *management* of the service is quite distinct from *regulation*. By regulation, we do not refer to the various economic approaches, such as through the market. Instead, we mean the totality of the processes and systems for assuring and improving the safety and quality of healthcare, including the regulation of healthcare professionals and the regulation of the institutions in which they work.

26 The regulation of the NHS in this broad sense must not, in our view, be in the day-to-day control of the Department of Health. While it is the proper role of government to establish the regulatory framework, to ensure safety and promote quality, that framework must be as independent as possible of the Department of Health. This is quite simply because it is not in the interests of the public or of patients that the monopoly provider should also set and monitor the standards of care. Instead, these functions must be carried out by independent bodies within a statutory regulatory framework. The regulatory bodies, embracing, as we have said, matters to do with safety, quality and standards as well as the competence of healthcare professionals, must themselves be co-ordinated and their efforts aligned by some overarching system. Duplication must be reduced. Equally, holes in the system must be stopped. Only in this way will the fragmentation and lack of clarity about responsibility for regulating the quality of healthcare, which was such a feature of Bristol, be addressed. And by insisting on independence from government, the systems to ensure safety and promote the quality of healthcare will be made secure from the vagaries of passing political pressures.

27 Let it be clear what we are saying. We are not saying: management bad; regulation good. We are saying that each has its role. Management must be for the Department of Health and exercised in every trust but, from the perspective of patients, regulation is a different enterprise. It is there to protect them against all political weathers. We admit that one way forward is to proceed as in the past through a subtle blend of regulation and management. This distinction could remain blurred as could the precise identification of who is responsible for what. The difficulty lies in the fact that this is the traditional 'insiders' fix. Those running things know what's what. Everyone else remains unsure and unclear and thus excluded. Only by making explicit that which has been implicit, will the interest of the patient and public be served, because *they* will then know what's what. This is the process which government has already begun. It should go further, towards a gradual realignment of management and regulation.

The structure of the Report

28 As we have said, a patient-centred approach informs the whole of our analysis and the recommendations which flow from it. In the chapters which follow, we consider the journey taken by a patient in need of healthcare, looking at the quality of the care received from the patient's perspective, and not from the perspective of what may meet the requirements of any healthcare organisation, any professional group or part of a profession, or the government of the day. We ask what the patient may properly expect of the NHS. To the extent that expectations may not currently be met, we seek to identify the problem and to make recommendations as to possible solutions.

29 Whether a patient's 'journey' through the NHS consists of a telephone call to NHS Direct, a consultation with a GP, a visit from the community health nurse, a visit to an NHS walk-in centre, a visit to an outpatient clinic, or a stay in hospital, every patient is entitled to expect:

- respect and honesty;
- care in a setting which is well led;
- competent healthcare professionals;
- care which is safe;
- care of an appropriate standard; and
- inclusion and involvement in the NHS, both as a patient and as a member of the public.

These form the themes of the chapters which follow. They are preceded by a chapter on the culture of the NHS. For it is the culture of an organisation that sets the conditions in which any proposed change must occur. Only if the prevailing culture of the NHS develops and grows in the direction which we advocate, will it be possible to achieve and sustain the long-term improvements to the quality of healthcare which we all seek.

Chapter 22: The Culture of the NHS

Introduction

1 At the centre of the patient's experience is an encounter with the culture of the NHS. This culture, by which we mean the attitudes, assumptions and values of the NHS and its many professional groups, conditions the patient's journey and thus the quality of care received. We believe it essential to explore the prevailing culture of the NHS ('the way things are done around here'), to understand its strengths and its problems and to consider how it may need to develop and grow.

2 As *'The NHS Plan'* put it, the NHS bears too many of the hallmarks of the 1940s: '… the whole culture is more of the last century than of this'.[1] We agree. However well we are able to meet our Terms of Reference in recommending systems and policies to 'secure high quality care', such systems and policies will never succeed if the deeper, underlying culture of the NHS remains the same.

3 To speak of the culture being outmoded or in need of change is not to say that it is uniformly negative. Indeed the culture of the NHS has many strengths. They include the values of public service and social solidarity which have been at the core of the NHS since its foundation. They also include the commitment to access and equity on which the NHS was founded and which *'The NHS Plan'*, when implemented, should help to reinforce. The dedication and commitment of all who work in the NHS is a further, some would say defining, strength.

4 We recognise and celebrate these features of the culture of the NHS. Yet it is clear that there are also aspects of that culture which have acted, and continue to act, as a barrier to improving care for patients. By drawing attention and giving emphasis to these less positive aspects of the culture of the NHS, we aim not so much to criticise, as to understand them and how they came about and thereby to suggest where change may be needed.

5 Before considering these cultural barriers to improving care in more detail, we need to refer to two particular influences. The first is the role of resources. We are not of the school that argues that any problem can be solved if enough money is thrown at it. Indeed, the evidence of Bristol demonstrates that without, for example, proper leadership, good communication, good relations between professional groups, and agreement on such crucial issues as who is in charge of the Intensive Care Unit (ICU), more resources on their own would not have made the difference. Thus, we must put any reference to resources in context. It is one of a number of factors influencing the culture of the NHS. In the NHS healthcare professionals and patients have been consistently asked to participate in and tolerate a service which has been increasingly underfunded *in terms of what has been asked and expected of it.* Underfunding, of course, is not a neutral or objective term. It means the provision of a lower level of

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[1] '*The NHS Plan*', Chapter 2, London: Department of Health, July 2000

funding than others would argue for. The NHS, like any other public service, is funded to a level arrived at in a fragile compact between government and governed. Moreover, this is a compact at the mercy of the nation's economy and the delicate balance involved in decisions about taxing and spending. This is how a parliamentary democracy works. What marks out the NHS, is that successive governments have made claims of excellence which simply have not been realisable, given the funds allocated. Patients have been led to have high expectations, only to be disappointed too often. Those working in the NHS have become increasingly frustrated that they are unable to give patients the service which they joined the NHS to provide. They have found themselves battered from all sides: taught what is the best, but expected to practise in circumstances in which 'getting by' is prized as success, and make excellence very difficult to attain.

6 A second influence of great importance on the culture of the NHS is that the NHS historically has been seen as more than a health service. It was seen as a national icon: a commitment to a particular set of values. This commitment and these values were challenged, particularly in the 1980s and 1990s. It is little wonder that, collectively or in groups, healthcare professionals have felt beleaguered and have reacted in ways that others might see as unhelpful. It is no surprise that many withdraw into a kind of professional bunker and view everything outside as a threat. For instance, many professionals saw the introduction in 1991 of the purchaser-provider split, trust status and contracting, as offending against the concept of public service by reducing healthcare to a commodity rather than a right. To protect patients, as they saw it, clinicians fought a rearguard action against what was termed 'management'. Suspicion became the order of the day, particularly among doctors and nurses, a mentality which some feel still pervades these professions: suspicion of government, suspicion of trust managers, suspicion generally borne of years of genuine frustration that the NHS was failing to provide them with the tools they needed. As they saw it, and with justification, they were not able properly to care for the patients they were there to serve. Managers for their part also felt a sense of frustration. They struggled to deliver the service which they aspired to give. The workforce was disenchanted and blamed them. The government, as they saw it, constantly bombarded them with initiative after initiative. It was no surprise, therefore, that some managers felt that they equally had neither the tools to manage the workforce nor the wherewithal to meet the targets imposed on them by successive governments. Little wonder too that the public started to question the NHS and to question healthcare professionals, as the dissonance between what the NHS had claimed to offer them and their own experience became apparent. The public became more consumer-minded. They came to demand more and better care and to show a greater readiness to complain if care fell short of what they expected.

7 This is the context in which the cultural problems within the NHS need to be properly and honestly addressed. Seen in context, it becomes clear that the problems are not intrinsic to a system of a publicly funded, national healthcare service, far less insuperable. Rather, they should be seen as responses to circumstances. Change the circumstances and there is the prospect of resolution. Make the patient the centre of the service. Set standards for the safety and quality of care. Support professionals. Liberate and empower the professionals, *all* the professionals, to do their jobs, within clear and agreed frameworks. Give them decent resources, equipment and facilities, and care of a high quality, delivered consistently across the service, will then be a realistic goal.

8 What this discussion of culture means for us here is that new models of patient-centred care for securing quality cannot simply be grafted on to the existing attitudes and ways of working within the NHS. The new models have to be accepted, endorsed and embraced by all who must make them work. They have to find their way into the very grain of the NHS. They must not be seen as a threat or challenge to fixed professional power bases. The way forward for everyone involved in the NHS and particularly for those who lead and manage the service, is to generate a new and different culture: one that builds on and reinforces the historic values of the NHS, but one which ensures that the actions taken in the name of those values truly reflect the interests of patients, now and in the future. In short we must begin the patient's journey by identifying the organisational culture and values which are necessary for the quality of care to improve and flourish.

The complexity of culture

9 It is important to avoid caricature when referring to 'culture' and to be clear what the word is intended to convey. We take it to refer to those attitudes, assumptions and values which condition the way in which individuals and the organisation work. It is also helpful to bear in mind Professor Robert Dingwall's view[2] that organisational culture is a complex notion and something which is often resilient to change. One reason for this may be that its complexity lies in the coexistence of competing cultures. This is very much the case within the NHS, where the cultures, for example, of nursing, medicine and management are so distinct and internally closely-knit that the words 'tribe' and 'tribalism' were commonly used by contributors to the Inquiry Seminars on this subject.

10 The positive aspects of tribalism are clear. Tribalism engenders a sense of belonging, a set of common goals, a sense of mutual support. Moreover, competition between various tribes may be beneficial if it creates an environment of creative tension within the organisation. The danger of tribalism, of course, is that where there are numerous tribes it can threaten to undermine the capacity of a large organisation to adhere internally to a set of agreed core values and to represent these values to the outside world. Moreover, when tribal groups fall out, or disagree over territory in an organisation such as the NHS, the safety and quality of the care given to the patient is put at risk.

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[2] Seminar 3. Professor Robert Dingwall, Professor of Sociology, University of Nottingham. Points for Discussion

11 The way forward must lie in creating an environment of mutual understanding among the groups rather than attempts by one group to gain dominance over others. If one group dominates in a service which calls on the skills of many groups, the interests of patients are not served. Indeed, as Dr Terry McNulty argued, the creative management of the tension between competing cultures involves finding the common ground amidst the diversity of values, accepting this diversity as a given.[3]

Some important features of culture

12 Organisationally, a sense of collective solidarity among the various groups of professionals in the face of what is seen as considerable adversity has been a cultural strength which has served the NHS well. We heard references to this type of 'Dunkirk spirit' during the evidence in Phase One and Phase Two. The General Medical Council (GMC) referred to 'a national "make do and mend" culture'[4] in the NHS: adverse circumstances seem to tap a particular quality in the national psyche. Objectively, of course, such an approach is ultimately hopeless. It exploits the preparedness of the professionals to sacrifice themselves, while exhausting them. As a recipe for the future, it is useless. What needs to be cultivated is a new sense of collective effort based on opportunity, rather than frustration.

13 A further cultural strength has been the capacity of the NHS to absorb change at a pace which would defeat many other organisations. The political nature of healthcare has meant that legislation, circulars, guidelines, targets and demands for data have rained down on those who work in the NHS. Amazingly, the NHS has kept going. But again, this has been at a significant cost to the energy and morale of those who work in it, and thus to the quality of healthcare.

14 In the face of the pace of change, and while treating ever more patients with constant pressure on resources, healthcare professionals have continued to fight for their patients' interests as they see them. This is a further strength of the culture of the NHS: the commitment of healthcare professionals to doing the best for their patients. This must not be overlooked, far less undermined, in any changes that take place.

15 Whatever the strengths, it is clear to us that there are certain negative features which also characterise the present culture of the NHS. To change a culture takes time; it takes a sense of direction and it takes determination. There are no short cuts. Patience is required. And, during this process of change, understanding *by* all *of* all is essential. If a way forward is to be charted, the first stage must be an open and honest appraisal of the culture in which healthcare is practised and an acceptance that it must develop. This process is not free from pain, particularly when those who work in the NHS

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[3] Seminar 3. Dr Terry McNulty, Senior Lecturer in Organisational Behaviour, University of Leeds Business School. Position Paper

[4] Seminar 3. General Medical Council. Position Paper

already feel bruised and hurt. But it is a process which must be negotiated, for change depends on a recognition of the need to change.

16 Part of this process of understanding involves acknowledging an apparent contradiction. It is that professionals as individuals or as a group within the NHS can, as we saw in Bristol, be enormously dedicated and caring, yet, *at the same time,* form part of, or represent, elements that need to change. We cannot state this point too emphatically: healthcare professionals are virtually universally dedicated as individuals. But, as members of separate professions and of a large organisation, the NHS, they may not always act in the interests of patients as a whole. Their particular culture may even work against these wider interests. This is not because the professionals involved, be they managers, doctors, nurses or others, are bad people. It is merely that they have come to view the world in a particular way and, as a consequence, are unable to see the wider interests of patients as a whole (rather than the patient before them) and the wider picture of the NHS.

17 One prominent feature of NHS culture, which still persists in parts of the NHS, lies in what one contributor to our Seminars referred to as the '… built-in traditional attitudes of some healthcare professionals …'.[5] Such attitudes discourage patients from asking questions, and lead to their being given only limited access to information, thereby preventing patients from participating fully in their care. In relation to medicine, Sir Donald Irvine has spoken of what he calls 'The cultural flaws in the medical profession [which] show up as excessive paternalism, lack of respect for patients and their right to make decisions about their care …'.[6] We heard in our Seminars that these flaws are evident in all parts of the NHS. They are not confined to one professional group but may be found at every level of the patient's encounter with the service. Yet it hardly needs to be said that such attitudes are redolent of a time now past, where those with professional expertise were automatically deferred to as 'knowing best'. Today, patients increasingly want to have more information about, and to be involved in, their care. This does not mean that they do not respect or value professional expertise. Rather, it means that such expertise has to be used in a different, sharing and more open way.

18 This old-style paternalism is evident in the adherence to the idea of hierarchy. As was revealed in the course of the Seminars and by the evidence in Phase One, the continued existence of a hierarchical approach within and between the healthcare professions is a significant cultural weakness. While the situation has changed somewhat over the past decade or so, the problem remains. Even today, in some places, it is assumed that a doctor's view is inevitably superior and that nurses are there to carry out a doctor's orders. This continues despite the very great efforts made by the nursing profession to create a relationship of mutual dependence and respect between doctors and nurses.[7] Many nurses in hospitals and elsewhere still do not feel

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[5] Seminar 3. Association of Community Health Councils for England and Wales. Position Paper

[6] Sir Donald Irvine. *'The changing relationship between the public and medical profession'*. Lloyd Roberts Memorial Lecture. Royal Society of Medicine, 16 January 2001. www.gmc-uk.org

[7] Seminar 3. The Royal College of Nursing. Position Paper

valued by their medical colleagues or by managers. A sense of hierarchy also persists within medicine. The role of a hospital consultant, for example, is regarded as of higher status than the role of a general practitioner. Indeed, Sir Donald Irvine, himself a GP and President of the GMC, has spoken of how, at the start of the NHS, general practice had a very low status with no impact on the culture of medicine.[8] Much has changed since then, but the resonance of these assumptions about ranks within medicine persist. More persistent still, perhaps, is the sense of hierarchy between different medical specialties within hospital medicine, such that, for example, as the evidence in Phase One indicated, if a surgeon is in the room, it is he, at least in his eyes, who is 'in charge'. Of course, if he is the person with the most appropriate skills to be in charge this is not a problem. It becomes a problem if status or title can be used automatically to supersede the authority of another more qualified to be in charge. Clearly, these aspects of the current culture of the NHS are simply inappropriate. They are a product of dated professional self-images which are already on the wane. Where they persist, they affect behaviour; they are a powerful force militating against teamwork, particularly among younger staff, anxious not to fall foul of those with power or authority.

19 Subservience or deference to a perceived superior can be a particular barrier when issues arise among healthcare professionals about a colleague's performance.[9] Although there is now a duty on doctors and nurses to protect patients from risk and not to suppress concerns about a colleague's performance, very many in practice today were educated and trained in a culture in which there was a reluctance to criticise or comment upon the conduct of colleagues, particularly those who were more senior or practised in the same team or specialty. This is the negative side of the tradition of group loyalty which has been a strength in times of relative adversity. It continues to be a negative aspect of NHS culture. Not only does it make it difficult for an individual to summon up the courage not to conform, but this sense of hierarchy also influences who gets listened to within the organisation when questions are raised.

20 A further cultural problem arises from the strong claim made by some doctors to 'clinical freedom.' The weakness is as much symbolic as actual, signifying as it does some claim to an autonomy which sits uncomfortably in a large, complex organisation seeking to adhere to agreed standards within limited resources. In essence, an appeal to 'clinical freedom' is a claim that in the care of a patient, the doctor's decision is the determining decision and may not be challenged. On one level, of course, this approach reassures patients that the doctor is 'in their corner' and puts their interests first. But, there is an all-too-real danger that the doctrine becomes merely code for 'doctor knows best' and will brook no argument. In a modern, managed healthcare system, where healthcare professionals must work in teams, such an approach may be counterproductive. It does not serve the interests of the patient. Equally, against a background of constrained resources, it may not always be right for the individual doctor treating a particular patient to insist on having his or her way,

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[8] Sir Donald Irvine. *'The changing relationship between the public and medical profession'*. Lloyd Roberts Memorial Lecture. Royal Society of Medicine, 16 January 2001. www.gmc-uk.org

[9] Some would see Dr Bolsin as having been in that position. See chapters on Concerns in Section One

if the price to be paid is to limit or impair the care available for other patients. It was for this reason that Sir Alan Langlands described clinical freedom as '… romantic notions … in a bygone age', and '… not a phrase I have heard for a very long time in the National Health Service'.[10]

21 Also problematic is the friction between clinicians on the one hand and managers on the other, akin, in places, to a type of guerrilla warfare. We have made it clear that, for us, *all* are healthcare professionals. They are all involved in different ways in serving patients and the public. The frustrations and difficulties of the past two decades, not least the changes in 1991, and the different perspectives of these two groups of professionals, have led to a degree of struggle and conflict, as unnecessary as it is unhelpful. This is not a struggle where one side is ever going to triumph over another: nor should it be. But, while it has existed, it undoubtedly has affected the quality of the care which patients have received. We have little doubt that once there is a real understanding of the various roles and responsibilities each must play in the NHS, this cultural barrier to change will begin to disappear. There will be a recognition that just as nurses and doctors work hard and that we need them to be highly skilled and caring, so the same is true of managers. They are hard-working, theirs is real work, and we need them to be good at their job. As the NHS Confederation put it in one of their papers for Phase Two:

> 'A relationship that in the past has suffered from much mutual mistrust must be rebuilt on a foundation of mutual respect. Managers and doctors each have very high levels of expertise that will serve the NHS far better if they are understood by all to be separate but equally beneficial. Tribalism must be eliminated and replaced by far better mutual understanding.'[11]

22 As with everything, there is a history to what the NHS Confederation calls 'mistrust'. In the period after the creation of the NHS, clinicians looked after all aspects of clinical care and 'administrators' were there to support. There was, as we have seen, a 'deeply rooted reserve' about becoming involved in clinical matters which went right to the top of government. The change in the 1980s and 1990s was dramatic. Managers were expected to manage, and that included all aspects of the NHS. They were understandably perceived by some clinicians, however, as being the people who limited or rationed the care which they were trying to deliver to their patients, or who asked for ever greater 'efficiencies'. This history must be put behind us. The quality of clinical care is self-evidently the responsibility of all who work in a trust (and is now explicitly so according to the principles of clinical governance). As the NHS Confederation put it:

> 'Doctors see themselves as accountable to their patients, their Royal Colleges, the GMC and their consciences. … From the Manager's point of view there is a higher imperative; to balance the twin pressures of limited supply of resources … with the

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[10] T65 p. 5 and T65 p. 106 Sir Alan Langlands

[11] Seminar 3. NHS Confederation. Position Paper

> ever increasing local demand for more and better healthcare. Both views are legitimate.'[12]

We would interject that the manager's imperative is not necessarily 'higher': it is merely different and that is the point. Sir Donald Irvine expressed well the need to move forward in his Lloyd Roberts Lecture when he said:

> '… it [the medical profession] needs to develop better communication with and respect for managers, to understand the pressures and constraints upon them. Doctors and managers together have to make the system work for patients. Only by working together and helping each other can they start to do so.'[13]

Looking to the future

23 The implications of our analysis are that necessary changes in the culture of healthcare can only be brought about if, *at the same time,* the root problems of resources and the capacity of managers to manage are comprehensively addressed. We have already referred to resources. We will address the issues of management in detail later. What we concentrate on here are the developments in aspects of the culture which we see as essential to allow the NHS to serve patients. We focus on the need to develop a culture of safety and of quality; a culture of openness and one of accountability; a culture of public service; a culture in which collaborative teamwork is prized; and a culture of flexibility in which innovation can flourish in response to patients' needs.

A culture of openness

24 We have already referred to that aspect of the culture of the NHS which tends to be defensive and secretive, and to old-style attitudes of paternalism and self-protection. This is not fertile ground for a patient-centred service in which communication, openness and honesty are essential to the restoration and maintenance of trust. We have no doubt that, as an organisation, the NHS and those who work within it must embrace a culture of openness. Equally, we are aware of how difficult this is to achieve. On the face of it, the recent past may suggest that circumstances are not propitious. Stories of scandal and malpractice seem to dominate the media coverage of the NHS. A complex, but accurate (and more fair), analysis based on systems and an understanding of how people function inside organisations is much more challenging to portray. Sometimes it can seem as though NHS problems all boil down to questions of individual responsibility and blame. Meanwhile, dissatisfied and damaged patients, frustrated by poor communication, having failed in their search for

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[12] Seminar 3. NHS Confederation. Position Paper

[13] Sir Donald Irvine. *'The changing relationship between the public and medical profession'*. Lloyd Roberts Memorial Lecture. Royal Society of Medicine, 16 January 2001. www.gmc-uk.org

explanations, defeated by the culture of defensiveness, resort to the media or the law, or both. And, of course, this requires that someone be singled out for blame.

25 It may be objected by some within the NHS that asking them to be open is to give 'the invaders the keys to the city'. But this is too pessimistic. If trust is to be established and maintained, there is only one choice available to those who work in the NHS. They must let in those currently kept outside. They must accept that the public are not 'invaders' and that, once let in, they will behave with the maturity which being an insider demands.

26 The process of embracing openness involves taking very many small steps. One such step is to make available to patients information on measures taken to safeguard safety. Another is the regular publication of information on the quality of care: in particular, on the outcomes of particular treatments at particular hospitals. Another is the prompt acceptance of responsibility when things have gone wrong, accompanied by an appropriate apology. All of these take courage. All may well, initially, attract hostile criticism. But, we are convinced that they must be done. As Professor Marc de Leval noted: '… physicians must become more open and comfortable with their fallibility and the patients must accept their own vulnerability.'[14] Some may object that, if the public had more information about clinical performance, they would not want to go to those hospitals which perform less well, and those hospitals which perform best of all would be overwhelmed with demand. In this regard the experience of New York state is instructive. In the early 1990s, information was made public showing mortality rates following coronary artery bypass grafts. The data referred to individual hospitals and individual surgeons. In fact, the net result of this greater openness was not a mass desertion of the poorly performing hospitals, quite the opposite. There was a rapid improvement in their mortality rates. The information, therefore, was used to improve outcomes for patients.[15]

27 For a culture of openness to succeed, those who work in the NHS must be confident that they will be supported by the organisation at all levels. Openness must be valued and rewarded. Otherwise, healthcare professionals will understandably be reluctant to embrace it. What this means, crucially, is that blame and stigma should not be the response of managers or colleagues. Adopting the words used by Professor Marc de Leval: while regretting them, we must all learn 'to treasure mistakes', because of what they can teach us for the future. This calls for an extremely mature organisation and, equally, a mature society. It means an abandonment of the easy language of blame, in favour of a commitment to understand and learn. It calls for significant leadership. It calls for practical action geared to being more open about error and mistakes and it calls, as we will argue later, for the removal of one of the greatest of all barriers to openness: the fear of clinical negligence litigation.

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[14] de Leval M. The Edgar Mannheimer Lecture, 1996

[15] Chassin MR. 'Improving the quality of care'. *'N Engl J Med'* 1996; **335**:1060–3. Centres with high mortality rates took radical action to improve their performance including temporarily suspending their coronary artery bypass programmes and restricting hospital admission privileges of some surgeons who performed a low volume of surgery and whose risk-adjusted death rates were found to be well above the state average

28 If the culture of openness between the NHS and the public has to change, so too does the internal culture within the NHS, so as to allow for greater openness with and between staff. Currently, there continues to be a sense among the workforce that they cannot discuss openly matters of concern relating to the care of patients and the conduct of fellow workers. There is a real fear among junior staff (particularly amongst junior doctors and nurses) that to comment on colleagues, particularly consultants, is to endanger their future work prospects. The junior needs a reference and a recommendation; nurses want to keep their jobs. This is a powerful motive for keeping quiet.

29 The workforce must feel that they will be safe if they wish to raise and have discussed matters of concern. Managers must put in place mechanisms to facilitate this process. We were much impressed during our Seminars by the way the airline industry has approached the issue by providing a neutral reporting system to which staff can report errors, near misses or concerns about safety. There is much here for the NHS to learn.

30 The editor of the *'British Medical Journal'* summed up the challenge well:

> 'We need a culture that allows doctors to express fears, doubts and vulnerabilities; identifies and helps those in difficulties; refuses to condone inappropriate delegation; values teamwork and continuous learning and improvement; and genuinely puts the interests of the patients first.'[16]

We agree. We would add that such a culture is needed not only for doctors but for all who work in the NHS.

A culture of accountability

31 Along with a commitment to a culture of openness should be a commitment to accountability. By accountability, we do not mean a system which relies exclusively on an approach where an individual or group is picked out and blamed, as if that was enough to remedy a particular problem.

32 The prevailing culture within the NHS is a culture of uncertainty. There is an obscurity, intentional or otherwise, from the point of view of the patient, as to who is responsible for, and thus accountable for, what. Two particular problems flow from this. First, in a large and complex organisation, which operates on very many levels, from national to local, it is not difficult for responsibility to be attributed to others. It can be laid at the feet of an amorphous Department of Health, or a particular technician working 'at the coal-face', or at a myriad of points in-between.

33 The second problem is that this state of affairs is simply unfair to those who work in the organisation. They do not know to whom they should go, with what problem. The frustration builds up and the organisation, and the patient, suffer.

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[16] Smith R. 'Managing the clinical performance of doctors'. *'BMJ'* 20 November 1999; **319**: 1314 –15 www.bmj.com

34 It follows that for the future, there needs to be a clear articulation as to who has responsibility for what and thus is accountable for it. This is not intended as a device to tighten the mechanisms for blame. It is a necessary prerequisite for an organisation to function effectively, to be able to assess its performance and respond accordingly and thereby to serve the interests of patients.

A culture of quality and safety

35 The safety of patients must be a paramount consideration in determining the way forward for the NHS. Safety is fundamental to achieving a high-quality service. As is apparent from the lessons of Bristol, it must be the responsibility of all staff in their various roles to create a culture of safety within the NHS. Standards, guidelines or protocols exist to indicate what the requirements of safety demand. It follows that to fail to meet or comply with them necessarily compromises patients' safety. In all organisations, however, not only in the public sector, corners are cut from time to time. One response is to seek to ensure that standards are adhered to. This approach is typified by the airline industry. The aim is to limit the exercise of discretion by individual operators, and eliminate a 'patch and mend' mentality. According to this approach, the standards themselves set the limit of safe conduct. If they are not complied with, the conduct is unsafe. Equally, if they cannot be complied with because of, for example, a shortage of resources, it cannot be safe to proceed.

36 There is much to recommend this approach, but it is not without disadvantage. Safety, in part, depends on the capacity of individuals to adapt and, listen to others, when faced with a problem. Too great a dependence on guidelines stultifies this creative capacity and is, thus, counterproductive in terms of safety. We accept this argument. It serves to show how complex the issues are. The argument does not address, however, but merely restates the central question: is there a point beyond which the exercise of creative discretion is inappropriate?

37 In the NHS, the question is made even harder, not least by the cultural assumption, born of long experience, that nothing would ever be done if the nurse or doctor waited until the relevant standards were set, or where they do exist were met. From one view, this is an anti-safety culture. From another, it is the mend-and-make-do culture which we saw earlier, a necessary pragmatism that keeps 'the show on the road'. The challenge historically has been the extent to which the NHS will compromise the culture of safety in favour of the culture of pragmatism. We will examine the issues raised in detail later [Chapter X- Safe Care]. Here we merely point out, by way of illustration, that the answer is that the culture of safety is more complex than it first appears. Pragmatism, it might be thought, must give way to observing the appropriate safety standards. In fact, both of the apparent responses to the fact that standards cannot be met have implications for safety. The first response may be to cease activity until remedial action can be taken. If the remedy is, for example, a new operating theatre, this means a long-term cessation of activity. This means, in turn, that fewer patients will be treated, or patients will have to wait longer, or they will have to travel further for treatment. All of these results have adverse consequences for the safety of the patients affected. This was one of the dilemmas of Bristol. Alternatively, the hospital can carry on offering the service, recognising that safety is being put at risk, but also recognising that those who are successfully treated without extra waiting and travel have gained in terms of safety.

38 Thus, where the culture of safety is compromised hospitals are in a 'lose/lose' situation. They put their patients at risk whichever course they adopt. The way forward depends, therefore, on an understanding by all of the nature of this problem, that it often cannot be solved quickly, and that the process of solution requires a series of co-ordinated steps. This is a process, not something to be achieved overnight. Questions of safety must be discussed in an open and transparent manner, so that all, particularly current and future patients, can make suitably informed decisions, not least in the light of the fact that in the process of moving to safer systems, compromises may have to be made along the way if the NHS is to continue to function.

39 It may be objected that to talk of a culture of pragmatism and compromise is to countenance and reinforce unacceptable levels of care. We would reply that, if the measures which we propose later concerning safety are put in place, the problem will be far less significant in the future. And, meanwhile, patients should be entitled to make choices, provided they have honest information.

A culture of public service

40 We referred earlier to what is seen by some as the tribalism of the various groups which make up the NHS workforce. Here we address a particular aspect of this tribal culture which seems peculiar to many consultants. It can be expressed by quoting the words used by Dr Hugo Mascie-Taylor who, in one of his papers submitted for Phase Two, wrote:

> 'It is interesting to observe the language that consultants use when describing where they work – they say they work at "St X's", or in London, they may say that they are "*on* at St Y's" but they rarely, if ever, say "I work *for* St X or St Y NHS Trust".'[17]

It needs to be said at once that there are consultants who do feel and profess a strong loyalty to their hospital. We do not quote Dr Mascie-Taylor's words, therefore, as constituting a literal truth. Rather, we ask, as does he, about the consultants' sense of belonging and to what or whom they feel greatest identity. The suggestion made is that there are degrees of identity or loyalty, beginning with their patients, peers and the relevant Royal College, then professional bodies, then the hospital and ultimately, at some distance removed, the NHS, as an organisation rather than an idea.

41 The issue is one of self-identity and belonging. The current education and training of the doctor inculcates a strong sense of loyalty and belonging to the professional

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[17] Seminar 4. Dr Hugo Mascie-Taylor. Position Paper (emphasis added)

group. This is by no means a bad thing: indeed, it has its advantages, in terms, for example, of the influence, advice and support of peers. The difficulty begins if the sense of belonging goes no further than merely the professional group. For with a sense of belonging goes a commitment to the wider enterprise, in this case the NHS and a sense of identification in its success, together with a desire to prevent its failure. If, on the other hand, the enterprise is 'nothing to do with me: I just work in it', a vital element in building a culture of high performance is lacking.

42 The problem is exacerbated if the other part of the medical workforce, the junior doctors, are only in any particular hospital for a short period of time, as they move from rotation to rotation. Notwithstanding their obvious dedication and hard work, it must be difficult to develop loyalty to any particular institution, or the larger NHS, save as a set of abstract ideas. Moreover, it could be said that the problem is further exacerbated if different professionals are employed on different contractual bases whereby, for example, nurses are treated differently from doctors.

43 For the future, duties and allegiances to professional bodies and groups must be aligned with the duties and responsibilities owed to employers (NHS trusts) and to the public. Now that chief executives have an overall responsibility for the quality of care delivered by the trust, it follows that they must have the necessary authority to carry out that responsibility. It is senior managers' responsibility to see that all healthcare professionals do their job properly. For this to be achieved, local arrangements for accountability need to be strengthened. Not least of these are the relevant contractual arrangements. As we shall say in greater detail later, the contractual relationship of all NHS healthcare professionals to their local employers should be on a similar basis. This will have particular implications for consultants. But, as the NHS Confederation put it in its evidence to Phase Two:

> 'The employer is accountable for the quality of care … and a framework which enables the employer to change the practice of employees must underpin that accountability.'[18]

A culture of teamwork

44 Teamwork is of crucial importance in its own right; its continued development will serve to break down the tribal barriers referred to earlier. Collaboration between professionals is the core of what we mean by teamwork. Many healthcare professionals will believe that they have always worked in teams, such that there is nothing new here. In the past, the 'team', more often than not, consisted of individuals from only one group of professionals, with the most senior person being in charge and the rest following, like it or not. Such historical arrangements may have suited administrative convenience or the niceties of professional etiquette but they did not necessarily suit the patient.

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[18] Seminar 3. NHS Confederation. Position Paper.

45 Teamwork as a means of serving the patients implies a multi-professional team and a sharing of responsibility. The team leader may not necessarily be the most senior member of the group and, crucially, may not be a clinician, if the circumstances are such that some other professional should take the lead. Leadership is based on ability and function in the context, rather than some title or professional qualification. Moreover, teams must cross the boundaries of profession and discipline. We note the efforts on the part of professional bodies to promote multi-professional teamwork. The GMC, for example, in January 2000 issued guidance on teamwork in medicine. It is, however, a sign of how much things need to change, and singularly ironic, that such advice about professions working together is issued by a single professional group. Multi-professional teamwork needs multi-professional guidance and multi-professional leadership. Teamwork is the collective collaborative effort of all those concerned with the care of the patient. Patients do not belong to any one professional; they are the responsibility of all who take care of them.

46 We conclude as we began. The culture of healthcare, which so critically affects all other aspects of the service which patients receive, must develop and change. Fundamentally, this will be achieved through education, through learning new ways to work and through forging new links within and between professional groups. It is instructive to recall the words of Professor Lucian Leape during one of our seminars: 'Culture is not amorphous, nor immutable; we are not powerless to change it. It is in some respects no more than the sum of the actions and attitudes of many individuals. Thus, if in some crucial areas of practice we can change the rules, the regulations and incentives, behaviour and, ultimately, attitudes will follow.' We agree. We now turn to a consideration of what the patient is entitled to expect from a changed NHS. We begin with respect and honesty.

Chapter 23: Respect and Honesty

Patients in their journey through the healthcare system are entitled to be treated with respect and honesty and to be involved, wherever possible, in decisions about their treatment.

Messages from Bristol

- The service in Bristol was based on a paternalistic approach to families and to the care and support they needed.
- The culture in Bristol was not one which encouraged openness and honesty in the exchange of information between and amongst healthcare professionals and between them and families.
- Support and counselling particularly at the time of bereavement did not have a sufficiently high priority.
- Communication was too often left by senior clinicians to nurses or junior doctors because it was time consuming and could be emotionally taxing.

Introduction

1 For a health service to be truly patient-centred, it needs to embrace a commitment to, respect for, and honesty towards, those it serves. Respect for others encompasses the need to see people as thinking, feeling, interacting beings for whom contact with the NHS will be different in each and every case. This means that patients must be seen first as people who live complex lives, rather than as clinical problems with a collection of symptoms. Respect for others also acknowledges difference and responds to individual needs without prejudice or assumption. Honesty implies openness and an exchange of information on all relevant matters. It means being open about risks, uncertainties and alternatives, as well as about the possible benefits of treatment. And it means clinicians being able to say that they do not have all the answers.

2 This chapter is about the relationship between the patient and the healthcare professional. We suggest how the quality of healthcare would be enhanced by a greater degree of respect and honesty in that relationship. We argue that the relationship needs to be based on partnership rather than on outmoded paternalism, and we stress the importance of involving patients, wherever possible, in decisions about their treatment and care. We suggest that much greater attention must be given to patients' needs for information and for support for them and their families. We stress that the communication skills of healthcare professionals are of fundamental importance in enabling patients to participate as partners in their care. We consider the need for a culture of openness and honesty within the hospital as a whole, and we argue for a duty of candour towards patients when things go wrong or concerns are raised.

Respect

3 Perhaps one of the most important features of a patient's experience when going into hospital is a sense of powerlessness and loss of control over personal decisions. Of course, patients are usually ill, and more than content to let others take care of them. But this should not be read as implying a readiness to have all decisions made for them, nor a willingness to be kept in partial or complete ignorance of what is going on. Good practice now demands better communication with the patient, and seeks to involve the patient, wherever possible, in decisions about treatment. Yet we were told, by a wide cross-section of patient groups during Phase Two, that there is still an image of patients as passive recipients *for* whom rather than *by* whom decisions are made. As one patients' group put it:

> 'Medical practice is essentially an intellectual pursuit. Being ill is a highly emotional experience. … patients are deemed incapable of deciding what is in their medical interests. They become clinical material to which things are done.'[1]

4 The imbalance of power between professional and patient arises for a variety of reasons. For example, patients generally have less knowledge about the healthcare system, its organisation and institutions than those who work within it. They possess a justifiable need to believe in the competence of the professionals caring for them. They may perceive themselves to be different in status from the professional, in terms of expert knowledge, class, gender or ethnicity. Structural factors can also inhibit patients' confidence: physical circumstances such as the patient being confined to a bed; or an awareness of the constrained amount of time for consultations whether on the ward, or visiting an outpatient clinic. We have no doubt that this sense of vulnerability is perhaps even more acute in the case of the parents of an unwell child. This feeling was expressed by a group which includes Bristol parents, as follows:

> 'The majority of parents who enter the NHS with a child who has a life threatening condition enter a world which is unfamiliar. A world of high tech machinery, a place where clinicians are making serious decisions which affect life and death

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[1] Seminar 7. Patient Concern. Position Paper

> outcomes. … The effect of being in such an alien environment can leave a parent feeling disempowered, scared, vulnerable and anxious.'[2]

5 If a sense of powerlessness is a common experience, and engenders feelings of frustration or worse, ways must be found to empower the patient, and, in the case of unwell children, their parents. We emphasise that we are *not* concerned to empower patients *at the expense of* healthcare professionals. The aim should be to foster an environment in which both patients and professionals feel that they are playing a mutually supportive role in the patient's care.

Honesty

6 A relationship based on respect will only flourish if there is a foundation of honesty in the exchanges between patient (or parent) and professional. During Phase Two, we heard that the honesty and openness of nurses and doctors makes a significant and positive difference to the patient's, or their carer's, ability to cope. For example, one mother wrote of a neurologist who had treated her daughter: 'Although what he had to tell us was so bleak, we appreciated his very direct approach. We wanted the truth as he saw it, and he respected our wish to be fully informed.' She went on to express her appreciation also of her daughter's cardiologist's ability to respond in '... a normal, human way ...' and the nurses' willingness to '... share part of themselves on a human mother-to-mother level.'[3]

7 We also received evidence of the importance of honesty in maintaining trust between parents of a sick child and clinicians. Richard Lunniss, father of William, told us:

> 'You cannot trust people if you do not think they are being honest, even if they are being nice. Once you think that they might not say the thing as it is, then you can never believe quite — there is no working relationship from that point on.'[4]

8 Justine Eastwood, mother of Oliver, also spoke of the need for honesty, particularly in the most difficult of circumstances when a child is very sick:

> 'I think you need to know. It hurts … It hurts to hear it, but you need to know the truth. I do not want to be told everything is going to be jolly and fine. It is a fact of life. … You do not want people to be cruel to you but you need honesty in a situation like that.'[5]

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[2] Seminar 7. Constructive Dialogue for Clinical Accountability. Position Paper

[3] Seminar 7. A mother's perspective on support for families when things go wrong in children's healthcare. Joanna Richards. Position Paper

[4] T95 p. 81 Richard Lunniss

[5] T95 p. 80 Justine Eastwood

9 We were equally struck by one of the submissions to Phase Two from the Royal College of Surgeons which acknowledged the importance of good communication but stated, starkly, that practice still falls short of theory:

> 'Proper communication between a patient and the surgeon responsible for their care is essential so that the patient can develop trust and is sufficiently informed to be a true partner in the decision making process. Unfortunately, this is the area of greatest compromise in the practice of most surgeons in the NHS and the source of most complaint by patients.'[6]

Partnership: involving patients and parents in decision-making

10 Many patients now wish to have a greater level of involvement in decisions about their care. One clear message from Bristol is that this is certainly true for parents who, almost always, want to be closely involved in their child's care. Even those who say that they would prefer not to know too much are entitled to be given the opportunity to be involved, to the extent that they would feel comfortable. An editorial in the *'BMJ'* captured the point well: 'For doctors the trick will be to determine which patients want to be offered choice and which prefer a passive role.'[7] That patients should be more active partners in decisions about their care is already acknowledged as public policy. The NHS Executive's Patient-Partnership strategy, relaunched in 1999, states clearly:

> 'Achieving [patient partnership] will require that patients are given the information that they want about themselves and their care and ensuring they are treated with respect and as partners in their care.'[8]

11 Partnership is also reflected in professional guidance. The GMC's guidance, *'Seeking patients' consent: the ethical considerations'*, for example, states: 'It is for the patient, not the doctor, to determine what is in the patient's own best interests. … you may wish to recommend a treatment or a course of action, but you must not put pressure on patients to accept your advice.'[9]

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[6] Seminar 7. The Royal College of Surgeons of England. Position Paper

[7] Editorial; 'Paternalism or Partnership?', *'BMJ'* 18 September 1999; **319**: 719 – 720. www.bmj.com

[8] Department of Health. *'Patient and Public Involvement in the New NHS'*, London: Department of Health, 1999. (Health Service Circular: HSC (99) 210) available from www.doh.gov.uk

[9] General Medical Council. *'Seeking patients' consent: the ethical considerations'*, November 1998. www.gmc-uk.org

12 It was suggested to us in Phase Two that involvement in decisions about care can also significantly improve a patient's prospects for recovery. Angela Coulter, a contributor to one of our seminars, wrote:

> 'Patients with hypertension benefit if they are allowed to adopt an active rather than a passive role in treatment, patients with breast cancer suffer less depression and anxiety if they are treated by doctors who adopt a participative consultation style, and patients who are more actively involved in discussions about the management of their diabetes achieve better blood sugar control. Patients whose doctors are ignorant of their values and preferences may receive treatment that is inappropriate to their needs.'[10]

13 This notion of 'partnership' between doctor and patient featured in a number of submissions to Phase Two, including one from the Royal College of General Practitioners (RCGP). The RCGP acknowledged that many doctors in practice today have been trained along the lines of a traditional model of consultation, in which the patient's only active contribution to the conversation is the presentation of symptoms. For many years now, however, the approach used in the training of GPs has differed from this traditional model. Instead, a model of partnership is advocated, in which: '… the patient and doctor meet as equals with different expertise. The doctor has the medical knowledge and skill, but the patient has personal knowledge and skill. …'[11] In this model of partnership, the whole structure of the consultation changes and the power in the relationship becomes more evenly shared. The RCGP also stated that partnership: '… is not to deny … that the professional has expertise. … for this partnership to work patients need information about the problem presented to them in a language that they understand. They may need time to consider. Patients may prefer a particular treatment. ... The professional needs to respect the patient's perspective and the patient needs to respect the professional and the service.'[12] The *'BMJ'*, in its editorial, argued similarly:

> 'Partners work together to achieve common goals. Their relationship is based on mutual respect for each other's skills and competencies and recognition of the advantage of combining these resources to achieve beneficial outcomes. Successful partnerships are non-hierarchical and the partners share decision making and responsibility. The key to successful doctor-patient partnerships is therefore to recognise that patients are experts too. The doctor is, or should be, well informed about diagnostic techniques, the cause of disease, prognosis, treatment options, and preventive strategies, but only the patient knows about his or her experience of illness, social circumstances, habits and behaviour, attitudes to risk, values, and preferences. Both types of knowledge are needed to manage illness successfully, so both parties should be prepared to share information and take decisions jointly.'[13]

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[10] Coulter A et al. 'Sharing decisions with patients: is the information good enough?', *'BMJ'* 30 January 1999; **318**: 318–322. www.bmj.com

[11] Seminar 7. The Royal College of General Practitioners. Position Paper

[12] Seminar 7. The Royal College of General Practitioners. Position Paper

[13] Editorial; 'Paternalism or Partnership?', *'BMJ'* 18 September 1999; **319**: 719 – 720. www.bmj.com

14 The importance of partnership was also emphasised by a submission to Phase Two from the Royal College of Nursing.[14] In it, the College argued that the development of skills to enhance partnership is vital for the professions, for example, in aiding patients to participate in making informed decisions about their care. The Royal College of Surgeons also recognise the trend towards partnership. It argued, as in fact did the RCGP, that patients will differ in their preferences and that this should be acknowledged.That said, in a patient-centred health service, a consistent approach to involving patients is needed. It can no longer be acceptable for patients, having been treated, as they are now for the most part, as equal partners by their GP, then to go into hospital and be confronted with old-style paternalistic attitudes from some consultants.

15 Many parents who gave evidence to the Inquiry commented in their statements, or through their representative groups, on the improvements which they felt were needed in the attitudes shown by healthcare professionals towards patients and particularly parents. Overwhelmingly, they emphasised the need for parents with a child in hospital to be involved in their child's care and for parents' expertise, as the people who know the child best and who care for the child, to be fully acknowledged and appropriately engaged. This approach is now regarded as good practice when children are in hospital. We believe that it should be standard, routine practice. We have no doubt that this approach, whereby parents and patients are alongside and in partnership with the professional, rather than following and doing what they are told, is the way forward for modern care in hospital.

Information

16 The exchange and provision of information is at the core of an open and honest relationship between healthcare professionals and patients. It is *also* an inextricable part of the caring for the patient. As the Royal College of Surgeons told us:

> 'The better informed and more involved a patient is, the more likely it is that they will: be better able to weigh up the pros and cons of treatment and make decisions about their care; be better prepared for what to expect of surgery; adhere to treatment regimes; be satisfied with their care – which has a positive impact on the outcome of treatment; be less likely to complain or sue should a complication occur.'[15]

17 One of the principal ways of empowering the patient is to ensure that they have the necessary information to allow them to understand and participate in their care to the extent desired. The ability to assess patients' needs for information requires the ability to listen, combined with a willingness to avoid second-guessing what they will want to hear, or be able to understand.

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[14] Seminar 7. The Royal College of Nursing. Position Paper

[15] Seminar 7. The Royal College of Surgeons of England. Position Paper

18 In the light of the contributions to our seminar on empowering patients, we identify four fundamental principles which should in future underpin any policy aimed at meeting patients' needs for information. First, trust can only be sustained by openness. Secondly, openness means that information be given freely, honestly and regularly. Thirdly, it is of fundamental importance to be honest about the twin concerns of risk and uncertainty. Lastly, informing patients and in the case of young children their parents must be regarded as a process and not a one-off event.

19 Translated into practical action, we believe that these principles should influence both the form and the content of information, and the process by which it is communicated:

- information should be given in a variety of forms (written, oral, audio-visual), it should be given in stages and be reinforced over time;
- information should be tailored to the needs, circumstances and wishes of the individual;
- information should be based on the current available evidence, and include a summary of the evidence and data, in a form comprehensible to patients and their carers;
- various modes of conveying information, whether leaflets, tapes, videos or CDs, should be regularly updated and developed and piloted with the help of patients and carers;
- patients and, where appropriate, carers, should always be given the opportunity and time to ask questions about what they are told, to seek clarification, and to ask for more information;
- patients and, where appropriate, carers, should also be given the sense of freedom to indicate when they do not want any (or more) information: this requires skill and understanding from healthcare professionals;
- before embarking on any procedure, patients and, where appropriate, carers, should be given an explanation of what is going to happen and, after the procedure, should have the opportunity to review what has happened;
- patients and carers should be supported in dealing with the additional anxiety sometimes created by greater knowledge; and
- patients should be told that they may have another person of their choosing present when receiving information about a diagnosis or a procedure.[16]

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[16] See Report of Seminar 7, Annex B. See also the article by Coulter et al. referred to in footnote 19 of this chapter

20 These principles and practical proposals are deliberately more comprehensive than is usual. They go further than most current guidance. By being more comprehensive, they serve to provide a protocol on which partnerships can be built and patients can know what to expect, rather than having to rely on the discretion of the professional to part with information. We note that the need for change in this direction is recognised. For example, the new edition of the GMC's code for doctors, *'Good Medical Practice'*, gives a higher priority than was previously the case to the importance of good communication between patients and doctors.[17]

21 What these principles make clear is that the issue is no longer *whether* to inform a patient, but *how* to do so effectively. There is a voluminous literature on the mechanics, as well as the principle, of informing patients. It has been argued that, because it is unclear what patients may wish to know or impossible fully to inform them (i.e. to the level of the professional), it is unwarranted, if not cruel, to impose information on them. We are not persuaded. We believe that healthcare professionals have a duty to empower patients: providing information is one means of such empowerment. We accept that each patient is different and may wish for varying amounts of information at various times, with the constant ability to say 'enough'. But this fact does not serve as a reason for not setting off on the information journey. Rather, it indicates how carefully the journey must be travelled and that healthcare professionals need good, all-round communications skills, if the patient's needs are to be respected and met.

22 In the particular case of children, their needs for information should also be assessed by listening to them and being led by their questions. Children will ask about what they want to know and must be answered truthfully and clearly. For those healthcare professionals who are inexperienced or lack confidence in talking to children, there are a number of people within the healthcare team who can advise and guide, for example, play specialists, social workers, psychologists and teachers. A reluctance by any professional to consult team members, for whatever reason, is counterproductive, as an holistic approach to the needs of the child within the family, combined with a multidisciplinary, multi-professional approach, is likely to be most effective.[18]

Improving ways of giving information

23 We have seen that the provision of adequate information is an essential prerequisite to the development of trust. It underpins the honesty between professional and patient. Thus it is essential that such information be clear, factual, and that it empowers the patient. We recognise that there are undoubtedly examples all around the country of good information being provided for patients, as the creative use of a range of media, such as leaflets, books and interactive videos and the Internet grows. Nevertheless, we heard in Phase Two that much of the current information for patients about treatment is out of date, or of poor quality. Criticism was particularly levelled at information

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[17] General Medical Council. *'Good Medical Practice'*, July 1998. www.gmc-uk.org

[18] We note the call for further research in Dixon-Woods M. et al. 'Partnerships with Children', *'BMJ'* 18 September 1999; **319**: 778–780. www.bmj.com

which is excessively optimistic, and that which has a tendency to downplay, or omit mention of, side effects, risks, uncertainties and controversies. We would add that too often the information given to patients seeks to encourage compliance with what is proposed, rather than to engage patients with the choices which are theirs to make, and thereby empower them. Much more creative thought needs to be given to ways of improving the quality and timeliness of information for patients. It is not just a question of the media that are used, although that is important. The quality of the content is also crucial. This is a much neglected area where the new NHS Modernisation Agency could play a role in identifying and disseminating good practice. Angela Coulter and her colleagues made a similar plea to the NHS Executive before *'The NHS Plan'* appeared. It still is relevant. They argued:

> 'The goals of the government's patient partnership strategy, which aims to promote shared decision making, will not be met unless patients are provided with good quality information about diseases and treatments. We call on the NHS Executive to:
>
> - 'Fund the development and evaluation of high quality patient information materials covering common clinical problems.
> - 'Commission patient information materials to accompany each of the evidence based guidelines to be commissioned by the National Institute for Clinical Excellence.
> - 'Establish a system for accrediting patient information materials and websites to help patients and health professionals identify reliable information.
> - 'Establish a system for disseminating good quality materials to patients, where appropriate making them available in general practitioners' surgeries, hospital departments, community pharmacies, consumer health information services, healthy living centres, public libraries, etc.
> - 'Ensure that each NHS Trust and primary care group [and now, primary care trust] has a designated senior member of staff responsible for ensuring that patient information meets high quality standards.'[19]

24 One of the recommendations in *'The NHS Plan'* was that, in future, patients should receive a copy of any letter about their illness or care which was written by one clinician to another. We support this recommendation wholeheartedly. We believe it will do much to empower individual patients. (Of course, patients are already entitled to see their medical notes, although some may not be aware of this.) We add, however, that, to the extent that technical matters may not be written about in a way that can be understood by the patient, the patient should be able to seek help from NHS Direct or from their GP. We add further that this practice must extend to parents

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[19] Coulter A, Entwistle V, Gilbert D. 'Sharing decisions with patients: is the information good enough?', *'BMJ'* 1999; **318**: 318–222. www.bmj.com

of those too young to take decisions for themselves. At some point, of course, the child's right to confidentiality will displace the claim of the parent. This is but a further example of the need to manage these conflicting claims and will need to be carefully addressed.

25 There is one additional, particular practice which we would commend for the future, especially in the case of parents whose children are ill. Patients, when meeting their doctor for an important consultation, to discuss a diagnosis, a course of treatment, or prognosis, should have an option to tape-record those discussions, so that they can listen again later to what was said. Tape recording facilities should be provided by the NHS to enable patients to make a recording. The patient would be able to take the tape home. If necessary a copy of any such tape could be kept with the medical record. We were told repeatedly by parents in the Phase One hearings that they remembered very little of what was said to them, on those particularly significant and hence very stressful occasions when their child's diagnosis or treatment was being discussed. We also heard that when two parents met the clinician, they often remembered different and sometimes conflicting messages. A simple measure such as enabling patients to tape-record a consultation, something already done in a number of places, could bring significant benefits to patients, families and professionals in terms of partnership and mutual understanding.

26 We should also notice here the increasing influence of the Internet.[20] Patients now have access to a great deal of information and data. The public's and patients' desire for more information is not going to go away, nor can it be readily managed or contained by professionals. It is particularly important that professionals should not perceive this development as an implicit attack on their expertise. Rather, they must adopt new strategies based on partnership. They must seek to explain and give meaning to what patients may have come across, and guide patients in their continuing search.[21] At the same time, and separately, efforts to guide the public towards those sources of information which can be properly relied upon and are of good quality should be pursued by professionals and the government. This has started to happen, to a degree, through NHS Direct Online, various hospital websites and the National Electronic Library for Health, but there is much more that could be done to provide patients and professionals alike with access to sources of information which both can trust.[22]

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[20] In 1999, there were, according to the *'BMJ'*, at least 100,000 health-related websites. Eysenbach G et al. 'Shopping around the internet today and tomorrow: towards the millennium of cybermedicine'. *'BMJ'* 13 November 1999; **319**: 1294. www.bmj.com

[21] See Sheppard S et al. 'Helping patients access high quality health information', *'BMJ'* 18 September 1999; **319**: 764–766. www.bmj.com

[22] See further Eysenbach G et al. 'Shopping around the internet today and tomorrow: towards the millennium of cybermedicine'. *'BMJ'* 13 November 1999; **319**: 1294. www.bmj.com

Communication skills: overcoming the barriers to effective communication

27 Patients are entitled to expect that those who care for them, doctors, nurses and others, will be able to listen, to explain and to communicate with them. Patients are also entitled to expect that healthcare professionals will be able to communicate effectively with each other. Whatever the circumstances, the need for good communication is constant and is integral to good care.

Time

28 Undoubtedly, pressures of time are a factor inhibiting good communication. This applies to all healthcare professionals whatever their skills. There is no escaping the reality that it takes time actively to listen, to assess a patient's need for information and to develop understanding of the patient's circumstances. We heard repeatedly that pressure of time means that patients often get a strictly limited amount of time to talk, particularly when seeing a consultant. This means that there is often no time for patients to ask questions or to take any real part in discussions about their care. The National Federation of Consumer Groups summed up the problem in a contribution to a Phase Two seminar:

> 'Lack of time is the problem that so often leads to thoughtlessness and lack of adequate information.'[23]

29 We were interested to note that in recent research into how hospital consultants in the Oxford region respond to patients' complaints, communication problems figured prominently in these complaints. 'Circumstances and work conditions' were cited by some of the consultants as factors which prevented them from communicating effectively. One surgeon is quoted in the study as commenting:

> 'Communication is an expensive luxury. I have never yet had a complaint from one of my private patients because in my private practice I have the time to handle all aspects of a case …'[24]

The point being made is clear: there is a relationship between the time to communicate and the resources available to the NHS. Time is a resource like any other resource. In the context of an NHS which has endured decades of constrained resources, the allocation of time to communicate with patients, though readily

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[23] Seminar 7. National Federation of Consumer Groups. Position Paper

[24] Mulcahy L. *'Disputing Doctors; a socio-legal analysis of doctors' responses to being called to account by patients'*. (just in press), Open University Press. Chapter 5. She also describes in the same chapter a consultant as saying 'When you know that something has gone wrong, that's when you pull out all the stops and over compensate by listening to the patient and making them feel you really care'

recognised by healthcare professionals as important, has been consistently squeezed. NHS trusts must ensure that the working arrangements of healthcare professionals allow them the necessary time to communicate with patients.

Awareness

30 Time, however, is not the only factor. The attitude which the clinician brings to an encounter with the patient also matters greatly. As we were told in Phase Two by the Royal College of Surgeons:

> 'Whilst the pressures on time undoubtedly contribute in some instances [to poor communication], the style of practice, sensitivity and personality of the surgeon are equally important.'[25]

31 This point was developed in an expert opinion commissioned by the Inquiry from Jean Simons, Head of Bereavement Services at Great Ormond Street Children's Hospital. Drawing on extensive research into parents' and patients' experience of the communication skills of healthcare professionals, she wrote:

> 'It was most patients' experience that although doctors thought in their interviews they were giving time and space for the patient to express their feelings, they were on the whole preventing the patient from doing so by their own need to give information (as they thought the patient needed to hear), changing the subject, offering premature and inappropriate reassurance, and insisting on their own agenda prevailing in the interview rather than partnering the patient in the discussion.'[26]

32 Thus, a further problem which needs to be recognised is that communication is not easy. The patient may be apprehensive. The doctor may be anxious to do a good job and may not be sure how much the patient wants to know or how much he or she should be told. Breaking bad news and dealing with bereavement is always hard, for the doctor as much as for the patient. Nowhere was this more evident in Bristol than in relation to communication about post-mortems. As Mr Dhasmana told the Inquiry:

> 'This used to be a most difficult period … I was always emotional during this meeting and the only way I could really, just, you know, express it was quickly get to the point. … It used to be very difficult for me to communicate very well at that time.'[27]

Humanity

33 We were told by participants in both Phases of the Inquiry that patients often expect the doctor to be touched by their plight. They do not feel that it is professionally inappropriate for the doctor to be uncomfortable or to be visibly moved by what he or

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[25] Seminar 7. The Royal College of Surgeons of England. Position Paper

[26] 10k Simons J. *'Giving Information to Parents with an Unwell Child'*, Annex B

[27] T87 p. 97–8 Mr Dhasmana

she is trying to say. It is obvious to us, therefore, that the ability to communicate on a number of levels, in a variety of situations, with people who feel both vulnerable and anxious should be regarded as one of the most fundamental and essential of the healthcare professional's responsibilities. This point was made forcefully by the Bristol Heart Children Action Group in its submission to Phase Two:

> 'The [medical] profession are removed from the needs of the users on an emotional level and because of the very difficult job they do, communication often only stays at a clinical level … The patient needs to be listened to in whatever form they express themselves … Gone are the days where the patient needs to be protected by the profession. Far more account should be taken about what patients want and feel they need to know …'[28]

Improving the capacity to communicate

34 Given all the various difficulties in communicating effectively, it is no surprise that there has emerged among healthcare professionals a mentality of compartmentalising communication into specific tasks, for example, gaining consent to an operation, giving bad news, gaining consent to a post-mortem. In fact, of course, this approach is the very antithesis of communication. It proceeds on the basis of there being a discrete, single matter to discuss, all other matters being off the point. This may appear to be cost-effective in terms of professionals' time. Also, it allows them to control the exchange, if such it is, and thereby limit their exposure to that which is discomforting. But ultimately it is not effective because it falls short of meeting the legitimate needs of the patient.

35 There is evidence that nurses are exposed, in their education and training, to a range of communication techniques and skills. The same cannot be said consistently of medical education and training which, even today, does not give sufficient significance to communication skills. In many medical schools they are still regarded as soft 'add-ons' to what is, in essence, a scientific education. The extent to which education in communication skills, such as it is, is carried through into post-registration training is also highly variable. Whereas for trainee GPs, communication skills form an integral and significant part of their training, this is not so for most doctors training to be hospital specialists. The result is that, all too often, senior hospital medical staff opt out of the job of communicating adequately with their patients. The point we seek to make is that virtually *every* encounter with a patient involves communication, and thus it should be *good* communication. It is not enough for the consultant to rely on the nurse or the GP 'to do all the talking'. Crucial as they are, nurses and GPs should not be used as a means whereby a consultant can avoid engagement. That said, healthcare professionals do not act alone; we were persuaded by the submission from the Royal College of Nursing that, in addition to those 'in the front line' who communicate with patients and serve as 'the companion on what is often a difficult and lonely journey', there should also be others who can provide

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[28] Seminar 7. Bristol Heart Children Action Group. Position Paper

support. Counsellors, patients' friends and others can play an invaluable role in giving and explaining information in a non-technical manner.[29]

36 The way forward lies in understanding that two quite distinct developments must take place. The first challenge is to foster, encourage and shape the attitudes of healthcare professionals, both as they enter and as they progress through the profession. The second challenge is to reinforce the attitudes of openness and preparedness to communicate by offering appropriate training in the relevant skills. As regards the development of what we might call the 'right attitudes', the starting point must be the selection of young people to be educated as healthcare professionals and then the education which they receive. The challenge is to maintain and build upon the attitudes which those starting out on a career in the NHS undoubtedly possess or aspire to: the values of caring, of comforting, of supporting and of truthfulness and honesty. So far from being blunted or lost, these qualities must be cherished and shown to be the true cultural tradition of healthcare. Equally, the challenge is to allow professionals already in the NHS to reclaim these attitudes by having the time, space and resources properly to care for their patients.

37 As regards training in communication skills, future doctors, nurses and all other healthcare professionals must be prepared adequately during their education and training. Priority must also be given to appropriate training in and the regular development of skills for those currently in practice. A comprehensive approach is called for. Communication skills are generic: they should no longer be packaged as though communicating was a series of discrete tasks which can be rehearsed and repeated with limited personal engagement. Communication skills go much wider than just the giving of factual information, the giving of bad news, or the obtaining of consent. They include listening skills, an ability to understand, to elicit and to assess how much information a patient wants, and not least the capacity to engage 'in a normal human way'. Communication skills are crucial to enabling healthcare professionals to fulfill their professional duties: without such skills they are left ill-equipped to care for patients, in the fullest sense.[30]

Support for patients and for families

38 A further feature of a patient-centred health service which respects patients' needs is the provision of support to patients and relatives by the NHS. We regard this as of very great importance. It should not be limited to the time actually spent in hospital but should extend to the time before admission and after discharge. We recognise that difficult questions arise as to the proper, and indeed effective, reach of the hospital, given its resources. Thus, we do not see the provision of the sort of support referred to

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[29] Seminar 3. The Royal College of Nursing. Position Paper

[30] See Chapter 25 on Competent Healthcare Professionals

here as being the exclusive responsibility of the hospital. A period in hospital is only one element along a continuum of care. Rather, we argue for the development of a more integrated approach to the provision of support services, whereby the respective roles of the hospital, the GP and local primary care team, the local Social Services Department and the various volunteer organisations are clarified and organised around the needs of the patient. We were struck by a strong theme which emerged consistently from parents' evidence in Phase One: that they felt abandoned, both in the hospital and later, after the discharge, or the death of their child. Very often, their need for support was closely linked to a need for information about their child's care, particularly when a child had died. Support is a subtle and complex process. It requires skill. Some patients may reject it. For others, it is a lifeline. What matters is that the hospital (with other organisations) has a system whereby information which addresses the needs of parents and patients on leaving hospital is communicated swiftly and that efforts are made to integrate a process of continuing care and support.[31]

39 To meet these needs for an integrated system of support, a hospital must have a well-developed system and a well-trained group of professionals whose task it is to provide counselling and support and to make the links to the various other forms of support (such as that provided by voluntary and social services) which patients may need. (We use the generic term support to include counselling, while conscious of the fact that counselling is distinct and calls for different training and skills.) The support which may be required is wide ranging. It can include, for example, information about disability benefits and the various other forms of help that may be available after discharge from hospital. It can include talking to someone who has had a similar experience. It can include factual information about what to do when someone has died, and longer-term support after bereavement. Crucially, this wide-ranging set of needs must not be regarded as an optional 'add-on', to be provided solely by untrained volunteers or untrained administrative staff; or in an 'ad hoc' way by healthcare professionals, according to whether they happen to be available at the time. It is integral to care and should be regarded as such. It is what patients (and others) are entitled to.

40 Support at a time of bereavement warrants special attention. In England about half of all deaths take place in a hospital.[32] For children, this figure is higher. When a child dies it is always traumatic and often unexpected. We believe that the provision of a professional bereavement service within hospitals is absolutely essential. This is especially so for families whose child has died.

41 Many families find emotional and social support from others who themselves have gone through similar experiences. They value the exchange of information and mutual understanding which such support groups offer, often long after they or their child left hospital. It is not necessary for each and every hospital to create such groups; what

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[31] A number of recommendations on this matter were made in the *'Report of the independent inquiries into paediatric cardiac services at the Royal Brompton Hospital and Harefield Hospital'*. April 2001. www.rbh.nthames.nhs.uk

[32] See this Inquiry's Interim Report *'Removal and retention of human material'*, 2000. Annex C

matters is that such groups, wherever they develop, particularly in the voluntary sector, are supported, and that means funded, as an important part of the healthcare process. Within the hospital, patients and families need to be told that such support exists and how to call upon it. Equally, healthcare professionals must be made aware and must be active in directing patients towards it. The proposed Patient Advocacy and Liaison Services could play an important role here; it is vital that these services are visible within each trust, that staff are familiar with what they can offer, and that these services are properly funded. NHS Direct and NHS Direct Online can and should also serve as a gateway to such groups.

Consent to treatment

42 We are concerned here with the process of obtaining consent. We do not intend to review the enormously complex legal and ethical issues raised and the extensive literature on them. We touched on some issues relating to consent in the context of post-mortems and the removal, use and disposal of human material in our Interim Report.[33] Here, we intend to make only some very general points.

43 We noted earlier that, when patients are in need of surgery or some other intervention, far too great an emphasis seems to be placed on the isolated act of obtaining written consent to the surgery on a form, rather than on the process of communicating, to which the signing of a consent form is just the end point. By this we mean that too great a regard is paid to the symbolic act of signing a piece of paper, rather than to the real task. The real task is a process which involves explaining what is to take place; setting out what is known about the risks, uncertainties, and possible negative consequences, about the specific performance of the trust, of the specialty and of the consultant unit (as that information becomes available), about any alternatives and about the likely outcome; considering and explaining how the patient will be affected; and seeking and answering questions. Such a process is the only proper way to gain the patient's informed authority to proceed.

44 We were saddened to hear a recently-qualified doctor describe, at one of the Phase Two seminars, how, as part of his training, he was sent 'to consent' patients. The very words used illustrate how fundamental is the lack of understanding of what should be going on in the guidance which he had received from those instructing him. A doctor seeks permission. Patients are being asked whether they want to give it. Before doing so they have the right to be told anything that may be material to the decision. The doctor has the duty to do this. Patients are not there to be 'consented'. They are there to be informed and asked if they wish to go ahead. Moreover, consent should be seen as an ongoing process of informed decision-making, permeating the whole process of

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[33] We acknowledge that the Department of Health has published new guidance on consent: *'Reference guide to consent for examination or treatment'*. London: Department of Health, April 2001

care, rather than a one-off event associated with obtaining formal agreement to specific procedures. This is all the more important when parents are making this decision on behalf of their child.[34]

45 Equally, the process of consent should not be seen as applying only to surgical procedures. It seems extraordinary that a surgical operation is surrounded with the formal trappings of written consent forms, yet when carrying out other clinical procedures, such as a physical examination, or an X-ray, it is not routine to advise a patient of what is going on, far less to seek permission. It is an ethical, as well as a legal, principle that a patient's consent is required for even the most routine of examinations which involve any form of touching. In this way, the patient's (or parents') right to choose is respected. This indeed is the essence of respect. By insisting on this, we would not wish to see a further bureaucracy of form-filling. Indeed forms are something of a distraction. We do not advocate more forms. We advocate more communication. As we have said, forms are of almost secondary importance, merely providing evidence of agreement. What we are emphasising is the primacy of the patient's choice; the right of patients to be asked if they wish to undergo the procedure, to be informed about the procedure and to be asked to agree.

The need for openness and honesty within the hospital

46 For respect, honesty and openness to flourish between healthcare professionals and individual patients there must be a culture of openness and honesty within the healthcare system as a whole. The hospital as an institution must be open with patients as to what they can expect, where and to whom they can go if they do not understand something, and what they may do if they wish to pass on suggestions or comments. During our oral hearings, we heard the frustration of parents at not being able to discover what was happening as regards the care of their child. A hospital committed to openness would involve and integrate the parent (or patient) into the pattern of care, rather than exclude them.

47 One example of an organisation which has chosen to pursue the goal of greater openness in the delivery of its services is provided by Brighton Healthcare NHS Trust. The Trust's 'Patient's Advocate' acts as 'friend within the system' for patients, their relatives or carers. She sees her role as being to improve communication. Penny Dunman, the current Patient's Advocate, recently stated: 'Almost always, lack of communication is at the root of people's anxieties'.[35] The service is designed to help

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[34] We consider the particular issues arising when parents must give their consent on behalf of their children later in Chapter 29 on Children's healthcare services

[35] *'Nursing Standard'* August 16–22 2000; vol 14 (48) p. 13

patients and their carers to deal with problems which they encounter in relation to their care within the Trust. The aim is to increase the level of satisfaction with the Trust's services while reducing the incidence of complaints. The advocacy service now includes induction and other training for hospital staff at all levels. Significantly, the advocacy service has had the support of the Trust's Chief Executive since its inception, demonstrating that cultural change and strong leadership go hand in hand. The Brighton example is significant because it shows what can be achieved with a 'one-stop shop' for patients: a place that both provides information to smooth the patient's journey, and acts as a source of support for early help and intervention to resolve patients' questions and concerns.

48 The Government's announcement in *'The NHS Plan'* of its intention to set up a Patient Advocacy and Liaison Service in every NHS trust and primary care trust is to be welcomed. The establishment of this service should be implemented in full as quickly as possible. Had such a service existed in Bristol, parents would have had a further place to turn to for advice and support when they needed more information or had unresolved questions about their child's care. We add, however, that such a service must be integral to the care of patients, not an optional extra. It is what patients and relatives are entitled to expect as they negotiate the unfamiliar and sometimes frightening environment of the hospital. And, as such, it follows that, as with other aspects of healthcare service, it must be given secure funding to enable it to provide an effective service to patients.

49 But this is only a part of a much wider approach which is needed. NHS trusts and primary care trusts must have systems which ensure that patients know where and to whom to go when they need further information or explanation. It is equally important that trusts themselves provide access to a wide range of sources of information, not limited to resolving concerns or complaints, which will guide and assist patients in the course of their care. The key is to ensure that the sources of information which are intended for patients, for example, the hospital's website, the liaison service and the various contact points throughout the hospital, are integrated and complementary. Moreover, there will be real opportunities in the future for the Patient and Advocacy Liaison Services, in a given geographical area, to collaborate so as to provide an effective, efficient and seamless service for patients. The provision of information for patients and the public would be a key area where such collaboration would benefit a local population. This opportunity must be grasped.

50 It is also vital that healthcare services routinely seek direct feedback from patients. This is not something to be feared but to be embraced. To hear, as we did during the oral hearings, the many comments and ideas that parents had about how they felt the care for their child could have been improved, and to know that there was no system at the time for capturing that rich vein of concern and advice, was to witness an enormous lost opportunity. The old culture of waiting until someone complains, then behaving defensively and changing reluctantly, has no place in a modern health service. That is why we strongly endorse the proposal in *'The NHS Plan'* that patients on leaving hospital be asked for their feedback. Further, rather than what we regard as old-style 'satisfaction surveys', formal, systematic structured surveys of patients' full experience of their care should be routinely conducted across the NHS and the results made public. Very often in the past, patients have had no alternative but to use the complaints system, simply because there was no other way to convey their views about the service which they had received. Used, as it must be, and used wisely, information from patients and their relatives should help the hospital, and the NHS generally, to identify emerging problems and to anticipate matters that might become the source of complaint in future if not resolved. The contrast which we seek to draw is between a system in which all interaction with patients becomes routed through a complaints system, such that comments become complaints, even if they did not begin as such, and a system which allows multiple opportunities for communication between the hospital and those it serves. The future lies in the latter.

When things go wrong

51 While by no means inevitable, it is likely that, despite the best efforts of the hospital's staff, there will be occasions when things go wrong. We need immediately to separate two matters: what happened and what the hospital should do about it. As regards what happened, distinctions derived from the law are commonly made between mistakes or errors on the one hand, and accidents on the other. These distinctions are concerned with the conduct of the hospital or its staff. They are not concerned with what has happened to the patient. They also ignore what we all know, that there are many factors which contribute to an event, not just the one that directly gives rise to it. In a patient-centred healthcare system, however, it is the effect on the patient which matters. Thus, we do not distinguish here between various kinds of events. We group them together as adverse events, meaning an unplanned event which results in harm to the patient.[36] We turn now to what the hospital should do in the case of an adverse event. Historically, of course, while hospitals may have been willing to disclose and discuss accidents, they have been unwilling to do so in the case of an error or a mistake because of the legal repercussions. We discuss this later in detail in Chapter 26 on Safe Care. What we say here is that even in the case of a mistake which might bring legal liability there is a duty of candour. This duty is part of and grows out of the culture of openness which we have called for. It is also a duty that is implicit in the notions of respect and honesty in dealings with patients.

52 With specific regard to an unplanned event which results in harm to the patient, the duty of candour should still apply even when mistakes are not immediately apparent and come to light later. This is so particularly when the patient may otherwise be unaware. There is already evidence that such an approach is being adopted within the NHS, for example in circumstances of misdiagnosis. We were also impressed by the policy of some US hospitals in this regard. For example, the Veterans Affairs Medical Center in Lexington, Kentucky, has a policy whereby, if it discovers an error of which

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[36] We propose later in Chapter 26 that the term 'sentinel event' be used. This term embraces adverse events *and* near misses and prevents disputes as to whether an event was one or the other

the patient and family are unaware, they disclose this to the patient, even if it involves error on the part of the hospital or its staff.[37]

53 During Phase Two, we heard from Professor Lucian Leape. He said that when things go wrong, patients generally want three things: someone to tell them what has happened; a clinician to say s/he is sorry that it has occured; and action to ensure that the event will not happen to anyone else. He said that in his experience patients do not want punitive action; they want responsible action. We would add that saying sorry has nothing necessarily to do with admitting any fault. Rather it is an expression of concern for the situation in which patients find themselves. We note also the research by Linda Mulcahy and others, reported in the National Audit Office's report on clinical negligence.[38] It stated that when serious problems occur, patients may want compensation, but they also want an admission; the prevention of future incidents; an explanation; and an apology. When things go wrong, patients should not have to struggle against the system and raise formal complaints. Thus, we believe that hospitals have a responsibility to be active and to investigate adverse events. Whenever it is clear that what went wrong is the result of action or inaction on the part of the hospital or its staff, they should be under a duty to be open and honest and to acknowledge this as early as possible, ensuring that any compensation due is paid swiftly. Difficult and uncomfortable though it will be, we are convinced that this degree of openness by hospitals and healthcare professionals is essential to the maintenance of patients' trust. It is the essence of respect for and honesty towards patients. And, as we argue later, the more that is known and understood about adverse events generally, the more it will become possible to address their causes and to prevent them in the future.

54 We draw attention to the fact that compensation for harm arising from adverse events is an enormously complex subject. Currently, patients may obtain financial assistance from a variety of unrelated sources, including state and employment related benefits and, where available, legal action. Some patients receive none. The system (if such it be) needs radical re-examination. We propose later, in Chapter 26 on Safe Care, that clinical negligence litigation be abolished. We accept that there must be a review of the implications of this proposal not least as regards compensation which arises from litigation. We favour an administratively-based system of compensation based upon the needs of patients rather than on the circumstances which gave rise to those needs.

The future of the NHS complaints systems

55 It will be clear from what we have said that an NHS which has respect for and honesty towards patients is not one which hides mistakes or waits for patients to complain. It is for this reason that we advocate openness when things go wrong and an active approach to seeking feedback and comments from patients. The more that difficulties can be addressed early on, by, for example, being open about error, by helping to resolve patients' concerns at an early stage and by the effective use of patients'

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[37] Wu AW. 'Handling hospital errors: is disclosure the best defense?', *'Annals of Internal Medicine'* Dec 21 1999; 131(12):970–2

[38] *'Handling clinical negligence claims in England',* Report by the Comptroller and Auditor General. HC403. Session 2000–2001: May 2001

feedback, the more it should be possible to reduce the extent to which the great variety of patients' concerns and questions coalesce into a generalised notion of 'a complaint'.

56 Of course, there will be times when a patient wishes to complain, or is justified in doing so. Thus, there also needs to be an open and easily accessible system for the patient or carer to follow in such circumstances. Currently, the complaints system operated in trusts is widely acknowledged to be cumbersome and bureaucratic. Despite efforts to reform it in the mid-1990s the system has too many layers and lacks a sufficient element of independence. The Government has committed itself to further reform of the system. The decision to establish Patient Advocacy and Liaison Services within trusts is a first and important component of a broader system to identify and respond to problems as early as possible. While we make no comment on the detailed operation of any new system, we offer the following observations. There should be a clear system in the form of a 'one-stop shop' in every trust, for addressing the concerns of a patient about the care provided by, or the conduct of, a healthcare professional. The Patient Advocacy and Liaison Service should be part of this system. The system must be kept as simple as possible. It must follow a well-established principle in handling complaints, that a complaint is best resolved as close as possible to the time and place it arose. The system must be easy to use and accessible. It must be integrated with other policies and systems (such as feedback from patients) and not be off to one side, so to speak, of the mainstream of the hospital's activity. It must also be understood to be part of a pattern of exchanges between healthcare professionals and their patients, and between the trust and patients. When serious complaints arise, which are not easily resolved, they should be dealt with swiftly and thoroughly, keeping the patient (and carer) informed along the way. There should be a strong independent element, not part of the trust's management or board, in any body considering serious complaints which require formal investigation. For this category of complaints, we support the Government's proposal to establish an independent advocacy service to assist patients (and carers).

57 Patients, for the most part, as we heard in our seminars, do not want to complain. Often they feel forced to because their concern has been ignored or not properly addressed. The message is clear: improve communication generally, be more open with patients, and complaints will go down. For the complaints which remain, the system in place must be open, minimally bureaucratic, receptive, and appropriately independent.

Chapter 24: A Health Service which is Well Led

Patients are entitled to expect that both the NHS and the hospital in which they are cared for is well led.

Messages from Bristol

- The national leadership of the NHS, as between government and professional organisations, was confused and fragmented. No one was really clear about who was ultimately responsible for standards and the quality of care.

- Accountability of the UBH/T to local health authorities and to the Department of Health was confused. Within the hospital, mechanisms of accountability between the central management and the clinical directors, and between clinical directors and clinicians, were unclear and ambiguous. In particular, no one was entirely clear who was responsible for maintaining and improving the quality of care for patients.

- Leadership in Bristol was fragmented: clinical leaders were expected to take responsibility for discrete areas of clinical care; managers were expected to focus on non-clinical matters. A separation was created which was hard to sustain. Delegation of authority from the Chief Executive to clinical directorates created 'silos' (discrete organisational units with very little communication between them) within the Trust. These were almost separate organisations. Strategic leadership from the centre was weak. Communication was up and down the system but not across it.

- There was a contradiction at the core of the organisation in Bristol: a rigid formal system of management, which separated clinical and non-clinical issues, coexisted with an actual system in which the Chief Executive and a small group around him really managed all aspects of the hospital. Those working in the hospital found this difference between the declared system and the actual system confusing and unsettling. The workforce felt alienated if they did not belong to the 'inner circle'.

- There was an insular 'club' culture, in which it was difficult for anyone to stand out, to press for change or to raise questions and concerns.

- The Trust Board, from its inception, was remote from the main activity of the hospital, which was, caring for patients. The Chair of the Board and non-executive directors were not routinely or systematically involved in formulating policy or monitoring the performance of clinical care.

1 In this chapter we argue that the highest priority still needs to be given to improving the leadership and management of the NHS, at every level. By this we mean that there needs to be a consistent effort from government and from the top of every NHS organisation to ensure that the NHS is organised for and works in the interests of patients, and to ensure that the quality and safety of care are central. It also means that there must be clarity as to who is responsible and accountable for the quality and safety of care. This applies at the level of organisation and at the level of individual healthcare professionals. In what follows, we address the issue of leadership in stages. First, we review, briefly, the recent history of how quality of care has been regarded in the NHS, including the changes introduced in the last three years. Secondly, we consider what further changes may be needed, in the light of Bristol, to the strategic framework for the quality of care provided by the NHS. Thirdly, we consider the arrangements for management and accountability *within* the NHS and ask whether these are such as to enable those directly responsible for managing NHS organisations to be able to deliver care of a good quality to patients. Fourthly, we examine in more detail the *external* checks and balances that are required to ensure that patients can have confidence in the quality of care.

The 1980s and early 1990s – national leadership in relation to the quality of healthcare

2 In the decades after the establishment of the NHS (in fact right up until the late 1980s) central government, through the Department of Health (and formerly the Department of Health and Social Security), interpreted its responsibility for the NHS largely in terms of planning and of allocating resources. It did not see itself as being responsible for, and thus accountable for, the quality of clinical care, either in terms of setting standards or of monitoring clinical performance.[1] Quality was regarded by government as a matter for individual healthcare professionals. For their part, healthcare professionals, particularly hospital doctors, had deeply embedded in their culture the notion of professional autonomy, often expressed in the form of 'clinical freedom'. This translated as the autonomy of professionals to manage the care and treatment of patients by reference only to what they considered appropriate for the individual patient. This did not mean that healthcare professionals thought of themselves as unaccountable. Rather, they saw their accountability as being to their profession and professional bodies and (to a lesser extent) the hospital as employer.

3 During Phase One of the Inquiry we received evidence from Sir Graham Hart, former Permanent Secretary at the DoH. Looking back to the 1980s he wrote:

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[1] See also Section One, Chapter 6

> 'There was a deeply-rooted reserve on the part of the Department – shared by the professions – about Departmental involvement in clinical performance. This was in general seen as the preserve of clinicians individually and, to some extent collectively.'[2]

This 'reserve' was reflected throughout the 1980s in the priorities which were set by government for those in charge of local acute hospitals. These priorities, reflected in targets, related only tangentially to the quality of clinical care received by the patient. Financial targets, targets to reduce waiting lists, and targets to increase the numbers of patients to be treated were predominant. These were, after all, the priorities of a Secretary of State answering to those concerned with spending tax revenue. The experience of patients, how well patients were treated, or how effectively, and with what impact on their health, were only at the margins of policy. Unsurprisingly, these issues in turn, did not rank high among the priorities of those who were in charge of hospitals providing acute care.

4 Over time, pressures grew on government to become involved in the quality of clinical care, no doubt reflecting the growth of consumerism generally. But the 'deeply-rooted reserve', whereby government and those who led and managed the NHS avoided involvement in issues of clinical quality, still exerted a powerful influence. Medical and later clinical audit were introduced, but very gradually and participation was voluntary. The *'Patient's Charter'*, when it was introduced in 1991, confined itself, in relation to quality of clinical care, to setting limits on waiting times for treatment. The reforms of the NHS in 1991 were partly driven by the view that the discipline of the market would lead to improvements in the quality of care. But the market was imperfect and fragmented. There were few standards. And such information as was generated about the quality of care was not routinely shared. Certainly very little was made public. Purchasers (health authorities and GP fundholders) had few real financial or other levers to bring about improvements in the quality of care, and in reality they had little choice of provider hospital.

5 While government played only a minimal role, those at the centre of the healthcare professions endeavoured to provide a degree of leadership. From the early 1990s onwards, a number of the Royal Colleges and other professional associations began to develop standards for the care of people with certain illnesses and conditions. This represented the translation of the notion of clinical freedom into a sort of collective professional approach. But it was leadership without authority. They had only very limited formal powers. The curious situation existed in which the right to lead in areas of clinical quality was claimed by the Royal Colleges, as a natural extension of clinical freedom, but the authority which ordinarily would accompany such leadership was absent.

6 Thus, as we saw in Section One, when serious concerns about the quality of paediatric cardiac surgical care in Bristol percolated through to the national level,

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[2] WIT 0040 0002 Sir Graham Hart

an organisational form of 'pass the parcel' was played out. Each organisation which might have been able to do something, passed the problem on, thinking it was some other organisation's or individual's responsibility. Hardly anyone involved had a clear sense of whom they should turn to, what action to take, or whether, indeed, it was their place to take any action. The situation was compounded by the fact that, in any event, there was no reliable way of evaluating the quality of the service, in the sense of outcomes of the care received by patients. This is what happens when national leadership on the issue of the quality of clinical care is weak: that, regrettably, was the way things were at the time.

7 Reference to Bristol allows us to re-emphasise that leadership at a national level, most particularly through the DoH, crucially sets the context within which leaders of trusts at the local level are able to carry out their responsibilities. With hindsight, it is possible to see that the absence, up to the late 1990s, of national leadership from government on the subject of the quality of clinical care had a role to play in the way in which events unfolded in Bristol. The quality of clinical care did not rank highly in the overall management of the NHS. Nor, until the Audit Commission was given a limited remit for the NHS in 1990, were there organisations external to the NHS which commented authoritatively upon matters touching on the quality of healthcare.[3] But we should stress again that this was no conscious abdication of responsibility on the part of successive governments. Rather, it was an aspect of the unstated compact between government and the healthcare professions, particularly the medical profession, which had helped to see the NHS established in the first place.

Recent changes

8 For a long time then, responsibility for clinical standards and for clinical performance was simply not thought to be a matter for government in its role of leading the NHS. This began to change when, in 1997, the Government started a programme of reform to bring matters concerning the quality of care into the mainstream of NHS management. We will examine in more detail the impact of these changes, but, briefly, we acknowledge here a significant change to the internal management of the NHS, namely the decision to place a legal duty on trusts and health authorities in relation to the quality of care. Whereas before 1999 a trust chief executive and trust board were not *required* to pay attention to the quality of healthcare, that has since changed. The 1999 Health Act states that each health authority, trust and primary care trust has a duty '… to put and keep in place arrangements for the purpose of monitoring and improving the quality of health care which it provides to individuals'.[4]

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[3] The Audit Commission's remit with regard to the NHS was to ensure the proper stewardship of public finances and to help those responsible for the NHS to achieve economy, efficiency and effectiveness

[4] *Health Act 1999 s18(1).* London: The Stationery Office, 1999

This duty falls effectively on the chief executive. We also note the decision to create, for the first time, at some distance from government, institutions respectively to set and to monitor standards of care. These institutions, the National Institute for Clinical Excellence (NICE) and the Commission for Health Improvement (CHI) thus mark a further break with the past. The introduction of these changes is intended to have an impact on the role of government at the centre of the NHS. In *'The NHS Plan',* the role and responsibility of leadership from central government was spelled out in clear terms: '… the centre will: set standards, monitor performance, put in place a proper system of inspection, provide back up to assist modernisation of the service and, where necessary, correct failure.'[5] The DoH, it went on, will also have a role in championing the interests of patients by applying both pressure and support.

9 These developments contain an implicit recognition that government has two key roles in relation to the NHS. It has a role in terms of leading and managing the NHS to ensure that it delivers that which taxpayers and patients want: care of good quality. It also has another role, one which government quite properly holds in many areas of society where there is one or a few very large suppliers of a service, namely to establish a system to protect the interests of the people who receive that service. Such a system, in essence, is a system of regulation. In the past, in relation to the NHS, it was thought that a system of regulation aimed at healthcare professionals alone would be enough. Bristol has taught us that this is not enough. It is also necessary to have a system for regulating the institutions which provide healthcare.

10 Thus, the approach of government is changing, and changing, we believe, in the direction which the lessons of Bristol would suggest is necessary. We would argue however, that for the future the change must be clearly analysed and focused. What is required is much more explicit recognition on the part of government that, as regards quality of care, it has two separate but related roles: good management of the NHS, and the organisation of good, comprehensive regulation of the quality of healthcare. In the past, as the example of Bristol so clearly demonstrates, neither of these roles was properly understood or performed.

11 For the future, it is clearly the responsibility of government to *establish* the systems both for good management and for regulation. But it does not follow that government should do both of them. Indeed, there is a clear conflict of interest were government to perform both of these roles. As we shall see later, regulation of the NHS cannot be for government. It must be independent of government. It must involve and reflect the interests of all, patients, public and healthcare professionals, as well as the NHS and government.

12 This delineation in the roles that government should play is both simple and clear: serving through the DoH as the strategic headquarters of the NHS, and establishing the system of regulation, of both institutions and healthcare professionals, by independent bodies. We will set out the detailed implications of this approach in the

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[5] *'The NHS Plan'.* London: Department of Health, 2000. Para 6.6

pages and chapters which follow. We admit that to pursue this direction will take political nerve. But if trust in the proper regulation of the NHS is to be regained and then maintained, it is a step which government must take.

13 We turn now to examine as the two separate but related elements of a well-led NHS: (a) leadership and management of the service, and (b) regulation to ensure, on behalf of patients and the public, that standards for the quality of care are set and implemented.

The leadership and management of the NHS

14 We recognise that, so long as the NHS remains a publicly funded service and that healthcare continues to be provided primarily through trusts, NHS primary care trusts and through staff employed by the NHS, the NHS is a state-run organisation with a virtual monopoly in the provision of healthcare. It follows from this that how resources are used within the NHS is subject to Parliamentary scrutiny through the accountability of the Secretary of State. This being so, we accept that management of the NHS must be the responsibility of the DoH. This is not to say that the Department should manage every detail of activity. Historically, as was set out in *'The NHS Plan':* 'The relationship between central government and the NHS has veered between command-and-control and market fragmentation. Neither model works. The NHS cannot be run from Whitehall'.[6] Nor, we would add, can it be run like a commercial organisation in which the values of public service and of the healthcare professionals are replaced by a culture of commodity and commerce, if it is to keep faith with its founding principles.

15 *'The NHS Plan'* recognises that the quality of care provided for patients will have the best chance of improvement when clinicians and managers have the freedom to lead and manage local services within a national framework. The Plan emphasises that, progressively, there will be less central control and more devolution as standards improve and services become more focused on patients' needs. The challenge will be to make that a reality.

16 We are in no doubt that intervention from the centre should only be contemplated when it adds value. Such value can most effectively be added at the strategic level, by establishing and monitoring national systems, rather than by direct intervention or directing the management of individual trusts or individual professionals. We recognise that this shift will take time, that a process of change is involved, but would argue that there needs to be progressively much greater self-discipline on the part of central government. The prime focus should be on supporting local management and on helping health authorities and trusts to deliver care which is safe and of a good

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[6] *'The NHS Plan'*. London: Department of Health, 2000. Para 2.31

quality. We understand, as we have already made clear, that if Ministers are accountable to Parliament they will be inclined to want to direct. Furthermore we recognise that there are, and should be, occasions on which central government must have the power to intervene and take action. But this must be carefully judged if a sense of local leadership is not to be undermined. The answer lies in a gradual understanding of what the centre is responsible for, together with the parallel development of local mechanisms whereby institutions and managers at the local level can be held accountable. And, in between, there is the necessary development of a middle tier of leadership and management able to see beyond the individual trusts and take account of the interests of the wider community. On this account we welcome the creation of the new health authorities which will take on this role.

Resources

17 We have noted the increases in the funding of the NHS since 1999. We have also made the point that if the NHS is to meet the claims made for it, the level of funding must increase yet further. This is because the various initiatives concerned with the safety and quality of care are not cost-free. Indeed, it is suggested that the cost of implementing the modernisation agenda will require significant additional funding, over and above that which is already planned. The point is simple yet crucial. If staff are to be properly trained and then motivated to continue in public service, this will cost money. If the ratio of healthcare professionals to patients is to improve, as it must if safety and quality in healthcare are to improve, this will cost money. If healthcare professionals are to have the necessary time and space, for example, to participate effectively in audit, to engage in continuing professional development, and to communicate properly with patients, this will cost money. If healthcare professionals are to have available the necessary equipment and facilities, this will cost money. If buildings are to be built, this will cost money. It would be the cruellest irony if it were demanded of chief executives that they deliver a healthcare service fit for the twenty-first century, while not giving them the necessary resources. Of course, government could change its mind and downgrade its commitment to what the NHS should provide and how good the service should be in terms of safety and quality. If it did, however, this would probably mean the end of the NHS. What government cannot do is to renew its commitment to a comprehensive, accessible healthcare service for all and then fail to fund it to the level of the demands government makes of it. Governments have got away with this in the past, but not now. Expectations have been raised and the public is watching.

Leadership at the level of the health authority

18 As we have indicated, there needs to be leadership at a level between the national and the local. The DoH cannot descend to the detailed needs of individual trusts and trusts need more guidance and, on occasions, control than can be exercised through general strategic direction. The history of the NHS over the past decades is one of wrestling with this problem without ever entirely resolving it. The recent decision to rationalise the intermediate tier and to have only 30 health authorities between the trusts and the DoH is, in our view, the right way forward. It allows the concerns and needs of a wider population than that served by any trust to be taken account of. It also allows national strategic goals to be translated into, and adapted to, the circumstances of a particular area and then passed down to the individual trust. Perhaps most importantly, in terms of the lessons of Bristol, it means that the actions and ambitions of trusts (including primary care trusts) can be co-ordinated according to some rational and cost-effective plan which serves the interests of all within the health authority. For example, a proposal by a trust to embark on a new area of healthcare service will have to be agreed by the health authority. If it is judged inappropriate, as not meeting or responding to the needs of the local population, funding would be denied. This is a powerful tool in the development of a better planned and more coherent NHS.

Leadership at the level of the trust

19 The chief executive: We have already indicated that the leadership exercised by central government and, to a degree, at the level of the health authority, conditions what may be done at the level of the trust. Equally, we have argued that it must be the role of the centre to establish an appropriate framework, including certain general principles applicable to all trusts, and then let the chief executive in the respective trusts get on with the job. From the perspective of the patient, the job of the chief executive is to ensure that patients receive care which is safe and of good quality.

20 Since 1999, as we have seen, it has been the duty of each health authority, trust and primary care trust to put and keep in place arrangements for the purpose of monitoring and improving the quality of healthcare which it provides to individuals.[7] We applaud this development, not only because it finally gives proper prominence to the quality of the care provided by the trust, but also because it identifies that responsibility and therefore accountability rest with the organisations which provide healthcare services. The game of 'pass the parcel' is no longer an option at local level. This is the way forward and we support it.

21 But there is another side to the coin. If trusts are to have this responsibility, they and their chief executives must be supported in carrying it out. The NHS at the centre must reinforce the duty to secure quality in healthcare and the message which the imposition of such a duty sends, by establishing and maintaining the framework necessary for chief executives to do what is asked of them. In short, they must given the tools for the job. We single out two of these 'tools' for special attention; they are:

- appropriate contractual relationships with trust employees
- support for the role of trust chief executive.

We also comment on the role of the trust board and of non-executive directors.

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[7] *Health Act 1999 s18(1)*. London: The Stationery Office, 1999

Contractual relationships with trust employees

22 Participants in our seminars who came from organisations other than the NHS frequently commented on the complexity of employment relationships in the NHS and on the extent to which it appeared that a chief executive and a trust's board can be disempowered by strong professional groupings, apparently beyond the chief executive's control to manage. We heard that there continue to be differences in the nature of the employment relationship between different groups of healthcare professionals and their employer, the trust. Specifically, hospital consultants have a unique employment status within the NHS. Even today, consultants would not necessarily consider themselves accountable or answerable to a clinical director, and clinical directors would not necessarily consider themselves accountable or answerable to the medical director. Nor would they see themselves as necessarily answerable or accountable to the chief executive. There continue to be uncertainties and ambiguities about accountability: the same general uncertainties as existed in Bristol in the 1980s and 1990s.

23 Consultants have an odd position in terms of the ordinary norms of employer-employee relations. They enjoy a job effectively for life. It is extremely difficult to remove them. The hours they spend actually dealing with patients are not regulated. They see themselves as largely autonomous, with their duty being owed to the patient and their sense of identification being to their professional peer-group. To that extent, they do not see themselves as employees at all. This point was brought out by Dr Hugo Mascie-Taylor, the Medical Director of the Leeds Teaching Hospitals NHS Trust. In a paper submitted to the Inquiry he wrote:

> '… it is fair to say that consultants are not managed like other NHS employees. Indeed, some would say that in some ways the consultant body still stands at the edge of the NHS rather than at the centre of it.'[8]

24 We are convinced of the need to restate the relationship between the consultant and the hospital. The principal means of doing so must be through the contract agreed between them. As in all such agreements, there should be a recognition on both sides of the other's interests. The trust must agree to provide the consultant with the time, space and the necessary tools to do the job. The trust must be enabled to provide suitable incentives to consultants and to other hospital doctors to encourage them to achieve high quality in the care of their patients. One means of so doing is to extend the system of Distinction Awards beyond the changes made in the late 1990s. These changes reflected a recognition that distinction in the care of patients, as well as in the performance of research, should be rewarded. This could be taken further and the system extended beyond hospital consultants to include junior doctors.

25 The trust must also underwrite its commitment to an open, fair and non-punitive environment, in which all employees feel safe to voice views and concerns. For their

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[8] Seminar 4. Dr Hugo Mascie-Taylor. Position Paper. The quotation is extracted from Dr Mascie-Taylor's chapter in *'Managing Medicine – a Survival Guide'* (1997) London: Financial Times Healthcare

part, consultants must accept that the time spent in the hospital and what they do in that time must be much more explicitly set out. They must also accept that failure to comply with contractual obligations places them at the same risk of some form of disciplinary action as any other employee. There is no reason why the consultant should be immune from such processes, or be protected by the current labyrinthine procedure, involving sometimes an interminable period of time of suspension on full pay (which is the near equivalent to immunity). We note the emergence of primary care trusts. We also note that GPs associated with these trusts have historically enjoyed a different relationship with the NHS from that of the hospital doctor. Our concern is with the acute hospital sector, but if systems of accountability and regulation are to be introduced effectively across the NHS, careful consideration will need to be given to the relationship between the GP and the primary care trusts.

26 We emphasise the importance of the contract because we see it as crucial that the hospital, through its chief executive, be able to manage itself. This is one of the most important tools which chief executives need if they are to be able to meet their obligations regarding the safety and quality of healthcare. It is a tool which any chief executive in any other organisation would take for granted. Moreover, in a patient-centred system of healthcare, it is clearly in the interests of patients that the chief executive be able to respond to any complaint that a consultant has not met his or her contractual duties as promptly as possible. Moreover, by enabling the chief executive to respond by reference to the contract between the consultant and the trust, the response is closer to the event, is more informed as to local circumstances and action can be taken more promptly. The process is thus made more effective and patients' interests are better served.

27 It must not be thought that we see a change in the employment relationship of the consultant as a panacea to all the difficulties faced by chief executives in leading and managing a trust. Nor, importantly, do we see it as some instrument for control. This is because the contract is part of a much larger picture. As we have said, that larger picture must be one of openness and, over time, increasing understanding and trust. The contract serves to facilitate the performance by both parties, employer and consultant, of their respective duties to the NHS. Indeed, one particular feature of any new contractual relationship must be that it sets out clearly the lines of accountability and responsibility within the hospital. Consultants must be able to know what is expected of them and to whom they should turn if they wish any particular matter to be dealt with. We were impressed by evidence that while a formal structure of management might exist in a hospital, some consultants might choose to regard it as a matter for others and not something of direct interest or concern to them. Equally, others felt unsure about their place in the organisation of the hospital and uncertain as to whom they should turn with regard, for example, to matters relating to the safety of patients. Setting out such matters in the employment contract would serve to reduce these difficulties.

28 Any discussion of the consultant's contract must address the question of the relationship between the powers of the employer and those of the body concerned with maintaining the register of medical practitioners. We will set out our views in due course on the wider issues of the regulation of healthcare professionals in general. Here, we focus on one matter of importance.

29 The General Medical Council (GMC) currently sets and publishes a Code of Professional Practice on how doctors should conduct themselves.[9] Breach of the Code can bring disciplinary action by the GMC, concerned with whether the doctor should remain on the register. This process is independent of the employer-employee relationship. But we think that there is good reason why the doctors' Code, as currently set down in the GMC's *'Good Medical Practice',* should be incorporated into the contract between the trust and all doctors, not just consultants. Nor should this be limited to doctors. The relevant Codes of Practice should be incorporated into the contract made between the trust and all other healthcare professionals. Breach of the Code would then be an employment issue, to be dealt with by the hospital in appropriate and agreed ways. This would mean that breaches could be dealt with, as we have already said, close to the event and in the light of local circumstances. If action is required in the interests of patients (this being the first and paramount priority), it could be taken with all due speed. What the relevant professional body (for example, the Nursing and Midwifery Council) might wish to do concerning the wider question of the healthcare professional's fitness to continue in practice would be a matter for it to resolve. We add that in circumstances in which the safety of patients is or may be at risk, the employer should be required to notify the relevant professional body of any action taken. The relevant professional body in turn, being concerned not just with discipline but all aspects of performance, can then take appropriate action.

Support for the role of chief executive

30 A feature of trusts since their appearance in 1991 has been the difference between the chief executive and many of the healthcare professionals, particularly the senior staff, in relation to their employment. While the latter have what amounts to security of tenure for life, the chief executive (and senior managers) have a far less secure status. Just as we suggest some paring down of the status particularly of consultants, so we see the need to develop a culture in which chief executives (and senior managers) may feel more secure in their employment. Currently, there is a sense in which the NHS is too greatly politicised and too closely managed from the centre. As a participant in one of our Seminars, with experience of life in the public sector, put it: '… the life of a Chief Executive is nasty, brutish and short'. In such a climate, the danger exists of demanding the head of the chief executive (or a senior manager) if some problem affecting a trust attracts sufficient adverse attention. To us, this is no different from the reflex of demanding that some healthcare professional should be 'struck off' when something has gone wrong. It is the culture of blame and it is unhelpful, as we have repeatedly asserted. It may satisfy an immediate desire for some punitive action but it rarely addresses the underlying issues. The same is true as regards a chief executive (and senior managers). There is a danger that they can be treated as sacrificial lambs, to achieve some quick political fix. This does nothing to

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[9] The General Medical Council. *'Good Medical Practice'*. 3rd Edition. 2001

ensure good leadership and management in the NHS; it does the opposite. It deters those who are otherwise capable and committed. For this reason, we are concerned that chief executives (and senior managers) receive appropriate support and enjoy the same degree of security of tenure as other senior professionals in the NHS. They must be allowed to lead and manage, and be supported in this. They must not be at the mercy of the government's anxieties about the headline of the day. The trust's board should be left to make its own decisions on the future of the chief executive, according to clear and agreed criteria.

The trust board

31 Leadership at the local level also depends on the trust board. The board consists of executive and non-executive directors. As regards the executive directors, in particular the medical and nursing directors, it is of crucial importance that appointments are based on real ability and commitment to leadership and management. Trusts should make training and preparation for the role of executive Director part of their overall strategy and seek to identify and support those who may be suitable for appointment. The NHS Leadership Centre, in conjunction with trusts, should develop programmes of training and support for clinicians and others who seek to become executive directors. The criteria and process for selection must be clear and open. Appointments must be made on the basis of ability. They must not be made on some notion of 'muggins' turn'. In one of our Seminars Hugo Mascie-Tayor pointed to the tendency to appoint the most senior consultant to the role of manager, and remarked that seniority does not necessarily guarantee managerial ability: 'In some cases the most senior consultants were actually those least likely to take a corporate view, and making them the manager simply allowed them to exercise their individualistic powers more easily.'[10] And, just as there must be a clear process for appointment, so there must be systems to support executive directors while in office and to review, periodically, their peformance.

Non-executive directors of trusts

32 As for the non-executive directors, a very clear message to emerge from Bristol is how readily the board's non-executive directors (and even to an extent the chairman) can be prevented from exerting the authority expected of them, simply by not being let in on issues. A strong chief executive, with support from executive directors, can seek to control what comes to the board and in what way. Once this approach takes hold, it is hard to overcome. Its consequence is that the board cannot effectively serve the public interest.

33 We were struck by the views expressed in our Seminars about the variation in the roles played by and the expectations held of non-executive directors. An overriding sense of lack of clarity and direction emerged. And, without sound knowledge of what might be happening in the trust, non-executive directors were often unable to challenge the views of the chief executive, or the executive directors. In our view,

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[10] Seminar 4. Dr Hugo Mascie-Taylor. Position Paper

non-executive directors have a crucial role to play as representing the public interest in the conduct of the trust's affairs. They must be people with a high level of ability and experience in the leadership and management of organisations. They should not all have a background in healthcare, since the views in organisational terms of those with differing experience can be of great importance. They should, however, have a commitment to public service. Given the importance of their role, the process of appointment must be open and transparent. As recommended in *'The NHS Plan'*,[11] there should be an NHS Appointments Commission responsible for the appointment of non-executive directors of trusts, health authorities and primary care trusts. The criteria for appointment must also be open and clear. We were pleased to note that *'The NHS Plan'* included a proposal to develop training for non-executive directors and to issue a standard job description. These are long overdue. There should also be a programme of induction which should refer to the principles and values of the NHS and the duties and responsibilities of non-executives with regard to the quality of care provided by the trust. This programme should be provided through the NHS Leadership Centre. The non-executive directors must be allowed to become thoroughly involved in the affairs of the trust. They must be let in and then assert the authority which is properly theirs. This is particulary so in the case of the Chairs of trust boards. They must be supported to exercise their authority and independence of mind, That is why we believe that the Chairs of trust boards should have a source of independent advice (or mentor) during their period in office drawn from a pool of experts assembled by the NHS Leadership Centre. We note here also, and endorse, the views expressed in a recent report from the Cabinet Office: that all non-executives members of boards in the public sector should receive suitable training, including best practice on recruitment, on performance management for leaders and on holding leaders to account.[12]

The future framework for the regulation of the quality of healthcare

34 We turn now to the second of the two fundamental elements required for a well-led NHS: regulation. First, we need to make clear what we mean by regulation. It is a broad term. It describes all those processes by which the safety and quality of healthcare are assured. It can be divided into two categories: the regulation of healthcare professionals and the regulation of healthcare institutions (hospital trusts, health authorities and primary care groups/trusts). The regulation of healthcare professionals, historically largely associated only with discipline, involves all matters affecting the performance of the professional. It covers, therefore, initial education, training, appraisal, continuing professional development and, where relevant,

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[11] *'The NHS Plan'*. London: Department of Health, 2000. Para 6.54

[12] Cabinet Office, Performance and Innovation Unit, *'Strengthening Leadership in the Public Sector'*. April 2001. www.cabinet-office.gov.uk

disciplinary action. The regulation of institutions is equally broad, addressing those systems which set, monitor and enforce standards and disseminate information on performance. This approach to regulation allows us to capture the whole varied range of activities which are concerned with safety and quality under one heading. What is currently a mass of ill- or uncoordinated activities can be reanalysed once it is recognised that they are part of a common process.

35 Once regulation has been properly defined, we need to ask who is going to be responsible for the two categories of regulation which we have identified. We begin with our conclusion. Regulation, as we have defined it, is not properly a task for central government, through the DoH. As a monopoly provider, it cannot be in the public interest for it also to set and monitor the required standards of performance. Its role must be to ensure that the standards of care once established are delivered. In our view, regulation must reside in bodies which are not directly under the control of government. The role of the Department should be to create the necessary regulatory framework and then stand back, only becoming involved when significant changes in the policy of regulation are involved.

36 As regards the regulation of institutions, we have noted that government, through the creation of bodies such as NICE and CHI, has gone some way to creating the sort of system which we regard as essential.[13] But two further steps are required. First, these bodies must be given greater autonomy and independence from central government's control. Second, there must be some overarching body which can integrate and co-ordinate the activities of all the various individual bodies concerned with safety and quality. Only if such a body exists will the risk which we identified in Bristol be avoided: the fragmentation of responsibility among a plethora of organisations and the danger that concerns fell through the cracks between organisations. This overarching body must be created by government to be at arm's-length from and independent of government. It could be called the Council for the Quality of Healthcare. We point out that this is the only *new* body which we recommend should be created. All the other bodies to which we refer already exist or are proposed in *'The NHS Plan'*.

37 We adopt the same approach as regards the other area of regulation, that of healthcare professionals. Currently, there are a large number of bodies involved in the activities which together constitute regulation. They include the new Nursing and Midwifery Council, the GMC, the proposed new body which will regulate the professions allied to medicine, the Royal Colleges, the various professional associations, the DoH, health authorities and trusts. Each operates in its own sphere, with, historically, little collaboration or co-operation. The various activities must be brought together and properly co-ordinated. The role of the various bodies must be clearly identified. And all of the bodies should be brought under the overall leadership of one overarching body. This body in turn must be independent of the DoH. It could be called the Council for the Regulation of Healthcare Professionals. (In effect this is the body

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[13] We note, however, the current difference in status of these bodies. NICE is a Special Health Authority of the NHS; CHI on the other hand is not part of the NHS but is a non-departmental public body allied to the DoH

currently proposed in *'The NHS Plan'*, referred to there as the Council of Healthcare Regulators.)

The regulation of healthcare institutions

38 We turn now to consider in greater detail the co-ordination of the regulation of healthcare standards and of the standards of healthcare institutions. We will deal in the next chapter with the regulation of healthcare professionals. Our starting point is to repeat that currently the state is virtually the monopoly provider of health services in this country. The public and patients are entitled, therefore, to expect that (a) there are systems in place to ensure that this monopoly is able to achieve its prime objective, healthcare of high quality for patients, and that (b) there are systems in place to ensure that this state monopoly is publicly accountable in this regard. Furthermore, such systems, if they are properly to do their job on behalf of patients, must be trusted both by the public and by healthcare professionals. This means, in our view, that they must be independent. They must be at one remove from party political debate. They must be seen to have a life and status of their own, free from changes in political fashion. Standards and quality in healthcare must be the sole priority of the body responsible for them, not one of a number of competing priorities. The NHS is quintessentially a statement of political values. Thus, it is inevitable and right that central government should seek to lay down the parameters of the NHS's activities, particularly in the realm of finance and priorities. But, once this is done, the systems for monitoring the extent to which it is meeting its stated aims must, in our view, be de-politicised, so as thereby to rekindle and maintain public confidence in the NHS. We believe that the framework which is gradually emerging could and should be made stronger and more independent in a number of respects.

39 To illustrate our point that there is some way to go, we refer to the system so far developed for the setting of standards in healthcare. The DoH remains very closely involved in the process, despite having set up an organisation, NICE, to carry out this task.[14] Sir Donald Irvine, Chairman of the GMC, recently asked, 'Can a centralised bureaucracy, led by a Minister of the Crown, be both standard setter and near monopoly provider?'[15] The tension between being a monopoly provider and setting standards needs careful analysis. On one view (Sir Donald's) there is a conflict of interest. The monopoly provider will always be tempted to interfere to make the standards match the needs of the day, or, more worryingly, the political priorities of the day. But, at the level of abstract analysis, it is perfectly plausible to take the opposite view from Sir Donald. Who better than the monopoly provider to set the standards? The monopoly provider knows what resources are available and can seek to tailor standards to resources. The same arguments could also be applied elsewhere: to the conduct of national audits of performance and to the publication of information about healthcare performance on a national scale. Who better than the monopoly

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[14] The DoH sets standards in 'priority' areas of healthcare through National Service Frameworks; it also determines annually the list of conditions in relation to which NICE should develop standards

[15] Sir Donald Irvine. *'The changing relationship between the public and the medical profession'*. Lloyd Roberts Memorial Lecture. Royal Society of Medicine, 16 January 2001. www.gmc-uk.org

provider to report on its own progress? It has access to all the data and can analyse and present it.

40 But we are not engaging in some abstract analysis of how best to organise the NHS. We are talking about how best to persuade those affected by it and those working in it to rebuild and retain their trust in the NHS. In our view that trust can best be rebuilt and sustained by central government continuing the process it has already begun of establishing an independent framework for quality assurance. This means in practice that the organisations which have been set up to support, sets standards for, and monitor the NHS must be given greater authority and independence. It also means that the organisation and funding of these organisations may have to be revisited to ensure that they are able to fulfil their respective roles. It means that in the regulation of healthcare institutions, the Department's role should be increasingly strategic: to establish 'offshore', as it were, a system of regulation; to support its authority; and to review its functioning over time with a view to improving it. This is a crucial lesson from Bristol. As we have said, adopting this role will take nerve and political courage. But it is the right way to secure the future of the public's trust in a national health service.

41 How should government go about this task? Our vision of the DoH's role in the future, in relation to regulation rather than to the management of the NHS, is that its responsibility lies in ensuring that a proper system is in place and that the various bodies are able to make their contributions to the overall framework of improving the safety and quality of healthcare. This is the extent and limit of the Department's responsibility. The issue here, and it is a complex and demanding issue, is how to set the proper bounds of the political on the one hand and the expert and the public on the other in a national health service. We take the view that the only system which will enjoy public trust and confidence is one in which the political responsibility is limited to creating the overall framework and monitoring it thereafter.

42 There are already organisations charged with bringing about improvements (CHI and NICE). These are not new bodies. We would incorporate them into the framework we propose. But they would have to be differently constituted. They should be made fully independent of the DoH. Indeed, that CHI and NICE are not sufficiently independent, is *already* creating a sense that both are limited in their powers to act. Neither body, for example, has the powers to enforce compliance with its reports, and both bodies look primarily to the DoH (the monopoly provider) for their membership, their resources, and to set their detailed agenda. By way of illustration, CHI's independence cannot be manifested or enjoyed as long as it is the Department rather than CHI itself which sets the targets for the number of trusts which must be inspected each year.

43 The type of model which we favour for CHI, NICE and the proposed National Patient Safety Agency is that of a body such as the Foods Standards Agency. The FSA is at arm's-length from government and while its overall general objectives and practices must be approved by government, the government's power to direct its activities is otherwise limited. Moreover, it has an explicit duty to ensure that members of the public are kept adequately informed about and advised in respect of matters which the FSA considers significantly affect their (i.e. the public's) capacity to make informed decisions.[16]

44 But, as we have made clear, we do not stop there. A plethora of organisations, all with their own ambitions and anxious to defend their 'territories', was one of the defining features of what happened in Bristol. To bring together the various activities of these agencies, to ensure that issues are not missed, and to give some kind of strategic direction, some further mechanism is needed.

45 Such a mechanism would ensure that the activities of the various parts are co-ordinated and integrated. This is the role central government currently presumes to play, but it does so unconvincingly. In particular, it tends to an extent to see the creation of the agency or organisation as a solution in itself, while retaining real control at the centre. Furthermore, as we have said, one of the principal lessons of Bristol is how various organisations can become blind to the activities of each other.

46 Thus, as mentioned earlier, we see the need for an overarching body to monitor and co-ordinate the activities of all the various agencies concerned with standards and quality. The Council for the Quality of Healthcare would have an independent status, once established by government. The various agencies would be required to report to it and would derive their authority from it. Its terms of reference would be laid down by statute and it would report both to the DoH and to Parliament. It would provide the much-needed leadership to ensure that patients receive care of a proper standard and quality. While the Secretary of State for Health would be responsible to Parliament for its activities, it would be understood that the Department's role was one of establishing and funding the Council, and setting and periodically reviewing its strategic framework, rather than being involved in its operational activities.

The Regulatory Councils

47 We see two Councils as the future framework for the regulation of the quality of healthcare: one to bring together and co-ordinate all those processes by which the safety and quality of healthcare are assured in healthcare institutions, and the other (already in *'The NHS Plan'*) to bring together and co-ordinate the various bodies concerned with all aspects of the regulation of healthcare professionals. It could be objected that the NHS is not short of organisations and bodies already. While we understand this possible objection, we reject it. First, there is a very great need to resolve the problem of fragmentation of responsibilities for assuring the quality of care within the NHS. The overarching organisations which we propose will achieve this. Secondly, the functions which would be undertaken by the Councils are purportedly already carried out by the DoH. We have suggested that they are not carried out with appropriate vigour, efficiency or independence. That they need to be carried out, however, is clearly recognised. The system we propose would simply do it in an appropriate manner. It may well be that, in time, the separate activities of the two

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[16] Section 7 Food Standards Agency Act, 1999

Councils could be combined in just one organisation with two branches: one to cover the regulation of professionals and the other to cover the regulation of healthcare institutions. In the interim, we have no doubt that there should be close collaboration between the Councils.

Chapter 25: Competent Healthcare Professionals

A patient is entitled to be cared for and by healthcare professionals with relevant and up-to-date skills and expertise.

Messages from Bristol

- There was no requirement on hospital consultants to keep their skills and knowledge up to date nor to demonstrate to anyone other than their peer group that they remained sufficiently skilled.
- Surgeons were able to introduce new techniques without any formal system of notification and without the need to demonstrate the necessary level of skill.
- Patients were cared for by distinct groups of health professionals. Collaboration and inter-professional teamwork were poorly organised.
- Appointments of clinicians to managerial positions on occasions were filled on the basis of seniority or 'muggins' turn' (next in line), rather than the ability to do the job.
- Clinicians undertaking managerial roles did not receive the necessary formal training or support.
- The communication skills of the healthcare professionals varied greatly.
- The systems in existence were not capable of assuring the competence of healthcare professionals.
- Poor or diminishing competence could not be adequately addressed until it became manifestly bad.

Introduction

1 We learned from both Phases of our Inquiry that what we heard about in Bristol, in terms of attitudes and in terms of competence, broadly defined, was not unique to Bristol. Nor was it limited just to the period of our Terms of Reference. Indeed, anyone reading the recent review into the Oxford Cardiac Services[1] would find uncanny similarities to what we describe in Section One in the case of Bristol. Yet it referred to

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[1] NHS Executive SE Regional Office. *'Report of the External Review into Oxford Cardiac Services. November 2000'*. www.doh.gov.uk/stheast

events between 1995 and 1999. The report into paediatric cardiac services at the Royal Brompton and Harefield Hospitals[2] only appeared in April 2001, yet it too has echoes of the events and circumstances of Bristol. The continued existence of shortcomings in professional competence clearly undermines the capacity properly to care for patients.

2 This chapter looks at the range of skills of healthcare professionals. We argue that, in the case of doctors and nurses, technical clinical skills are a necessary but not a sufficient qualification to practise as a healthcare professional. For the future we must expand our understanding of what constitutes professional competence. Attitudes and interpersonal skills must be recognised as having value alongside clinical skills. This has consequences for the way in which future healthcare professionals are selected and educated. In the second part of this chapter we consider the systems for ensuring that competence is acquired and then maintained throughout the professional's working life. We identify areas where these systems need to be strengthened. We give particular attention to the way in which professionals acquire *new* clinical skills. Some of our observations relate to particular professions but most relate to *all* healthcare professionals (managers, doctors, nurses and other healthcare workers).

Professional competence

3 When we talk of professional competence, we refer to patients' expectations that the professional they come into contact with will be up to the job. Professionals should be able to do that which they profess they can do. From the patient's point of view, it is shocking to think that this might not be the case. Indeed, the need for healthcare professionals to acquire and maintain appropriate levels of competence is so obvious that it would seem unnecessary to refer to it. The patient simply expects that the healthcare professional has up-to-date knowledge and skills. A healthcare professional's competence from the patient's point of view is not negotiable. Moreover, when we talk of professionals, we repeat that we mean all of the professionals who make the NHS work: doctors, nurses, the professions allied to medicine,[3] managers and other healthcare workers.

4 Levels of competence quite properly will vary. A consultant or a nurse ward manager will have a wider and deeper level of competence than the junior doctor or newly qualified nurse. Yet, even at the start of a professional life, competence should meet a critical minimum level. Competence will also vary at the level of specialist expertise. Consultants working in a highly specialised field, by declaring themselves to be

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[2] *'The Report of the Independent Inquiries into Cardiac Services at the Royal Brompton and Harefield Hospitals'*, April 2001. www.rbh.nthames.nhs.uk

[3] The term 'professions allied to medicine' is usually taken to include professionals working in the fields of physiotherapy, occupational therapy, speech and language therapy, audiology, dietetics, podiatry, counselling and orthoptics

specialists, profess that they have (and thus should have) a greater level of competence in the particular area than a consultant who is a generalist.

5 Professional competence requires a firm educational grounding, followed by a period of formal training to acquire the relevant knowledge and skills in the workplace. Thereafter, continued competence rests on a combination of education, continuous development, confidence and experience.[4] It depends on the motivation of individual professionals to learn and develop and the extent to which their employer supports them and enables them to do so. It also depends on the professional standards which they are required or expected to meet, and on the wider systems for ensuring that those standards are adhered to.

6 Thus, acquiring and maintaining professional competence involves collaboration between the individual, the educational institutions, the employer, and those who set and enforce standards of professional competence. Individual healthcare professionals, once qualified, need to be sufficiently motivated and have sufficient incentive to maintain and develop their competence. If the process of keeping knowledge and skills up to date is neglected, the professional's level of competence will diminish. It is crucial, therefore, that the working life of healthcare professionals be so structured as to allow them to meet these requirements. This means that the employer must provide professionals with sufficient time and opportunity to maintain existing skills, and to acquire and consolidate new skills. Thus, the work environment in the NHS must support and enable the process of continuous learning, through well-planned strategies for continuing professional development. As for those who set standards, they must ensure that their frameworks of professional standards are and remain appropriate to the needs of patients and professionals and are, in fact, observed.

7 Professionals' competence also depends upon professionals themselves having an honest understanding of their abilities. It is crucial that errors in practice, or gaps in skill or knowledge, are acknowledged as early as possible and used as an opportunity for learning, rather than being suppressed or hidden out of fear of blame or sanction. Learning through mistakes can often be a very effective way of improving competence and understanding. But to acknowledge errors and shortcomings, professionals must feel safe to do so. Employers, therefore, must create an environment which enables this to happen.

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[4] The term 'education' usually refers to the undergraduate period when prospective healthcare professionals are working towards an initial qualification; the term 'training' usually refers to that period after qualification when the professional is acquiring further specialist skills; the term 'continuing professional development' generally refers to activities undertaken by a qualified and trained professional to maintain their skills, during the course of a working life

Broadening the notion of competence

8 Clearly, healthcare professionals must be technically competent to do the task they profess to do, but technical competence is no longer sufficient, if indeed it ever was. A major lesson of our Inquiry is that there are a number of non-technical, non-clinical skills of doctors, nurses and managers which are crucially important to the care of patients. We have identified six key areas. They appear to have been relatively neglected in the education and training of healthcare professionals in the past. They must not be in the future. They are:

- skills in communicating with patients and with colleagues;
- education about the principles and organisation of the NHS, how care is managed, and the skills required for management;
- the development of teamwork;
- shared learning across professional boundaries;
- clinical audit and reflective practice; and
- leadership.

9 Clinical skills are essential, but patients are entitled to expect that the healthcare professionals caring for them will also possess these non-clinical skills. Education and training in them must be accorded a greater priority in the future and this should apply at all stages of a professional's career: education, training and continuing development. Healthcare professionals cannot fulfil their responsibilities without having these skills. In the case of doctors we are aware that ever since the Todd Report in 1968[5] a range of non-clinical subjects have been taught in medical schools. But, with notable exceptions, it is sadly the case that these subjects (for example, communications, medical sociology, or health and society) have not been accorded the importance they require. Whereas students are increasingly examined in them, the problem remains that they are dismissed as having a low status by those who teach basic sciences and this attitude rubs off on the students.

10 Education in the areas which we have highlighted must become fully integrated into the undergraduate curricula of relevant courses. They must be much more than mere 'add-ons', tolerated as extraneous burdens on what some might see as the 'real' clinical curriculum. It is in the formative years of undergraduate education that attitudes are forged and skills imparted which shape the quality of engagement with patients for years to come. Efforts to improve and expand professional competence

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[5] Lord AR Todd. *'The Todd Report'* (1968). Royal Commission on Medical Education. (Cm. 3569)

through undergraduate education, however, will only succeed if the skills of newly qualified professionals are reinforced throughout professional life and also valued by those currently in senior positions. That is why we argue that these six areas must also be given a high priority at all levels of professional preparation and training. They should also form part of the plans and practices of NHS employers for the continuing professional development of their employees.

Communication skills

11 We are concerned here with attitudes – the frame of mind which the professional brings to the job. The pre-eminent attitude must be that the NHS is a service for the public. The needs of the patients must be the driving concern. This calls for a recognition of the need to establish and maintain good communication with patients and with fellow professionals. It calls for a commitment to respect patients, and to be honest and open towards them. And here, honesty includes the obligation of professionals to be honest with themselves about their abilities. An attitude of public service also calls for the ability to convey uncertainty without fearing that it will appear weak. It calls for retaining and conveying a sense of open-mindedness in the dialogue which is the patient's journey. Perhaps most important of all, it calls for a sense of shared humanity, sympathy, understanding, an ability to engage with the patient on an emotional level, an ability to listen, an ability to assess how much patients wish to know about their condition and treatment, and an ability to convey information with clarity and sympathy. Caring is not just 'what nurses do'. It is what all healthcare professionals should do. In our view, therefore, the attitude of public service which we describe is the essence, the affirmation, of professionalism, not its antithesis.

12 There is already evidence that medical schools are developing their curricula to reflect the importance of personal and interpersonal skills. Largely in response to the General Medical Council's (GMC's) 1993 document, *'Tomorrow's Doctors'*,[6] most courses now include modules on communication skills. Medical schools also recognise that doctors, in addition to acquiring a core of clinical knowledge and skills, must develop attitudes appropriate for professional practice. But the extent to which education in these non-technical, non-clinical areas is integrated into the curricula, and the relative weight given to them, varies considerably. The GMC's reports of recent visits to medical schools[7] demonstrate this. We commend the curriculum of Southampton University's Medical School as one where very great efforts have been made to integrate the education and training in personal and interpersonal skills into all parts of the curriculum.[8]

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[6] We note that, as this Report goes to press, a newer edition of *'Tomorrow's Doctors'* is in preparation. It includes a renewed emphasis on the importance of communication skills in undergraduate medical curricula

[7] See the GMC's website www.gmc-uk.org where these reports are published

[8] We note the considerable emphasis placed on communication skills in the training of GPs, in the course of their professional training, over the past three decades

Education about the principles and organisation of the NHS, about how care is managed, and the skills required for management

13 One of the most surprising features of the current approaches to the education of healthcare professionals, particularly in medical schools, is the relatively low priority accorded to teaching in two areas which are central to a career in the NHS. We refer to an understanding of the NHS, its values and how it operates, and to the way in which the NHS's services are managed. The consequence is that many future healthcare professionals graduate with a lamentably insufficient awareness and understanding of the organisation in which the vast majority will spend their working lives. We welcome the recognition of the problem in *'The NHS Plan'*, in which it is proposed to provide new, joint training across professions in the principles and organisation of the NHS.[9]

14 The importance of such education and training cannot be overstated. An understanding of the values and principles on which the NHS operates has a profound bearing on such intangible but crucial factors as the future professional's sense of belonging and identity. If, for example, a doctor's or a nurse's education is geared to encouraging identification first and foremost with a professional group, the interests of which may not always coincide with those of the wider NHS, the seeds of tension and conflict are sown. If the organisation of the NHS is explained, a signal is given that it is important to the professional's life. By learning about the NHS, future healthcare professionals become aware from the outset that the NHS is a service *both* for the *particular patient* currently needing care, *and* for the *generality of patients*. This opens the way to an understanding of the challenges and dilemmas faced by those who are responsible for running and managing the service for the benefit of all and who, therefore, must serve both patien*t* and patien*ts*.

15 As regards management, it is increasingly the case that healthcare professionals are involved in decisions about the management of services. Indeed, many individuals may take up specifically managerial roles at different points in their careers. But an understanding of management is not just about preparation for a role as a 'manager'. This is because all healthcare professionals are involved in management, in the sense that any patient is exposed to a process of care, which should be a managed process involving professionals working together. Thus, we regard it is as imperative that future healthcare professionals preparing for a career in clinical care, as early as possible in their education, be made aware of what management of healthcare processes and organisations entails, the type of decisions which those specifically designated as managers must make and the skills which management requires. This should include an understanding of the management of resources, and an awareness of the choices to be made in organising and delivering services for people with widely different needs and in greatly different circumstances. To the extent that some healthcare professionals, not least hospital doctors, who are not involved in management in its usual sense, currently continue to view managers with less than outright affection,

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[9] *'The NHS Plan'*. London: Department of Health, 2000. Para 9.18

some education in management could also serve to change the relationship between the two groups.

16 Indeed, we consider that there would be considerable advantage if both medical schools and schools of nursing were to collaborate more closely within and across universities with the various centres of management and policy which teach about the health service and about public sector management. Such collaboration would strengthen the opportunities for those developing careers as healthcare professionals to learn at an early stage about the principles of management and leadership. It would also give those with a non-clinical background who are working towards a qualification in management, the opportunity to gain exposure to some of the clinical and ethical issues which they will subsequently face in a career in health service management. Indeed, after completing their initial education, there should be many more opportunities than at present for managers and clinicians to 'shadow' one another for short periods, to learn about their respective roles and work pressures. This is but one of a number of possible initiatives that should be developed to help to break down the artificial and negative barriers which have grown up between managers and clinicians.

The development of teamwork

17 Healthcare professionals in hospitals have always worked in teams of one sort or another. These teams, however, have tended to be somewhat rigid and hierarchical. Until recently, an example would have been the team called the 'firm' of a particular consultant. With the introduction of what are known as 'care pathways' for patients suffering from certain illnesses, care is increasingly being organised around the needs of the patient, rather than around the institutional arrangements of the hospital, or of a group of professionals. This is undoubtedly the way of the future. Teamwork, therefore, will have to become increasingly more flexible, involving varying groups of professionals from a variety of disciplines and from a variety of specialties and organisations, all working together. And this will be so, as much in hospitals as in community and primary healthcare. All prospective healthcare professionals, therefore, must receive education and training in the meaning of teamwork, how to work effectively in multidisciplinary teams, how to deal with the issues of accountability which arise in teams, and the role of teams in providing healthcare. We owe this both to the professional and the patient. This education and training should not be confined only to the early years of preparation. Issues related to teamwork must also be included in specialist training. We note the comments during Phase One of Sir Barry Jackson, President of the Royal College of Surgeons:

> '… there is teamworking … between different specialties with similar interests for the patient … But the concept of a formalising of that team approach between anaesthetists and surgeons and pathologists and radiologists per se so far as training purposes are concerned, has not been something that has been addressed by my College hitherto, or currently… and it may be that this is something which needs addressing in the future'.[10]

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[10] T28 p. 56 Sir Barry Jackson

A similar point was made by the NHS Confederation in one of its papers to Phase Two: 'Doctors are rarely trained to work in a multidisciplinary manner within a whole system …'.[11] In our view, this is something which must be addressed.

Professionals learning together

18 We have said that one of the most effective ways to foster an understanding about and respect for various professional roles and the value of multi-professional teams is to expose medical and nursing students, other healthcare professionals and managers to shared education and training. We add some further detail here.

19 We believe that the process of shared learning must begin as early as possible. As we have said, the benefits of bringing together undergraduate students from different disciplines to be educated together should be explored with vigour. Our preference, in time, would be to go further. While recognising the challenge it represents, we urge that thought be given to creating an undergraduate first year of entry which is common to all, whatever discipline they may wish ultimately to pursue. In this year, there would be a common core curriculum, aimed not so much at inculcating technical knowledge but at a broader understanding of health, healthcare and the NHS. This would involve the creation of an educational framework in which aspiring healthcare professionals could initially take a range of courses which would equip them to work in the field of health and healthcare, although not necessarily as a nurse or doctor. Thus, students could come to the view that, rather than practise medicine, it is management or nursing or another healthcare profession which they prefer, and thus go on to specialise in courses which are wholly geared to those careers. Equally, a student contemplating nursing may wish to switch to studying medicine. It may immediately be objected that there is such a disparity in the educational qualifications of the various groups of students that it would be impossible to teach them all together. Our reply is simple. They will have to work together later.

20 One enormously beneficial result of this approach would be to engender mutual understanding and respect among those starting out on the road to becoming healthcare professionals. It would help to address the damaging inter-tribal rivalries, which we identify as a weakness in the current culture of the NHS. We recognise that this approach would have significant implications for the organisation of the initial phases of the healthcare professional's education, but we do not think that they are insurmountable. To this end, the Council for the Regulation of Healthcare Professionals (which we referred to in the last chapter and discuss in greater detail later) should make it a priority to promote common curricula and shared learning across the professions. We think, therefore, that the right approach would be to pilot such courses in three or four universities, and to evaluate their impact before any larger scale changes were introduced.

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[11] Seminar 3. The NHS Confederation. Position Paper

21 Throughout professional life there must be more opportunities than exist at present for healthcare professionals to learn and develop together. Some examples undoubtedly already exist, such as the scheme whereby young doctors, about half of whom go on to a hospital career, can spend some of their pre-registration year as house officers working in general practice. But such examples are relatively rare. At the level of specialist training for doctors, while the quality of such training has improved, there is now almost too great an emphasis on expertise in a single specialty. This is too narrow an approach. In their 20s and 30s, many young hospital doctors training to be specialists need to have regular opportunities to train with others in other areas of medicine, and with other healthcare professionals with whom they will share the membership of a team later on. This is equally true of established healthcare professionals for whom, we believe, there should be more opportunities to train and learn together in areas of shared concern. For example, it should be the norm for surgical teams (the surgeon, anaesthetist, theatre nurses, operating department assistants) to have time together, and with other teams such as those in the Intensive Care Unit, to review and develop their performance as a team. We also believe that there should be many more courses within the curricula of continuing professional development which are open to professionals from a variety of disciplines and backgrounds. The days when courses were designed exclusively for doctors, or exclusively for nurses, should be behind us. What matters is that those caring for patients with a particular condition or illness learn and develop their skills together to provide the best possible care for their patients.

Clinical audit and reflective practice

22 Clinical audit, the process whereby healthcare professionals reflect on and improve their and the team's clinical practice is fundamental to improving the quality of care received by patients. The NHS is already committed to the notion that participation in clinical audit will be compulsory. It is essential, therefore, that those entering the healthcare professions are given a good grounding in the basic skills of clinical audit: what it is; how it should be conducted; what is meant by team-based audit; how to understand and interpret data; how to use published material and evidence of effective practice; how to use national standards and guidance; how to understand the nature of error and mistakes; and how to learn from them. We see this as an area that cries out for a common core curriculum for the professions. If we expect multi-professional team-based clinical audit, it makes no sense at all to educate nurses, doctors and other healthcare professionals about clinical audit along separate lines. Equally, those already in practice should be able, as part of their continuing professional development, to gain access to further training in clinical audit, and there must be opportunities for clinical teams, who carry out shared audit, to train together.

Leadership

23 We heard in our Seminars about the characteristics of leadership best suited to the NHS. Arguments were put to us that the NHS needs a more 'transformational' style of leadership, a style which emphasises setting a direction, motivating people and managing significant change. This was contrasted with a more conventional style, referred to as ‘transactional’, which focuses on planning, organising and problem-solving. While it is not for us to adjudicate on the value of one style over another (indeed skills of both types are probably essential for senior managers and for the chief executive of a trust), what matters is that there should be a place within the NHS to consider such questions and to offer advice. The Centre for Leadership, announced in *‘The NHS Plan’*, must be that place. A priority for the Centre should be to offer guidelines as to the leadership styles and practices which are acceptable and are to be encouraged, and those which are not.

24 We have referred earlier to the need for better education in communication and listening, interpersonal skills, and trust and respect for others. These skills are the essence of good leadership. The task of developing them, as we have seen, starts at the very beginning of a healthcare professional’s education. Furthermore, we have pointed to the value of different professional groups developing the necessary skills together. Indeed, in the specific area of leadership training, in developing and funding programmes in leadership skills, the NHS should focus its investment in supporting joint education and multi-professional training open to nurses, doctors, managers and other healthcare professionals. As the NHS Executive told us in one of its papers for Phase Two: ‘It … makes sense for doctors, nurses and managers to learn together about what makes for effective leadership and to do this earlier in their careers’.[12]

25 We emphasise that leaders of the calibre needed by the NHS at all levels do not just emerge. It is also a mistake to expect that those who are skilled in one aspect of healthcare, or those who have risen to a certain level of seniority in their profession, will by that fact alone automatically make good leaders. Leaders must, to a large degree, be made. The skills of leadership can be taught, acquired and developed, although of course individuals will vary in the extent to which they are able to deploy these skills effectively. Thus, given the continuing and pressing need in the NHS for people with leadership skills, we believe that active steps must now be taken to identify and train people within the NHS who have the potential to take on leadership roles. This must not be confused with old-style succession planning: making sure that there is always someone to replace a person in a given post. What we are referring to is a more comprehensive investment in developing the skills and talents of leadership, so that professionals can exercise those skills at whatever level they work within the NHS, be it leading a small clinical team, a larger directorate, or a major trust.

26 Given the need for programmes to develop skills in leadership at all levels of the NHS, an early task for the NHS Leadership Centre must be to take a firm grip on the myriad of existing programmes. It should develop a framework which would better reflect the values and purpose of the NHS. We heard that the many existing leadership schemes include: the NHS Leadership programme; the NHS Nurse Leadership programme; the British Association of Medical Managers (BAMM) Leadership programme for medical managers; the Royal College of Nursing (RCN) Leadership programme; and the NHS Development programme for finance managers. Further, much money is spent by the

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[12] Seminar 4. The NHS Executive. Position Paper

NHS on leadership programmes provided by non-NHS bodies, such as the King's Fund and various business schools. We are not advocating a single leadership programme, or that the NHS should no longer use providers of such programmes who are outside the NHS. Instead, what is needed is some proper assessment of the relative value of the many programmes offered, with a view to deciding which and what to support. Moreover, there clearly must be a greater emphasis on multi-professional programmes. In an NHS which puts the patient first, and seeks to integrate all aspects of care around this goal, the rationale for separate leadership programmes for nurses, for doctors, and for managers, looks increasingly anachronistic.

27 It should be clear that we believe that the NHS Leadership Centre should not be regarded as a luxury. It must receive a proper and sustained level of funding. The Centre should be involved in all stages of the education, training and continuing development of all healthcare professionals. The Centre should invest in developing leadership skills from within the NHS and support those who are already in positions of leadership. This makes sense for the patient. We note the recent publication of a Cabinet Office report on leadership in the public sector. We believe that all our observations on leadership in the NHS are consistent with the key findings of that report.[13]

28 By way of conclusion to this part of the chapter, we also believe that competence in *all* of the non-clinical, non-technical areas which we have identified must be formally assessed, with results counting towards professional qualifications, whether as a doctor, nurse or other healthcare professional. Only in this way will the signal be sent that these are important matters, going to the heart of concern for patients.

The systems for assuring competence

29 Just as we are concerned with the patient's journey, we are also concerned with the journey taken by the person who seeks to be a healthcare professional. At each step in that journey, in the interests of patients and the public, systems must be in place to ensure that the aspiring professional (and subsequently the qualified professional) has and maintains the requisite competence.

30 We turn now to the question of regulation. As we have said, this is a broad term. It is not merely concerned with discipline and poor performance. To be effective in the service of patients, professional regulation should be understood as encapsulating all of the systems which combine to assure the competence of healthcare professionals: education, registration, training, continuing professional development and revalidation, as well as disciplinary matters. It should be concerned to promote good

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[13] The Performance and Innovation Unit of the Cabinet Office. *'Strengthening Leadership in the Public Sector'* (March 2001). www.cabinet-office.gov.uk

practice at all stages of a professional's career. It should include control of access to relevant professions through setting educational standards and ensuring that they are met. It should assure competent performance, through the setting of professional standards. It should require measures such as appraisal, continuing professional development and revalidation. It should also include the capacity to deal with poor performance and misconduct, although if appropriate efforts are made to assure good performance in the course of a professional's working life, the incidence of poor performance requiring some form of disciplinary action should be significantly reduced. There are clear indications that the body which currently regulates some aspects of a doctor's career, the GMC, is moving towards this notion of regulation as a more comprehensive and active process. The proposals to reform the regulation of nurses and midwives, and the regulation of the professions allied to medicine are also moving in this direction.[14] In addition, we do not overlook the role of the employer-employee relationship in the overall framework of regulation: it must complement other mechanisms of regulation by fostering good performance. Thus, the employer should have in place systems and resources to enable and support healthcare professionals to maintain and develop their competence, as well as systems to identify and act on failing or poor performance as early as possible.

31 In the paragraphs which follow we consider in greater detail the systems for assuring competence. We do so against the background of the need which we have identified to create an independent council for the regulation of healthcare professionals, at arm's-length from government. The task of this council will be to co-ordinate and integrate in the interests of patients the activities of the various bodies currently involved in what we call Professional Regulation. We will return to this overarching professional regulatory body once we have examined the various elements which together constitute professional regulation. We start with the system which applies at the outset of professional life when young people are first selected to be educated as healthcare professionals, and later we look at the systems in place to assure competence during a professional's working life.

The selection of future healthcare professionals

32 If the future healthcare professional, to be adjudged competent, must, in addition to technical and clinical skills, be able to display appropriate attitudes and competence in such areas as communication, the question inevitably arises as to the criteria for selecting those who are to become healthcare professionals. Are the criteria sufficiently broad to take account of the need for the full range of qualities and attributes which patients are entitled to expect? Is there a system for ensuring that the criteria are applied? Of course, much can be done in shaping the future healthcare professional by improving the undergraduate curricula. But this alone will not be sufficient. The task begins at an earlier stage: the attributes, attitudes and skills which form the criteria for initial selection also need to be appropriately broadly based.

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[14] See: *'The New Nursing and Midwifery Council: A consultation document'*, August 2000. www.doh.gov.uk/nmconsult; and *'Establishing the New Health Professions Council'*, April 2001. www.doh.gov.uk/hpcorder

We concentrate on entry to medical school. But the points we make apply to aspiring entrants to all healthcare professions.

33 We heard during Phase Two of the Inquiry that selection for medical school has been criticised for its superficiality. It is generally based on the information contained in a university application form and on an interview which, where it takes place, in some cases lasts no more than 15 minutes. Heavy reliance is placed on high academic achievement, in particular on achieving top A level grades in scientific subjects. We heard that, in the past, medical schools have also been accused of elitism, a lack of fairness and transparency in the process of selection, and of not selecting from a diverse range of social and ethnic backgrounds. Moreover, and remarkably since the NHS both contributes a substantial amount of the funding of the education and employs most graduates, the selection process is conducted with very little input from the wider NHS or from the public.

34 There is some evidence that the GMC's guidance to medical schools *'Tomorrow's Doctors'*, published in 1993, has begun to influence selection. Medical schools are beginning to take account of the applicants' personal qualities, interests, communication skills and relevant work experience in an attempt to select those who have the potential to be versatile, flexible and sensitive professionals. This is only a beginning. And, to the extent that many medical schools would say that they have done this for years, a somewhat greater commitment may be called for. We note that the GMC is in the process of revising *'Tomorrow's Doctors'* so that it incorporates the GMC's thinking about the qualities of a good doctor, as set down in *'Good Medical Practice'*. *'Good Medical Practice'* is a sensitive account of the duties and qualities of a doctor and crucially espouses a patient-centred approach to healthcare. Thus to match the attributes of a 'good doctor' with those of young people seeking admission to medical school is a significant development – in the past, to the extent there has been any such match, it has been coincidental.

35 There is also evidence, at the margins, of diversification of routes into medical education. There is at least one successful 'access' course for nurses and other healthcare professionals to prepare for entry to medical school. A small number of medical schools, including two which have recently been established, encourage, or intend to encourage, applications from those currently working in other healthcare professions. Some medical schools, such as that at Newcastle University, are seeking to widen access to medical education by reintroducing a pre-medical programme for those who do not possess a predominantly scientific background. Others, such as Guy's, King's and St Thomas's School of Medicine in London, have developed a scheme to target and give special access to students from local schools who would not normally either consider applying, or be considered qualified to apply, to medical school.[15]

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[15] See *'Performance Indicators in higher education. Higher Education Funding Council'*. HEFC 00/40. 1998/99. www.hefce.ac.uk
For example, whereas 25% of all young full-time first degree entrants in 1998/99 came from Social Class III, IV or V, the equivalent figures for the group including medical students was only 12%

36 We regard this diversification as important. We need to guard against future generations of doctors and other healthcare professionals being drawn from too narrow an academic and socio-economic base. Patients want doctors to be clinically competent, and thus doctors must be able to understand scientific method and principles. But, as we have said, this is not all that being a doctor entails. An understanding of science may be a necessary condition for entry to medical school, but it cannot be sufficient. The future doctor must also have demonstrated other qualities, not least a capacity to be open-minded, comfortable with uncertainty, free of preconceived views and capable of recognising and responding to ethical issues.

37 We heard arguments during our Seminars that it would be desirable to make medical education an entirely postgraduate course of study. Postgraduate entry, it was suggested, would ensure that the student would be more mature, more widely educated, and more likely to have chosen to study medicine after careful reflection, something that may not be true of applicants who are still in their teens. Leaving aside the financial implications of such a change (on which we heard no evidence and thus make no comment), we are not persuaded that a wholesale move to a graduate-only entry is justified. What is important is not the age at which the student begins, but what the student has previously studied and been exposed to, the criteria guiding selection, and the way in which the curriculum is thereafter organised and delivered.[16]

38 We referred earlier to the GMC's publication *'Tomorrow's Doctors'*. Although the GMC has a statutory responsibility for the standards of undergraduate medical education, entry to medical school is governed by the regulations of the particular university, which is an autonomous body. The GMC states that it seeks to influence the criteria for selection through the Council of Heads of UK Medical Schools. The Council for its part has indicated that the attributes they seek in applicants to medical school are similar to those set out in *'Tomorrow's Doctors'*. But we have not seen evidence to convince us that such indications are systematically being translated into practice. The current state of affairs is far from satisfactory. There is no formal means whereby medical schools can be required to follow the GMC's or any other body's advice. We take the view that the criteria for the selection of entrants to medical school are a matter for discussion and agreement in a community wider than the individual university's medical school and the GMC. At the very least the public and the NHS should be involved.

39 The selection of those who wish to become nurses has equally been subject to re-examination recently. Nurses are selected for pre-registration programmes by reference to the UKCC's baseline entry criteria. The institutions of higher education which provide these programmes may impose their own criteria, but these can only be more, not less, demanding than those required by the UKCC. The Royal College of Nursing told us that it supports the philosophy of widening access to nursing education programmes. It advocates an openness towards older applicants and an

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[16] We note that a number of medical schools have introduced courses that admit graduates in non-medical subjects to a course which enables them to qualify as doctors in four years instead of five

acknowledgement of 'existing life skills' when considering applications. There is also support for a process of interview and selection which is not only transparent, but also includes representatives from the universities and from the prospective employers, the NHS trusts. The logic behind this approach is one of 'joint ownership' of student nurses, paving the way for support for students throughout the three-year pre-registration programme and into employment as qualified nurses.[17] We add our support to this approach and point out that it is compatible with, indeed it can be dovetailed into, the approach to multidisciplinary education to which we referred earlier.

Postgraduate medical training

40 Historically, for doctors, the GMC has set the outline of the curriculum for undergraduate medical education. Medical schools have then stipulated, by virtue of students' having passed the required examinations, that they were sufficiently competent to be registered as medical practitioners. Responsibility for the organisation of the next stage, the training of specialists and GPs, rests with the various postgraduate deans. Their job is to ensure that the training complies with the requirements laid down by the various Royal Colleges. Thus, ultimately responsibility lies with the Royal Colleges. This responsibility in relation to hospital doctors includes, among other things, setting the curricula and examinations to qualify as a specialist, and visiting individual trusts as part of a process to accredit them as suitable for the training of specialists. Postgraduate medical training is specific to doctors, as being a necessary prerequisite to being appointed to a career (specialist) post, although, of course, further training is also required of nurses and others before they may take up certain specialist positions.

41 Clearly the patient is entitled to expect that the Royal Colleges, in carrying out their responsibilities for the supervision of postgraduate training, will place the wellbeing of the patient at the centre of their concerns. In this way the public can be confident that the system for assuring professional competence is secure.

42 The evidence which we heard about the BRI in Bristol suggested that, in the past at least, this was not always the case. Visits to inspect the BRI as suitable for training purposes were sometimes less than rigorously conducted.[18] Moreover, the relationship between approval as a training hospital and the consequent ability of the hospital to attract staff and provide a service, meant that decisions on training took on a significance which went much further than issues of training. If approval was withheld, a hospital could not attract junior staff. The service provided, therefore, either had to be curtailed (rarely seen as an available option), or offered with overstretched staff. This latter consequence is what happened as regards paediatric cardiology in Bristol. In general terms, the likely impact of withdrawing training recognition was all too evident to visiting inspectors from the Royal Colleges, but they faced a genuine dilemma. It is not hard to imagine circumstances in which approval

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[17] Seminar 5. The Royal College of Nursing. Position Paper

[18] See Section One, Chapter 16

of a hospital for training purposes was as much driven, for good reasons, by the idea of maintaining the viability of a service as by the need to guard standards of training on the public's behalf.

43 We are not persuaded that to leave the crucial task of approving and supervising postgraduate medical training to the Royal Colleges alone is in the public interest. We believe that to obtain and maintain public confidence, ways must be found to involve others in the process, through some appropriate body. We note the proposal in para 8.28 of *'The NHS Plan'* to create a Medical Education Standards Board (MESB). The aim is to replace the existing, somewhat fragmented and, as has been suggested, less than ideal system, and to provide a co-ordinated, coherent, robust and accountable approach to postgraduate medical education (which we take to mean training). We believe that this is the right way forward. Crucially, the new Board will include members from the NHS and the public, as well as from the Royal Colleges. The Royal Colleges do have a legitimate role and one which perhaps only they can carry out, in assessing elements of professional competence. But the force of the proposal is that they should be brought into a larger and more accountable system. We agree. We agree further with the principle stated in *'The NHS Plan'* that the Board's task will be to 'ensure that patient interests and the service needs of the NHS are fully aligned with the development of the curriculum and approval of training programmes'.[19]

44 The MESB, although an important and welcome development, will, despite the Board's title, touch on only one element of the continuum that comprises a doctor's education, training and professional development, namely, the training element. Supervision of undergraduate medical education, as we have said, is a matter for the GMC and the universities. Supervision of continuing professional development for doctors, as we shall see, is shared between the Royal Colleges and the employer. This degree of fragmentation does not serve doctors well; it makes it difficult to ensure that the principles of good medical practice are embedded into all aspects of a professional's lifelong education. Such fragmentation also makes it difficult to introduce changes which apply to all doctors currently in practice, and not just the newly qualified. For this reason, we support greater co-ordination of all the activities which make up the continuum of doctors' education, training and development. The GMC is probably best placed to do this, with its responsibility to ensure that doctors meet generic standards of professional practice throughout their working life. By taking the lead in co-ordinating these efforts, the GMC could ensure that expertise is shared, and crucially, help to ensure that all the policies on training of the various bodies are in alignment and capable of adjustment to meet the changing demands that society places upon doctors. It follows that the MESB should be a subgroup of and report to the GMC.

45 Just as there is a case for vertical integration of responsibility for the components of a doctor's lifelong education, the same case, we believe, applies to nurses and midwives, and to the professions allied to medicine. In each case there should be one

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[19] *'The NHS Plan'*. London: Department of Health, 2000. Para 8.28

body charged with oversight of all aspects of education, training and professional development, to ensure that the respective components are appropriately integrated.

46 So far, we have addressed the need for proper systems for each of the respective groups of healthcare professionals. It is crucial now to point to the fact that there is no single body which stands above the detail to provide consistency and overarching strategic direction for all professional groups. The Government has announced its intention, in *'The NHS Plan'* (para 10.15), to establish a UK Council of Health Regulators. The Council's role, on which we comment more in detail later, will be to help to co-ordinate activities and to act as a forum in which common approaches across the professions could be developed. Developing common approaches to education, training and development should be one of its priority areas. This is a particularly necessary and relevant role for the future of the NHS, as the boundaries between the various professions in a number of respects have started to merge and to overlap. It would also provide leadership and direction for the implementation of the common themes for education and training which we referred to earlier.

47 So far, we have considered the initial education and training of healthcare professionals. But assuring competence does not stop there. Other systems are needed to help to assure their competence at other points in their careers, and to ensure that the interests of patients and the needs of the NHS are taken into account.

Maintaining professional competence during a working life

48 The arrangements to ensure that healthcare professionals maintain and develop their competence whilst working in the NHS are currently fragmentary and apply differentially to the various groups of professionals. As far as professional requirements are concerned, for some healthcare professionals, for example nurses, the pursuit of continuing professional development has long been required as a condition of continued practice. It may be thought surprising, however, that as we write this Report this is not so in the case of hospital consultants. Once they have acquired the necessary qualification, they can currently practice for life without any formal requirement to undergo any further professional development as a condition of continuing practice. Schemes do exist in some of the Royal Colleges. But currently, as an indication of the fragmented approach we referred to earlier, whether professional development is required by the College of a doctor depends on the relevant Royal College. For instance for members of the Royal College of Surgeons and the Royal College of GPs, it is compulsory. For members of the Royal College of Paediatrics and Child Health and the Royal College of Physicians, although continuing professional development (CPD) is expected, it is not compulsory. But whether or not the College requires CPD affects only the relationship between the doctor and the College. It currently has no wider implication for working in the NHS. A number of proposals and indeed changes have been made, particularly since this Inquiry was set up. But it is important to remember that it remains a matter for individual doctors whether and how they maintain their skills and knowledge during a working life of 30 or more years. Patients have no assurance that the doctor they see has the appropriate level of knowledge and skill. This cannot continue.

49 It does not require much reflection to see that *from the patient's point of view* this state of affairs is unsatisfactory. Of course, in practice, the vast majority of consultants are constantly developing their skills and knowledge, but the patient's wellbeing should not depend solely on the individual hospital doctor's motivation. It is not enough to argue, as has been the case in the past, that the hospital doctors can be left to recognise their own needs and limitations. Furthermore, it is very often those who do not feel the need to submit themselves to further development and training, who, in the absence of some formal system, may pose the greatest threat.

50 Similar issues arise as regards the system of appraisal. Whereas it has been commonplace for nurses and for junior hospital doctors to undergo annual appraisal, it has not been so for hospital consultants. Only now, in the middle of 2001, for the first time, is a system of appraisal for consultants being introduced. Many consultants have never undergone an appraisal in their working lives. Furthermore, in the case of GPs since technically they are independent contractors and have no employer, no system of appraisal for them has been developed. Without regular appraisal, the NHS has no formal means of assisting systematically with professional development nor any means of monitoring an individual professional's performance.

51 It is important to note that some of the shortcomings we point to are widely acknowledged, by the Government and by the GMC, and that, for example, important changes concerning appraisal and revalidation are under discussion. We believe that the formal systems and resources to support professionals in maintaining their competence need to be part of a comprehensive framework whereby the NHS *and* all the healthcare professions, jointly, embrace three separate but interconnected practices: *continuing professional development, periodic appraisal* and *revalidation.*[20] These three activities are not, and must not be seen as, oppressive activities, as just another burden on healthcare professionals. Nor should they be seen as activities from which one or other professional group is wholly or partly exempt. Rather, as most healthcare professionals now recognise, participating in CPD, appraisal and revalidation represents the affirmation of their professional status: that they are willing to keep themselves professionally fit on behalf of patients, and that they are accountable for so doing. Historically, compared with nurses and GPs, hospital doctors have been slow to develop systems to assure competence during working life. That has started to change, but in the interests of patients, the pace of change must quicken. In what follows, therefore, we use the specific example of hospital doctors, but the general points we make apply equally to all the healthcare professions.

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[20] Revalidation, in general terms, is a mechanism whereby healthcare professionals are required regularly to demonstrate to external assessors that they remain fit to practise, and thus are entitled to continue to be registered or recognised as a doctor, nurse or other healthcare professional

Continuing professional development (CPD)

52 CPD must be part of a process of lifelong learning for all healthcare professionals. Its purpose is to help professionals to care for patients. A secondary purpose, but one which must not be ignored, is to help professionals to be fulfilled in their work. It is crucial that CPD is supported by both the NHS and the professions. Within the NHS, CPD must be underpinned by a commitment to make available the necessary resources in terms of time, funding and assistance with career development. The contract between the trust and the healthcare professional should provide for the funding of CPD and should stipulate the time which the trust will make available. The incentives, in other words, must be in place. The culture of the workplace has to be one which values learning and acknowledges the benefits it will bring for the organisation as a whole, particularly as it affects patients.

53 CPD is not just a case of attending courses and conferences, albeit that these have their place. There should equally be a strong element of professional development within the workplace, since this is where skills and competence are put to the test. 'Shadowing' the work of others, visits to centres of excellence, having a 'mentor' and undertaking clinical and professional supervision are amongst the strategies which can be used as part of work-based professional development. Moreover, if doctors, nurses and others must keep up to date with developments, knowledge about developments must be readily accessible. This, in turn, means access to information technology and the skills to use it. This may well call for training and funding for which employers will need to make provision.

54 Clearly, allocating sufficient time and resources to CPD in a planned and organised manner is of crucial importance for all healthcare professionals. They are equally important to those who manage hospitals. When staff shortages are common and all resources are stretched, there is a constant temptation to limit in one way or another the ability of professionals to take time to study and train. It was put to us by the Royal College of Surgeons, for example, that the methods employed by surgeons for maintaining standards range from traditional lectures and practical skills training in a laboratory to a proposed process of external peer review as part of revalidation. However, they pointed out that there are financial considerations for all forms of CPD. Anatomical workshop sessions are particularly expensive and this can limit the opportunities for trainees to participate.[21] We welcome the fact that, since April 2000, all trusts have been required to have in place a training and development plan. Such plans seek to ensure that the resources devoted to continuing professional development meet the needs of patients as well as the aspirations of individual professionals. We believe that such plans must be backed with sufficient resources. CPD, as well as being good for patients, provides an incentive for professionals and thereby helps to attract and retain highly motivated individuals.

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[21] Seminar 5. Royal College of Surgeons of England. Position Paper

Appraisal

55 Appraisal is a common feature in most large organisations. The annual appraisal of all healthcare professionals should, in our view, be the norm. For most, it is. For hospital consultants and general practitioners, however, it is the exception. This must change. We are pleased to note from *'The NHS Plan'*[22] that the Government has agreed in principle with the British Medical Association (BMA) that annual appraisal and effective job plans will be made compulsory in the new consultants' contract. We believe this commitment must be kept and be implemented in full as soon as possible.

56 We see annual appraisals as an essential part of an overall strategy aimed at maintaining competence and thereby securing safe care and improving the quality of care in hospitals. The obligation to participate in appraisal is of such importance that we take the view that it should apply to all NHS employees and be incorporated into employment contracts, including, as we have said, consultants' contracts with the trust. Indeed, we regard appraisal as sufficiently important that it should extend to GPs and a requirement to undergo periodic appraisal should therefore be incorporated into the terms of service of GPs' contracts with the NHS. Some doctors have expressed concern at what they see as a mechanism for judging or even victimising them. But this is to misunderstand the exercise. Appraisal itself is a neutral activity: what matters is the principle on which the appraisal proceeds. We believe that appraisal in the NHS should be constructive and facilitative, with a particular emphasis on what the employer can do to enable healthcare professionals to do their job well and to fulfil themselves in the workplace. For this reason, it is vital to distinguish between appraisal and revalidation. They are separate exercises with different purposes, even though appraisal may well inform the process of revalidation. Appraisal should focus on past performance, on the maintenance and development of skills as they touch on competence, and on job fulfilment. Revalidation, by contrast, is concerned with ensuring that the appropriate levels of skill necessary for continued competence have been and are maintained.

Revalidation

57 Revalidation in general terms is a mechanism whereby healthcare professionals are required regularly (for example every three or five years) to demonstrate that they remain fit to practise. It involves the submission of evidence to external assessors of continuing competence. In the case of the system proposed for doctors, it is linked to registration in that, if they cannot demonstrate evidence of continuing competence, their registration, and thus their right to practise as doctors, may be called into question and, ultimately, may be withdrawn. A form of revalidation already exists for nurses and for many of the professions allied to medicine. In fact, the practice in the case of nursing is closer to re-registration and is not the same as the revalidation process proposed for doctors. Essentially, every three years, nurses have to submit evidence of the CPD that they have undertaken in order to maintain their registration. There do not appear to be arrangements whereby the individuals are visited in the

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[22] *'The NHS Plan'*. London: Department of Health, 2000. Para 8.21

workplace by a group of assessors. We take the view that external assessment is a very important feature of the process and that methods should be devised to implement it in the case of nurses and others. In the case of senior healthcare managers, no system of registration or formal recognition currently exists. It would need to be developed alongside the introduction of revalidation for other healthcare professionals. We acknowledge that proposals for a system of revalidation for doctors are at an advanced stage of development. Thus we make our comments about the need for the revalidation of healthcare professionals, aware that the potential value of this mechanism is already coming to be widely recognised, by the public, as well as within most of the professions.

58 The call for the revalidation of healthcare professionals marks a significant break with the past. Until very recently, at least in the case of medicine, it was regarded as a sufficient assurance of competence that young, newly qualified healthcare professionals had passed the relevant examinations, and had received guidance and support from more senior colleagues. Thereafter, throughout the whole of their working life, there were no mechanisms, whether within or outside the professions, whether from employers or bodies concerned with registration and discipline, to assess and check a professional's competence. Of course, most professionals developed and improved their competence through experience. And, many have seen it as part of their professional duty to undertake continuing professional development. This is still the case today. For some, however, competence did (and does) not grow with experience. Others did (and do) not pay much attention to continuing professional development. And others tried their best but their competence diminished with time. Remarkably, there was no system in place to spot waning competence, to support these professionals and to protect patients. Only when things went dramatically wrong was action taken, and then, too often, it was too late for the patient and the professional. Thankfully, this state of affairs has been recognised as unacceptable. Both government and the various professional bodies have begun to develop systems of retraining and revalidation, whereby any shortcomings in a professional's competence can be identified and addressed at a much earlier stage than would have been the case in the past.[23]

59 We believe that regular revalidation must be mandatory for all healthcare professionals, and that a requirement to undergo revalidation should be incorporated into the contract of employment between the professional and the relevant body within the NHS. Every effort must be made to develop and implement systems of revalidation as soon as possible. We recognise that some current proposals do not have the wholehearted support of some healthcare professionals. We do not see this as a reason for delay, far less for not proceeding. The public is entitled to this form of protection. Revalidation will assure the public that the doctor, nurse or other healthcare professional caring for them meets agreed levels of competence. Healthcare professionals will benefit also. Revalidation offers them the opportunity to address any shortcomings that they may have in an environment of learning and

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[23] The GMC's performance assessment procedures, introduced in 1995, represented a first tentative step albeit limited, in that it is a system which is reactive and insists upon performance being 'seriously deficient'. See www.gmc-uk.org

support, rather than in a context of sanction and blame. It also offers healthcare professionals some protection against unfounded criticism of their professional competence. We find very helpful the observations made by Professor Darzi (Professor of Surgery at Imperial College School of Medicine) and colleagues in relation to the skills of surgeons:

> ‘A specific and sensitive test of operative competence could also detect important problems and might improve surgical outcome. Revealing underperformance early would allow for further training or career guidance towards other less practical specialties. The surgical profession needs a reliable and valid method of assessing the operative skill of its members. A driving test may not be a guarantee against accidents but it makes it less likely that you career off the road. Surgeons, the public, and politicians need reassurance.’[24]

60 We do not comment on detailed aspects of current proposals of the GMC. There are, however, two important issues to which we must draw attention. Revalidation, as one of its aims, offers protection to the public. For it to gain and retain public trust and confidence, it cannot be a mechanism which is entirely controlled by the professions themselves. We believe that there must be some external perspective in the periodic review of a healthcare professional, that is, a person or organisation external to the professional’s own profession and external to the employer. We do not contemplate that this external involvement should take the form of a ‘patient’s representative’. Indeed, we doubt the existence of such a generic entity. Rather, it should be someone with an understanding of the public interest. To the extent that the person’s view may be informed by the views of patients, so much the better. We note that the GMC is conducting research into how they might capture the views and experiences of a range of patients for use in a doctor’s revalidation. We commend this approach. It should, however, be in addition to, and not in place of, an external presence on the revalidating team.

61 Our second point relates to the wider context in which revalidation of healthcare professionals is conducted. Currently, each of the healthcare professions, to the extent that they are establishing a system of revalidation, are doing so on their own. Thus, for example, a system for doctors is being developed by the GMC; a system for nurses, developed by the UKCC, is already in place; and each of the professions allied to medicine have their own requirements for regular re-registration of their members. As we have said, no system currently exists for senior managers. No single body is responsible for ensuring that these various systems are sufficiently rigorous and robust to protect the public. There is no mechanism of review to consider whether the systems are consistent and aligned. There is no mechanism for ensuring that the systems for revalidation of healthcare professionals are integrated into other initiatives for protecting patients, such as the inspection by the Commission for Health Improvement (CHI) of NHS trusts, or the publication of national data on clinical outcomes. This is in the tradition of the ad hoc, fragmented approach which has

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[24] Darzi A, Smith S, Taffinder N. ‘Assessing operative skill’. Editorial: *‘BMJ’* 3 April1999; **318**:887–8. See also Smith SG et al. ‘Objective assessment of surgical dexterity using simulators’. *‘Hosp Med’* 1999; **60(9)**:672–5

characterised the management of the NHS for too long. It is not in the interests of patients. There must be an overarching mechanism to co-ordinate these many systems to ensure that they are properly aligned, and capable of protecting patients. This should be a further priority for the Council for the Regulation of Healthcare Professionals.

Managers

62 Clearly those formally designated as managers, whatever their background, must be prepared adequately for management roles within the NHS. Moreover, they must also be required to participate in continuing professional development, appraisal and revalidation on a basis similar to that proposed for other healthcare professionals. Just as with other healthcare professionals, these obligations should be incorporated into the contract between the manager and the trust. We recognise that currently, while the appraisal of managers is common, CPD and revalidation are significantly underdeveloped. We would expect to see the Council for the Regulation of Healthcare Professionals, together with organisations such as the Institute of Healthcare Management and the British Association of Medical Managers, collaborating to draw up proposals as a matter of urgency. It is inappropriate that one group of healthcare professionals should be excluded from this process of maintaining competence. We note here the strong support for this idea expressed by the Institute for Healthcare Management in a paper for Phase Two:

> '… this Institute believes that managers should be subject to the same constraints and regulations on behaviour as those imposed by clinicians' professional bodies. … The Institute is exploring whether a Code of Professional Conduct should become part of an IHM "fitness to practice" certificate incorporating initial management training, adherence to the Code and evidence of CPD.'[25]

Clinicians who hold managerial positions

63 The events in Bristol teach us that when clinicians hold positions with formal managerial responsibilities, such responsibilities cannot properly be undertaken in the clinician's spare time. Where clinicians take on too many managerial roles in an unstructured way it is not good for patients and not good for the service which the clinicians are supposed to manage. Bristol also teaches us that management cannot properly be undertaken by clinicians who do not have the requisite skills in leadership and management. We heard during Phase Two that there continues to be a tendency to appoint the most senior consultant to the role of clinician-manager, even though seniority clearly does not necessarily guarantee managerial ability. This is not to suggest in any way that clinicians should not move into managerial roles on either a part-time or a full-time basis, nor to say that they should become disengaged from the issues of managing trusts and the NHS. On the contrary. We believe that the Griffiths Report (1983)[26] was right in advocating a much greater involvement of clinicians in management. The problem has been the implementation of this philosophy. We

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[25] Seminar 5. Institute for Healthcare Management. Position Paper

[26] Griffiths R. *'NHS Management Inquiry'*. DHSS, 1983

discovered that the situation of clinician-managers in Bristol, where they lacked time and support for their managerial roles, was commonplace at the time, and that it still persists today, despite incremental improvements to protect more time for managerial duties. We also discovered that there was nothing unusual about the practice of senior clinicians taking turns to hold managerial roles. For the future, however, where a clinician holds managerial responsibilities which go beyond immediate clinical practice, sufficient time in the form of allocated sessions must be made available and protected to enable the clinician to carry out that role. Furthermore, the clinician, before appointment to a managerial role, must have the essential skills to undertake that role, with access to training and support made available by the trust. In the hospital sector, this applies particularly but not exclusively to the role of clinical director and to other roles where the individual is expected to be part clinician and part manager. The roles of medical director and director of nursing are now, for the most part, full-time posts.

64 Not only do we endorse the views expressed in the Griffiths Report, we would go further. We believe that there should be positive incentives to encourage senior clinicians to take on senior managerial roles. These incentives should be professional as well as financial. A significant barrier to this at present is the difficulty of returning to full-time clinical practice having once become involved in management. One way in which clinicians holding senior managerial posts currently attempt to resolve this problem is by maintaining some modest involvement in clinical practice of perhaps one or two sessions per week. We see a real dilemma here. Many clinicians who hold managerial roles understandably may wish to return to full-time clinical practice, which is their vocation. Thus, they wish to maintain their clinical skills. But, from the patient's point of view this may not be satisfactory. The safety and quality of clinical practice may be compromised by the fact that the clinician's modest involvement is simply not enough to maintain the necessary clinical skills. This is not a matter on which we can be prescriptive, because safe levels of clinical practice will vary according to clinical specialty. Our aim is to point out the possible negative consequences for the patient. We believe that experts in each specialty, together with managers from the NHS, should consider this matter with a view to setting down the minimum level of regular clinical practice necessary to enable a clinician to provide care of a good quality. Clinicians not maintaining this level of practice should not be entitled to offer clinical care. This rule should also apply to all other clinicians who, for whatever reason, are not in full-time practice, and not be limited to those in part-time managerial roles. Attention should also be given to creating incentives so that clinicians who are sufficiently skilled and motivated to become managers are able to do so while retaining a prospect of returning to clinical practice. This should include incentives such as training and support whilst in the managerial role, and training and assistance to return to a clinical role subsequently, should the clinician so wish. The proposed system of revalidation for doctors, and the re-registration systems of other healthcare professionals, need to be sufficiently flexible to allow for these movements out of and back into clinical practice. Perhaps one way of enabling this would be to have special categories of professional registration which are for clinicians who are currently serving as managers, as indeed there might be categories for clinicians undertaking other types of non-clinical work.

Acquiring and developing new skills to an appropriate level of competence

65 We turn now to an issue which was a central feature of the Bristol story: how is a healthcare professional to acquire competence in a new clinical activity so as to enhance skills while at the same time safeguarding the interests of patients? Given its prominence in the Bristol story we concentrate on surgery. What we say, however, is not limited to surgery, but applies to any circumstance in which the healthcare professional proposes to carry out a clinical procedure with which he is unfamiliar and which, by its nature, exposes the patient to a risk of significant harm.[27] The issue we refer to is sometimes characterised as the problem of 'the learning curve'. The implication of this expression is that, as regards carrying out new procedures, competence is acquired gradually: that there is an upward gradient of success, with, and this is crucial, an implicit assumption that failure initially is inevitable and, by that token, justifiable. The common example is the surgeon attempting a new procedure, but this issue applies equally to any doctor or nurse who embarks on a new procedure, wherever it is performed on the patient (hospital, GP practice or other clinic). There are, in fact, at least three different sets of circumstances which require consideration:

- the procedure is known and already carried out in the trust, but the particular healthcare professional is performing it for the first time;
- the procedure is known, but is being done for the first time in the trust; and
- the procedure is being done for the first time anywhere.

66 From a patient's point of view, there is a paradox. Innovations are desirable and should be introduced, but they should be tried out on someone else first! Three guiding principles may offer a way around the paradox. The first is the need for supervision; the second is the need for openness and honesty with the patient; the third is the need for an agreed and established system within the hospital for managing innovation.

Supervision

67 If a procedure has already been carried out in the trust, it is both possible and, indeed, essential, that the surgeon carrying out the procedure for the first time should be suitably trained and be directly supervised by colleagues who have the necessary competence and proficiency, until the relevant degree of expertise has been acquired; that is, the patient is not exposed to a risk greater than the norm.[28] If the procedure is

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[27] There is a difference between a planned departure from current surgical practice, and doing something which could not be planned but is a response to a situation which arises. The latter is not included within our definition of innovation. We are concerned instead with the circumstances in which the doctor decides *in advance* to innovate

[28] For an example of 'a surgical teaching initiative' which 'had a major effect on … outcomes' see Lehander Martling A et al. 'Effect of a surgical training programme on outcome of rectal cancer in the County of Stockholm'. *'Lancet'*, 2000; **356**: 94–6

one which has not previously been performed in the trust, the surgeon carrying it out must have obtained appropriate training in a place where expertise in the procedure is established. He must further ensure that, initially, he is supervised within his own trust by someone who has the necessary expertise. This is the process which Sir Barry Jackson, President of the Royal College of Surgeons of England, described in Phase One as mentoring. We see a further role for the Royal College of Surgeons. It already has a unit for the training of surgeons. With appropriate assistance from the NHS, this unit should be developed to provide training in new technologies and procedures. It should also explore the question of whether there is an age beyond which surgeons, specifically in areas such as paediatric cardiac surgery, should not attempt new procedures or even should not continue in a particular field of surgery.

68 If a procedure is being carried out for the first time anywhere, a distinction should be drawn between undertaking a variation of an existing procedure and carrying out a genuinely new innovation. Of course, these are not polar opposites: any particular procedure may lie somewhere along a spectrum. In our view, when any new and hitherto untried invasive clinical procedure is attempted, the surgeon concerned should inform the trust's or the local research ethics committee.[29] The committee, the composition of which may need to be re-formed so as to consider such matters, will need to be satisfied that the surgeon has undertaken all necessary preparation (for instance, through the use of simulation). The committee will then decide where, along the spectrum of innovation, the proposed procedure lies, and on what matters it needs to be satisfied. It may be objected that this approach is unnecessarily burdensome and will hamper innovation. We make two observations. Healthcare professionals intending to introduce innovations in other areas of diagnosis or drug treatment are expected and expect to seek the approval of the local research ethics committee before embarking on what is, in effect, an experiment.[30] We see no reason why new surgical treatments should be treated differently. Secondly, there is intrinsic value in the act of making an application to the local research ethics committee. The applicant (the surgeon in our case) will have to set down the arguments and reasons for proceeding. This will cause reflection on a wide range of matters, not least the interests of patients, before embarking on any innovation. We accept that surgeons, undoubtedly, already go through a process of reflection. Some surgeons may object that, to go a step further and present a proposal to the local research ethics committee, is unwieldy and bureaucratic. However, to the patient it is a desirable, indeed necessary, safeguard.[31] The lesson of Bristol is that when it comes to innovation it may not always be enough to leave the decision to the professional. Some system of reflection and accountability is essential.

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[29] It may be that only complex procedures should attract this requirement. This is a matter properly for consultation

[30] We acknowledge that a considerable amount of standard practice is on one level experimental since its efficacy has not been demonstrated, but we do not see this as a reason for dispensing with the need to demonstrate efficacy and competence in new procedures. See Chalmers I, Lindley R. 'Double Standards on Informed Consent to Treatment', which appears in *'Informed consent in medical research: respecting patients' rights in research and practice'*. Tobias J. (Ed). London: BMJ Books, 2000

[31] See de Leval M. 'Lessons from the arterial-switch operation.' *'Lancet'*. Vol 357, 9 June 2001. Professor de Leval writes that the 'dilemma of scientific progress and clinical application of new treatments must be addressed by society at large.'

Openness

69 A further safeguard for patients is the requirement that the surgeon be open and honest with them, or, in the case of children, with their parents. Patients are entitled to know what experience the surgeon has, how experimental or innovative a procedure is, and that this may be the first occasion on which the surgeon has carried out the procedure. This knowledge is essential if patients' consent to treatment is to be valid. Conversely, not to inform patients about a matter of such significance in terms of their healthcare is a violation of their rights. Furthermore, it is not open to surgeons to say that they would not be able to innovate if the patient always had to agree. This is to put the surgeon's desire to innovate above the patient's right to choose. It also fails to acknowledge the willingness of patients to participate actively in the development of medical care, provided their interests are respected.

Managing innovation

70 Trusts should have a system in place to manage innovation. Such as system should recognise the need for training and ensure that it is made available; it should ensure the involvement of the research ethics committee and see that local protocols reflect the need for openness and real consent from the patient. Clearly, there must be someone within the trust whose task it is to see that a system is in place and it is observed. This responsibility should rest ultimately with the chief executive, since, in our view, it is part of the statutory responsibility for quality of care.

Disciplinary action

71 We now come to the final element in the process of the regulation of healthcare professionals. If it begins with regulating entry into the profession, it ends, for some, in disciplinary action because of poor performance or misconduct. Of course, as more effort is focused on supporting healthcare professionals to develop and maintain good performance, the incidence of poor performance may decline. But it will happen from time to time. Our concern is how it should be dealt with.

72 We have already made it clear (in Chapter 24, A Health Service which is Well Led) that it must be the employer first and foremost who should be able to deal with poor performance and misconduct. We have proposed that the professional Codes of Conduct be incorporated into the contract between the healthcare professional and the relevant NHS employer. If this approach is accepted, the employer will be able to act not only in the case of breaches of duty owed as an employee but also when the professional has failed to observe the profession's Code of Conduct. In both circumstances, there would be a breach of contract enabling the employer to take appropriate action. Moreover, by empowering the employer in this way, issues can be resolved promptly and fairly, taking proper account of local circumstances, rather than be left to drag on through some lengthy process as is so often the case now.[32]

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[32] One approach worthy of consideration is that represented by the Code of Practice published by ACAS in 1997 and brought into force by the Employment Protection Code of Practice (Disciplinary Practices and Procedures) Order 1998, SI 1998/44

73 Whatever the employer may do, there is also the question whether the healthcare professional should be entitled to continue to practise or whether a limit on the individual's practice, including removal of recognition or registration, is called for. This aspect of regulation of professionals historically has been the responsibility of various professional bodies: the GMC, the UKCC for Nursing, Midwifery and Health Visiting and the Council for the Professions Supplementary to Medicine. As has been said, no professional regulatory body currently exists in the case of managers but we urge that it should.

74 We are aware that there are continuing discussions about the disciplinary role of the GMC in particular. We wish to make the following observations. All professional bodies charged with responsibility for disciplining their members must constantly keep in mind that they do so on behalf of the wider public. The trust granted to them is that they act in the public interest to preserve and maintain the safety and quality of healthcare provided to patients. To acquire the public's confidence and trust, these professional regulatory bodies must let the public in, to a degree not hitherto contemplated. The old binary approach to discipline – serious or nothing; removal from the register or nothing – is beginning to be dismantled. But the pace of change is not fast enough and the public's patience is running out. The professional bodies must be more flexible in their approach to what constitutes misconduct and practice that warrants disciplinary action; they must deal with cases as far as possible at a local level and they must have available a range of actions to meet the problem before them which both serve the interests of the public and the needs of the professional.

The Council for the Regulation of Healthcare Professionals

75 Regulation, as we have defined it, therefore, extends from entry into a profession, to continuing in it, to ensuring that competence is up to date through revalidation, to processes of support for improvement and, if that fails, to removal from the register. The purpose of the system of regulation must be to assure the public of the competence of healthcare professionals and, when necessary, to protect them. As such it needs the widest involvement of professionals, of the principal employer and of the public. It cannot achieve its purpose if it is a system which is designed and operated solely by particular professionals for their professional peers. Nor can it achieve its purpose if it is solely a matter for employers within the NHS. An effective system of professional regulation must be owned collectively. Further, it needs an independence from the professions and from government which allows it to act in the public interest. In short, we see a need for a single overarching view to be taken of education, training, development and discipline of *all* the healthcare professions. This role as we suggested earlier could and should be played by the body proposed in

'The NHS Plan' (the Council of Healthcare Regulators), which we believe should be more accurately named the Council for the Regulation of the Healthcare Professions. Thus, for *each* group of healthcare professionals (doctors; nurses and midwives; the professions allied to medicine; and managers) there should be one body charged with overseeing *all* aspects relating to the regulation of professional life: education, registration, training, continuing professional development, revalidation and discipline. The bodies should be: for doctors, the GMC; for nurses and midwives, the new Nursing and Midwifery Council; for the professions allied to medicine, the reformed professional body for those professions; and for senior healthcare managers, a new professional body. Each of these bodies would be represented on the new Council, as would representatives of the NHS and the general public. It should be established as soon as possible with a broadly based membership as we have indicated. All of the existing bodies which regulate the healthcare professions in one respect or another would be members. It would provide the unifying principles and the co-ordination necessary to ensure that the various bodies, and there are many, all serve the needs of the public. The Council will of course draw on the skills and the expertise of these bodies, the Royal Colleges, the professional organisations, the trusts and the NHS. But it will be independent of all and have a strong element of public participation. We believe that the Council should have statutory powers to require the various bodies to act in the interests of patients and conform to principles of good regulation. It should also seek to ensure that in practice the bodies regulating healthcare professionals behave in a consistent and broadly similar manner. The Council should, in our view, report to and be accountable itself to Parliament. In the future, regulation of the healthcare professions must be seen in the round and organised accordingly.

Chapter 26: The Safety of Care

Patients are entitled to receive care which is safe and which exposes them to as little harm as possible.

'… we understand you do not come to work to make errors and we want to minimise the risk that you will do so.'[1]

Messages from Bristol

- The absence of a culture of safety and a culture of openness meant that concerns and incidents were not routinely or systematically discussed and addressed and thereby unsafe practices continued unchecked.
- The physical environment and working arrangements were as important to the safe care of patients as the technical skills of clinicians.
- The absence of systems for monitoring the safety of clinical care at national or local level put the care of patients at risk.
- The absence of a systematic approach to learning from things that went wrong prevented effective remedial action from being taken.

Introduction

1 In this chapter we are concerned with safety: that the care which patients receive will be safe. This is not just something which patients are entitled to; it is something they take for granted. But Bristol teaches us that this trust may be misplaced. Care may not be safe. Thus in what follows we examine: what safe care involves; what action is needed to ensure a higher and more consistent degree of safety for patients in the future; and what barriers stand in the way of achieving this.

2 The complexity of modern medical care makes it an increasingly risky enterprise. While the vast majority of patients receive safe treatment, it comes as a surprise to many to know that errors, mistakes or accidents occur every day in every corner of the NHS. These have become known collectively as adverse events.[2] They are often grouped together with another category of event called 'near misses', a term which is self-explanatory and is borrowed from the airline industry. So as to avoid the

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[1] James Bagian, engineer and former astronaut, head, US National Center for Patient Safety, Veteran's Adminstration

[2] We take the term 'adverse event' to mean the occurrence of an untoward and an unplanned event which results in harm to a patient

distractions associated with allocating an event to one or other of these categories we propose, later in this chapter, that a single term, 'sentinel event', be used in the future. In describing current practice, however, we use the term 'adverse event'. We referred in Chapter 21 to the recent pilot study carried out by Professor Vincent. It suggested that around 5% of the 8.5 million patients admitted to hospitals in England and Wales experience an adverse event which may be preventable with the exercise of ordinary standards of care.[3] We accept the authors' caveat about the difficulties of generalising from a pilot study. But let us be clear about what the study's findings suggest: up to 425,000 patients a year, over 1,000 patients a day, suffer an adverse event *which is avoidable*. How many lead to death we do not know, but, as we suggested in Chapter 21 it could be as high as 25,000 people a year. Full-scale studies in the United States[4] and in Australia[5] indicate that a similar incidence of error or mishap occurs in both of these countries. If the estimate for Britain is broadly accurate, and further work is urgently needed to establish the full extent of the problem, then we face a profoundly alarming state of affairs.

3 The issues which lie behind these figures are complex. Safety is a relative, not an absolute term. What constitutes safe care can change over time as known risks are better understood and managed, and new risks emerge with new procedures and forms of treatment. Furthermore, the extent to which a treatment or a procedure is safe, or risky, or unsafe can vary according to a patient's condition and state of health. Some procedures and treatments, such as open-heart surgery, are inherently risky, whatever the patient's condition. Others, such as the administration of aspirin or a routine injection, might on the face of it, appear to carry a low risk. Yet, if the wrong drug is inadvertently administered, or the wrong dose or concentration given to a patient, so narrow may be the margin of safety that the consequences can be catastrophic.

The components of safe care

4 The individual healthcare professional's ability to do what is proposed with proper competence and skill is, of course, crucial in ensuring safe clinical care. But professional competence is only part of the picture. Good people, with good skills and good intentions, sometimes make mistakes. How can this happen? To begin to answer this question, we need to understand that healthcare professionals work in a system. They work in NHS buildings and make use of equipment and drugs provided to enable them to care for patients. Any number of these surrounding factors, or latent conditions, can give rise to error. A misalignment of switches on a ventilator, an

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[3] Vincent C, Neale G, Woloshynowych M. 'Adverse Events in British Hospitals: Preliminary Retrospective Record Review'. *'BMJ'* 2001; **322**: 517–19. www.bmj.com

[4] Brennan TA, et al. 'Incidence of Adverse Events and Negligence in Hospitalised Patients. Results of the Havard Medical Practice study I'. '*New England Journal of Medicine'* 1991; **324**: 370–6

[5] Wilson RM, et al. 'The Quality in Australia Healthcare Study'. *'Med J Aust'* 1995; **163**: 458–71

instrument which shows a false reading, or the unclear labelling of drugs, can have grave consequences for the safety of patients. As we saw in Bristol, the organisation of care in two separate buildings for seriously ill children undergoing high-risk surgery had serious consequences for the safety of the children and the outcomes of their care.

5 Working arrangements, as well as the physical environment, also influence healthcare professionals' performance. Most now work in teams of varying kinds. To function effectively in support of patients, teams need to be well led and there must be good communication, both within and beyond the team. If the team does not work well together, if it is not well-led or if communication is poor, the safety of the patient is compromised. Healthcare professionals also work under the pressure of long hours and heavy demands. Evidence from other sectors in which professionals handle complex information and make decisions under pressure, such as in the nuclear and airline industries, suggests that such pressures, if not properly managed, can affect an individual's judgment even when faced with routine tasks, thereby jeopardising the safety of others. All of these factors can have a bearing on the safety of clinical care, no matter how dedicated or competent the healthcare professional may be. The potential impact of these surrounding factors, when combined together, was summed up well by Professor Lucian Leape, drawing on Professor James Reason's work:

> '… accidents in complex systems occur primarily through the concatenation of multiple small factors or failures, each necessary but only jointly sufficient to produce the accident. Often these small failures or vulnerabilities are present in the organisation long before an incident is triggered.'[6]

To translate this general principle into something recognisable to all: what airline would ask a co-pilot to be in the cockpit, let alone have to land the plane after being on duty continuously for 24 or more hours? Yet, hospitals routinely still expect junior doctors to be on call (or on duty) and to care for ill patients in such circumstances, notwithstanding, indeed by virture of, the current arrangements made in light of the European Working Time Directive.[7]

Pressure for change

6 Thankfully, a number of factors are forcing change. Knowledge and understanding of how multiple causes contribute to things going wrong is increasing all the time. Major inquiries in other areas of public life have played an important part (notably the inquiries into the sinking of the *Herald of Free Enterprise*[8] and the fire on the

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[6] Leape L, et al. 'Promoting Patient Safety by Preventing Medical Error' (editorial). *'Journal of the American Medical Association'* 1998; 280 no. 16

[7] 93/104/EC. And see HSC 1998/240

[8] Mr Justice Sheen, *'1987 mv Herald of Free Enterprise'* (formal investigation). London: HMSO, Report of Court No 8074

Piper Alfa platform).[9] The work of academics has been influential,[10] as have the major studies already referred to on the incidence of error in the USA and Australia. All of these have begun to influence thinking about safety, and about the possible extent and causes of avoidable error, in the complex system of the NHS.

7 Within the NHS itself, a major pressure for change is the duty of care recently imposed by law on trusts to ensure that the quality of care delivered to patients is of a proper standard. This is helping to focus attention on the risks to which patients are exposed and on risk management. Another pressure is the rapidly growing awareness of the cost of adverse events, in both human and financial terms. Professor Vincent's study suggests that the cost may be as high as £1 billion a year. The mounting bill for clinical negligence arising from claims against the NHS is part of that cost. The National Audit Office reported recently that the liability in March 2001 for clinical negligence settlements could be as high as £3.9 billion.[11] The report also stated that the total annual charge to NHS income and expenditure accounts for provisions for settling claims has risen sevenfold since 1995/96. Of course, it must always be remembered that the cost of error has a direct effect on the resources available for the care of patients. The funds to meet claims for clinical negligence in hospital (which includes the cost of dealing with claims that are ultimately abandoned), are drawn from taxpayers' money. This money could otherwise be available for healthcare services. Moreover, to the extent that adverse events cause moderate or permanent impairment to the health of those affected, such events have a further direct impact on health services. The NHS and the social services have to bear an extra burden of care of the NHS's own making. All this is quite aside from the human toll exacted by unsafe and careless systems and practices, in terms of the impact on the individuals themselves, their families and their livelihoods.

8 Pressure for change is also growing out of a greater understanding of the nature of adverse events: that many are avoidable and rooted in the systems of care. Patients and healthcare professionals see that it is possible to do something about them. The starting point must the realisation that such is the potential for the occurrence of adverse events in these times of ever more complex care, that a concern for the safety of patients must be both constant and active rather than sporadic and reactive. The implications of the words of Sir Cyril Chantler, former Dean, Guy's, King's and St Thomas's Medical and Dental School, must be grasped. He wrote: 'Medicine used to be simple, ineffective and relatively safe. Now it is complex, effective and potentially dangerous.'[12] Of course, with very rare, notorious exceptions, healthcare professionals and healthcare organisations seek to help patients. They do not *intend* to harm them. But, we now know that safety is not just a matter of what an individual

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[9] The Hon Lord Cullen. *'The Public Inquiry into the Piper Alfa Disaster'* London: HMSO, 1990

[10] See particularly the work of Professor James Reason, University of Manchester, and, in relation to healthcare, that of Dr Charles Vincent, University of London; Professor Donald Berwick, President, Institute for Healthcare Improvement, Boston MA, USA and Professor Lucian Leape, Adjunct Professor, Harvard School of Public Health, Cambridge MA, USA. See also the seminal work of the US Institute of Medicine, particularly *'To err is human'*. Washington, DC: National Academy Press, 1999. www.nap.edu/readingroom

[11] The figure of £3.9 billion comprises 'provisions to meet likely settlements for up to 23,000 outstanding claims … £2.6bn' and 'a further £1.3bn to meet likely settlements for claims expected to arise from incidents that have occurred but have not been reported.' *'Handling clinical negligence claims in England'*. Report by the Comptroller and Auditor General. HC 403 Session 2000–01, 3 May 2001. www.nao.gov.uk

[12] Chantler C. 'The Role and Education of Doctors in the delivery of Healthcare'. *'Lancet'*, 3 April 1999; **353 (9159)**: 1178–81

'at the sharp end' of care and treatment may do. Indeed, a professional can be as competent as possible, and yet a patient's safety may still be at risk. What the NHS corporately, and each individual trust, must do is engender a culture of safety, by putting in place systems which maximise safety. Equally, healthcare professionals must ensure that, in caring for patients, the safety of the patient is their paramount consideration. Care will only be safe when a concern for safety is recognised and embraced by the individual *and* the organisation.

Past and present approaches to clinical safety

9 Until the recent past, very little attention within the NHS was given to the wider, organisational context of clinical safety, or to the relationship between a healthcare professional's actions and the work environment. The tendency was, and to a large extent still is, to see safety in negative terms. The focus was on those adverse events which had the most serious outcomes – death and disabling injury – and on the more egregious examples of a healthcare professional's conduct: in other words, to look at individual cases and for singular causes, for which someone could be found to blame. There was no place in this approach for seeking to understand the cause of the event, to learn from it, and to share that learning so as to avoid similar events in the future. Instead, there was the false assumption, that, when something went wrong, invariably it was caused by a negligent or incompetent individual. What we now know, and must understand for the future, is that adverse events in healthcare, as elsewhere, are very often caused by a much wider range of factors.

10 At the level of the hospital, again until the recent past, 'safety' as an issue would not commonly have been understood as being concerned with clinical care. It had much more to do with non-clinical matters, such as the means of escape in the event of a fire; the safety of procedures to deal with hazardous materials; and the protection of patients from such harm as slipping on wet floors, or falling out of bed. In this regard, the evidence from Bristol is striking. Throughout the whole of the period of the Inquiry's Terms of Reference, the guidance in force on the reporting of accidents and untoward incidents was still that issued by the Ministry of Health in 1955. The majority of all of the incidents recorded in the incident logbooks for the cardiac wards in Bristol relate to non-clinical events, such as falls and inadvertent self-harm. This is how the safety of patients was regarded, and to a degree still is, not just in Bristol but generally. We were informed by Mr John Gray, Manager of Legal Services at the UBHT, that there was no formal policy or mechanism which required incidents to be reported or investigated, far less for the lessons to be learned and shared. For serious 'near misses' or major accidents, the UBH/T did, however, have an informal system for reporting based on professional judgment. In adopting this approach to patients' safety, the UBH/T, according to Mr Gray, was not unusual. It was doing no more than following standard practice at the time. Mr Gray stated that there was '… much less emphasis on written procedures than there is today, but it would be wrong to interpret lack of a formal record as indicating lack of attention or lack of action where these were obviously necessary.[13] … In effect, staff operated to unwritten protocols where

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[13] WIT 0137 0028 Mr Gray

matters such as the reporting of accidents and untoward occurrences were standard practice and fundamental.'[14]

11 One relatively recent initiative, at least as regards adverse events which amount to clinical negligence, is the clinical negligence scheme for trusts put in place by the NHS Litigation Authority (NHSLA).[15] The aim of the clinical negligence scheme is to reduce the incidence of events leading to claims for compensation, by pressing trusts to develop their systems concerned with clinical risk and safety. Trusts now pay annual premiums to the NHSLA. They are offered financial incentives in the form of discounts on premiums if certain standards are met (such as standards in relation to the trust's policies on risk management, on health records and on its response to major clinical incidents). While this arrangement is undoubtedly sensible, in that it constitutes an incentive for trusts to be more active in protecting patients, we note that the incentives, in terms of the discounts on premiums, are relatively small. We note further that the bulk of payments for clinical negligence are still met directly by the NHSLA, thus insulating trusts from the full financial impact of error. We also note that, to the extent that there are incentives for improvement, they are purely financial. While these are of concern to those involved in senior management, it is unlikely that such signals are relevant to those healthcare professionals involved in the day-to-day care of patients.

12 In their recent report the expert group chaired by the Chief Medical Officer (CMO) stated that: 'The NHS is failing to learn from the things that go wrong and has no system to put this right.'[16] The NHS is only now at the early stages of creating a systematic mechanism for identifying, analysing, and learning from adverse events, with a view to reducing or preventing errors in the future. Much of the information required to help to prevent adverse events, as a result of which patients are harmed, is either not collected at all, or is to be found in a patchwork of over 1,000 unconnected and different systems. The very few national systems which do exist, such as the National Confidential Enquiries, and the reporting systems of the Medicines Control Agency and the Medical Devices Agency, work in isolation from each other and are limited in their scope. Thus, the capacity of the NHS to analyse the causes of adverse events, to make known the lessons learned and to embed those lessons within the systems and practices of care, is extremely limited.

13 Clearly this must change. The CMO's report was a seminal and important step along that road. We strongly support and endorse the thrust behind the expert group's recommendations, principally that there should be: a unified system for the reporting and analysing of adverse events; a more open culture in which errors can be brought to light; and a system for ensuring that lessons are learned and practice is changed to reduce the incidence of errors in the future. We note the decision to implement the

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[14] WIT 0137 0029 Mr Gray

[15] The NHSLA was set up in 1995. Through its clinical negligence scheme for trusts, it pools the costs of trusts' liabilities for clinical negligence arising from incidents occurring after 1 April 1995

[16] Department of Health. *'An Organisation With a Memory: Report of an expert group on learning from adverse events in the NHS'*. London: DoH, 2000

report's recommendations through the creation of a National Patient Safety Agency.[17] Since the agency is not yet in operation, we confine ourselves here to commenting on the CMO's report, not least since the agency's purpose is to act on the report. We will, however, make one point of general importance. We note the tendency of government to respond to issues by creating new bodies or institutions. While sometimes justified, there is always the danger that the creation of the institution is seen as an end in itself; that by its creation the problem is solved. Furthermore, it is a central message of this report that in the past the NHS has suffered from too many bodies acting independently, with no overarching integration and co-ordination. We agree with the main direction of the CMO's report. We believe, however, that its recommendations should go further. If the full implications of Bristol are to be grasped, more change and of a more radical nature will be needed. In the remainder of this chapter, we set out what form that change might take:

- We believe that more attention must be given to establishing a proper baseline of knowledge about the extent and nature of adverse events and near misses in the NHS; without this we will never know in the future if improvements have been made.

- We make some observations on the Department of Health's (DoH's) proposed new system for reporting of adverse events and near misses.

- Reporting of error is crucial to the improvement of safety. We consider in depth how to tackle two major barriers which stand in the way: the current focus on blame and the recourse to clinical negligence litigation. The experience of reporting systems used in some US hospitals and in the aviation industry are instructive.

- We argue for a higher profile to be given to design-led solutions to tackle some of the underlying causes of error.

- We consider the importance of fully integrating safety into clinical governance and the external review of trusts.

- We emphasise that the starting point must be the need to create a culture of safety, so we consider this first.

Creating a culture of safety

14 Placing the safety of patients at the centre of the hospital's agenda is *the* crucial first step towards creating and fostering a culture of safety. This means that safety must be

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[17] The creation of this agency was announced in April 2001. *'Building a Safer NHS for Patients'*. Department of Health. www.nhs.org.uk

everyone's concern, not just that of the consultant, or the nurse in charge. Even less should it be represented as being solely the concern of a person bearing a title such as 'Safety Officer' or 'Clinical Risk Manager'. That merely succeeds in giving the impression that safety is for 'someone else' to look after and that, somehow, the issue has been appropriately dealt with. The safety of patients, the safety of their clinical care, is a matter for everyone, from the trust boardroom to the ward assistants. Safety requires leadership from the highest level of management. It requires constant vigilance. It should be considered in everything that the organisation does. It is not a short-term project but a commitment for 365 days a year. A culture of safety can only really be created when a concern for patients' safety is embedded at every level of the organisation.

15 Central also to a culture of safety is an understanding that adverse events occur and that people and the organisations of which they are part *do make mistakes*. To err is human. A culture of safety, therefore, is one that seeks not so much to eliminate as to analyse and thereby anticipate adverse events including errors and, in the light of that analysis, to organise systems and practices which, as far as possible, prevent them. Some types of adverse event can be eradicated, of course, and when this is possible it must be done. Others cannot, but their impact can be substantially reduced. Barriers or defences can be built into systems so as to help avert them, or to contain and mitigate their potential for harm. As Professor James Reason suggested at one of our seminars: 'Though we cannot change the human condition, we can change the conditions under which humans work.'

16 Constant vigilance is, therefore, a feature of a culture of safety. This point was made forcibly by Professor Marc de Leval, Professor of Cardiothoracic Surgery, Great Ormond Street Hospital for Children NHS Trust. There is, he said, a need for a pervasive mindset of chronic unease, or intelligent wariness.[18] This is not the same as encouraging fearfulness. The line between them is fine, but the latter must be avoided. It raises defences and can easily lead to paralysis. Organisations which adopt an attitude of vigilance do not assume that 'no news is good news'. They recognise that 'no news is in fact no news'. They are thus more likely to be on the lookout for errors and consequently are better prepared to respond when an incident does occur. On this analysis, it is important that people are aware of what they do not know, are aware of where danger may lie, know what should not happen and what is unacceptable, know what to do when problems are identified and know that these will be handled quickly. As the Secretary of the US Anaesthesia Patient Safety Foundation wrote recently: 'The price of patient safety is eternal vigilance'.[19,20]

17 Perhaps the most fundamental feature of a culture of safety is the need for the hospital to create an open and non-punitive environment in which it is safe for healthcare professionals to report adverse events, safe to admit error, safe to admit when things

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[18] See report of Seminar 6, Annex B

[19] Gaba DM. 'Anaesthesiology as a Model for Patient Safety in Health Care'. *'BMJ'* 2000; **320**: 785–8. www.bmj.com

[20] The metaphor of the 'squirrel on the lawn' was suggested at a Phase Two Seminar: even at the time when all appears safe, the squirrel remains ever vigilant

have almost gone wrong, and safe to explore the reasons why. Adverse events, especially clinical errors, very often go undetected and unreported because of fear: the fear healthcare professionals have of being blamed and perhaps more fundamentally, the fear of what it will mean for them to acknowledge that through their conduct a patient has actually been harmed, the last thing they intended. This goes beyond a fear for job or reputation. The sense of apprehension was captured by Albert Wu, writing in the special edition of the *'BMJ'* on medical error:

> '… although patients are the first and obvious victims of medical mistakes, doctors are wounded by the same errors; they are the second victims. Nurses, pharmacists and other members of the healthcare team are also susceptible to error and vulnerable to its fallout. Given the hospital hierarchy, they have less latitude to deal with their mistakes: they often bear silent witness to mistakes and agonise over conflicting loyalties to patient, institution and team. They too are victims.'[21]

Without a culture of safe reporting, it will be impossible systematically to collect information about the incidence of adverse events, especially errors. Without knowing what is going on, no organisation can take a valid view on how safe it is for the patient to be there, far less take any necessary corrective action. Without knowing, there can be no learning. Without learning, there can only be the risk that it will happen again.

18 The essential features of a culture of safety are, therefore:

- Concern for the safety of patients should be embedded in the NHS as a whole, and be the responsibility of everyone who works in a trust.
- There must be an awareness and understanding of safety and an appropriate means of managing issues relating to safety at all levels of the NHS.
- Human fallibility is an inescapable reality: thus, systems are needed to anticipate all types of adverse event, to eradicate them where possible and mitigate their effects.
- A mindset of constant vigilance is crucial.
- Fear is the enemy of safety: an open and non-punitive environment, in which it is safe to admit and report adverse events, especially errors, is fundamental.
- Adverse events offer an opportunity to learn and to make changes for the better, not an occasion merely to punish and forget.

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[21] Wu AW. 'The Doctor Who Makes Mistakes Needs Help Too'. '*BMJ* ' 2000; **320**: 726–7. www.bmj.com

The extent of adverse events and near misses – the urgent need to establish a baseline

19 There is a pressing need for research into some of the central questions about the type and extent of adverse events and near misses in the NHS. We need to be able to answer such fundamental questions as: What is the current scale of adverse events and (to the extent that it can be discovered) near misses? How do they arise? Can they be classified? How can they be guarded against? The Australian and US studies are of value, but they are some years old, and relate to different systems of healthcare. There are almost certainly issues of specific relevance to the NHS which need to be identified. The study of British hospitals by Professor Vincent, while extremely important, is a pilot study. We believe that major studies of the NHS, along the lines of those undertaken in Australia and the US, must be carried out in the UK. Such studies would be an invaluable source of information against which to measure progress. They are an essential part of the task of developing a coherent approach to safeguarding patients. They should be made a priority.[22]

A national reporting system

20 We fully support the principles behind the recommendation of the CMO's expert group and reflected now in the creation of the National Patient Safety Agency that there be a national system for reporting adverse healthcare events and certain specified near misses. Assuming such a system could be made to work, we have no doubt that it would provide an excellent means for identifying patterns of behaviour, for learning and for disseminating lessons throughout the NHS. We make the following comments and suggestions regarding the proposed new national reporting system:

- The national system must be rooted in sound, standardised local reporting systems. There should be clear protocols as to the categories of information which must be forwarded to a national database. It is vital to have good reporting systems locally, so that an event or near miss can be understood in the circumstances in which it arose, and appropriate action taken. It is no less important to have a first-class national system, because of the need to identify patterns, and to share lessons quickly and effectively throughout the NHS. The national and local systems are interdependent and mutually supportive.

- We believe that the national database would be best managed by an independent organisation, outside the NHS and the DoH. This would ensure that a high degree of confidence would be placed in the system by the public; they would see that it was outside the ambit of political influence or control. The managers of the national database should be required to publish summary reports on patterns of adverse events and near misses at least every quarter (and, if necessary, monthly) together with any proposed remedial action.

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[22] We note in this respect the research proposals contained in *'Building a Safer NHS for Patients'*, Department of Health. www.nhs.org.uk April 2001

- To prevent the system's becoming bureaucratic and preoccupied with definitions of what constitutes an 'adverse event' or a 'near miss', we propose the adoption of the more inclusive term, 'sentinel event'. This has been defined as 'any unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof'.[23] The phrase 'or the risk thereof' includes any variation in procedure, a recurrence of which *would* carry a significant chance of a serious adverse outcome. We endorse the principles reflected in this definition but accept that it may require further refinement. We use the term 'sentinel event', as understood here, for the remainder of this chapter.

- The national reporting system should operate broadly in the following manner. It should receive its information from trusts. It should indicate those *categories* of sentinel event as regards which it requires to be informed, for example, failures in equipment or medication errors. The national system should also make provision for recording information from individual healthcare professionals who, for whatever reason, do not feel confident in informing their local trust. The opportunity should exist to report a sentinel event in confidence. In any case where the safety of patients is in question, those who manage the national reporting system must inform the trust concerned. There must be guarantees in place to ensure that no disciplinary or discriminatory action may be taken against the relevant healthcare professional for the act of reporting. To the extent that a disclosure of such information by a healthcare professional to the national reporting system could not correctly be said to come within the Public Interest Disclosure Act, the Act should be amended.[24]

- The NHS has the unique advantage of being a single organisation with one headquarters. Once a good reporting system is put in place, there is every chance that it will be able to identify and disseminate the lessons to be derived from a particular sentinel event. What is needed is the will to make this happen, the acknowledgement that safety really does matter and, crucially, the resources to put in place good, efficient, standardised and accessible systems for reporting.

Reporting sentinel events: the barriers to openness

21 As we have said, a national reporting system requires there to be effective systems of reporting at a local level. We turn now, and in some detail, to the question of how to ensure the local and national systems for reporting sentinel events can work effectively. It is one thing to set up a reporting system, quite another for people to use it. At a recent summit on Medical Errors and Patient Safety Research in the USA, the Joint Commission on Accreditation of Healthcare Organisations stated:

> 'Today, the blame-and-punishment orientation of our society drives errors underground. Indeed, we believe that most medical errors never reach the

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[23] Seminar 6. The term 'sentinel event', and this definition, were drawn to our attention by the Royal College of Nursing; the term is widely used in the USA by the Joint Commission for the Accreditation of Healthcare Organisations

[24] Or, perhaps more simply, the Secretary of State should, by order under s.43F of the PID Act designate to whom, including the National Patient Safety Agency, disclosure in respect of patients' safety may be made. We deal later with healthcare professionals' reporting to local systems

> leadership level of the very organizations in which they occur. Therefore, although there is much rumination over the statistics published about medical errors, we believe that no one has a real handle on the actual numbers because all the incentives to report are negative.'[25]

Although written about the USA, this aptly describes what we believe to be the state of affairs here. We have already referred to the lack of openness in the NHS which acts as a major barrier to obtaining information about the incidence of sentinel events, particularly error. We need now to understand more clearly what causes this lack of openness, so as to be able to overcome it and move forward.

22 There are a number of causes which must be confronted. The first can be called the myth (or imperative) of infallibility. The idea of the healthcare professional as giver of life, restorer of health, or as one who does not make mistakes, is a dominant theme in the culture of healthcare. This makes it extremely difficult, particularly given the expectations placed upon professionals by the patient, for them to speak up and point out that things have not gone as expected. To admit this is to fail the myth and thus appear a failure. Professionals assume that the patient expects infallibility and consequently find it very hard to admit that they are fallible.

23 Secondly, in the particular case of errors, quite apart from any errors of their own, healthcare professionals find it difficult to speak up about the errors of others. There is what can be called a code of silence – that aspect of professional culture which causes 'tribal' groups to close ranks and keep problems within the group. There is a real sense of 'There but for the grace of God go I'. The pressure of hierarchy within the professional group also plays a part. As a consequence, junior staff, or those from other specialties or disciplines, are inhibited from speaking out. We were struck by the evidence of a recent study to evaluate the reporting of adverse incidents in an obstetrics unit, quoted by the Royal College of Nursing (RCN) in one of its papers to the Inquiry. Of 196 adverse incidents, as defined by relevant protocols, identified as arising during the delivery of 500 babies, fewer than a quarter were reported by the staff. The RCN told the Inquiry that:

> '… the main reasons put forward for the non-reporting of errors were fears that junior staff would be blamed, high workload and the belief (even though the incident was designated as reportable) that the circumstances or outcome of a particular case did not warrant report.'[26]

24 Thirdly, fear of exposure and blame, whether in the press or through litigation, with the consequent loss of standing, career prospects, or even livelihood, is a further powerful inhibiting factor. As a society we are still trapped in a culture which, when things go wrong, is one of blame. The assumption is often made that there has been an

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[25] 'National Summit on Medical Errors and Patient Safety Research'. September 2000. *'Statement of the Joint Commission on the Accreditation of Healthcare Organisations'*. Available at www.jcaho.org

[26] Stanhope N, Crowley-Murphy M, Vincent C, O'Connor A, Taylor-Adams SE. 'An evaluation of adverse incident reporting'. *'J Eval Clin Pract'* 1999; **5(1)**: 5–12. See also Seminar 6. The Royal College of Nursing. Position Paper

error. Moreover, errors are personalised to an individual, the better to find 'the person responsible', who can then be dealt with. And of course, the media, eager for a name, and lawyers, needing someone's 'fault' for their client to point to, reinforce this approach. Errors in the NHS, as elsewhere, are seen not as matters to learn from, but as moral lapses deserving of blame.

25 Blame and fault find their expression most strongly in the system of clinical negligence litigation. We regard the impact of clinical negligence litigation to be of such importance that it warrants scrutiny here. To state our conclusion first, we believe that both the threat and the reality of litigation to claim damages for clinical negligence serve as barriers and disincentives to openness within the NHS. Moreover, we consider that they are perceived as such across the NHS. Currently, it is open to patients to bring a legal action if injury is wrongfully done to them in the process of receiving medical care (if, indeed, they are aware that such an injury has been done, for very many patients never become aware of it).[27] The legal action is based on an allegation of negligence on the part of a healthcare professional or an NHS trust: that their conduct fell below the standard which the law requires, and that this failure caused the damage of which the patient complains.

26 The system of clinical negligence litigation in England and Wales forms part of what is known as tort liability.[28] The theory behind the system, as it has evolved, is that by bringing a legal action for damages, the claimant is not only seeking financial compensation for the injury which has been suffered, but is also seeking to achieve two further objectives. The first is to hold the NHS to account. The second, through the combination of public exposure and the award of damages, is to help to prevent similar incidents from occurring again by creating an incentive for trusts and healthcare professionals to act more carefully.

27 We referred earlier to the issue of financial compensation: how best to address the financial needs of those who are harmed in the course of healthcare. What concerns us here is whether the system of clinical negligence litigation achieves its other stated aims: accountability and deterrence. If it does, then it may be justified as a system, even if at the same time it operates as a barrier to openness. If it does not, and in our view it fails on both counts, it clearly works against the interests of patients' safety.

28 Taking accountability first, clinical negligence litigation requires that there be someone (or some organisation) to blame for having been at fault. Thus, it institutionalises the notion of blame as the ultimate remedy. Accountability, on the other hand, suggests a system in which performance is assessed and reviewed against standards; blame may follow or be part of that process, but it cannot *be* that process. Clinical negligence litigation does not represent a systematic approach to accountability, far less to the proper analysis of error. Rather, it is an entirely

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[27] We note in this respect a finding from research in the USA, which showed *inter alia* that very few victims of negligent injury filed malpractice claims. Weiler PC et al., *'A Measure of Malpractice. Medical Injury, Medical Litigation and Patient Compensation'*. London: Harvard University Press. 1993

[28] A tort is a civil wrong giving rise to liability and a remedy ordinarily in the form of financial compensation

haphazard process. Furthermore, any system of accountability, to be effective, requires that there be openness about who is accountable and for what. There is no such parallel in the system of clinical negligence litigation. Few cases ever actually see the light of day in court. Indeed in many of the more obvious cases of error, where it is clear to the trust, the NHS Litigation Authority, or a defence society, that a hospital or a particular professional was at fault, the claim is settled and no public airing of the issues ever takes place.[29] What might be learned from such cases cannot thus be shared across the NHS. Other hospitals and healthcare professionals, indeed even those in the same institution, may not learn of, and thus from, the case. Paradoxically, those cases which are not settled, and thus become publicly known, tend to be those in which it is less certain that a hospital or a particular professional was at fault. Thus, at its extreme, we have the bizarre situation under the current system of clinical negligence litigation, in which the worst excesses rarely come into view, while the more borderline cases attract the attention of the press and public. This is a far cry from any system for holding the NHS to account for its conduct and its errors.

29 What about deterrence: does clinical negligence litigation act as a form of deterrence? Patients who suffer harm through some kind of clinical error commonly express the view that the one goal which they seek to achieve through litigation is to prevent what happened to them from happening to others. According to this approach, for deterrence to work, there must first be a way to convey to the NHS the relevant information about the particular error. Secondly, there must be some sort of systematic approach, whether by sanction or incentive, to securing a change in the behaviour of healthcare professionals and of trusts, so that the causes of the error are identified and eradicated, or that their effects are mitigated. As regards deterrence through the dissemination of relevant information, we have already seen that the system of clinical negligence litigation operates against this aim. Many cases are handled locally and not widely known about. Of those that do reach the NHS Litigation Authority, many are settled without attention to any notion of learning the wider lessons. The scale of the opportunities lost by the NHS to learn from litigation is described in the CMO's report *'An organisation with a memory'*. One source of information alone, the NHS Litigation Authority's database, has the details of some 14,000 claims. It is an indictment of the current system (if such it can be called) that none of the sources described in the CMO's report has ever been used systematically to analyse the causes of error and to suggest lessons for the future.

30 The system of clinical negligence litigation could be said to fare equally poorly in terms of the second point we raised earlier: the deterrent effect of the types of sanction or incentives which it invokes. On one level, since the NHS and healthcare professionals historically have had access to little systematic information about the incidence of error across the NHS, they can hardly have been expected to resort to some systematic approach to deterrence, so as to tackle the root causes of error. At another level, clinical negligence litigation does have a significant deterrent effect on

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[29] Around 800 new claims are settled annually by the NHS Litigation Authority arising from incidents in trusts; a further 700 new claims are settled annually by the medical defence organisations arising mainly from incidents in primary care. See *'An Organisation With a Memory'*, p. 61

behaviour, but the effect is almost entirely perverse. By institutionalising blame it breeds defensiveness. The instinct is to cover up and deny. Errors cannot be treasured if, by acknowledging them, the healthcare professional or hospital may be sued. As Professor Troyen Brennan of Harvard University Medical School said recently, clinical negligence litigation frustrates monitoring, slows the movement to overcome the incidence of error, and feeds a cycle of public anxiety, more litigation and more secrecy.[30]

31 It is crucial for healthcare professionals and the hospital to discuss in an appropriate audit meeting what may have gone wrong. If a record is kept of such a meeting the records could later be acquired by legal representatives, through a process known as 'disclosure', should a patient wish to pursue a legal claim against the hospital. What can be learned if nothing can be recorded and analysed? The incentives in practice, therefore, are not so much to manage and reduce error as to cover it up when it happens. So much may be at stake for the individual healthcare professional that, on balance, it still seems the easier course to stay quiet than to speak up, whether about their own conduct or that of a colleague. That is not to say that healthcare professionals invariably take the easier course. It is just that we must be clear and honest about which way the incentives drive behaviour.

32 Notwithstanding all these other arguments, perhaps the strongest argument against the assertion that clinical negligence litigation promotes deterrence is the most obvious one: errors continue to take place on a very significant scale. Indeed, the scale and the nature (particularly the multiple causes) of error are such that the system of clinical negligence litigation barely scratches the surface. At best, it could be characterised as sweeping up, occasionally, after the event.

33 It is our view, therefore, that the culture and the practice of clinical negligence litigation work against the interests of patients' safety. The system is positively counter-productive, in that it provides a clear incentive not to report, or to cover up, an error or incident. And, once covered up, no one can learn from it and the next patient is exposed to the same or a similar risk.

Overcoming the barriers to openness

34 Having considered the barriers to openness, we turn now to the changes necessary to overcome them, always bearing in mind the objective we seek to achieve: to ensure that the maximum effort and energy is spent to improve safety across the NHS. This can only be achieved when we have created an environment of openness so as to give rise to a systematic flow of information.

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[30] *'The Litchfield Lecture'* May 2001. The Oxford Medical Society

Replacement of clinical negligence litigation

35 The system of clinical negligence litigation is now ripe for review. It is over 20 years since it was last considered as part of the review carried out by a Royal commission under Lord Pearson.[31] Much has changed in the NHS and in the practice of medicine since then. The system is now out of alignment with other policy initiatives on quality and safety: in fact it serves to undermine those policies and inhibits improvements in the safety of the care received by patients. Ultimately, we take the view that it will not be possible to achieve an environment of full, open reporting within the NHS when, outside it, there exists a litigation system the incentives of which press in the opposite direction. We believe that the way forward lies in the abolition of clinical negligence litigation, taking clinical error out of the courts and the tort system. It should be replaced by effective systems for identifying, analysing, learning from and preventing errors along with all other sentinel events. There must also be a new approach to compensating those patients harmed through such events. The abolition of recourse to clinical negligence litigation would be a major step in changing the climate and the incentive for reporting when things go wrong and, we believe, encourage the openness essential for improving safety. Although our view on what needs to happen is clear, we recognise that such a radical change is likely to have wide implications, not least in terms of any new system of compensation. We recognise, therefore, that the way forward lies in a review by an expert group of the entire system of clinical negligence litigation, with clear terms of reference to consider alternatives to the current arrangements. The review must also address needs arising from harm, both financial and emotional, and how they should be compensated.

Reporting systems

36 Within the NHS itself, a policy of reporting sentinel events which is both open and non-punitive should be pursued. (By a non-punitive policy we mean a policy which expressly indicates that the NHS prizes information and it will not punish those who report errors, including their own, except in circumstances of criminal behaviour.) The adoption of such a policy need not await the outcome of the examination of clinical negligence litigation, although any system of reporting will remain imperfect until that wider issue is tackled.

37 What we envisage through this policy is the creation of a new compact of trust between the hospital and the workforce, made in the cause of patients' safety. Healthcare professionals must be able to know that they can come forward. They must feel safe to do so. The hospital must continually reassure them by its actions that this is so. Of course, patients also must come to understand and accept this process. They will first need to be persuaded that lessons are, in fact, learned and that, where they have been harmed, they can and will receive their due, whether it be an apology or compensation, without the need for clinical negligence litigation. But, according to Professor Leape, the public will accept it. He points out that the public's principal interest lies in what is being done about a problem. They do not expect perfection,

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[31] Lord Pearson. *'The Royal Commission on Civil Liability and Compensation for Personal Injury Reports'*. HMSO, 1978

they accept that things can go wrong, but they do expect honesty and action.[32] To bring about this change of policy, indeed of philosophy, will represent a major challenge of leadership. The NHS and trusts must make it clear that they will not criticise but, indeed, prize those who report errors. Only where there is criminal behaviour (which thankfully is very rare), will there be a place for blame.

Making reporting as easy as possible

38 We now turn to the challenge of making policy become reality. We focus on the local level because that is where any system of reporting succeeds or fails. We begin by making two general points. Reporting must be made as easy as possible, using all available means of communication (including a confidential telephone reporting line). The policy on reporting and an explanation of how to report and, crucially, to whom, should be integrated into all elements of a trust's internal communications activities, induction training and other staff training. Staff must know what is expected of them and what systems are in place to enable them to report.

Incentives to report

39 We propose a system of measures to encourage healthcare professionals to report sentinel events. The incentives, which should be reflected in healthcare professionals' contracts and in the rules of professional bodies, should include:

- Immunity from disciplinary action by the employer for healthcare professionals who report a sentinel event within 48 hours, except where they themselves have committed a criminal offence.

- Immunity from disciplinary action by professional bodies for healthcare professionals who report a sentinel event within 48 hours, except where they themselves have committed a criminal offence.

- An option to report on a confidential basis, unless the public interest demands otherwise.

- The possibility of disciplinary action against a healthcare professional by the employer or the relevant professional body if a sentinel event is covered up or not reported.

Confidentiality

40 There may be circumstances in which healthcare professionals will only report a sentinel event if guaranteed confidentiality, specifically that they will not be identified or identifiable as the source of the report. Fear of recrimination from colleagues may be one such circumstance. For this reason, the option of reporting in confidence must exist. Clearly, once a sentinel event is reported, it will then be the job of the relevant executive director of the trust and the chief executive to take appropriate action.

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[32] See report of Seminar 6, Annex B

41 Confidentiality can be a valuable device in reassuring employees and encouraging the reporting of sentinel events. Moreover, if attempts were made to abuse confidentiality by using it as a cloak to hide wrongdoing, other healthcare professionals could (and would) speak up. The trust chief executive in the exercise of their statutory duty to ensure the quality of care, would have to investigate and act. In this context we would add that, were any healthcare professional to seek to prevent the employer from taking any action by consistently reporting their own errors within the required time, thereby avoiding disciplinary action, the employer would have the option of referring the professional to, in the case of doctors, the National Clinical Assessment Authority. Similar systems, providing the opportunity for professional assessment and, where necessary, retraining should be put in place for all other healthcare professionals. This would not constitute disciplinary action; it would, however, protect the safety of patients.

Acting on reports

42 The trust, in receipt of reports from staff, must act. All sentinel events should be subject to a form of structured analysis which takes into account the wider factors within the organisation which may have given rise to the event, as well as the conduct of individuals. This analysis is best done within the organisation in which the event occurs and as close as possible to the time of the event. We have in mind and commend something akin to the process of 'root cause analysis'. Borrowed from the world of engineering, this process allows all of the factors which might have contributed to an event to be identified and analysed. It was recently advocated by the DoH[33] and has been used successfully for some years in the USA by the Joint Commission for the Accreditation of Healthcare Organisations. The analysis in turn forms the raw material for a plan of action designed to address the failures or omissions which have been identified.

Learning from what is already working in the NHS

43 In developing such a system there is much that can be learned from the emerging experience within the NHS. It is encouraging to see evidence of a move towards open reporting as revealed in the inspection reports of the Commission for Health Improvement (CHI). For example, in relation to Southampton University Hospitals NHS Trust, CHI stated: 'A new process for reporting adverse incidents was introduced in early 2000. An important feature is that reporting of non-clinical and clinical incidents is combined'. Yet it also noted: 'In common with staff in most other health organisations though, some staff in the Trust feel reticent about raising concerns about colleagues – especially doctors about other doctors and other staff about doctors'. In relation to North West Wales NHS Trust, CHI wrote: 'The Trust states that its approach to managing risk is to ensure that it develops a culture of "no blame" … The evidence clearly indicates that the Trust has made significant progress in achieving this.'[34]

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[33] *'Building a Safer NHS for Patients'*, April 2001, p. 38, Department of Health. www.nhs.org.uk

[34] See Commission for Health Improvement. *'Clinical Governance Reviews'*. 2000/01. www.chi.nhs.uk/eng/report/index

Learning from other industries and other healthcare systems

44 There are also lessons to be gained from the experience of other industries and other countries. A non-punitive approach to reporting possible breaches of safety has long been part of the culture of the aviation industry. In this country and in the United States, programmes for safety in aviation encourage pilots to report incidents to their companies, allowing immediate corrective action (see Box A below). In this way, airlines learn. Safety is protected. Passengers travel safely.

Box A: Examples of aviation safety reporting systems

British Airways

- The British Airways Safety Information System (BASIS) is a tool for safety management, developed and introduced by British Airways in 1990 and now used by 150 organisations around the world.
- It supports the process of investigating possible breaches in safety and is predicated upon a philosophy that puts safety at the centre of the organisation.
- An open reporting culture is a key to the success: '… the fundamental principle behind BASIS is that an open, penalty-free reporting culture be developed and supported. This encourages staff to contribute high quality safety information without fear of recrimination.' To support the culture, letters are sent to staff thanking them for their report and giving them details of the investigation.
- BASIS produced a database of over 43,000 incidents for 1999. Through the analysis of trends, BASIS helps airlines and other related organisations to adopt strategies to prevent adverse events and to promote safety.

Source: Seminar 6 report, and website of the BA Safety Information System: www.basishelp.com

Aviation safety reporting system – the US federal system

- Eligibility for limited immunity from disciplinary action for non-criminal offences is a powerful incentive to report. No immunity is given if the event is deemed intentional; where there is a question of qualifications; or, if the report is filed after 10 days.
- The number of reports of events is around 30,000 a year. Data have been used to redesign aircraft, air traffic control systems, airports, and for the training of pilots.
- Management of the system is contracted out to an independent third party.

Source: Barach P, Small SP. 'Reporting and preventing medical mishaps: lessons from non-medical near miss reporting systems'. *'BMJ'* 2000; **320**: 759–63; www.bmj.com

45 A number of hospitals in the USA have also successfully implemented open reporting systems (see Box B below). That some hospitals in the USA have been able to do so while clinical negligence litigation flourishes may suggest that such litigation is not a barrier to openness, despite our previously expressed views. The response is complex. The crucial difference, apart from any structural differences between the law and practice in England as compared with the various states in the USA, may lie in the source of the funds for compensation. In the USA, the hospital claims from its insurer which passes on the cost in increased premiums for healthcare insurance, which the hospitals pass on to the patients in increased healthcare costs. In the UK it is the service provider, the NHS, which pays the cost and, short of increasing taxes, or taking funds from elsewhere in the public sector, money spent on meeting claims is money not spent on care. Thus, the financial impact and incentives in the USA and the UK are different.

Box B Safety reporting systems in US hospitals

The Luther-Middleford Hospital in Eau Clare, Wisconsin

- In 1997, a team under a clinician, Roger Resar, undertook an assessment of errors in medication and found that patients were probably at risk of two to three drug errors during a stay.
- A non-punitive system of reporting was established, first in just one department but now throughout the hospital.
- Reports of errors from nurses and technicians rose by up to sevenfold in the first month after the system was introduced in spring 1998. The number of errors reported levelled off in time as changes to systems were put in place to tackle some of the underlying factors leading to the errors reported.
- The hospital has, as one of its stated objectives, 'to provide safe care'. There is a commitment to safety within the hospital, and a determination to apply thinking about safety to everything it does.
- The hospital's president and CEO (Chief Executive Officer) says, 'We have worked hard at changing the cultural fear of punishment. Now we tell people they'll get in trouble if they don't report an error – and they have a 48 hour period to let us know if something has gone wrong'.

Source: Findlay S (Ed) *'Reducing medical errors and improving patient safety; success stories from the front lines of medicine'*. Washington, DC: The National Coalition of Health Care and the Institute for Healthcare Improvement, February 2000. www.nchc.org

The Veteran's Administration – the healthcare system for US veterans and their families

- The VA includes 172 hospitals and employs 200,000 people. Features of the patient safety system include a safety events registry to which staff are encouraged to report all incidents that caused significant harm to a patient.
- Reported errors are subject to analysis leading to corrective action and preventive measures, rather than punitive action (the sole exception being a criminal or a deliberately unsafe act).
- Individuals who suggest broadly applicable safety improvements qualify for bonuses of up to $5,000; institutions can receive up to $25,000.
- The head of the VA's National Center for Patient Safety, James Bagian, an engineer and former astronaut, says 'The old model was, you stressed who was at fault. The new model is that we understand you do not come to work to make errors and we want to minimize the risk that you will do so.'

Source: Findlay S (Ed) *'Reducing medical errors and improving patient safety; success stories from the front lines of medicine'*. Washington, DC: The National Coalition of Health Care and the Institute for Healthcare Improvement, February 2000. www.nchc.org

Designing safer systems, buildings, equipment and pharmaceuticals

46 By bringing more information about sentinel events into the open, it becomes possible to understand their causes and to act accordingly. Very often the causes can be minimised by designing safer systems and equipment. This approach of looking at systems is exemplified by the reports into an incident in Nottingham in 2001 when a young patient was mistakenly given the drug vincristine by spinal injection.[35] This was a catastrophic clinical error; the patient died two weeks later. The reports considered how the human systems (of staff induction and training) and the equipment used for giving injections, should all be changed across the NHS to reduce substantially the risk of a similar error occurring elsewhere again.

47 In terms of occupational health and safety, the Health and Safety Executive (HSE) has a well-developed system for collecting, analysing and acting on information about unsafe materials or practices. Under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 1995, all employers are required to report relevant incidents. The incidents are analysed and where patterns emerge, action is taken to improve guidance and to seek changes. One among many examples is the recently produced guidance to safeguard flat-belt conveyors in the food and drink industries. An analysis of accidents caused by machinery in these industries over a ten-year period showed conveyors to be the cause of 30% of injuries investigated by the HSE. The new guidance covers legal requirements for, and safe design of, new conveyors as well as guidance on maintenance for old as well as new machines.[36]

48 During the Inquiry's seminars, we were impressed by the extensive experience of anaesthetists in applying a 'systems approach' to safety. The work of the Royal College of Anaesthetists and the Association of Anaesthetists of Great Britain and Ireland deserves to be commended. Through their emphasis on protocols and guidelines, and in their influence on the design of equipment, they have helped to make remarkable advances in the safety of anaesthesia over the past 30 years. The field of anaesthetics (and of anaesthesiology in the USA) has led the way in the use of 'engineered safety devices', meaning devices that physically prevent errors. One example, quoted in a recent article in the *'British Medical Journal'*, is the system in the operating theatre of gas connectors that are designed so as prevent a gas hose or cylinder from being installed in the wrong site.[37] In healthcare as a whole, however, it is well recognised that the adoption of an approach to solving or addressing specific hazards by designing equipment differently is under-explored.[38] This is to be regretted, given the

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[35] Toft B. *'External Inquiry into the adverse incident at Queen's Medical Centre Nottingham on 4th January 2001';* and Woods K. *'The Prevention of Intrathecal Medication Errors'*. NHS Executive, April 2001. Both reports available at www.doh.gov.uk

[36] See HSE Press Release E072:01, 23 April 2001. www.hse.gov.uk/press. The original RIDDOR regulations were made in 1985 and themselves expanded on a form of reporting accidents obligatory in factories before that

[37] Gaba DM. 'Anaesthesiology as a model for patient safety in health care'. *'BMJ'* 2000; **320**: 785–8. www.bmj.com

[38] See *'An Organisation With a Memory'*, p. 78

great pool of knowledge and skill amongst the medical profession and within the NHS. Organisations within the DoH, such as the Medicines Control Agency, the Medical Devices Agency and NHS Estates also have a wide range of experience of the effect of design-led solutions on improving safety and on changing the conditions which give rise to unsafe practices. For the future, therefore, we regard it as of great importance to develop this area of research and development. We take the view that the new National Patient Safety Agency should, as a matter of urgency, bring together managers in the NHS, representatives of the pharmaceutical companies and of the manufacturers of medical equipment, members of the healthcare professions and the public to tackle what are some of the more fundamental and persistent underlying causes of unsafe practices. The aim should be to seek to apply approaches based on engineering and design so as to reduce (and eliminate to the extent possible) the incidence of sentinel events. In this context, we commend in particular the example of the Australian Incident Monitoring Study (AIMS) in anaesthesia, which, since 1998, has held ten national consensus conferences bringing together all interested parties to discuss ways of reducing the rate of adverse incidents in anaesthesia.

Incorporating a concern for safety into systems and policies

49 We argued at the outset of this chapter that a concern for the safety of patients must be visible at every level of the NHS. But it must be more than a concern. The systems and policies of the NHS and of individual trusts must incorporate that concern, reflect it and thereby promote the safety of patients. Commitment to safety is not a separate, autonomous, 'self-contained' policy. It must be embedded in everything which the NHS does, from, for example, the education and training of healthcare professionals, to the design of buildings and equipment, to protocols for treatment, care and the administration of drugs, to the systems for responding when things go wrong.

50 We believe that one development in particular is called for. At the level of individual trusts, we take the view that an executive member of the board should have the responsibility for putting into operation the trust's strategy and policy on safety in clinical care, so as to protect the safety of patients. Further, a non-executive director should be given specific responsibility for leading the strategy and policy aimed at securing safety in clinical care. This concern for safety should be linked to existing systems for clinical governance, by ensuring that this non-executive director also serves as the Chair of the board's clinical governance committee. Through this leadership, the attention of *all* healthcare professionals will be directed towards safety. It will be the responsibility of *all*. It may also be helpful to note here, in the light of what we learned from the events of Bristol, that it must be made clear that, should it ever arise, the chief executive has the duty and the authority to close down even on a temporary basis a particular service if it poses too great a threat to the safety of patients. We describe in the next chapter a process by which trusts should be validated, rather than inspected, by CHI. It should always be open to trust chief executives, in pursuit of their duty to protect patient safety, to call in CHI to advise on whether a service or a facility is unsafe.

Chapter 27: Care of an Appropriate Standard

Patients are entitled to care and treatment of an appropriate standard informed by current knowledge.

Messages from Bristol

- The absence of explicit agreed clinical standards of care for patients who received paediatric cardiac surgical (PCS) services, whether in Bristol or elsewhere, made it very difficult, either at the time or subsequently, to assess the quality of care.

- Standards of care in Bristol, as elsewhere, were regarded as a matter for individual clinicians to determine, doing the best for their patient, based on their professional skills and the knowledge they could acquire over time.

- As regards the monitoring of the PCS service, a good deal of data was available at the time in Bristol about the PCS service. Yet the nature of the data coupled with the prevailing mindset were such that no real understanding of performance emerged, whether of Bristol or of other hospitals, for the purpose of comparison. To the extent that the clinicians at the time understood and reflected on their performance, they only had to satisfy *themselves* that the service was of sufficient quality. There was no systematic mechanism for monitoring clinical performance. Explanations of poor performance could be advanced which were plausible but lacked evidence, in the absence of sound data.

- As regards the absence of both explicit standards and any rigorous monitoring of outcomes, the Bristol PCS service as a specialty was little different from other areas of clinical practice at the time.

- From the perspective of parents whose children were cared for in Bristol, it was assumed by many that because the UBH/T was designated as a ‘supra regional centre’, its standards of care and treatment were amongst the best in the country.

- Few parents whose children were cared for in Bristol had any idea that there was no real way of knowing this: that there were no agreed standards of care and not only no external monitoring of clinical performance but no real mechanism for doing so.

Introduction

1 The term standard is in essence a neutral term. What we import into it here is an element of quality. Any level of performance can meet some standard. But the standard which we are concerned with is that which properly serves the interests of the patient. Thus we take the term 'standard of care' to mean an agreement on what a patient is entitled to expect as good practice in a particular context, based on the best available evidence. A standard of care, therefore, sets the boundaries of what is good practice. It also, however, needs to be sufficiently flexible to allow for minimum standards and standards of exemplary practice to which a service can aspire. In this chapter we examine briefly the approach to standards of clinical care in the past, and we consider the impact of recent policy changes. We argue that the systems for setting and monitoring standards of clinical care can and should be further improved. We advocate a new approach to setting of standards for hospitals, and we set out proposals for a more rigorous and better co-ordinated system to monitor the performance of the NHS as a whole.

The past: an absence of standards and of monitoring

2 Clearly, patients wish for a good outcome[1] (where this is possible). But this disarmingly simple proposition is easier to state than to define. It contemplates agreement on what amounts to a good outcome, and sometimes patient and professional may disagree. It further contemplates ways of assessing, measuring, recording and comparing outcomes, so as to produce information which would allow the patient and the professional to come to a view as to what is 'good'. It also calls for an understanding of the relationship between outcome on the one hand, and treatment and care on the other, bearing in mind that there can be many variables which affect a person's health, whatever treatment and care they may receive. The link may be more obvious and visible in some areas of medicine (such as therapy with drugs), than in other areas of treatment. Until recently, apart from a few exceptions, this information and understanding have barely existed in any significant way. Thus perhaps the most essential tool in achieving, sustaining and improving quality of care for the patient was lacking. Hospitals and the NHS could tell you about throughput (number of patients treated), bed occupancy (the proportion of beds occupied in the

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[1] We take as our definition of a health outcome one cited by the Royal College of Physicians in its paper for Seminar 6: 'A change in health, health related status, or risk factors affecting health. A health outcome may be the result of the natural history of the disease or may be the effect of interventions designed to prevent or to treat it.' (Derived from Pearson M et al. (Eds). *'Outcome Indicators for Asthma'*; report of a Working Group to the Department of Health, London. Royal College of Physicians Research Unit and Oxford Unit of Health Care Epidemiology. London: NHSE, 1999)

hospital), and, latterly, the costs involved. But, generally speaking, quality of outcome was a closed book.

3 The explanation is complex. One powerful factor lies in the historical origins of the NHS. As we have already said, until at least the early 1980s, the Department of Health (DoH) regarded quality of care as essentially an issue for healthcare professionals: something the Department should not interfere in. Thus there was no imperative from the centre to generate information about the quality of care as we understand the term today, and consequently, there was no reliable national picture of the quality of care. For their part, healthcare professionals often monitored their own work at a local level, reviewing, for example, deaths and complications. But with very little or no comparative data from other units or hospitals, based on agreed criteria and subject to rigorous analysis, all they really had to go on in judging how well they were doing was little more than anecdote. Furthermore, there were no systems, either within the hospital or elsewhere, to identify poor clinical outcomes or take action, unless or until some scandal broke, or a pattern of performance was so poor as to attract attention. Papers were presented at conferences, articles were written in journals, and colleagues met and discussed their work. But all of this was piecemeal and of varying value.[2]

4 Until well into the 1990s, the notion that there should be explicit standards of care which all healthcare professionals and hospitals should seek to meet, and which would apply to patients across the NHS, simply did not exist. We heard evidence in both Phases of the Inquiry, for example, that clinical standards were regarded as a matter for individual doctors to address within their own practice. The Royal College of Physicians, for example, told us that 'Quality of care was simply left as a matter for individual doctors to supervise within their own practice until the 1980s.'[3] Such an approach, in which individual professionals were responsible for all stages of their own work, was the norm in healthcare (as it was in other areas of professional practice such as the law). Its weakness lay in the lack of anything against which professionals could test their performance. At its worst, it led to complacency and an erosion of self-questioning. Reliance on experience became a substitute for continuing self-appraisal. Variations in practice were seen as the proper exercise of professional choice rather than as evidence of differing standards. A further weakness lay in the assumption that the presence or absence of decent equipment and decent facilities made little or no difference to the quality of care: that all that was needed was to rely on well-trained professionals to do their best. That was not fair to professionals. One of the crucial insights from Bristol is that leadership and management of a hospital, the organisation of patients' care, and the state of a hospital's buildings and equipment, are as relevant as, and interact with, the competence of healthcare professionals in influencing the standard of care. The conclusion must be that the standards and quality of healthcare are not, and cannot be, a matter solely for healthcare professionals.

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[2] For information about how paediatric cardiac surgeons kept up to date in the 1980s and 1990s see Annex B

[3] Seminar 6. Royal College of Physicians. Position Paper. Also see Summary Report of Seminar 6 at Annex B

The gradual shift towards an interest in standards and in monitoring

5 The Royal Colleges and various specialist associations of healthcare professionals, sometimes allied to Royal Colleges and sometimes not, issued, and indeed continue to issue, suggested standards of care (as distinct from standards of professional practice), guidelines and guidance to their members. Other organisations also contributed and contribute from time to time, such as the British Medical Association (BMA). The DoH, through the Clinical Standards Advisory Group,[4] also played a role. But all of this guidance was advisory. It was seen as an exhortation to best practice. There was no assumption that it should normally be followed. Indeed, none of the various bodies had any authority to cause their guidance to be followed. What such guidance constituted was an extension of the notion that standards were for the individual professional, to the idea that they could be for the profession as a group. There was rarely, if ever, any involvement of non-professionals in the development of the guidelines, nor any coherence necessarily between the various guidelines.

6 As regards information on performance which could help clinicians to reflect on and to improve the quality of care, there were exceptions to the general lack of data, most notably in the case of four national Confidential Enquiries.[5] The reports of these Confidential Enquiries covered only certain specified areas of healthcare. They depended on the co-operation of clinicians to submit data. Not all did so. The data were then aggregated and anonymised. This process encouraged the participation of professionals who were otherwise anxious at comparisons being made which might not be informed. It inevitably meant that comparisons could not be easily made. In particular, the prospect of patients gaining any information on the performance of Dr X in Unit Y in Hospital Z was lost. A similar process was evident in Bristol. The Society of Cardiothoracic Surgeons collected and distributed in aggregated form data about mortality rates in paediatric cardiac surgery (from the UK Cardiac Surgical Register). While ahead of other specialties in this regard, participation was voluntary. The data were made available only to those surgeons who were members of the Society, though they in turn could decide to make the data more widely available. The Society itself did not make the data known to the various hospitals nor to the public.

7 As regards the role of learned journals (and other literature) as a source of reliable information on practice whereby professionals could compare their performance with that of others, it was accepted wisdom that bad results were less likely to be written up in the literature. The data on performance were assumed to be skewed. The picture presented in the literature and the reality of everyday treatment were, consequently, regarded as some distance apart. It followed that all healthcare professionals whose performance did not meet the standards achieved in the literature were able to persuade themselves that it was the literature not they who were out of line. Thus, until recently, the patient and the doctor were steering their way towards quality of care with only the crudest of maps.

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[4] The Clinical Standards Advisory Group existed between 1991 and 1999. Its function was to advise the Secretary of State, as requested, on standards of clinical care in the NHS and on access to and availability of services to NHS patients

[5] They are the Confidential Enquiries into (1) Maternal Deaths (since 1952) (2) Stillbirths and Deaths in Infancy (since 1992) (3) Peri-operative Deaths (since 1987) and (4) Suicide and Homicide by people with Mental Illness (since 1992)

Clinical audit: the policy and the practice

8 The shortcomings of this approach have increasingly come to be realised. Relying on each individual to maintain his knowledge of the latest literature, research and best practice has become an unrealistic proposition with, on the one hand, the increasing complexity and variety of information, and, on the other, the growing demands on professionals' time to care for patients. Meanwhile, the variations in the outcome of healthcare which exist across the country today (to the extent that they are understood), serve as an indictment of the old way of doing things. In a patient-centred healthcare system, the standard of care patients can expect should be determined by something more than the capabilities of individual healthcare professionals and the vagaries of individual hospitals.

9 In 1989 the first attempt was made to introduce a more systematic approach to improving the quality of clinical care in the NHS. The DoH formally adopted a policy of requiring hospitals, and later trusts, to undertake medical, later extended to clinical, audit. The idea that clinicians should take time to reflect on their practice and make any necessary change to it was well accepted (if not widely practised or supported). The new policy introduced an element of formality. It was accompanied by ring-fenced funding, and local co-ordinating committees were established. At the time this was a significant step, but with the benefit of hindsight and experience we can now see how limited a step it was.

10 The story of the initiative to introduce a national system of clinical audit has not been a happy one. The ring-fenced resources were not always used effectively, and were sometimes deployed for other pressing needs, given the extremely tight financial constraints in the NHS generally at the time. Furthermore, the whole initiative was suspected by healthcare professionals of being a tool of managerial control. And, because participation was voluntary, the implementation of audit in any given hospital was fragmentary, with some clinicians participating and others not. The practice of clinical audit, if not the policy, came to be regarded by many as at worst a failure, at best, not a signal success.[6] Thus if clinical audit was the tool whereby performance and outcome were to be measured, both locally and nationally, its relative failure meant that, by the late 1990s, the NHS was almost as ill-equipped as ever to address the issue of quality. Patients have not been well served.

Recent developments

11 It is now widely accepted that this state of affairs has to change. Patients are entitled to expect that their care will be of such quality as is consonant with good practice, based on sound evidence. To adopt the words of the White Paper *'A First Class Service'*:

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[6] See the Expert paper prepared for the Inquiry: Walshe K and Offen N. *'An evaluative commentary on systems for review and audit at the United Bristol Hospitals/NHS Trust 1984–1995'*. See Annex B 10m

> 'High quality services should be available to all patients. At present, there are unacceptable variations in the quality of care available to different NHS patients in different parts of the country. This has to change'.[7]

12 A number of recent developments suggest room for guarded optimism for the future. The first is that, with an injection of funds into the NHS, attention can begin to move beyond issues of cost and efficiency to embrace more fully the issues of the quality of care. We say again, however, that without a continued increase in funding, progress along the lines which we propose will simply not be sustainable. Second, to signal the importance of quality and standards, the Government, for the first time in 1999, placed on trusts and health authorities a statutory duty to establish and maintain arrangements for monitoring and improving the quality of healthcare. Clearly, if the chief executive of a trust is legally responsible, and publicly accountable for making something happen, the odds of its happening improve. Third, Government has made it clear that it will set national standards for clinical care in the form of clinical guidelines developed by the National Institute for Clinical Excellence (NICE), and through National Service Frameworks (NSFs) developed by the DoH. Fourth, initiatives are in hand to monitor performance. The Commission for Health Improvement (CHI) is required to inspect each trust every four years to review clinical governance arrangements.[8] In addition, part of CHI's work will be to undertake a programme of reviews to see how well the guidelines developed by NICE and the NSFs are being implemented. Further, CHI with the Audit Commission will jointly publish information annually on the performance of the NHS, including performance against a selected number of clinical indicators, such as rates of survival from different forms of cancer. Such initiatives represent a start, albeit belated, on the road to understanding and then improving quality of care.

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[7] Department of Health. *'A First Class Service; Quality in the New NHS'*. London: The Stationery Office, 1998

[8] According to CHI: 'Clinical governance comprises the clinical and managerial systems, procedures and working practices that NHS organisations should have in place to ensure that patients receive the best possible care.' For background to clinical governance reviews see: www.chi.nhs.uk. Examples of systems which form part of clinical governance arrangements include clinical audit, risk management and the arrangements for staffing and staff management

Box A – Current arrangements for setting national standards of care

Clinical Guidelines from the National Institute for Clinical Excellence (NICE)

- NICE is a Special Health Authority for England and Wales. It is part of the NHS. Its role is to provide patients, healthcare professionals and the public with authoritative, robust and reliable guidance on current 'best practice'.
- Its guidance refers both to particular technologies in healthcare (medicines, medical devices, diagnostic techniques and procedures) and the clinical management of specific conditions.
- One of the four main strands of NICE's work is to set 'clinical guidelines for clinicians and patients'. Around 20 topics are addressed annually. A list of topics is set and agreed annually by the Secretary of State for Health and by the Welsh Assembly. A long-term objective identified by NICE is to achieve a full description of clinical practice.

Source: www.nice.org.uk

National Service Frameworks (NSFs) from the Department of Health

- NSFs were first announced by the Government in the White Paper *'The New NHS'* (1997). NSFs set national standards and define service models for a specific service or care group. They aim to put in place programmes to support implementation of the standards and to establish performance measures against which progress within an agreed timescale can be measured.
- The first two 'Frameworks' were the Paediatric Intensive Care Framework and the Calman-Hine report on Cancer Services. Three more are in place: Mental Health (1999); Coronary Heart Disease (2000); and Care of Older People (2001). Others, in preparation, include: Care of People with Diabetes, to be published later this year (2001); and one for Children's Health Services. When NSFs are written they include some clinical performance indicators which can be used to monitor implementation of the framework.
- The Department of Health develops each NSF with assistance of an expert group of health professionals, service users and carers, health service managers, and other relevant bodies.

Sources: NHS Plan 2000, www.doh.gov.uk

Scope for building on recent developments

13 To point to the potential for improvement and to possible shortcomings in the arrangements currently being established or proposed is not to criticise for its own sake. It is really to recall our central concern: can we be sure that events similar to those which happened in Bristol are not happening now or will not happen in the future? If we cannot be sure, and we do not think that we can be, we must highlight shortcomings in the various current proposals which prevent us from being so. We believe that more attention needs to be given to co-ordinating the setting of standards; addressing uncertainty where there are no standards; ensuring that standards are sufficiently comprehensive; and improving the ways in which standards are monitored. We deal with each of these in turn.

Insufficient co-ordination in setting standards

14 As we mentioned previously, many of the Royal Colleges and specialist professional organisations since the late 1980s, have issued, intermittently, standards and guidance for the treatment of a range of conditions. In the last two to three years, probably in response to the widely acknowledged vacuum in this area, this work has intensified. We list here a few examples. The Royal College of Nursing told us that its current work '… includes setting national standards and clinical guidelines …'.[9] The Royal College of Physicians, through what is now its Clinical Effectiveness and Evaluation Unit, has since 1990 produced guidelines for the care and treatment of over 90 conditions. In the particular clinical areas which are of interest to this Inquiry, the Royal College of Surgeons of England recently issued guidance on children's surgery;[10] and, with regard to the removal and retention of human material, the Royal College of Pathologists issued guidance in 2000, only to be followed by the BMA and the DoH, each with its own guidance on the same topic.

15 There is much to be welcomed here, not least the preparedness of the Royal Colleges and other bodies to seek to fill the previous vacuum. But there are also disadvantages in the appearance of a host of guidelines from different bodies, some, indeed, on the same subject. Trusts and healthcare professionals may not know which standards should be followed, or what status or authority the standards have. Furthermore, patients do not know what to expect or what they are entitled to. Indeed, if patients with a particular condition were to seek to refer to the guidelines which relate to the care of their condition they might find several, aimed at different specialists, emanating from different Royal Colleges and professional associations. Equally, they might also find standards developed by local clinicians, or by the DoH, or possibly by NICE. Or, they might find none at all. It has to be said also that there is frustration on the part of the Royal Colleges and professional associations, as we heard during Phase One that, where they have developed standards, they have no means of ensuring compliance. The written evidence of Dr Michael Godman, then President of the British Paediatric Cardiac Association, was typical: 'It is clear, however, that there is at present a vacuum in relation to the enforcement of standards. The Royal Colleges are primarily concerned with training and neither the Department of Health nor Purchasers/Commissioners for Services have set clearly defined standards by which centres can be judged.'[11]

16 There is also the potential for confusion if NSFs are written so as to include particular clinical standards other than those developed under the auspices of NICE. NSFs are laid down by the DoH. We have already referred to what we regard as an essential role of the DoH: to be the headquarters of the NHS. It is entirely compatible with this role that the DoH should seek to lay down NSFs, if Frameworks mean addressing broad issues concerning priorities, the effective use of resources, and the organisation of care. But it should not be part of the DoH's role also to seek to set standards for clinical care, whether as part of NSFs or not. If it does so, it goes beyond what we regard as its proper role. It adds to the confusion as to which standards apply if they should appear in an NSF and be issued by NICE. It also undermines the role of NICE as the body charged with setting standards. We recognise that the new arrangements introduced in 1999 are still, to a degree, bedding down. But, in relation to NSFs,

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[9] Seminar 6. The Royal College of Nursing. Position Paper

[10] The Royal College of Surgeons of England. *'Children's Surgery – A First Class Service'*. London, May 2000

[11] WIT 0047 0005 Dr Godman

we take the view that it should be the role of NICE to establish the detailed clinical standards which patients are entitled to expect, and thereby lend substance to these Frameworks.

Confusion as to the availability of standards

17 Although the task of setting national standards has begun, uncertainty is created in those areas of healthcare for which, currently, there are no national standards. The public are left uncertain as to whether there are any standards for the care and treatment of their particular condition, or whether such standards as may have been produced by a Royal College, or on some local initiative, are appropriate. There is a danger that conditions which are not categorised as 'national priorities' may be given too little attention. And, of course, where there is no standard, there is no agreed benchmark against which to monitor performance and learn lessons.

18 Hence, we consider that a timetable over the short, medium and long term should be published, and revised periodically, for the development of national clinical standards, so that the public may be consulted and kept aware of those areas of healthcare which are covered by such standards and those which will be covered in the future. Target dates should be set by which clinical standards will have been prepared for all major conditions and illnesses.

Comprehensive standards

19 Standards relating to the quality of clinical care must not be seen solely in relation to care at the bedside. One of the significant lessons of Bristol is the effect which the organisation and management of a service has on the quality of clinical care. Thus standards must also relate to all the relevant aspects of management of care. This is clearly recognised in the *'Manual of Cancer Services Standards'*.[12]

Problems with regard to monitoring standards

20 Local monitoring: the responsibility for delivering care of good quality to patients must be a matter for individual trusts, and for the healthcare professionals within those trusts. The arrangements for clinical governance in the NHS now recognise this. As part of the process of providing care of good quality, there must be systems in place to enable trusts and healthcare professionals to monitor and assess their performance against agreed standards, and to compare or 'benchmark' their performance against that of other units in similar circumstances offering similar services. The process of clinical audit, which is now widely practised within trusts, should be at the core of a system of local monitoring. Yet, in order undertake audit effectively, clinical teams need time. They need to generate and have access to data of good quality about their own performance and about that of other teams in similar trusts. Further, they need to know how to analyse and to interpret such data, or to have access to the necessary expertise to help them to do so. And they need to have the necessary support, in terms

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[12] NHS Executive. *'Manual of Cancer Services Standards'*. December 2000. The manual includes standards for the way in which multi-disciplinary clinical teams should work and standards for the organisation and management of cancer networks and cancer units

of administrators and information technology, to be able to do this. Currently, throughout the NHS, there is considerable scope for improvement on all of these fronts. On the matter of data, for example, there continue to be a plethora of systems, of varying quality, for collecting, coding, validating and analysing clinical information.

21 National monitoring: it remains very difficult for a particular trust to compare itself with another equivalent trust, or for a given unit or specialty within a trust to be compared with one in other trusts. We acknowledge the further development, since 1999, of clinical performance indicators, and the DoH's proposals for extending the range and type of these indicators.[13] But we are also mindful of the scepticism with which clinicians continue to view much of the data used for such national clinical indicators. Many are based on Hospital Episode Statistics (HES) data which are collected and collated by the DoH from the various patient administration systems of trusts. This Inquiry's extensive investigations into the HES data have confirmed that their quality and reliability improved steadily in the 1990s. But the data are still not highly trusted by clinicians for a variety of reasons, not least the conventions which are used to code clinical information and the fact that the data are coded in hospitals by non-clinician coding staff.[14]

22 With regard to those clinical audits which are organised on a national basis (which differ from national clinical indicators in that they take a detailed view of the care of patients with a given condition), the few such audits as exist cover only a small proportion of the total of care in the NHS. This itself reflects the shortage of national standards. Yet such audits are an important tool in assessing the quality of care because of the type of comparative data they can produce. The Royal College of Physicians told us that its Sentinel Audit of Stroke considered over 7,000 cases drawn from 80% of the hospitals treating patients who had suffered a stroke. By drawing on such a large number of cases it was possible to identify patterns and make comparisons on a wide scale and thus to separate the best performing from the worst performing units with considerable confidence.[15] Such national audits are vital for the future; they will only come to have real meaning when there are standards to which such audits relate.

23 Currently, the future for national comparative audits appears to be unclear. NICE provides some funding to various Royal Colleges for the audit of certain specialties on a national scale. NICE is also responsible for the four national Confidential Enquiries. It is CHI, however, which has been set the task of monitoring whether the standards set by NICE have in fact been implemented. CHI is also responsible for monitoring the National Service Frameworks and, with the Audit Commission, has already commenced its first review (of the Cancer Framework). A third body, the National

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[13] We note in particular a recent document *'NHS performance indicators: A consultation'*. Department of Health, May 2001. www.doh.gov.uk/piconsultation

[14] See Annex A Chapter 19 and Annex B (Sections 7 and 8) for the disagreements about the quality of HES data between clinicians in Bristol and the Inquiry's experts on statistics

[15] Rudd A, et al. 'The national sentinel audit of stroke; a tool for raising standards of care'. *'J Roy College Physicians'*. London: 1999; **33**: 460–5. Other examples of national audits include those led by the Royal College of Surgeons of England on liver transplantation and on sino-nasal surgery

Specialist Commissioning Group, commissions and, intermittently, conducts national audits of those services it funds, one example being the UK national audit of intrathoracic transplantation. All of this is important work, undertaken with the intention of developing and improving clinical care. All of it is work which has implications for trusts. It is trusts, at the sharp end of the delivery of healthcare, which must deal with the various apparently unconnected and uncoordinated collections of data and respond to whatever analysis or report emerges subsequently. Looked at from the perspective of the patient, the various collections of information, whether national clinical indicators, national audits or reviews into particular standards, appear to be fragmented, with no proper co-ordination, with variable feedback to trusts and healthcare professionals, let alone to patients themselves.

24 One area in which there remains a serious gap is the absence of a mechanism, outside trusts or individual clinical teams, for taking a view of the whole range of clinical performance, drawing on clinical indicators, the results of national audits, and on other relevant data. We would describe this process as surveillance. Such a mechanism of surveillance would contemplate a body or organisation with the responsibility and the expertise actively to analyse data and other evidence, to spot trends over time and to identify patterns of poor (and good) performance, either in a particular hospital, or in a particular specialty across a number of hospitals. Such patterns would not necessarily be evident to those who provide a service, or, though evident, they may be ignored or overlooked for whatever reason. The DoH acknowledged this gap in April 2001 when it stated: 'The NHS does not have a systematic way of monitoring the occurrence of poor clinical outcomes of care unless they are manifest as serious events.'[16] The purpose of such surveillance must be: to identify those whose performance lies outside the ordinary pattern of overall performance; to draw attention to this; to see that questions are asked; to ensure that the reasons for the performance are identified and understood; and to take action if it is needed. Until such a form of surveillance exists, there remains the possibility that patterns of poor performance will continue to go unaddressed or unrecognised. We also have in mind that such surveillance could identify those whose performance is consistently good. Such information could help to prompt improvements elsewhere. Thus, although much important progress is under way, lack of clarity, lack of co-ordination, the continuing possibility that important matters are ultimately not dealt with by any organisation, since each thinks the other is doing it, or because no one has the responsibility to act, all mean that problems remain to be solved.

25 The recent progress to which we have referred in developing standards of care, whatever its drawbacks, begins to point to the way forward which the NHS needs to follow if it is to take standards of care seriously so that patients consistently receive an appropriate quality of care. But they are only a beginning: the magnitude of the task should not be underestimated. It will need to be properly resourced. The development of standards and the production of good guidance takes time and expertise. But without them, there will be no way to evaluate and improve the quality of care. We set

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[16] *'Building a safer NHS for Patients; implementing An organisation with a memory'*; para 52. Department of Health, April 2001. www.doh.gov.uk

out now a number of steps that we regard as essential to future thinking about standards of care, and to future arrangements for monitoring their implementation.

Setting standards for clinical care

26 We have already argued that the emergence of a variety of standards of clinical care from a variety of organisations, while it shows a willingness to become involved, may produce more confusion than clarity. One of the themes of Bristol was that, while a large number of organisations were involved in one way or another in paediatric cardiac surgery, each thought the other was looking after the matter of standards (and, to a degree, performance in relation to those standards), such that the concern for quality fell through the cracks between the various organisations.[17] That lesson from Bristol leaves us in no doubt that there must be some body or organisation which takes overarching responsibility for the setting of standards. This does not mean that this body itself should necessarily draft the standards, only that it is there to see that they are developed, agreed and kept up to date.

27 The organisation best suited to do this is NICE. It already has authority from the Secretary of State to develop clinical guidelines which can form the basis of, and embrace, standards. If required, it would have to be given any necessary additional statutory authority to develop and manage a programme of setting standards, along with the necessary additional resources. In turn, NICE must engage and make full use of the expertise of relevant organisations such as the Royal Colleges and the specialist professional associations. It must draw on the expertise of senior management in the NHS. It must also fully engage the public, patients and carers, as indeed it is seeking to do. The principle would be that of the hub and spokes. The hub would be NICE. It would have overall responsibility and be accountable. The spokes would be the contributing elements: the Royal Colleges, the specialist professional associations, the public and the NHS. In this way, standards would be co-ordinated and managed across the whole of healthcare. It would spell the end to the cottage industry of various bodies developing standards for the NHS and issuing them independently. There will be one authoritative organisation, NICE, under whose aegis all standards for the care provided by the NHS would be issued. All such standards should be made public.

Patient-centred standards

28 It follows from all that we have said about the need for care to be organised around the needs and interests of the patient, that the standards must be built around patients and their conditions. While this appears obvious, it has two significant implications. It means first that, ordinarily, standards will not be drawn up by, and solely addressed

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[17] See Annex A Chapters 4 and 20–31

to, one group of professionals. Patients, particularly those in hospital, are seen by, and need the care of, professionals in different disciplines, often working in teams. Patients are also seen within NHS facilities, and the quality of those facilities and the way in which care is organised, as we have learned, affect the standards of care. Patients also need timely access to care. Thus the standards must address, reflect and incorporate the roles and responsibilities of those in the team who from time to time will care for the patient and the physical facilities in which care is provided. They must include guidance as to how promptly patients should get access to care. They must also address such matters as the way in which care for people with a given illness or condition is organised as between primary, community and hospital care. This conclusion adds further strength to the view that the setting of standards must be the responsibility of an organisation, NICE, which can co-ordinate the activities of the different professional bodies involved and ensure that the patient's perspective and the patient's journey are taken into account. The second implication is that patients and the public must themselves be involved in the setting of standards, so that their interests and concerns are fully taken into account.

The authority of standards of clinical care

29 What authority should the standards have and what should follow if they are not observed? We have said that NICE must have the legal authority to take the lead in developing and issuing standards. But that does not address the matter of what authority the standards themselves may have. Should some standards be obligatory? Care is needed here. To describe standards as obligatory means for us that they must be followed and that, if they are not, some action will follow. We accept that some standards should be obligatory. We also accept that other standards will serve as aspirations to be achieved over time. When we use the term obligatory we do not mean that failure to observe the standards would bring legal sanction. This would create a nightmare situation in which legalistic arguments would intrude into the care of patients. Further, in the case of standards addressed to healthcare professionals, it would deny the professionals the proper exercise of discretion to tailor care to the needs of the individual patient. It would bring an undesirable element of rigidity, where flexibility and responsiveness to the requirements of individual patients are essential.

30 Thus, in the case of the healthcare professional, where standards are not followed we look to the professional's contract. We see the obligation to observe the standards which are issued by NICE as being necessarily incorporated into the contract of employment between a healthcare professional and his employer. Failure to comply with the standards, without acceptable justification,[18] would then entitle the employer to take whatever action was deemed appropriate. Initially it could involve retraining. It need not, indeed it should not, result in some automatic response of suspension or

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[18] Guidelines and standards must cover the majority of patients, but we accept that they have to be applied flexibly. We agree with the view of the Royal College of Physicians that there will be times when it is right for clinicians to deviate from a guideline as long as there is a justification for the change in plan, and it is recorded in the patient's notes. See Seminar 6. Royal College of Physicians. Position Paper

disciplinary action save where warranted.[19] To the extent that the standards constitute good practice, professionals who observe them can rebut any allegation of poor quality of care. Professionals who do not observe them would be required to justify their conduct.

Generic standards for healthcare organisations

31 We note that in Scotland the standards set by the Clinical Standards Board include what are described as generic standards, that is, standards which are addressed to the hospital as a whole. These are distinct from standards which focus on the care and treatment of patients with a particular illness or condition. We have already observed that, in relation to Bristol, the standard of care was significantly influenced by factors which were not specific to the healthcare professionals, were generic to the hospital as a whole. For example, the state of the buildings and of equipment, the quality of the leadership, and the Trust's policies and procedures all had an impact on the adequacy of care for children with congenital heart disease. It was the healthcare organisation, as much as (or more than) the healthcare professionals, which caused the problems. This leads us to the view that there needs to be increasing rigour in preventing trusts from continuing to offer a clinical service (or services) when the service falls below the agreed standards and is consistently less than adequate. Professor Mike Richards, the Government's National Cancer Director, addressed this very point when launching the *'Manual of Cancer Services'* in 2001. He said: 'The public want to know that the service they are getting is a good one. If a hospital is way off the standard we want, should we be having patients dealt with by that sort of service? The answer must be no ...'[20] We believe this is fundamentally the right approach. We would add that, in practice, should matters so deteriorate and not be capable of rapid improvement, this would mean the suspension or closure of services, and the re-provision of the service in another hospital. Clearly such drastic action and all the consequent upheaval it would produce would be very much the last straw. In particular, it must not mean that a poor service is starved of resources so that it gradually 'withers on the vine' and patients suffer ever diminishing standards. Support, not sanctions, is the preferred approach. We explain, later on, the wider system which we believe should be put in place to give effect to this approach.

32 We have made it clear earlier (Chapter 25 – The Competence of Healthcare Professionals) that the process of validating and revalidating healthcare professionals as being competent to do their job is an important component of ensuring the safety and quality of healthcare. In the future all healthcare professionals will be expected to participate in such a process. In our view, it is equally important that trusts, including

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[19] We found the approach adopted in the DoH's publication *'Supporting Doctors, Protecting Patients'* to the balance between support and discipline too heavily weighted in favour of the latter, particularly with regard to too-ready recourse to suspension

[20] Charter, D. 'Red Tape row over cancer treatment'. *'The Times'*, 19 Jan 2001

primary care trusts, also participate in a formal process of validation and revalidation, a process which is of a different order from, but in parallel with, that which healthcare professionals will undergo. We choose the term 'validation' not only to mirror the process recommended for healthcare professionals but also to indicate that while akin to licensing it contemplates more. Licensing tends to be thought of as a 'one-off' event, whereas to us validation is a process. What makes validation akin to licensing is the element of permission to continue.

33 The analogy of the airline industry is instructive. It provides a service of potentially high risk. All elements of the industry are subject to standards for safety and quality which are monitored. While the competence of individual airline employees is regularly checked and revalidated, and the airworthiness of aeroplanes is frequently checked, the airline company itself must also seek certification from the regulatory body to entitle it to operate an air service. Thus the individuals who operate the service, the equipment they use, and the organisation which provides the service are all subject to a form of external regulation.

A system for validating healthcare organisations

34 We see the need for a shift from the current notion of inspection of healthcare organisations in England towards one of validation. Inspection is a single event. It implies a 'checking' mentality, and carries negative and punitive overtones. Validation, on the other hand, implies a constructive approach and a continuous process. We see it as a process with a clear aim: to help in the improvement of the quality of healthcare. It would include, but not be confined to, external assessment. The organisation itself would evaluate its own performance in the light of established standards, and be subject to external validation checks and visits. In what follows we set out how a system of validation of trusts would work.

35 The first stage in the process of validation is the setting of generic standards which will form an objective basis for assessment, and which all trusts must meet in order to be validated and thereby be entitled to provide NHS services. These standards will focus on matters such as the patient's experience and whether the trust is responsive to patients' needs. They will also address the trust's systems for ensuring that care is safe and of good quality (corporate management, clinical governance, risk management, clinical audit, the management and support of staff, and the management of resources). The basis for many of these standards in fact already exists, in one form or another, whether as legal requirements imposed on the trust, or in the form of guidance from the DoH and other bodies. Once translated into standards, we believe they should be obligatory. By this we mean that, unless the standards are met, the trust would not have the necessary validation. Periodically, each healthcare organisation in the country would receive a visit from external assessors to ensure that the standards were being complied with. (Sometimes, we believe, visits should be unannounced.) Thus, for example, the current routine visits by CHI would no longer be 'inspections' but would become visits to validate a trust as suitable to offer NHS services. The system should be flexible. It would be a matter for CHI to determine how frequently it should visit a trust.

36 Compliance with the standards laid down on systems, facilities and staff, would mean that the trust would be granted validation and thus be entitled to offer NHS services. Ways might be explored to recognise circumstances where a trust exceeded the obligatory standards, or offered particularly good or exemplary service. The standards themselves, and the results of external assessment, will be made public and be easily accessible and visible throughout the trust and in the local community.

37 The validating body should adopt an approach which is flexible and seeks to support organisations. Its aim must be to promote continued improvements in the quality of care in the NHS. That said, however, it should have powers to act if standards fall such as to threaten the quality of care or the safety of patients. If any area of practice were to fall below the required standard, the organisation would be put on 'validation watch'. An action plan and a timescale would be agreed for any problems to be remedied. If certain key areas of practice failed to improve, or fell significantly below the required standard, such as seriously to threaten the quality of care received by patients, it would remain open to the validating body to withhold, suspend, or even withdraw, validation.

38 We believe that the switch from a system of inspection to one of validation would further the overall direction of current policy. It would be achievable within the existing structure of CHI, but would take a change in emphasis and approach which we believe would be welcomed within the NHS and by the public.

Rationalising the 'inspection industry': a single body to validate healthcare organisations

39 Currently there is no effective co-ordination of the various external inspections and assessments that trusts are required undergo, or of the generic standards they are required to follow. Apart from putting an unnecessary administrative burden on trusts in dealing with these activities, there is inconsistency and an inevitable fragmentation of the process, with the consequent danger that matters are overlooked. Thus instead of the National Health Service Litigation Authority (NHSLA), the Royal Colleges, the Health and Safety Executive, the Audit Commission and numerous other bodies issuing standards independently and considering separate aspects of the trust's management, in the future these various standards and forms of external inspection must be integrated into a single validation process. There must be a single, coherent, co-ordinated set of standards with which NHS organisations have to comply, overseen by a single validation process and a single validating body. By a single validating body, we do not mean that one body should itself set all the standards and or undertake all aspects of the process.[21] What we mean is that one body should be in overall charge, ensuring that the generic standards exist, that they are consistent and coherent, and

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[21] We see scope for collaboration between a programme of validation led by CHI and the many voluntary accreditation programmes currently available and used by many trusts

capable of implementation within an organisational setting. Further, that a single body should take a view as to how well the trust meets all the generic standards. CHI, suitably structured so as to give it the necessary authority and independence, is well placed to adopt this role.

40 The place and role of the Audit Commission is a specific example of the case for rationalisation. In terms of its role of ensuring the proper stewardship of public finances, which is carried out through the Commission's District Audit Service, we see no overlap with other bodies. Indeed this activity must continue. But in terms of its other role of helping those responsible for the NHS to achieve economy, efficiency and effectiveness, there is now a degree of overlap with the role and functions of CHI. We recognise that during the 1990s the Audit Commission helped to fill a vacuum in addressing issues to do with clinical effectiveness and comparative performance. Our concern, however, is that notwithstanding the high quality of their work they continue to provide reports on such matters, even though other bodies, in particular NICE and CHI, are now established. In proposing a single validating body and the rationalisation of the inspection industry, therefore, we see the need for reappraising the future of this second role of the Audit Commission.

Validation in the private sector

41 These generic standards must apply wherever patients receive healthcare services paid for by the NHS. This would include all trusts within the NHS and those organisations in the voluntary or the private sector which treat patients paid for by the NHS. It is plainly not acceptable for a patient to receive care paid for by the NHS in a private hospital if the standards of care are below those which apply to NHS hospitals. Thus there must be a system whereby, if private hospitals are to provide care to NHS patients, they must first achieve validation against the obligatory standards established within the NHS. Currently, the Government's intention is that private hospitals which provide acute care will be inspected, not by CHI, but by a new body, the National Care Standards Commission.[22] There must be a serious question as to whether it is in patients' interests for there to be two separate systems of inspection, applying different standards, one set for the private sector and another for the public sector. Patients are entitled to expect that, wherever they are treated as an NHS patient, the standards stipulated by the NHS will apply. Thus we would urge that, with regard to patients treated in the private sector and funded by the NHS, the approach adopted by the National Care Standards Commission replicates that which applies to patients treated within the NHS.

Validation of services or facilities within a trust

42 We also see considerable benefit to patients in taking a further step, by extending the process of validation of trusts to cover discrete, identifiable services within a trust. This

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[22] The National Care Standards Commission, established under the Care Standards Act 2000 and due to be fully operational in 2002, is a non-departmental public body with a remit to regulate residential care homes and private and voluntary healthcare in England. It will set national minimum standards, inspect, investigate complaints against registered services, and report to the Secretary of State on the range and quality of regulated services

will involve setting or developing existing standards for those services. In some circumstances it would be appropriate for the standards to focus on a particular set of clinical conditions, for example, services for people with cancer, or services for children with congenital heart disease. In other circumstances, the standards could focus on a particular facility within the hospital, such as the accident and emergency service, or the day surgery service. Thus, a local hospital or a primary care trust might be granted validation to provide day surgery, but not major acute surgery. It might be granted validation to run a minor injuries unit but not a major accident and emergency department. A large acute hospital might be granted validation to provide services designated as specialist services. One crucial consequence of this approach is that a hospital would not be able to offer a new service unless it met the standards necessary for validation. It would not be acceptable for a trust to aim to develop the service so as to be able to meet the standards at some point in the future. Moreover, by offering a service to the public which was not validated, chief executives would be in breach of their duty to ensure the quality of the services offered.

43 This process of validation would have very significant consequences for patients and their carers and families. To take the example of children's acute hospital services, parents in the future would know that a given hospital had received national validation to provide inpatient facilities for children, and thus that the hospital met the national standards on staff trained in paediatric care; suitable facilities for children; and child- and family-centred care. Thus they would know that the hospital had been validated to undertake paediatric surgery. They would know that the hospital had been validated to provide paediatric intensive care. Moreover, since the standards would be a matter of public knowledge, the public would know the standards to be expected. The public nature of the standards and the link to validation, which would be known to all those who work in and use the service, will act as a powerful and continuing incentive to maintain the standards. Validation of healthcare organisations would also be significant for the healthcare professionals. It would constitute an independent and public affirmation of the service of which they were a part.

44 We recognise that, in this as in any form of regulation, there will be costs as well as benefits. The costs of extending the process of validation to specific services are difficult to determine in the abstract. They will depend on the way the system is implemented. We believe that in time the benefits, in terms of the quality of care for patients, of there being nationally stipulated standards and a system of validation, will outweigh any direct costs. And there could be savings from better co-ordination and a rationalisation of the various inspections which trusts currently undergo. We recognise, however, that there is a case for proceeding carefully. We do not therefore suggest that a system of validating particular services be introduced all at once across the country. This would be to invite the sort of chaos which has dogged numerous other initiatives. Rather we urge that approaches to the validation of specific services be developed, piloted and evaluated, prior to their implementation on a national scale. Children's acute hospital services in general, and paediatric cardiac surgery in particular, should, we believe, be included in any pilot. Should the pilot be successful, the category of discrete service which should be a priority for this form of validation are those specialist services which are currently funded by, or meet the criteria for funding, set by the National Specialist Commissioning Advisory Group (NSCAG), the successor body to the Supra Regional Services Advisory Group (SRSAG).

Monitoring of performance

45 Monitoring performance is a crucially important activity which warrants careful analysis. Fundamentally, its role must be to help to improve the quality of care, not to point the finger or to blame. It is important for two reasons. First, it enables clinical teams, through the process of clinical audit, to review and improve the quality of the care they provide to patients. Both local audit and national audit have a role in achieving this. Second, by the publication of information on performance, the public are included and informed about how well their NHS is performing and how well standards are being met. Thus information on performance and its publication are crucial elements in the accountability of the NHS to the public. Monitoring performance entails a number of phases which we consider here in turn.

Information and clinical audit

46 Here we refer to the need to be able to collect information about performance, to assess it, to change and improve it where necessary, and, just as importantly, to revisit the standards with a view to changing or developing them. Information is the basic building block of any system of standards and quality. In the past, there have been great difficulties in collecting information, based not only on the technical problems associated with establishing proper systems for doing so, but also on differing approaches as to what should be recorded, and then how it should be classified and grouped for analysis.

47 It is a truism that central to any process of reporting and recording information is agreement on what is being reported. Regrettably, lack of agreement, as to how, for example, to categorise a particular procedure, or what period of time should be used to measure the outcome of a procedure, has bedevilled initiatives in the fields of audit and performance assessment. We heard from Professor de Leval, Professor of Cardiothoracic Surgery, Great Ormond Street Hospital, in the course of a Phase Two Seminar[23] that, even in the relatively small and cohesive world of paediatric cardiac surgery, three ways of categorising procedures exist at an international level, and it is extremely difficult for those involved to agree on which one to adopt. Indeed, Professor de Leval went so far as to urge that, in the absence of agreement, a solution should be imposed. Otherwise, he argued, progress would be impossible and the loser would be the patient. We agree that standardised methods of reporting and classification of information are crucial, both in paediatric cardiac surgery, and

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[23] Summary Report of Seminar 6. See Annex B

generally. We are persuaded that, in the case of paediatric cardiac surgery, with the active engagement of the Royal Colleges, the DoH and other interested bodies, agreement can be reached. But, if it cannot, the issue is sufficiently important to warrant the imposition of standardised categories by the NHS Information Authority.

48 We have seen that there have been sections of the medical profession in the past who have been suspicious of data collection and audit. It is important to understand the basis for this suspicion. Fundamentally, it arises from an anxiety that data would be either inaccurate, or that, when analysed, complexities such as case mix will not be adequately explained or understood. There are concerns that data will be interpreted and used in an uncritical way, to support criticism or invidious comparison. We note and welcome the point made to the Inquiry by the Royal College of Physicians on this matter: 'physicians are not frightened or worried about having data to judge … their performance, as long as those data are seen to be an accurate and fair representation of best care. Most in fact welcome the opportunity to have reliable data to monitor and improve the service they offer. The chance to do this jointly with management could be a huge opportunity for the NHS to make major improvements that would benefit patients.'[24]

49 We believe it important for the future that these anxieties and aspirations are acknowledged. In practical terms this should not mean that information about performance should be hidden. What it does mean is that serious attention must be paid to the development of robust methodologies which can be applied to data so as to give as fair and accurate a picture as is possible. Variables such as case mix and where possible, in the case of surgery, operative risk must be allowed for, so that, wherever feasible, it is possible to compare like with like. It also means that data must be properly analysed with appropriate expertise. We referred in an earlier chapter (Chapter 25 – The Competence of Healthcare Professionals) to the need for a higher priority to be given to educating healthcare professionals about clinical audit and the use and interpretation of data. In addition to this, we consider that clinical teams need to be able to have access to support and guidance in the process of analysis, and that such support and guidance should be available either in, or through, a central clinical audit office which should exist within each trust.

50 Clearly, for progress to be made in this vital area, some rapprochement is essential between the various healthcare professionals: the managers, the doctors, the nurses and others. A crucial first step is to make the process easier for the clinicians. They complain with justification that they do not have the necessary time or resources to collect and classify information properly, and that they work with multiple and incompatible clinical IT systems. At the same time, because they are not involved, clinicians are sceptical of the value of information collected and coded by non-clinicians, principally the information which is collected in hospitals' Patient Administration Systems, and which, in turn forms the basis of the national Hospital Episode Statistics (HES) and numerous national clinical indicators.

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[24] Seminar 6. Royal College of Physicians. Position Paper

51 We have seen in Bristol in all too graphic detail, in what was in reality a small PCS service, how the surgeons, cardiologists and anaesthetists compiled separate sets of data, for similar purposes but without reference to each other. Looking back this now seems tragic. We have seen how the surgeons in Bristol and elsewhere had confidence in general in their 'own' data recorded in their personal logs or through their departmental systems, but distrusted the data in hospital administrative systems, and in the UK Cardiac Surgical Register. And we have seen that the tendency was to criticise or explain away the statistics, rather than to ask questions or do something about what the data may imply. We have also seen that data existed at a national level, in the form of the HES database. We have discovered that (at least from 1991), when cross-matched with other sources of data, it is reliable. But, we have discovered that at the time covered by our Terms of Reference the use of HES as a means of learning about mortality rates, for example, was not properly recognised.

52 For the future, we are persuaded of the conclusion reached by our Experts: '… the current "dual" data collection in separate administrative and clinical systems is wasteful and anachronistic.' We also agree with their suggestion as to the way forward: 'A vital aim should be two-way linkage between administrative and clinical systems.'[25] We do not advocate abandonment of current systems, far from it. What is needed is much greater attention to improving and streamlining the processes of data collection, coding and validation and to ensuring that respective systems can communicate with each other. The aim must be to collect data as a by-product of clinical practice and to reduce the multiplicity of methods and systems for collecting data. Collecting similar data on different occasions, in slightly different ways, for different purposes, is the discredited way of the past. The contribution that audit can make to improving the quality of care is simply so important that it must be given the priority it needs. It must be underpinned by systematic and reliable systems for collecting and analysing information which have the confidence of healthcare professionals, of those who manage the healthcare system, and the public. It must also be properly resourced, both in terms of funding and of dedicated support staff.

53 Second, as part of the culture of openness which we referred to earlier, and for the benefit of patient and professional alike, information and the results of audit must be shared within the hospital. The corollary is, of course, that, as we have said, healthcare professionals must feel that it is 'safe' to share such information. They must be able to work in an environment of mutual understanding and support, in which the overriding purpose is to put patients first. Thus professionals must be entitled to add explanations and caveats to data, so as better to inform those who might study the results made available. Each trust should have, as we have said earlier, a central clinical audit office, which, apart from supporting the process of audit within the trust by providing advice and expertise, can ensure that audit is undertaken and that the results are brought together for the trust as a whole. We note that this is already taking place in most trusts as part of their arrangements for clinical governance. We would add one final point. Healthcare professionals are now coming to see audit as central

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[25] Spiegelhalter D, et al. *'Monitoring Clinical Performance: A statistical perspective'*, November 2000. See Annex B 9c

to their role of caring for patients. We believe that in a patient-centred healthcare service, this recognition should be reinforced by making participation in clinical audit an explicit element in a healthcare professional's contract with the employer.

54 At the national level, we are convinced that it would be of benefit to the quality of healthcare if the monitoring of clinical performance were brought together and co-ordinated by one body. This would include the co-ordination of national audits and the validation and presentation to the public of information about performance in relation to national standards. It would also include filling the gap which we referred to earlier, the absence currently of a mechanism for surveillance, to review trends in performance over time and between trusts. We propose that all of these activities should be brought together under an independent Office for Monitoring Healthcare Performance which should be part of CHI. Its role could include:

- taking the lead in validating and publishing data, collected from within the NHS, on performance in relation to national clinical indicators and nationally agreed standards (this is already undertaken by CHI and the Audit Commission);
- guiding and funding the audit activities of the Royal Colleges and of the various medical organisations (such as, for example, the Society of Cardiothoracic Surgeons), so as to ensure that such activities are part of a wider strategy for auditing clinical performance;
- incorporating the audit functions currently performed by NICE (the funding of national audits by Royal Colleges and the Confidential Enquiries), and the multi-centre specialty audits necessary to monitor the implementation of standards;
- providing guidance on good practice in the analysis of data on performance, at both national and local levels, in particular, on the application of statistical techniques and methods; and
- providing a mechanism for the surveillance of data about performance (clinical indicators, the results of national audits and other relevant information) with a view to identifying patterns of poor (and good) performance.

The Office for Monitoring Healthcare Performance should be part of a reconstituted CHI, which itself must be fully independent of government and the DoH. It would play a key role in supplying rigorous and robust information about the performance of each trust. This in turn could be passed back to individual trusts and would be used in the process of validating trusts.

Informing the public and the professional

55 Information arising from audit and review must be disseminated so that those in a position to do so may take appropriate action. This clearly includes the relevant healthcare professionals and the trust chief executive. Does this mean that the information should also be made public? We recall that our central concern here, as elsewhere, is with the creation of a culture within the hospital and beyond which is patient-centred. If this is the aim, then the question of publication admits of only one answer. The public, who are patients in another guise, should have access to the analysed data. We believe that the data which are put into the public domain should relate not only to the performance of the trust as a whole, but should also describe the performance at the level of a specialty and of the consultant unit.[26] Performance at the level of a specialty or a department is important. It is an intermediate point between the trust as a whole and a consultant unit. Further, it offers an opportunity to address the performance of a service from the *patient's perspective*, and should include the contribution to care not only of doctors but also a cross-section of healthcare professionals.

56 It will be objected that audit data are complex and hard to understand. The public will be misled and draw unwarranted conclusions. Healthcare professionals will be unfairly criticised. All of these are, of course, real risks. But they are risks that must be faced and resolved. The alternative, of continued secrecy and anonymity, is no longer a real option. A new compact between the community and its hospitals must be forged in which the public must accept that the price of information is a considered and responsible reaction to it.

57 This new compact is much more likely to be forged when the next stage in improving quality through information is taken. Systems must be put in place within the hospital to take account of and, crucially, to respond to what the data describe. In a flexible organisation, all those involved in the hospital, at whatever level, should have a part to play in determining the appropriate responses. But also patients and the general public must be involved. (We will consider later how best this can be achieved.) By involving the public, not only does the hospital show that it is listening, but the public gains a degree of ownership and understanding of what can and should be done.

58 We said earlier that a concern for safety must be embedded in the organisation. We repeat this in relation to quality. It must be seen as the concern of all, not merely the responsibility of the chief executive. We are seeking in our approach to create a continuing and continuous interaction between on the one hand safety, the standards of clinical care and the standards of professional competence, and, on the other, the validation of hospitals to provide healthcare services. And, by involving patients and the public, a network of support is created as well as a collective will to sustain and improve the quality of care.

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[26] We take the term ‘consultant unit’ to mean a consultant and the team of doctors who work under his or her supervision

Chapter 28: Public Involvement Through Empowerment

The public are entitled to expect that means exist for them to become involved in the planning, organisation and delivery of healthcare.

Messages from Bristol

- The absence of any system for consulting parents and learning from them denied the hospital a valuable source of information about the care and service it provided.
- The absence of mechanisms for involving parents and families effectively in the care of their children led many to feel excluded.
- The absence of a clearly identified person and a place to turn to, led to a sense of bewilderment in many parents.

The issue

1 For a healthcare service to be truly patient-centred it must be infused with the views and values of the public (as patients past, present or future). The public must be involved. To be involved, the public must be empowered in the sense in which the word is used in the evidence of the NHS Primary Care Group Alliance. It suggested that public empowerment means: 'a public that is sufficiently informed as to be able to formulate meaningful views about quality and direction in the planning and delivery of health care; which views are listened to and acted on by commissioners and providers of NHS health care at the core of their decision making.'[1] We gratefully adopt this view.

2 In Chapter 23 (Respect and Honesty), we considered the entitlement of individual patients to more and better information and a greater degree of involvement in their care and treatment. In this chapter, we take a wider view. Here we consider how to empower and involve patients and carers in improving the quality of healthcare services generally. We explore how to involve the public as citizens in decision-making about the NHS, their NHS. The problem, while simple to state remains intractable: it concerns how, in a modern democracy, a public service such as the NHS can have embedded within it not only the principle that it exists to serve the public, but also mechanisms to ensure that this aspiration is translated into reality.

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[1] Seminar 7. The NHS Primary Care Group Alliance. Position Paper

Past experience

3 There has been no shortage of efforts and initiatives aimed at involving patients and the public in the NHS. But we detected a widely felt unease that too much of this effort has been of token value and has not succeeded in empowering patients. Indeed, *'The NHS Plan'* states clearly: 'Patients are the most important people in the health service. It doesn't always appear that way. Too many patients feel talked at, rather than listened to. This has to change.'[2]

4 Over the years, institutions, such as community health councils, have been created; 'lay'[3] people have been taken onto regulatory bodies (e.g. the General Medical Council and the United Kingdom Central Council) and onto hospital management committees and then trust boards as non-executive directors; and procedures have been adopted to consult the public, in such cases as the proposed closure of a hospital.

5 The result, however, has not been a sense of growing empowerment, such that the public, as patients or as taxpayers, after all these years of supposed involvement, feel truly in partnership with the professionals who run and provide our healthcare service. Indeed, the evidence from Bristol is the opposite: a sense, among many parents, of disempowerment, of inability to get the healthcare service to address their needs, and of bewilderment about where or to whom they could turn for help.

6 The reasons for this state of affairs are complex. To the extent that they can be identified, they allow us to suggest alternative approaches. A principal reason must be the lack of real power enjoyed by the bodies set up within the NHS to give the public their voice. Without power, such bodies swiftly become 'talking shops', attractive to those who like to talk but ineffective in terms of translating talk into action. The involvement of the public and patients – if it is always heavily outweighed by that of professionals on, for example, regulatory bodies, or if the role which the public are expected to play is not clear, for example on trust boards – gives the appearance of public involvement without any real substance. Public 'consultation', whereby the public are presented with a 'fait accompli', or their views are ignored, leads to disengagement and cynicism. The net effect is frustration, loss of trust and an increasing lack of interest amongst the public in the bodies and structures that are supposed to promote their interest.

7 At the same time, healthcare professionals in the NHS have increasingly tended to regard public involvement as at best a token, not to be taken too seriously, and at worst troublesome, challenging well-laid plans, and raising what are perceived to be awkward questions. The barriers to effective public involvement were mentioned by many participants at a Seminar on this topic (see Box A) and were summed up well by the NHS Primary Care Group Alliance in its paper to the Inquiry. We agree with the

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[2] *'The NHS Plan'*. London: Department of Health, 2000. Para 10.1

[3] In this chapter we do not use the term 'lay' to describe members of the public, since the term itself sets up a barrier between the 'professional' and the so-called 'lay' person. This, in turn, serves to exclude members of the public from making an effective contribution

Alliance's view on the need for a shift in culture towards the involvement of patients and the public. It wrote: 'Being sincere about involving patients and the public in making decisions about their own care or about local health services involves a shift of power. Until individuals working in the NHS are ready for that, any user or public involvement in decision making will be a token event.'[4] We believe that the time is overdue for that 'shift of power'.

Box A

Barriers to effective involvement of patients and the public in the NHS include:

From within the NHS –

- a negative culture towards empowering the public that pervades the NHS;
- a lack of awareness of the benefits of an empowered public;
- a lack of clarity about how to get public representation;
- the difficulties in reaching a cross-section of the public.

From amongst the public –

- a feeling that public engagement exercises are just exercises in public relations;
- a sense that there is no commitment to act on any views obtained from them;
- practical difficulties, such as lack of time, skills or confidence;
- a sense of being a lone voice amongst professional experts.

Source: Adapted from the NHS Primary Care Group Alliance's Paper and other Seminar 7 papers

The changing direction of policy

8 Since the mid-1990s, successive governments have signalled a shift in policy towards a greater emphasis on the involvement of the public and patients in healthcare. Recent initiatives have placed this involvement in the NHS of the future at centre stage.[5] This represents a major development. We agree strongly with *'The NHS Plan'* when it states: 'NHS care has to be shaped around the convenience and concerns of patients … patients must have more say in their own treatment and more influence over the way the NHS works.'[6] This matters not only because, as citizens who 'own' the NHS, we have a moral and political right to be involved, but also because greater involvement will bring greater feedback from the public and this in turn will help to improve the quality of healthcare. We would add, however, that the measures adopted must be fit to do the job. Public confidence in the NHS cannot afford another period of rhetorical flourish not matched by real action.

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[4] Seminar 7. The NHS Primary Care Group Alliance. Position Paper

[5] See *'Patient and public involvement in the new NHS'*. London: Department of Health, 1999; and *'The NHS Plan'*. London: Department of Health, 2000

[6] *'The NHS Plan'*. London: Department of Health, 2000. Para 10.1

What is needed

9 If the NHS is properly to recognise and reflect the public interest, we have to ask what is needed, both at the level of principle and of practice, in the day-to-day affairs of such a large and complex organisation. Historically, the views and wishes of the public have been articulated indirectly, through politicians and healthcare professionals. The Secretary of State, as an elected politician, answers to Parliament and the people for all aspects of policy within the NHS. Healthcare professionals on the ground have daily contact with patients and a strong sense of what patients want. Yet society is changing and involvement by proxy is no longer seen to be enough. The public are no longer prepared to be passive, trusting and grateful recipients of what is made available. They are no longer prepared to hope that their views will be fully reflected by the professionals. That is not a criticism of professionals; it is just a reflection of the way the world has changed. Increasingly, with public services as with commercial services, the public are ready to challenge, prepared to question, and have come to expect that services will be responsive to their needs.

10 Thus the starting point for a consideration of how the public's interests may effectively be reflected and safeguarded, is that the public itself, in some shape or form, must be directly involved. The public must be included. In the world of professional services, this is still a problematic proposition. The challenge is to find new ways of involving the public which will work and which are embedded in the fabric of the system. There must also be ways which take account of changes in society, whereby *representative* democracy appears to be less trusted than a democracy which is *participatory*: 'leave it to others' being supplemented or even supplanted by 'do it yourself'. Moreover, the public who must be engaged is not some, largely notional, 'general public', conceived as a homogeneous entity with common views and needs. Such an entity may be relevant when truly national health issues arise, affecting, for example, the identification of national priorities or the introduction of a highly specialised service. But there are other, disparate publics, divided or grouped according to such criteria as where they live, their age, their gender, their ethnic background or their particular healthcare needs. These many sections and groups also need to be involved.

11 Two questions warrant consideration. First, what are the most pressing matters on which these various publics should be heard: essentially, what is the agenda for public involvement? Secondly, how, for the future, can we ensure that the involvement of the public and patients is effective: essentially what principles should underlie and inform any decisions about the mechanisms for involvement?

What is the agenda for public involvement?

12 There are, perhaps, four principal areas in which the involvement of the public is most pressing, arising from a commitment to a patient-centred NHS. They are: the development and planning of services; the operation and delivery of services; the competence of healthcare professionals; and the protection of vulnerable groups. In each case the public must be involved at all levels from the national to the local.

The planning and development of services

13 The aim of a patient-centred service is that it be designed and planned to address the needs of the particular sectors of the public it exists to serve. Thus strategic planning at national level, including the priorities set by government, must have input from the public. Equally, at local level, the particular needs of the communities served by the NHS must also be acknowledged through involvement of these communities. This means involvement in the initial development of options for change as well as consultation on those options. Too often in the past, when major changes in service are needed, local communities have been excluded from the process of developing ideas and options. As a result, consultation has often been perceived by the public as a gesture or a sham. There are genuine and difficult problems involved in the re-organisation of local services, and the only way to gain public acceptance is to let in the public much earlier in the process.

The operation and delivery of services

14 As regards public involvement in the *operation* of the NHS, two concerns are central: safety in the care of patients and high quality in the delivery of the service. What we contemplate here is effective involvement of the public, at national and local levels, both in setting and reviewing the standards to be met regarding the safety and quality of care, and in monitoring the observance of those standards. In the past, these have been seen as matters solely for healthcare professionals on which, given the technical nature of the issues, the 'lay' public were thought to have little to offer. The issues are not only technical. Indeed, if the quality of the care given to patients is to be taken seriously, there are some matters on which only patients are qualified to speak, for example, the extent to which any particular service accords with the needs of the patient. It was the NHS's current weakness in this regard, its unresponsiveness to the interests and needs of the public, which contributed towards the NHS being ranked below a number of European countries in the World Health Organisation's recent analysis of national healthcare services.[7] The views of patients and the public are relevant not only to the standards to be observed by healthcare professionals; but also to the standards and performance of hospitals. We have already proposed, in Chapter 27, a system of validation of trusts. Clearly, as elsewhere, the public must be involved in this process.

Assuring the competence of healthcare professionals

15 We are concerned here with the network of measures designed to assure the competence of healthcare professionals. This is the other side of the coin of concern for safety and quality. The public are entitled to be involved at all levels and stages:

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[7] *'World Health Report 2000. Health Systems: Improving Performance'*. The UK healthcare system was ranked number 19, compared on a range of factors with the healthcare systems of 191 countries worldwide. www.who.int

in both setting and agreeing the systems for assuring competence and in their operation.[8] As regards individual healthcare professionals, assuring competence embraces initial registration, the continuing monitoring of performance through continuing professional development (CPD), appraisal and revalidation, and the application of disciplinary measures when necessary. Historically, the public has only been involved in the last of these. However, we see them all as an interrelated whole in which the involvement of the public is essential if a truly patient-centred service is to emerge.

16 In particular, we would expect the public to have a role in those bodies charged with setting standards for education and training and with controlling access to the professional register. Involvement of the public in these activities serves at least two valuable functions. First, the public can participate in the process of setting and reviewing the criteria for admission to the profession.[9] After all, the professional is going to be caring for the public as patients. Secondly, public participation in this process serves as a warranty that the public's interests are being safeguarded and as a reminder that the profession exists for the public.

The protection of vulnerable groups

17 Bristol was about the treatment of infants and children. It has been the unhappy history of the NHS that the interests of children have not commanded the importance which they deserve. Indeed, such has been the neglect of these interests that we propose significant changes in Chapter 29 (Children) to the way in which children's healthcare is managed and delivered in the future. Children are a part of the public. Because of their youth and immaturity, however, they are largely excluded from having a say in what happens to them. The involvement of the public, therefore, in the case of children, so as to safeguard children's healthcare services, must largely be achieved through those who can speak on behalf of children. But this does not mean that children's views are to be ignored nor that they should not be sought. We agree with the Royal College of Nursing (RCN), when it wrote in one of its papers for Phase Two:

> 'Until recently children were rarely asked to comment upon the services they receive. Instead it was assumed that adults could represent children's views … We believe more emphasis needs to be placed on the development of methodologies which could be used to gather children's views and perceptions of their care.'[10]

18 For this reason, in Chapter 29, we advocate for children a children-centred healthcare service. To achieve this, we propose measures aimed at ensuring that both children and their parents are involved in the planning, organisation and delivery of their care.

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[8] We note the initiatives of various Royal Colleges in involving the public in their activities: The Royal College of General Practitioners (RCGP) has had a patient liaison group since 1983, the Royal College of Surgeons of England (RCSE) since 1999. Equally proposals are under consideration for expansion of the representation of the public on the General Medical Council (GMC)

[9] This would be in addition to involvement in the selection of those admitted to university to study to become healthcare professionals, which we referred to earlier

[10] Seminar 7. The Royal College of Nursing. Position Paper

In this way, children's needs and interests, and those of their parents, will be properly taken into account. Of course, children are not the only vulnerable group in our society. The elderly and infirm, people with disabilities and those with learning disabilities are among other groups which must be included rather than excluded. The point we wish to stress is that the agenda for involving the public must take account of the needs and contribution of vulnerable and hitherto excluded groups.

19 We now turn to consider what are the proper mechanisms for empowering and involving the public.

Involvement at a national level in the formation of health policy

20 The recent and growing recognition that the public must have more opportunity to be involved in the NHS is beginning to take effect. There have been a number of initiatives to involve the public and patients at national level, some examples of which are shown in Box B.

Box B

Examples of recent initiatives to involve patients and the public in the formation of national policy on healthcare:

- *'The NHS Plan':* groups representing patients and carers were involved in the process of developing the Plan and are represented on the 12 working groups charged with implementing the Plan.
- The Commission for Health Improvement (CHI), amongst its 'project boards', has one devoted to patients and the public. CHI inspection teams include 'citizen and lay' inspectors.
- The National Institute for Clinical Excellence (NICE) is seeking to ensure that arrangements are in place for the participation of patients and the public in all areas of its work.
- The NHS Research and Development Strategy is committed to involving the public as active participants in setting priorities and commissioning research.
- Since 1998 the Department of Health has undertaken a national annual survey of patients' views.

21 In terms of the quality of care, the first and most obvious method of ensuring that the public's interests are served is to involve the public adequately and appropriately in those bodies concerned with establishing and monitoring standards. This means that the involvement of the public must be embedded at every level in the structures of the National Institute for Clinical Excellence (NICE), the Commission for Health Improvement (CHI), and the soon to be established National Patient Safety Agency. The public must also be involved in the development of National Service Frameworks. What must be made clear is the crucial role played by involving the public. Not only does it ensure that the standards of care meet the needs and expectations of the public, it also serves to ensure that the public can trust in the system.

22 We note particularly the efforts of NICE to involve the public. A recent paper on the patient's voice states:

> 'In the past, patient representatives in guidelines working groups have sometimes been expected to provide little more than passive co-operation within a clinically dominated process. The Institute's aims for patient participation in guideline development should be much bolder.'[11]

We agree. We would add that while NICE perhaps understandably talks of being 'bolder', to us it is not a question of boldness, but of doing what is right. There must be, in short, an unstinting commitment on the part of organisations in the NHS to engage with the public and patients, to involve them, to listen, to maintain a dialogue and to be responsive to what they have to say.

Involvement in local health services

23 In one sense there is nothing particularly new in saying that the public should be involved in their local health service. This was acknowledged as long ago as 1974 when community health councils were first established, and there has long been a requirement on local health services to hold public consultation exercises on proposals to close a hospital. Thus the principle of involving the public in some form is well established. It is the practice that has come to be seen as poor.

24 A sense of frustration with the mechanisms for involvement at a local level contributed, in 2000, to a series of proposals from government to increase the extent of that involvement and to seek to make it more closely engaged with the delivery of healthcare services. A summary of the proposals is at Box C.

Box C

Summary of recent proposals to involve patients and the public in the formation of policy and the operation of the NHS at a local level:

- There should be a statutory duty on NHS trusts and health authorities to consult and involve the public concerning the planning of services, the development of proposals for change, and decisions about the operation of services.
- Each trust should have a Patients' Forum, to provide direct input into how NHS services should be run.
- Each trust should have a representative of patients on its board.
- In each locality there should continue to be a body to represent patients' views.
- Local authorities should have powers to scrutinise proposals for making significant changes to local health services.
- There should be a national body to represent patients' views.
- Patients leaving hospital should be invited to give their views and each trust, in its annual report, should be required to publish a summary of the views expressed.

Sources: Department of Health. *'The NHS Plan'*, 2000 and The Health and Social Care Act, 2001

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[11] *'Patients' voices: Achieving a patient and carer focus for the Institute's work'*. National Institute for Clinical Excellence, 2000. www.nice.org.uk

25 These proposals represent a significant agenda for change. They have not received universal support, not least as regards the proposed abolition of community health councils (CHCs) and their replacement by Patients' Forums and Patients' Councils. The fear is that the forums and councils will not have sufficient independence and distance from the trust and local health services to inspire confidence and challenge decisions. It is fair to say, however, that CHCs were open to criticism not because they lacked independence but because they lacked power. In a sense, they were a tolerated mechanism for venting public concern, because ultimately they could do nothing.

26 It is of crucial importance that the central goal is kept in sight: that of embedding the involvement of the public in the mainstream of a trust's activities. The involvement of the public must not be some side-show, off to one side. As the NHS White Paper *'A First Class Service'* stated, the involvement of patients and the public '… should not be a discrete, "add-on" task but part of the way all NHS organisations work.'[12] We agree. What is important now is not to allow the process of involving the public to become overtaken by debates about the precise mechanisms to be used: what groups there should be or how they should relate to each other. That is to lose sight of the central challenge which is how to engage and involve the public and patients so that the quality of care which the NHS and each trust deliver can continuously improve. That is the only agenda. Thus, rather than commenting in detail on current proposals, which may, of course, change, we think it more important to draw out certain general principles to guide decision-making in the future about the mechanisms or structures which are necessary. They are principles which in our view apply to the involvement of the public at both national and local levels.

Principles to inform future decision-making about how to involve the public and patients in the NHS

27 We should say that in drawing up these principles, we have been greatly assisted by the papers submitted for our seminars. Of particular assistance was the paper from the RCN.[13]

- **Patients and the public are entitled to be involved wherever decisions are taken about care in their NHS**

The contribution which patients and the public can make to the organisation and to the delivery of healthcare should be sought and valued. The NHS was created as a service to serve the public. Thus the involvement of the public in its future direction is both proper and necessary. The perspectives of patients and of the public must be

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[12] Department of Health. *'A First Class Service; Quality in the New NHS'*. London: The Stationery Office, 1998

[13] Seminar 7. The Royal College of Nursing. Position Paper

heard and taken account of wherever decisions affecting healthcare are made, including by professional organisations such as the Royal Colleges.

- **The involvement of patients and the public must be embedded in the structures of the NHS and permeate all aspects of healthcare in the NHS**

All aspects of strategy, policy-making, and the delivery of healthcare, can benefit from the involvement of patients and the public. Thus mechanisms are needed to include them in the formal structures of organisations. Arrangements must also be made to ensure that the advice and views of patients and the public are heard. Bodies such as Patients' Forums and Patients' Councils undoubtedly have a role, but they must not become devices for ghettoising the public and patients. Thus they are not a substitute for the involvement of patients and the public in the mainstream of activity.

- **Information**

Without information, patients and the public will remain disempowered. It is essential that they receive and can gain access to the information they need to participate fully at whatever level their contribution is sought.

- **Healthcare professionals must be involved in the process**

While our concern here is to empower patients to be involved in the organisation and delivery of healthcare, we recognise the importance of striking a partnership in this endeavour with healthcare professionals. This will be of enormous lasting value in taking the process forward. Thus there must also be a recognition of the need to educate and train healthcare professionals so as to develop an understanding and appreciation of the role which patients and the public can play.

- **Honesty about the scope of involvement**

Some decisions can and should be made by the public. Others cannot. Between these two extremes there is scope for a wide range of public involvement. The guiding principle should always be to ensure the greatest possible involvement of the public and patients, unless there are good reasons for acting otherwise. To ensure that confidence is retained and trust not put at risk, whatever the context, the *scope* of involvement of the public should be identified and made explicit at the outset.

- **Transparency**

It is important that the processes by which patients and the public become more actively involved in the healthcare process are open to scrutiny, and are transparent in the way that they work.

- **Effectiveness**

The mechanisms for public involvement should be evaluated. Changes to these mechanisms and structures should draw on the evidence of what works. The NHS Modernisation Agency could play an important role here. We need to learn and understand the most effective forms of involvement in terms of helping to improve the quality of healthcare. The goal must be the widest possible involvement of patients and the public in the NHS at local level.

- **Training, development and preparation**

A high degree of participation from some individuals will be required. It is important, therefore, that such individuals are properly prepared and supported through, for example, the provision of training and guidance.

- **Funding**

To be effective the involvement of the public and patients requires proper funding. This particularly includes the provision of sufficient resources for those involved, such as payments for childcare or loss of earnings or time spent preparing for and attending meetings. The various bodies should have an appropriate budgetary allocation to meet such costs. It is on such apparently minor issues, but matters of great importance to the individuals concerned, that the involvement of the public often founders. Without financial support, many, with the best will in the world, cannot take part.

- **Involving different groups**

It is important that all patients and members of the public have the opportunity to become involved. But such involvement should not be limited to 'patients' groups' or those representing the interests of patients with a particular illness or condition. The net must be cast widely, not least to ensure that the broad range of experience of the NHS is captured. That said, it is unlikely that, through representation alone, the full range of the public's views will be obtained. Thus it is important to encourage the use of professionally conducted surveys, at a local and national level. The surveys should be seen as part of a strategy for public empowerment.

28 It is important to mention here the particular role which primary care trusts (and groups) can play. With their power to place contracts with hospitals, primary care trusts (PCG/T) are in a strong position to exert an external influence on the quality of care. In a PCG/T of 200,000 patients and 100 GPs there will be in the order of at least one million consultations a year. PCG/Ts, therefore, should be especially vigilant to ensure that they have in place arrangements to discover and take account of patients' and the public's views. This should include seeking patients' views about the care which they have received in hospital and on matters which they consider could be improved. One mechanism for achieving this could be through the PCG/T's Patient and Advocacy Liaison Service. The views of patients can then inform the process of contracting with hospitals. Clearly, there will need to be a much greater degree of involvement and empowerment of patients and the public than simply to have a single 'representative' on the PCG/T board.

29 On a separate matter, there is an argument as to whether there is a need for government to establish some body at a national level to represent the public's interest but which stands *outside* the organisational structure of the NHS. There is some force in the idea of some form of permanent watchdog: a national, publicly funded body to represent and promote the patient's perspective. There are, however, counter-arguments. First, by being outside the system, the scene may be set for the development of confrontational attitudes between the patients' watchdog and the NHS which serve the interests of neither. Secondly, without formal powers to challenge or change, the body may soon lose credibility and be seen as 'toothless', a gesture towards public engagement rather than a reality. If, on the other hand, the body were given formal powers, it would, perhaps, endanger the creation of that partnership between professional and public which we regard as the essential building block for the future, by appearing to endorse the sovereignty of patient power. This would be to go too far. A patient-centred service is not a patient-dominated service.

30 Accordingly, we are of the view that, on balance, the priority should be that the public's interests are embedded into all the organisations and institutions concerned with quality of performance within the NHS. In this way the public is 'on the inside', rather than 'on the outside'. Moreover, in wider constitutional terms, it leaves the field clear to democratically elected politicians to be, as they must be, the final arbiters of the wider public interest, able to weigh both competing priorities within the NHS, and the relative claim of the NHS as against those of other sectors of public service.

Chapter 29: The Care of Children

Children are entitled to healthcare which is specifically designed to meet their needs as children. Parents are entitled to be involved in and informed about the care of their children, save in exceptional circumstances.

Messages from Bristol

- The specific healthcare needs of babies and young children undergoing open-heart surgery were too readily subordinated to the need to care for adult cardiac patients.
- There was no system to establish and indicate who had responsibility for the management and care of these children and their families during the various phases of care.
- In the absence of effective planning or service frameworks for children's acute healthcare at national or local level, the particular needs of children were not effectively met.
- The relative lack of concern for the particular needs of a group of highly vulnerable individuals, whatever the degree of dedication of particular individuals, meant that for this among other reasons, the quality of care for children who received open-heart surgery at the Bristol Royal Infirmary was less than it should have been.

Introduction

1 We argue that children and their healthcare needs should be given greater recognition and higher priority in the health service. We suggest that a National Service Framework (NSF) for children is urgently needed and welcome the Government's recent recognition of this. We make proposals for improving the leadership of children's healthcare services at every level. Finally, we address two areas of particular concern arising from the events in Bristol: staffing and communication.

2 All of the principles and recommendations in this report, though not intended specifically to address healthcare services for children, will, once implemented, have a marked effect on children's services. In addition, however, there are a number of issues which are particular to the provision of healthcare services for children and which we believe demand special attention.

3 The relatively low status in the overall scheme of things which was given to healthcare services for children undergoing open-heart surgery in Bristol is all the more poignant given that there existed within the Bristol group of hospitals a dedicated children's hospital, with expertise in looking after sick children. Sadly, that expertise was not linked effectively to the BRI. The comment of Dr Peter Martin, consultant paediatrician, who worked as a senior house officer at the Bristol Royal Hospital for Sick Children between 1988 and 1989, is telling:

> '… myself and colleagues thought it was rather bizarre that the sickest children post-operatively were managed in a unit where the resident staff were generally not paediatrically trained and the nursing staff were also not paediatrically trained. This was in stark contrast to the children requiring less intensive surgery who were looked after on a paediatric intensive care unit with paediatric anaesthetists, resident and paediatric medical staff, as well as of course, nursing staff who only looked after ill children.'[1]

4 National and professional organisations concerned with the provision of children's healthcare services contributed to the first Seminar in Phase Two of the Inquiry. The clear message from their submissions was that shortcomings in acute healthcare services for children were by no means unique to Bristol. More disturbing, they told us that, while there has undoubtedly been improvement since 1995, notably in the fields of paediatric intensive care and in a number of specialist services for children with specific conditions such as cleft lip and palate, children's healthcare services as a whole still remain a low priority. This was borne out in evidence throughout the Inquiry. We were told, for example, that healthcare services for children are still, generally, fragmented and poorly co-ordinated. Furthermore, we were told that although well-established guidance exists, the extent to which it is implemented varies across the country. There is no system for ensuring that the guidance is put into operation, nor are there any sanctions against those trusts which persistently fail to implement it. The particular performance of those services connected with children's healthcare, as distinct from the quality of services in general, is not systematically monitored. Thus it is not surprising that very little information is available locally or nationally about the quality of such services.

5 We welcome the decision of the Department of Health (DoH) to begin to develop a National Service Framework for children (March 2001). Such a framework should help to overcome the reluctance of some of those responsible for planning and managing healthcare services to recognise the particular requirements of children and families. In our view, one of the central priorities for the Framework must be acute care for children, including that which takes place in district general hospitals as well as in the more well-known specialist hospitals for children. It is in the general, non-specialist hospitals that constant vigilance is especially needed to ensure that the particular needs of children are not overlooked. The Framework must address this.

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[1] See Annex A Chapter 9 for further evidence about the split site and split service

The priority given to children's healthcare services

6 Children and young people up to the age of 16 make up about 20% of the population. They enjoy better overall health than ever before. Nevertheless, they make significant use of acute healthcare services. We were told by the Royal College of Paediatrics and Child Health that the number of children admitted to hospital albeit for short periods has been steadily increasing: 'By the age of 2 years, about 25% [1 in 4] of children will have experienced one or more hospital admissions.'[2] We were also informed by the DoH that: 'After the age of 5 approximately 1 in 12 children are admitted [to hospital] each year with over half of such care being provided by the surgical specialties'... futhermore: 'In each year 1 in 5 children attend an Accident and Emergency Department ...'.[3]

7 This degree of recourse to healthcare services has not been adequately matched by any measures aimed specifically at meeting children's needs. This has not been for want of trying by those who have addressed the issues. Indeed, it is a remarkable feature of children's healthcare services that, over a period of 40 years, successive independent reports have made the same or similar recommendations. All, in their different ways, have called for a greater priority to be given to children's healthcare services:

> 'Greater attention needs to be paid to the emotional and mental needs of the child in hospital, against the background of changes in attitudes towards children, in the hospital's place in the community, and in medical and surgical practice. The authority and responsibility of parents, the individuality of the child and the importance of mitigating the effects of the break with home should all be more fully recognised.' (Platt Report, 1959)[4]
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> 'The special needs of children which arise from the fact that they are growing developing persons should be reflected in the facilities that are provided for them and, perhaps more important, in the training of those who care for them. We want to see a service which is child-centred and we believe that this must be a service in which the professional staff are adequately trained and experienced in the special needs of children.' (Court Report, 1976)[5]
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> 'Children have special health care needs because they are physically and emotionally different from adults ... The root cause of hospitals failing to apply the principles is often a lack of attention of many clinicians, managers and other staff

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[2] Seminar 1. The Royal College of Paediatrics and Child Health. Position Paper

[3] Seminar 1. NHS Executive, Department of Health. Position Paper

[4] *'The welfare of children in hospital'*. The Platt Report. Ministry of Health, Central Health Services Council. London: HMSO, 1959

[5] *'Fit for the Future: The Report of the Committee on Child Health Services'*. Volume One. London: HMSO, 1976

> to these special needs and the needs of children's families.' (*'Children First: A Study of Hospital Services'*. Audit Commission, 1993)[6]
>
> 'At present health services for children do not always consider the specific need of children. Children's health services … are too often based on traditional custom and practice or indeed on professional self-interest. Children's health services must be needs led, not based on historical patterns or the self-interest of provider groups.'[7] (*'Hospital Services for Children and Young People',* Health Select Committe, 1997)

8 All of these reports urged that the needs of children and their parents should be the central principle informing arrangements for children's healthcare services. Remarkably, some would say scandalously, despite the consistency of these recommendations over such a long period of time, there has been an equally consistent failure fully to implement these fundamental principles, a failure which continues to this day.

9 Sue Burr, Paediatric Nurse Adviser at the Royal College of Nursing (RCN), reflected the frustration of many healthcare professionals when she told the Inquiry:

> '… I think we probably have the best guidance in the world in relation to the welfare of children and young people in hospital – if only that was implemented …'[8]

10 Despite our censure, we recognise that there has been some improvement over the years in services and guidance. The proposed NSF must take these improvements further. We were also reminded by the DoH of its current guidance: *'The Welfare of Children and Young People in Hospital'*[9] which states that service for children which is of good quality:

- 'provides for the child as a whole, for his or her complete physical and emotional well being and not simply for the condition for which treatment is required;
- 'is child and family centred with children, their siblings and their parents or carers experiencing a "seamless web" of care, treatment and support, as they move through the constituent parts of the NHS;
- 'admits children to hospital only if the care they require cannot be as well provided at home, in a day clinic or on a day care basis.'[10]

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[6] *'Children First: A Study of Hospital Services'*. Audit Commission. London: HMSO, 1993

[7] *'Hospital Services for Children and Young People'*. House of Commons Health Select Committee (Session 1996–97) Fifth Report. London: HMSO, 1997

[8] T34 p. 46 Miss Burr

[9] DoH. *'The Welfare of Children and Young People in Hospital'*, HMSO, 1991

[10] Seminar 1. NHS Executive, Department of Health. Position Paper

These principles are right, but it must be remembered that as we write this Report it is ten years since they appeared. Words must become action.

11 The DoH referred us to developments such as the standards set out in the *'Patient's Charter'*. It also pointed to the marked improvement in the quality and availability of paediatric intensive care services, in response, among other things, to the tragic events surrounding the death of Nicholas Geldard.[11] Other developments include a significant increase in the number of trained children's nurses working with children in local district hospitals, and the establishment of Diana nurses to care for sick children at home. There has also been a fundamental shift towards the greater involvement of parents or carers during a child's stay in hospital. The RCN and the relatively recently created Royal College of Paediatrics and Child Health have been particularly energetic in seeking to raise professional standards, and in exerting pressure on government to consider child-centred care in its widest sense.

12 All of these developments have tended to concentrate on standards which have to be reached. Important as these are, we are also concerned with the action which has been taken. As the Audit Commission and the Health Select Committee made clear, it is not so much that good ideas and good guidance are lacking. Indeed, as we have found, there is a remarkable consensus across the professions caring for children in hospital about the standards which should apply in the provision of children's healthcare. The problem lies in action, in translating the words into deeds. The difficulty appears to be systemic: the absence thus far of any overall framework of care, of management systems and, above all, of leadership and political will, all of which are needed to ensure that good practice is indeed implemented.

13 In this chapter, therefore, we have not sought to revisit or rewrite the already very comprehensive guidance and principles set down by the Royal Colleges and others. The principles set down by the Audit Commission in 1993 strike us as robust and we endorse them. These six principles state that children and young people's health services should be built around:

- child- and family-centred care;
- specialist skilled staff;
- separate facilities;
- effective treatments;
- appropriate hospitalisation; and
- strategic commissioning.

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[11] A major effort to improve the availability of facilities for paediatric intensive care followed the death from a brain haemorrhage in December 1995 of 10-year-old Nicholas Geldard. No paediatric intensive care bed was available in his home city of Manchester, and he had to be taken by ambulance to Leeds, where he died

14 What we focus on is action. Indeed, had the principles set out in the DoH's 1991 guidelines and the Audit Commission's report been implemented in Bristol, a good number of the shortcomings in care would have been addressed much earlier. Forty years have elapsed since inadequacies in children's services in the NHS were first identified and proposals for improvement were articulated. In the light of the pressing need for improvement, the questions which guide us are: why is action so slow in coming; why do children's health services continue to be undervalued? We are in no doubt that there must be a fundamental shift in attitude and approach, so that action to improve children's healthcare services is taken at every level of policy-making and of management. Without such a shift, exhortations to good practice will continue to be uttered. But there will be no guarantee that a neglect of children's needs, similar to that which we saw in Bristol, is not happening now and will not happen again.

The healthcare needs of children and young people are different from those of adults

15 We start with what seems to be a difficulty on the part of policy-makers and health service managers fully and consistently to accept or acknowledge that the healthcare needs of children and young people are different from those of adults. It seems so obvious that it hardly needs to be said: just as children differ from adults in terms of their physiological, psychological, intellectual and emotional development, so they differ in their healthcare needs. They experience and see the world differently. Children are in a constant state of growth and development which creates particular needs and demands which are of a different order from those affecting adult patients. Their relative physical and emotional immaturity, in comparison with adults, has implications for both the treatment which they receive and the physical environment in which they are cared for. Children communicate their thoughts and feelings in a very different way from adults. Effective communication with children as patients (often through a combination of play, one-to-one interaction, and by communication with parents) is seen by professionals involved in paediatric healthcare as crucial to the child's physical and psychological wellbeing. Thus the ability of staff to care appropriately for children is crucial. Skills, understanding and knowledge are required which are different from those of staff who mostly care for adults.

16 There is still a continuing lack of recognition of the need for the holistic, child-centred approach to the care and treatment of children which has been advocated for the past 40 years. Liz Jenkins, Assistant General Secretary of the RCN, told the Inquiry:

> '... I do think that the majority of adult qualified nurses and doctors see children as small adults, who simply need smaller beds and smaller portions of food. They do not see them as a client group that have wholly different needs.'[12]

17 Children's needs are ordinarily expressed through their parents, who are usually the primary providers of their care. But there are also important differences between children and their families. Their interests do not always coincide. Equally, children

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[12] T34 p. 33 Mrs Jenkins

are different at various stages of development: infancy, childhood and adolescence. Thus, although as a group they are different from adults, children and young people cannot be seen as a homogeneous group. In short, a child-centred approach to healthcare is complex.

18 Of the many examples of the complexities of caring for children with their parents we mention just one here: the issue of obtaining consent to treatment. As is well known, the role of a child who is to be treated in the process of gaining consent to that treatment is problematic. As children grow towards maturity, they achieve greater control over what can be done. But until the child reaches adulthood at 18, the law places certain limits, at least on what can be refused, if a parent decides otherwise. We do not wish to review this exceedingly complex area here. We do, however, wish to make some observations. In the case of a baby or young child, there is no question of the child giving or withholding consent. It is the parent who must do so. This is a very heavy burden to bear, particularly when the child is seriously ill. Asking parents' to give their consent on behalf of their child is of a different order than asking them to give their consent for themselves. There will always be agonies of doubt and, if events turn out badly, of self-recrimination. For this reason, the principles which we set down earlier, in Chapter 23 on Respect and Honesty, must be scrupulously observed. Consent by a parent is quintessentially a process. It has little to do with putting a signature on a form, and everything to do with being taken along a journey of information, advice and support which equips the parent as much as possible to make the necessary decision. Nor can there be any justification for holding information back, however well intentioned the motive. This is because it is the parent's responsibility to make a decision which is in the child's best interests. That responsibility falls (and weighs heavily) on the parent, not the doctor, the nurse, or anyone else. To carry out this responsibility the parent therefore needs the fullest possible account of what is proposed, the alternatives, the risks and the possible outcomes. Once informed, of course, the parent may ask for help and should be supported. This is what is meant by the principles of respect and honesty which we referred to earlier. And on this theme of respect, we add one final point. A child may not be sufficiently mature to give consent, but may be able to participate to a degree in the process. All those caring for the child must be alert to this and must involve the child to the extent compatible with the child's capacity to comprehend what is involved.

A framework for the future of children's healthcare services

19 We state at the outset that we recognise that the health of children depends on a variety of factors, of which healthcare is only one. Thus we welcome the efforts under way on a broader social front to improve education and to tackle child poverty, particularly for more vulnerable families. These will have lasting benefits for the general health of children. In parallel with these efforts, we insist that the quality of children's healthcare services must also be improved.

20 The need to agree and issue the National Service Framework (NSF) for children, on which work has recently begun, is urgent. The DoH's 1991 guidance needs to be updated and brought into line with other developments in the NHS. Furthermore, changes are taking place within the NHS, such as the rapid development of primary care groups and trusts, which will have a direct impact on children's health services. In the absence of a strategic planning framework to provide guidance on models of good practice, and to set minimum standards, important decisions on the future of healthcare delivery are still being taken in a vacuum.

21 It is evident to us that the new framework must provide an overall strategy to enable trusts and health authorities to focus on the whole range of services which, taken together, constitute children's healthcare services. The following are amongst the key issues that need to be addressed: how to achieve greater integration of hospital and community healthcare services for children; the future arrangements for acute care and for specialised services for children; how to improve the commissioning of children's healthcare services so that it is based on children's needs rather than on providers' convenience; and the need for sufficient paediatrically trained staff.

Greater integration of healthcare services for children

22 Healthcare services for children are currently provided at every level of the NHS: primary care, in the community, and in hospitals (Accident & Emergency, secondary care and specialist tertiary care). As we have said already, historically, it is a feature of the provision of healthcare in hospitals that the care is organised around the needs of the organisation or the healthcare professionals. Children's healthcare services are no exception. This must change. Child-centred care must be care centred around the child. Strategic guidance is needed, based on evidence from the UK and abroad, as to which type of organisational model would best achieve the optimal integration of all the relevant services so that they are organised around the needs of children and their families, rather than around the needs of providers.

23 We were told of emerging models of service in England such as that in Newham, London, where a community trust manages the whole range of healthcare for children, including the acute ward in the local acute hospital trust. The Royal Liverpool Children's NHS Trust runs a 'hospital at home' service for children with long-term needs. Efforts are also being made around the country to establish paediatric clinical networks to share good practice. One example is the Partners in Paediatrics Network, a partnership of acute and community trusts in Staffordshire, which work together on matters such as manpower planning, professional education and planning paediatric care. Outside the UK, we were particularly impressed by the high level of integration achieved in Philadelphia in the USA, where the Philadelphia Children's Hospital runs the paediatric wards in a number of local district hospitals, as well as the community health clinics for children and some primary care centres. While all aspects of this model may not be transferable here, given the well-established strengths of our primary care system, we take the view that there is much to learn from the Philadelphia experience. We see scope for a pilot project where a large children's hospital, with its experience in paediatric care and leadership in children's healthcare, could take responsibility for the management of children's acute healthcare and community services in a number of related general acute hospital trusts in a specific geographical area. Thus, for example, in the future there could be Birmingham Children's Hospital 'at' Walsall Hospitals NHS Trust; or Great Ormond Street Hospital 'at' the Greenwich Healthcare NHS Trust. These are just illustrations of what might develop into a hub and spoke model, where the hub is the specialist paediatric hospital, and the spokes are district general hospitals which include paediatric care amongst many other services. Equally, the development of primary care trusts offers significant opportunities for the closer integration of primary care, community care and general paediatric secondary care, always provided that the system created is informed by a comprehensive view of children's needs. This is the crucial message of the experience in Philadelphia. Not only must the services be more closely integrated, they must also all be imbued with the philosophy of child-centred care.

The future of acute and of specialised services for children

24 The NSF must address the complex question of the location of acute and specialised healthcare services for children, and the extent to which they should be close to healthcare services for adults. Where rebuilding programmes are already under way, local services are facing fundamental questions about where to locate children's acute services in relation to general acute services. We are convinced that the optimal arrangement for children's acute hospital services is that they be located in a children's hospital. Ideally, the children's hospital should be physically as close as possible to, but separate from, an acute general hospital. Such an arrangement means that children can be cared for in a paediatric environment, whilst giving easy access to specialist help from the acute hospital, *if* it is needed. This is the arrangement now achieved in Bristol with the new children's hospital, opened in 2001. In the past, open-heart surgery and post-operative intensive care for children took place in the BRI, away from the children's hospital, in a setting which was primarily for the care of adults. The proximity of a children's hospital was not enough to influence the quality of care for the children once they were taken into an environment intended for the care of adults.

25 It is possible to achieve care of high quality within children's hospitals which are at some physical distance from an acute general hospital. Indeed, there are several very successful examples of such hospitals in the UK. The difficulties lie in access to certain facilities which may not routinely be found in a children's hospital. Equally, there may not be access to certain specialists, the appointment of whom could not be justified in a children's hospital given the infrequent call on their services. Clearly, these difficulties can be overcome to a degree by good management and organisation of care.

26 As regards specialist or tertiary services for very sick children, we have already touched on the general issues involved in Chapter 27 (Standards). It is important here to make clear some points of principle. We do not presume to indicate, not least because we do not have the relevant information, what services should be where, or how many centres there should be which specialise in any particular specialty. Instead, we confine ourselves to the factors which should guide such decisions. We take the view that in the case of specialist services, the premise must be that the quality of the care received by children will depend on the level of skills and competence of the healthcare professionals. Given the comparative variety of the conditions treated through specialist services, the necessary level of skill and competence will only be acquired if the number of centres is limited. The continuum can be expressed: fewer centres, greater competence, the greater the possibility of better outcomes for the children. It is also crucial to add that there must be a sufficient volume of work in any one centre to enable the clinicians to achieve a good level of success in outcome.[13] Advice should be sought from the experts on the appropriate number of patients to be treated to achieve good outcomes.

27 If this is the proper way forward, it is crucial that there should be a mechanism which can make it happen. This involves not only the designation of the particular centre as an approved centre, but also, and this is a crucial lesson from Bristol, the power to *prevent* other centres from carrying out the particular specialist service. We note that in their submissions to our Seminar, both the DoH and the Royal College of Paediatrics and Child Health (RCPCH) used the expression 'if' specialist services were to be concentrated in a limited number of centres. Clearly, somebody has to decide about such concentration, and equally clearly (and perhaps more urgently) somebody has to decide who will make such a decision. We take the view that this issue, the location of specialist services for children, must be addressed in some proper degree of detail in the proposed NSF.

28 We add a further point. We are taxed by the relevance, in making decisions on the location of specialist services, of geography. We are conscious that equality of access to care would seem to be threatened if care is concentrated in a small number of centres of excellence. This was one of the dilemmas of Bristol's designation as a supra regional centre. Moreover, we recognise that for children with complex health problems and their families, we are not merely talking of one episode of surgery or of treatment, but a long-standing relationship with the centre concerned. For parents and children regularly to have to travel long distances is a hardship in many ways, not least in terms of the financial cost. On balance, however, we regard the most important consideration to be the quality of the care which the child is entitled to. If this can only be provided at some distance from the child's home, then this must be accepted. The alternative of providing sub-standard care closer to the child's home is not an

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[13] Spiegelhalter D, *'An investigation into the relationship between mortality and volume of cases in surgery for congenital heart disease from 1984 to 1995'*, May 2000. See Annex B 7d

option we should any longer be prepared to accept. We are reinforced in our view by the fact that a clear message from Bristol was that parents were prepared to travel long distances if this meant that their child would get good care. We only add that, if our view is accepted, parents must not be left without assistance. Easily accessible financial help, probably through new Family Support Funds held by the specialist centres themselves, should be available, as should suitable accommodation provided at or very close to the hospital. We think it essential that necessary financial assistance be made available promptly to meet costs incurred when a family is a great distance from home, caring for a sick child. This assistance must be administered flexibly and be available to a wider group of people than is the existing Hospital Travel Costs Scheme, which is very restricted and in any case offers only the most basic support. Thought should also be given to the use of modern technology, e.g. the use of video telephones, to enable children to remain in touch with their families.

How to improve the commissioning of children's healthcare services so that it is based on children's needs rather than on providers' convenience

29 The new NSF must state that arrangements should be put in place to ensure that children's healthcare services are commissioned locally in an integrated way. Attention should be drawn to examples of good practice. What this means is both deceptively obvious yet radical. It contemplates that, in planning healthcare services for children, the starting point is the needs of children in that particular locality, rather than, and this is the important point, what those providing a variety of services have hitherto been in the habit of providing. The services are planned around the children, rather than the children taking whatever is on offer and not receiving what is not on offer. The work of the East London and City Health Authority, which has set up a system of locality-based commissioning for children's services, is a good example of integrated commissioning.

The need for sufficient, paediatrically trained staff

30 Until the proposed NSF appears, the future direction of children's healthcare services will remain unclear. Thus, identifying the number of paediatrically trained nurses and doctors which will be required in the future is currently problematic. It is imperative, therefore, that the professionals who care for children should be fully involved in the development of the NSF, and engaged in analysing the implications for levels of staffing. Equally, it is imperative that the NSF be agreed and implemented as a matter of urgency. We deal with staffing issues in more detail later on.

31 We believe that the proposed NSF must also:

- set standards which must be observed, as well as those to which services should aspire, while leaving appropriate room for innovation and adaptation to local needs. Too often in the past, the failure to stipulate standards which are mandatory has undermined efforts to ensure that proper standards of care are delivered;

- establish incentives (including but not limited to financial incentives) for the improvement of children's healthcare services, with particular help for those trusts which most need it; and

- set out plans for the publication of information about the quality and performance of children's healthcare services at national level, at the level of the individual trust, of the specialty, and of individual consultant units.

32 We have said earlier in our Report that we believe the inspection of trusts by the Commission for Health Improvement (CHI) should be developed so that it becomes a system whereby hospitals are validated to provide services. Once the system is established, we believe that, in the case of children's healthcare services, there should be a specific process of validation, such that trusts would only be permitted to provide healthcare services for children if they meet the appropriate standards in a range of relevant areas, including numbers of paediatrically trained staff, a proper level of paediatric facilities and an environment imbued with the values of paediatric care. In this regard, we note the proposal of the Royal College of Surgeons in a recent report from its Paediatric Forum.[14] It recommends that inpatient surgery on children should only be undertaken in those hospitals which provide comprehensive paediatric facilities. It then lists proposed minimum requirements which any district acute hospital must meet if it includes surgery on children amongst its services. This is precisely the type of requirement we have in mind. By contrast, it is currently still the case that there is no mechanism to ensure that hospitals which do not meet such standards refrain from undertaking surgery on children.

Leadership of children's healthcare services

33 Children are a vulnerable group. They lack the means to speak up for themselves in the complex world of healthcare. It falls to adults, therefore, to protect their interests. If adults fail to do so, they fail the children to whom they owe a duty of care and who have rights which demand protection.

34 We come back to the question, who provides leadership for children's healthcare services? Currently, there is no single, influential, unifying voice, with political influence or power, which serves as an advocate for children's needs. Rather, at best, there is a loose network of institutions, voluntary organisations and individuals, often from within the healthcare professions specialising in children's health, which put the case for greater value to be accorded to children's healthcare services. Sadly, these have little or no power systematically to bring about change. We comment on the need for this to change, on the need to take up the cause of children's healthcare, in the paragraphs which follow.

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[14] The Royal College of Surgeons of England. *'Children's Surgery – A First Class Service'*. London, May 2000

Leadership in government

35 The lack of clear leadership at the level of national government was demonstrated until recently by allocation of ministerial responsibility for children's health and healthcare services amongst Ministers in the DoH. A Minister of State had responsibility for 'child and adolescent mental health services', and for 'family issues'. A Parliamentary Under-Secretary had responsibility for 'maternity and child health'. There was no Minister, of whatever status, charged with responsibility for all aspects of 'health and healthcare services for children and young people'. Frankly, this is well nigh a national scandal. We note and welcome the shift in policy reflected in the unification of issues relating to children's health under the auspices of a single Minister responsible for 'children's health, including Children's Task Force.' This development must now be reflected in a more integrated approach to children's healthcare throughout the NHS.

Leadership in the NHS

36 Few English health authorities have a senior officer with specific responsibility for commissioning children's healthcare services. Apart from free-standing children's hospital trusts, there is scant evidence within trusts which care for children as well as adults that any senior, board-level manager, or non-executive director, is responsible for taking an overall view of the entirety of healthcare services for children and young people within the trust. This may reflect a historical reality that services have tended to be managed by reference to specialty (for example, cardiac surgery) rather than by reference to patients. A way must be found within healthcare organisations to allow the voice and needs of those who use the service to be heard, as well as that of the specialists (it is not a case of 'either/or'). In our view, it is this absence of a significant voice for children, at any level of policy-making or management within the NHS, which both signals and reinforces the low priority given to children's healthcare services. Thus all acute care trusts which care for children as well as adults should have a designated executive member of the board whose responsibility it is to ensure that the interests of children are protected and that they are cared for in a paediatric environment by paediatrically trained staff.

37 Speaking up for children's healthcare services also calls for clinical leadership. Despite the efforts of many individuals, there are considerable barriers in the way of progress. Paediatrics, as a specialty, historically has had a low status. This can be seen in those acute hospital trusts which are not exclusively devoted to the care of children, where the importance of children as a distinct group of patients, and of those who provide children's healthcare services, is not systematically recognised at a senior level. We were told, for example, by the RCN, that, according to a comprehensive survey which it undertook in 1998, few acute hospital trusts have a paediatrically qualified nurse working at a level of seniority above ward level. Thus, nurses with specialist training in the care of children are not routinely involved in the development of policy within a trust. They struggle to influence the development of appropriate child-centred policies, especially in areas where children receive care alongside adults, such as in general surgery, outpatient departments, and in accident and emergency.

38 We have already noted and commended the efforts of two of the Royal Colleges in taking a lead on developing standards for children's healthcare services. This has taken place, however, in a wider context in which, as we have said, paediatrics as a specialty, historically, has been undervalued within the clinical professions. This was a strong theme in the evidence from the RCN. The late Professor David Baum, then President of the Royal College of Paediatrics and Child Health (a Royal College since 1996), told us:

> 'Across the world, the independent voice of paediatrics has been later than physicians and surgeons as an identifying group in the world of medicine ...'[15]

In the light of the evidence which we heard and read, we believe that a very substantial effort is required to change the way in which children's healthcare services are thought about, led and managed.

A new voice for children

39 It was suggested to us that the only real way to secure a sustained improvement in the priority accorded to children's healthcare services is to develop new institutional arrangements. These would be designed to ensure that some organisation or body takes specific responsibility for raising the quality of children's healthcare and for ensuring that any guidance is consistently implemented. We agree. We recognise, however, that there are different schools of thought as to what such an institutional arrangement should be. One approach is to promote improvements in children's healthcare services in the context of children's rights generally and alongside other children's services, such as education and social care. This could be achieved by the office of an independent Children's Commissioner. It could also be achieved by a greater integration of the working of the various government departments involved. Another suggested approach is to maintain the focus on healthcare and, within the existing organisational structures, find ways of elevating the leadership of and priority given to children's healthcare services. These approaches are not mutually exclusive. We consider each in turn.

A broad-based approach

40 In the course of the Inquiry it became apparent that the picture presented to us of children's healthcare services, that of fragmentation, patchy implementation of guidance, a variable regard for the particular needs of children, and the absence of information about and monitoring of performance, is a picture which is not unfamiliar to other areas of children's services, most notably the services for children in the care of local authorities. It was put to us that there is a wider systemic weakness in the formation of policy in government, in that the particular needs and the voice of children and young people are generally given a low priority. This is despite the recognition in the UK of the UN Convention on the Rights of the Child, such that this recognition may appear to some to be a triumph of gesture over action.

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[15] T18 p. 21 Professor Baum, then President of the Royal College of Paediatrics and Child Health

41 We have been deeply touched by the evidence that, in terms of public policy, the interests of children have for far too long been neglected. Although it is beyond our remit, we consider there to be merit in the arguments we have heard for the creation of an office of Children's Commissioner. Various arrangements are emerging in the UK with regard to the status and authority of such an office as well as to the range of issues which could fall within its jurisdiction. Understandably, since there is as yet little experience of such an office, the evidence as to its relative effectiveness has yet to emerge. The Welsh Assembly has appointed a Children's Commissioner for Wales with a remit, under the Care Standards Act 2000, to review and monitor all social care services for children, including, for example, children's homes and fostering and adoption services. The Scottish Parliament is also considering the creation of a similar office with a wider remit: to monitor the implementation of the UN Convention on the Rights of the Child. Recently, the Welsh Assembly initiated a public consultation exercise on proposals to widen the role and powers of its Children's Commissioner so that he could review the effect on children in Wales of the exercise or proposed exercise by the Assembly of any of its functions.[16] The Scottish proposal, if it goes ahead, would seem to embrace the advocacy of children's rights to healthcare, that being one of the wide range of services provided by the state on which the Convention touches. We note also here the joint initiative of the Save the Children Fund and Oxfordshire County Council. They state that they have established the first Children's Rights Commissioner in a local authority in the UK. The aim of the initiative is to establish standards on children's rights, which can be incorporated across the local authority's agencies into all policy documents, planning proposals, initiatives, funding applications and monitoring.

42 A range of other approaches with the aim of raising the quality of children's services is emerging. For instance, in the case of standards of care in local authority homes, the new National Care Standards Commission in England will have a Children's Rights Director with the responsibility to inspect and regulate homes where children are in care. At the same time, and arising from the Government's policy to address the social exclusion of children and young people, the Prime Minister in June 2000 announced the establishment of a new Cabinet Committee on Children and Young People's Services. The Committee is charged with ensuring the coherence and success of the Government's policies on preventing poverty and underachievement among children and young people. Healthcare and health services are not specifically mentioned as falling within the responsibility of the Committee, although a Health Minister is amongst its members. This must change. The Cabinet Committee should specifically include in its remit matters to do with healthcare and health services for children and young people.

A focus on healthcare

43 As we have made clear, the issues involved in improving the quality of children's healthcare services warrant particular and urgent attention. We see real value in

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[16] The Children's Commissioner for Wales, Mr Peter Clarke, was appointed in March 2001. In the same month the National Assembly for Wales published a consultation paper on proposals for new and extended functions under the Children's Commissioner for Wales Act 2001

including healthcare services within the remit of broader-based initiatives, such as that of the office of a Children's Commissioner, designed to promote the rights of children and to improve the ways in which the needs of children are properly met. Indeed, there could be positive advantage in terms of the better integration of a whole range of services intended for children. There is, however, a danger that the specific improvements needed in the field of healthcare could easily be swamped by other needs in other areas. For this reason it is important to examine another approach to raising the priority of children's healthcare services: the development of institutional mechanisms which are designed for this, and only this, task.

44 We take as a starting point, by way of analogy, the approach which has been adopted to improve health services for older people. There is now within the NHS a National Director for Services for Older People whose role it is to lead a programme of change and reform in four areas earmarked for improvement: assuring standards of care, extending access to services, promoting independence in old age, and ensuring fairness in funding. We are impressed by this approach.[17] A parallel initiative for children's healthcare services in the form of a National Director for Children's Healthcare Services would be of real and lasting benefit, always provided that it was combined with a strong commitment by government at ministerial level and a strong national framework for children's healthcare services, both of which we have referred to earlier.

Specific issues

45 It is not our intention, as we have said, to rewrite the principles and (long-standing) guidance relating to children's healthcare services. There are, however, two matters of such importance that we wish to single them out for special mention. They are the staffing of children's healthcare services, and communication between healthcare staff, children and their parents or carers.

The staffing of children's healthcare services

46 It is worth recalling the words of the late Professor Baum:

> '… it is manifestly the case that children should be looked after by children-trained staff … we have to break through barriers of small people needing fewer staff to the understanding that these are whole-time people, these children and babies, who require whole-time staff and the sicker they are, the more complex the health care techniques, the more dedicated completely preoccupied attention [is needed] from the nursing staff attending, therefore the more are needed in the whole staff of the hospital and that produces tremendous difficulties, both in having the budget to

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[17] One of the Panel would go further and also recommend the appointment of a Children's Commissioner, as discussed earlier

> employ the staff, but downstream or upstream to have enough nurses coming through that training.'[18]

47 The acceptance that children are distinct from adults requires, in turn, the acceptance of the need for the care of children to be provided by appropriately trained staff. We have said this already. What this means is that all healthcare staff who treat children must have training in caring for children. This is especially so in relation to paediatric intensive care. For nursing in acute hospitals, there are very clear standards as to the number of nurses trained in the care of children who should be available: they are set down by the DoH in its 1991 guidance. The standards require that at least two Registered Sick Children's Nurses (RSCNs) (or nurses who have completed the child branch of Project 2000) be on duty 24 hours a day in all children's departments and wards in the hospital and that there be an RSCN available 24 hours a day to advise on the nursing of children in other departments. These standards should serve as the minimum standards and should apply where children are treated (save in emergencies) to take account of changing patterns in the provision of acute healthcare services. We also believe, however, that the standards should be reviewed as a matter of urgency.

48 According to a recent RCN survey of acute healthcare provision for children, around seven in ten trusts met the DoH's standard for the level of paediatric nursing.[19] Those trusts which did not meet the standard mentioned cover for night duty as a particular difficulty. We were told that, although there is no shortage of people applying to qualify as children's nurses, there *is* a pressing need for well-trained and highly-skilled nurses to cope with the growth in paediatric sub-specialties, which are amongst the most technologically advanced and labour intensive areas of nursing. We were also told that turnover among staff often leads to a lack of continuity of staff with the appropriate level of knowledge and expertise.

49 As with nursing so with medicine and surgery, there is no place in the NHS of today for occasional paediatric practice. Children deserve better. We are convinced from the experience of Bristol that all doctors who treat children, both in hospital and in primary care, should receive appropriate training and continuing professional development in paediatrics.

50 In terms of surgery, in the light of what we have previously said about the particular characteristics and needs of children, we believe that surgery, of whatever type, on children should be a sub-specialty, carried out by designated surgeons who have undergone appropriate training. This is not to say that there is no scope for mixed adult-paediatric practice. To argue this would be impractical and, in any event, there is no strong evidence to suggest that a mixed practice in itself is unsafe. Moreover, it ignores the fact that children grow up and, to the extent that they need further surgery, the paediatric cardiac surgeon, for example, familiar with responding to congenital heart defects must be able to care for them. What matters is that surgeons who operate

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[18] T18 p. 36 and T18 p. 39 Professor Baum

[19] Royal College of Nursing. *'Children's Services: Acute Health Care Provision'*. London: RCN, June 1999

on children, no matter that they also operate on adults, must be trained to care for children, and they must undertake sufficient operations on children to maintain their skills. The report of the Paediatric Forum of the Royal College of Surgeons of England recommends specific paediatric training for all surgeons who operate on children. It suggests that a minimum of one paediatric operating session[20] a fortnight be performed. We endorse the principle underlying this proposal: that there must be a minimum level of regular operating sessions. We doubt, however, that it is advisable to have a generic minimum level: the minimum level is likely to vary according to the particular paediatric surgical specialty. As a matter of priority, the GMC, the body responsible for the revalidation of doctors, should agree with the Royal College of Surgeons of England the appropriate number and range of procedures which surgeons who operate on children must undertake to retain their validation. Some areas of expertise may require more sessions than others. In the case of PCS, based on our experience of events in Bristol, we believe that one session a fortnight is probably too infrequent an engagement with children to maintain competence. While we do not stipulate the required number of sessions we are persuaded that an average of four sessions a week should be the minimum number required. Clearly this must be agreed as part of the process of revalidation as a matter of urgency. We express no view as to whether this should also apply to other paediatric surgical specialties. We recognise, however, that, over time, implementing this approach is likely to have consequences for the way in which general surgery on children is organised.

51 As regards medical care, clearly what was said about the surgeon applies also to the anaesthetist and others: if they are to care for children they must be trained to do so and periodically demonstrate that they have maintained their skills. And there must be enough of them. It may also be appropriate here to point out that with the growing influence of primary care groups and trusts, there is a strong case for saying that the expertise of GPs in paediatric care could be improved. A number (two or three) of GPs on a primary care trust (PCT) should be required to undergo additional professional training (with appropriate support) in paediatrics and then become the 'children's experts' within the PCT. This would take us a step further towards integrating children's healthcare into all aspects of the health service. A still further step which we recommend is that each health authority and primary care group/trust should designate a senior member of staff to have responsibility for commissioning children's healthcare services locally.

Communication between healthcare professionals, children and their parents or carers

52 Children, once they grow out of infancy, are acute observers of the mood and body language of others. It is impossible to avoid communicating with them. For this reason, good practice is now founded on the principles of truthfulness, clarity and awareness of the child's age.[21] In practice, this means that healthcare professionals

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[20] We take the term 'session' to mean half of a working day

[21] We have been greatly assisted in this section by expert advice from Jean Simons. See her paper at 10k in Annex B: *'Giving information to parents with an unwell child; an expert opinion'*

who care for children must be able to listen to children, to respect their needs for information and to be prepared and able to give such information in the right amount and in a way which is suitable for the child's age. Clearly, this is not necessarily a straightforward or easy matter. It causes us again to reinforce our view that those who care for children must be trained in paediatrics and in the special skills of communicating with children about illness and treatment.

53 In the case of children still in infancy, communication is with their parents. We were left in no doubt that one of the principal lessons from Bristol is that parents wish to be treated with respect. They want their particular knowledge of their child to be valued, and they wish to be included in the process of caring for their child. Parents are entitled to nothing less, and good practice now reflects this. Our experience of receiving the evidence of parents, 238 of whom gave formal written statements to the Inquiry, is that they do not, for the most part, expect healthcare professionals to have all the answers. What they do expect is that their concerns as parents will be addressed. As Jean Simons, Head of Bereavement Services, Great Ormond Street Hospital for Children, points out, parents become angry or frustrated when a healthcare professional unilaterally decides which topics are 'too difficult' for them to deal with. Making such assumptions, or avoiding certain issues altogether, are not good practice. Healthcare professionals caring for children should be trained in the particular skills necessary to communicate with parents. There needs to be a willingness on the part of the healthcare professional to be more open with parents about difficult issues, and to assess to what degree the parents want to discuss them.

54 Of particular difficulty is the issue of false hope. Parents in Bristol, as would any parent, wanted only the best possible for their children, not least the chance of life-saving treatment. Having heard from so many parents as to how they felt the doctors at Bristol led them to believe their children would get better, or would not necessarily have permanent side effects after surgery, we were struck by Jean Simons' comment:

> '… the reliance and trust most patients place in doctors to give them cause for hope, can lead doctors to concentrate on discussing the aspects of treatment which can give cause for hope at the expense of realistic information about what the treatment may do to the patient's quality of life, or indeed what truly realistically the treatment could be expected to achieve.'

55 This is a real human dilemma. Healthcare professionals, especially those caring for children, share this hope for the future. But all have to guard against allowing this natural human instinct to get in the way of being straightforward with parents. There is no single or easy solution to this. What is called for is constant awareness and vigilance amongst those involved in supporting the parents of sick children in hospital to ensure that they are not inadvertently avoiding the difficult issues. One very practical step which we recommend is, systematically, to seek feedback from parents several weeks after their child has been in hospital about their perceptions of the experience. Such feedback could then be regularly reviewed in clinical team audit meetings and appropriate lessons learned.

Recommendations

Introduction

- The issues addressed in Section Two of our Report are complex and have challenged every developed country.
- There are no right answers; just, perhaps, less wrong answers.
- Cultural and institutional change takes time and can be slow, requiring patience and forbearance.
- Nothing can be achieved ‘on the cheap’: not only must funding for the NHS continue to grow in a sustained manner, but ways must be found to protect it as far as possible from the ordinary turbulence of economic cycles.
- There are no quick fixes, but progress is possible and can be achieved. We reject both the ‘magic wand’ and ‘nothing can be done’ schools of policy.
- Change can only be brought about with the willing and active participation of those involved in healthcare: the public, patients, healthcare professionals, trusts and health authorities, and government.

Purpose of the Recommendations

- To meet our Terms of Reference.
- To advance the central notion of a patient-centred healthcare service committed to continuous improvement. We adopt as our starting point that the NHS exists to serve patients.
- To promote a new culture within the NHS: a three-way partnership of respect, honesty and openness between:
  - NHS and public;
  - professionals and patients; and
  - professionals and professionals.

- To give effect to the following:
  - The patient must be at the centre of everything which the NHS does.
  - The commitment and the dedication of staff in the NHS must be valued and acknowledged: those caring for patients must themselves be supported and cared for.
  - There must be openness and transparency in everything which the NHS does.
  - The impact of the way in which services are organised on the quality of care which patients receive must be recognised: the quality of care depends on systems and on facilities, as well as on individual healthcare professionals.
  - All those involved in healthcare – doctors, nurses, other healthcare professionals, and managers – are collectively healthcare professionals: each group must recognise and acknowledge the contribution of others in the service of patients.
  - The safety of patients must be the foundation of the NHS's commitment to the quality of its services.
  - Sentinel events, that is, errors, other adverse events, and near misses, which occur during the care of patients, must be seen as opportunities to learn, not just as reasons to blame.
  - There must be clear and understood systems of responsibility and accountability: a culture of blame is no substitute for such systems.
  - The quality of healthcare must be guided by agreed standards, compliance with which is regularly monitored.
  - The role of central government in relation to the NHS should be:

    a) to act as its headquarters in terms of management; and

    b) to create independent mechanisms for regulating the quality of healthcare and the competence of healthcare professionals.
  - The various independent bodies must themselves be co-ordinated so as to avoid the fragmentation of responsibility which arose in the past. Existing bodies, suitably shaped, must be used. We recommend the creation of only one new body.

The nature of the Recommendations

- Our Recommendations are grouped together under various headings reflecting the themes highlighted in our Report. We identify those Recommendations which we consider sufficiently important to merit early implementation. Other Recommendations we recognise will take some time to implement, either because further debate is required, or because they require other changes to be in place.

- The Recommendations are interlocked and interrelated. They are parts of a jigsaw: each needs the other to complete the picture. We believe that action needs to move forward in relation to all the themes simultaneously. We do not place a priority on one theme over another.

- We have deliberately chosen not to cost the Recommendations we make. This is not least because, with many of our Recommendations, change can be achieved by doing things differently within existing resources. We estimate that around half of our Recommendations could be implemented with no or relatively modest expenditure. A significant number relate to changes already underway. Furthermore, many of the fundamental changes needed in the way in which the NHS currently works concern attitudes and culture. The resources needed for these changes are not necessarily financial. That said, the NHS continues to confront the consequences of long-term underinvestment. We make it clear that, to achieve that which patients are entitled to expect of the NHS, will require sustained additional funding. To fail to provide it would be to fail the NHS and thus to fail the public.

- Whether, how and over what time frame these Recommendations are implemented will be a matter for government and for others. We are conscious of the fact that the NHS has only recently begun to digest and respond to *'The NHS Plan'*. The Department of Health (DoH) is setting a series of targets to be achieved to implement the Plan. A further report, such as this one, with many Recommendations might seem like the last straw. But this would be to misunderstand this Inquiry and the nature of our Recommendations. First, we make no apology that there are a large number. It would be a surprise if it were otherwise, given the nature of our task. Secondly, our Recommendations are not in the form of performance targets: tasks which must be achieved in a certain way by a certain date. Thirdly, they are not addressed specifically or exclusively to trusts or to professional bodies or Royal Colleges or even to the NHS. They include all and go beyond them. And fourthly, while there are some which call for urgent action, many of the Recommendations are about a process of change over time. They build on each other and can be organised accordingly.

The structure of the Recommendations

- The story of Bristol was about children. There are a number of issues particular to the provision of acute healthcare services for children which demand special attention. As a consequence, we make a series of Recommendations which focus specifically on healthcare services for children.

- We also include Recommendations addressed to the care and treatment of children with congenital heart disease, including paediatric cardiac surgery.

- Because the focus of the Inquiry was on services provided within the acute hospital sector of the NHS, our Recommendations are addressed principally to that sector. Throughout we use the word 'trust' to refer to an NHS acute hospital or healthcare trust. We do not intend to refer to any other type of trust. Whenever we wish also to include primary care trusts we specifically say so.

- Throughout the Recommendations we use the term patients. In the case of young children and those otherwise unable to decide for themselves this should be taken to include parents and carers.

- Perhaps the most significant change we call for is one which does not attract a specific Recommendation. This is the change which is needed in the culture of the NHS. We see changes to that culture as being a product of the Recommendations as a whole. If the Recommendations are implemented, changes in the culture will follow.

- To reflect the patient's journey, the Recommendations are divided into categories as follows:

  - respect and honesty;
  - a Health Service which is well led;
  - competent healthcare professionals;
  - the safety of care;
  - care of an appropriate standard;
  - public involvement through empowerment; and
  - the care of children.

The Recommendations

Respect and honesty

Partnership: involving patients

1 In a patient-centred healthcare service patients must be involved, wherever possible, in decisions about their treatment and care.

2 The education and training of all healthcare professionals should be imbued with the idea of partnership between the healthcare professional and the patient.

3 The notion of partnership between the healthcare professional and the patient, whereby the patient and the professional meet as equals with different expertise, must be adopted by healthcare professionals in all parts of the NHS, including healthcare professionals in hospitals.

Keeping patients informed about treatment and care

4 Information about treatment and care should be given in a variety of forms, be given in stages and be reinforced over time.

5 Information should be tailored to the needs, circumstances and wishes of the individual.

6 Information should be based on the current available evidence and include a summary of the evidence and data, in a form which is comprehensible to patients.

7 Various modes of conveying information, whether leaflets, tapes, videos or CDs, should be regularly updated, and developed and piloted with the help of patients.

8 The NHS Modernisation Agency should make the improvement of the quality of information for patients a priority. In relation to the content and the dissemination of information for patients, the Agency should identify and promote good practice throughout the NHS. It should establish a system for accrediting materials intended to inform patients.

9 The public should receive guidance on those sources of information about health and healthcare on the Internet which are reliable and of good quality: a kitemarking system should be developed.

Communicating with patients[1]

10 Tape-recording facilities should be provided by the NHS to enable patients, should they so wish, to make a tape recording of a discussion with a healthcare professional when a diagnosis, course of treatment, or prognosis is being discussed.

11 Patients should always be given the opportunity and time to ask questions about what they are told, to seek clarification and to ask for more information. It must be the responsibility of employers in the NHS to ensure that the working arrangements of healthcare professionals allow for this, not least that they have the necessary time.

12 Patients must be given such information as enables them to participate in their care.

13 Before embarking on any procedure, patients should be given an explanation of what is going to happen and, after the procedure, should have the opportunity to review what has happened.

14 Patients should be supported in dealing with the additional anxiety sometimes created by greater knowledge.

15 Patients should be told that they may have another person of their choosing present when receiving information about a diagnosis or a procedure.

16 Patients should be given the sense of freedom to indicate when they do not want any (or more) information: this requires skill and understanding from healthcare professionals.

17 Patients should receive a copy of any letter written about their care or treatment by one healthcare professional to another.

18 Parents of those too young to take decisions for themselves should receive a copy of any letter written by one healthcare professional to another about their child's treatment or care.

19 Healthcare professionals responsible for the care of any particular patient must communicate effectively with each other. The aim must be to avoid giving the patient conflicting advice and information.

Support services for patients

20 The provision of counselling and support should be regarded as an integral part of a patient's care. All hospital trusts should have a well-developed system and a well-trained group of professionals whose task it is to provide this type of support and to make links to the various other forms of support (such as that provided by voluntary or social services) which patients may need.

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[1] See also Recommendations 59 and 60 which focus on the communication skills of healthcare professionals and Recommendations 187–191 concerning communication between healthcare professionals and children and their parents

21 Every trust should have a professional bereavement service. (We also reiterate what was recommended in the Inquiry's Interim Report: 'Recommendation 13: As hospitals develop websites, a domain should be created concerned with bereavement in which all the relevant information concerning post-mortems can be set out in an appropriate manner.')

22 Voluntary organisations which provide care and support to patients and carers in the NHS (such as through telephone helplines, the provision of information and the organisation of self-help groups) play a very important role. Groups which meet the appropriate standards as laid down by the NHS should receive appropriate funding from the state for the contribution they make to the NHS.

Consent to treatment

(In relation to post-mortems and the removal and retention of human material, we restate here those Recommendations from the Inquiry's Interim Report which related to consent: 'Recommendation 26: Obtaining parents' consent should be seen as a process, and not just the signing of a form. As part of that process, parents should be allowed proper time to reflect and be informed that they may change their minds until such time as they sign a form indicating their consent.' 'Recommendation 27: As part of that process, parents should have access to: advice and information which is comprehensible, accessible, and in a form which allows it to be taken home if desired.')

23 We note and endorse the recent statement on consent produced by the DoH: *'Reference guide to consent for examination or treatment'*, 2001. It should inform the practice of all healthcare professionals in the NHS and be introduced into practice in all trusts.

24 The process of informing the patient, and obtaining consent to a course of treatment, should be regarded as a process and not a one-off event consisting of obtaining a patient's signature on a form.

25 The process of consent should apply not only to surgical procedures but to all clinical procedures and examinations which involve any form of touching. This must not mean more forms: it means more communication.

26 As part of the process of obtaining consent, except when they have indicated otherwise, patients should be given sufficient information about what is to take place, the risks, uncertainties, and possible negative consequences of the proposed treatment, about any alternatives and about the likely outcome, to enable them to make a choice about how to proceed.

27 Patients should be referred to information relating to the performance of the trust, of the specialty and of the consultant unit (a consultant and the team of doctors who work under his or her supervision). (See further the Recommendations on care of an appropriate standard.)

Feedback from patients

28 Patients must be given the opportunity to pass on views on the service which they have received: all parts of the NHS should routinely seek and act on feedback from patients as to their views of the service. In addition, formal, systematic structured surveys of patients' experience of their care (not merely satisfaction surveys) should be routinely conducted across the NHS and the results made public.

29 NHS trusts and primary care trusts must have systems which ensure that patients know where and to whom to go when they need further information or explanation.

30 We endorse the initiative in *'The NHS Plan'* to establish a Patient Advocacy and Liaison Service in every NHS trust and primary care trust. The establishment of this service should be implemented in full as quickly as possible. Once established, patient advocacy and liaison services must be given secure funding to enable them to provide an effective service to patients.

31 Trusts and primary care trusts must have systems for publishing periodic reports on patients' views and suggestions, including information about the action taken in the light of them. (See further the Recommendations on care of an appropriate standard.)

32 So as to provide for patients an effective, efficient and seamless information and advocacy service, consideration should be given to how the various patient advocacy and liaison services in a given geographical area could most effectively collaborate, including in relation to the provision of information for patients and the public.

Responding to the patient when things go wrong

33 A duty of candour, meaning a duty to tell a patient if adverse events[2] have occurred, must be recognised as owed by all those working in the NHS to patients.

34 When things go wrong, patients are entitled to receive an acknowledgement, an explanation and an apology.

35 There should be a clear system, in the form of a 'one-stop shop' in every trust, for addressing the concerns of a patient about the care provided by, or the conduct of, a healthcare professional.

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[2] An adverse event is an unplanned event which results in harm to a patient. We use the term 'adverse event' rather than 'sentinel event' in this instance so as to exclude 'near misses'

36 Complaints should be dealt with swiftly and thoroughly, keeping the patient (and carer) informed. There should be a strong independent element, not part of the trust's management or board, in any body considering serious complaints which require formal investigation. An independent advocacy service should be established to assist patients (and carers).

37 There should be an urgent review of the system for providing compensation to those who suffer harm arising out of medical care. The review should be concerned with the introduction of an administrative system for responding promptly to patients' needs in place of the current system of clinical negligence and should take account of other administrative systems for meeting the financial needs of the public. (See further the Recommendations on the safety of care.)

A Health Service which is well led

38 The DoH's roles in relation to the NHS must in future be made explicit. The DoH should have two roles. It should be the headquarters of the NHS. It should also establish an independent framework of regulation which will assure the quality of the care provided in and funded by the NHS, and the competence of healthcare professionals.

The regulation of the quality and safety of healthcare

39 The framework of regulation must consist of two overarching organisations, independent of government, which bring together the various bodies which regulate healthcare. A Council for the Quality of Healthcare should be created to bring together those bodies which regulate healthcare standards and institutions (including, for example, the Commission for Health Improvement (CHI), the National Institute for Clinical Excellence (NICE) and the proposed National Patient Safety Agency).
A Council for the Regulation of Healthcare Professionals should be created to bring together those bodies which regulate healthcare professionals (including, for example, the General Medical Council (GMC) and the Nursing and Midwifery Council); in effect, this is the body currently referred to in *'The NHS Plan'* as the Council of Healthcare Regulators. These overarching organisations must ensure that there is an integrated and co-ordinated approach to setting standards, monitoring performance, and inspection and validation. Issues of overlap and of gaps between the various bodies must be addressed and resolved.

40 The two Councils should be independent of government and report both to the DoH and to Parliament. There should be close collaboration between the two Councils. The DoH should establish and fund the Councils and set their strategic framework, and thereafter periodically review them.

41 The various bodies whose purpose it is to assure the quality of care in the NHS (for example, CHI and NICE) and the competence of healthcare professionals (for example, the GMC and the Nursing and Midwifery Council) must themselves be independent of and at arm's-length from the DoH.

42 All the various bodies and organisations concerned with regulation, besides being independent of government, must involve and reflect the interests of patients, the public and healthcare professionals, as well as the NHS and government.

The management of the NHS at the local level

Contractual relations between trusts and employees

43 The contractual relationship between trusts and consultants should be redefined. The trust must provide the consultant with the time, space and the necessary tools to do the job. Consultants must accept that the time spent in the hospital and what they do in that time must be explicitly set out.

44 The system of Distinction Awards for hospital consultants should be examined to determine whether it could be used to provide greater incentives than exist at present for providing good quality of care to patients. The possibility of its extension to include junior hospital doctors should be explored.

45 The doctors' Code of Professional Practice, as set down in the GMC's *'Good Medical Practice'*, should be incorporated into the contract of employment between doctors and trusts. In the case of GPs, the terms of service should be amended to incorporate the Code.

46 The relevant codes of practice for nurses, for professions allied to medicine and for managers should be incorporated into their contracts of employment with hospital trusts or primary care trusts.

47 Trusts should be able to deal as employers with breaches of the relevant professional code by a healthcare professional, independently of any action which the relevant professional body may take.

The chief executive and senior management

48 The security of tenure of the chief executive and senior managers of trusts should be on a par with that of other senior professionals in the NHS.

The trust board

49 The criteria and process for selection of the executive directors of a trust board must be open and transparent. Appointments should be made on the basis of ability and not on the basis of seniority.

50 The NHS Leadership Centre, in conjunction with trusts, should develop programmes of training and support for clinicians and others who seek to become executive directors.

51 As recommended in *'The NHS Plan'*, there should be an NHS Appointments Commission responsible for the appointment of non-executive directors of NHS trusts, health authorities and primary care trusts.

52 Newly appointed non-executive directors of trusts, health authorities and primary care trusts should receive a programme of induction: this should refer to the principles and values of the NHS and their duties and responsibilities with regard to the quality of care provided by the trust. This programme should be provided through the NHS Leadership Centre.

53 A standard job description should be developed by the NHS for non-executive directors, as proposed in *'The NHS Plan'*.

54 Throughout their period of tenure, non-executive directors should be provided with training, support and advice organised and co-ordinated through the NHS Leadership Centre.

55 The Chairs of trust boards should have a source of independent advice (or mentor) during their period of office, drawn from a pool of experts assembled by the NHS Leadership Centre.

56 Arrangements should be in place in the standing orders of trust boards to provide for proper continuity in the management of the trust's affairs in the period between the cessation of the Chair's term of office and the commencement of that of a successor.

Competent healthcare professionals

Broadening the notion of professional competence

57 Greater priority than at present should be given to non-clinical aspects of care in six key areas in the education, training and continuing professional development of healthcare professionals:

- skills in communicating with patients and with colleagues;
- education about the principles and organisation of the NHS, and about how care is managed, and the skills required for management;
- the development of teamwork;

- shared learning across professional boundaries;
- clinical audit and reflective practice; and
- leadership.

58 Competence in non-clinical aspects of caring for patients should be formally assessed as part of the process of obtaining an initial professional qualification, whether as a doctor, a nurse or some other healthcare professional.

59 Education in communication skills must be an essential part of the education of all healthcare professionals. Communication skills include the ability to engage with patients on an emotional level, to listen, to assess how much information a patient wants to know, and to convey information with clarity and sympathy.

60 Communication skills must also include the ability to engage with and respect the views of fellow healthcare professionals.

61 The education, training and Continuing Professional Development (CPD) of all healthcare professionals should include joint courses between the professions.

62 There should be more opportunities than at present for multi-professional teams to learn, train and develop together.

63 All those preparing for a career in clinical care should receive some education in the management of healthcare, the health service and the skills required for management.

64 Greater opportunities should be created for managers and clinicians to 'shadow' one another for short periods to learn about their respective roles and work pressures.

Leadership: skills and capacity

65 An early priority for the new NHS Leadership Centre should be to offer guidelines as to leadership styles and practices which are acceptable and to be encouraged within the NHS, and those which are not.

66 Steps should be taken to identify and train those within the NHS who have the potential to exercise leadership. There needs be a sustained investment in developing leadership skills at all levels in the NHS.

67 The NHS's investment in developing and funding programmes in leadership skills should be focused on supporting joint education and multi-professional training, open to nurses, doctors, managers and other healthcare professionals.

68 The NHS Leadership Centre should be involved in all stages of the education, training and continuing development of all healthcare professionals.

The systems for assuring competence

69 Regulation of healthcare professionals is not just about disciplinary matters. It should be understood as encapsulating all of the systems which combine to assure the competence of healthcare professionals: education, registration, training, CPD and revalidation as well as disciplinary matters.

70 For *each* group of healthcare professionals (doctors, nurses and midwives, the professions allied to medicine, and managers) there should be one body charged with overseeing *all* aspects relating to the regulation of professional life: education, registration, training, CPD, revalidation and discipline. The bodies should be: for doctors, the GMC; for nurses and midwives, the new Nursing and Midwifery Council; for the professions allied to medicine, the re-formed professional body for those professions; and for senior healthcare managers, a new professional body.

71 In addition, a single body should be charged with the overall co-ordination of the various professional bodies and with integrating the various systems of regulation. It should be called the Council for the Regulation of Healthcare Professionals. (In effect, this is the body currently proposed in *'The NHS Plan'*, and referred to as the Council of Healthcare Regulators.) (See Recommendation 39.)

72 The Council for the Regulation of Healthcare Professionals should be established as a matter of priority. It should have a statutory basis. It should report to Parliament. It should have a broadly-based membership, consisting of representatives of the bodies which regulate the various groups of healthcare professionals, of the NHS, and of the general public.

73 The Council for the Regulation of Healthcare Professionals should have formal powers to require bodies which regulate the separate groups of healthcare professionals to conform to principles of good regulation. It should act as a source of guidance and of good practice. It should seek to ensure that in practice the bodies which regulate healthcare professionals behave in a consistent and broadly similar manner.

74 It should be a priority for the Council for the Regulation of Healthcare Professionals to promote common curricula and shared learning across the professions.

The education of healthcare professionals

75 Pilot schemes should be established to develop and evaluate the feasibility of making the first year's course of undergraduate education common to all those wishing to become healthcare professionals.

76 Universities should develop closer links between medical schools and schools of nursing education with a view to providing more joint education between medical and nursing students.

77 Universities should develop closer links between medical and nursing schools and centres for education and training in health service and public sector management, with a view to enabling all healthcare professionals to learn about management.

78 Access to medical schools should be widened to include people from diverse academic and socio-economic backgrounds. Those with qualifications in other areas of healthcare and those with an educational background in subjects other than science, who have the ability and wish to do so, should have greater opportunities than is presently the case, to enter medical schools.

79 The attributes of a good doctor, as set down in the GMC's *'Good Medical Practice',* must inform every aspect of the selection criteria and curricula of medical schools.

80 The NHS and the public should be involved in (a) establishing the criteria for selection and (b) the selection of those to be educated as doctors, nurses and as other healthcare professionals.

Post-qualification training and continuing professional development

81 In relation to doctors, we endorse the proposal to establish a Medical Education Standards Board (MESB), to co-ordinate postgraduate medical training. The MESB should be part of and answerable to the GMC which should have a wider role. (See Recommendation 70.)

82 CPD, being fundamental to the quality of care provided to patients, should be compulsory for all healthcare professionals.

83 Trusts and primary care trusts should provide incentives to encourage healthcare professionals to maintain and develop their skills. The contract (or, in the case of GPs, other relevant mechanism) between the trust and the healthcare professional should provide for the funding of CPD and should stipulate the time which the trust will make available for CPD.

84 Trusts and primary care trusts must take overall responsibility through an agreed plan for their employees' use of the time allocated to CPD. They must seek to ensure that the resources deployed for CPD contribute towards meeting the needs of the trust and of its patients, as well as meeting the professional aspirations of individual healthcare professionals.

Appraisal

85 Periodic appraisal should be compulsory for all healthcare professionals. The requirement to participate in appraisal should be included in the contract of employment.

86 The commitment in *'The NHS Plan'* to introduce regular appraisal for hospital consultants must be implemented as soon as possible.

87 The requirement to undergo periodic appraisal should also be incorporated into GPs' terms of service.

Revalidation

88 Periodic revalidation, whereby healthcare professionals demonstrate that they remain fit to practise in their chosen profession, should be compulsory for all healthcare professionals. The requirement to participate in periodic revalidation should be included in the contract of employment.

89 The public, as well as the employer and the relevant professional group, must be involved in the processes of revalidation.

90 The new Council for the Regulation of Healthcare Professionals should take as a further priority an early review of the various systems of revalidation and re-registration to ensure that they are sufficiently rigorous, and in alignment both with each other and with other initiatives to protect the public. The Council should also seek ways to incorporate managers (as healthcare professionals) into the systems of CPD, appraisal and revalidation.

Managers

91 Managers as healthcare professionals should be subject to the same obligations as other healthcare professionals, including being subject to a regulatory body and professional code of practice. (See Recommendation 70.)

Clinicians who hold managerial positions

92 Where clinicians hold managerial roles which extend beyond their immediate clinical practice, sufficient protected time in the form of allocated sessions must be made available for them to carry out that managerial role.

93 Any clinician, before appointment to a managerial role, must demonstrate the managerial competence to undertake what is required in that role: training and support should be made available by trusts and primary care trusts.

94 Clinicians should not be required or expected to hold managerial roles on bases other than competence for the job. For example, seniority or being next in turn are not appropriate criteria for the appointment of clinicians to managerial roles.

95 The professional and financial incentives for senior clinicians to undertake full-time senior managerial roles should be reviewed: the aim should be to enable senior clinicians to move into a full-time managerial role, and subsequently, if they so wish, to move back into clinical practice after appropriate retraining and revalidation.

96 To protect patients, in the case of clinicians who take on managerial roles but wish to continue to practise as clinicians, experts together with managers from the NHS should issue advice as to the minimum level of regular clinical practice necessary to enable a clinician to provide care of a good quality. Clinicians not maintaining this level of practice should not be entitled to offer clinical care. This rule should also apply to all other clinicians who, for whatever reason, are not in full-time practice, and not only to those in part-time managerial roles.

97 To facilitate the movement of clinicians in and out of managerial positions, the proposed systems for the revalidation (and re-registration) of doctors, nurses and professions allied to medicine should distinguish between professionals who are managers and also maintaining a clinical practice and those who are not. Those who are not maintaining a clinical practice should be entitled to obtain the appropriate revalidation (and re-registration) to restart a clinical practice, after retraining, and should be assisted in doing so. (See Recommendation 95.)

98 The relevant professional regulatory bodies should make rules varying the professional duties of those professionals, whose registration they hold, who are in full-time managerial roles, so as to take account of the fact that, while occupying such roles, they do not undertake responsibility for the care of patients.

The acquisition and development of new clinical skills

99 Any clinician carrying out any clinical procedure for the first time must be directly supervised by colleagues who have the necessary skill, competence and experience until such time as the relevant degree of expertise has been acquired.

100 Before any *new* and hitherto untried invasive clinical procedure can be undertaken for the first time, the clinician involved should have to satisfy the relevant local research ethics committee that the procedure is justified and it is in the patient's interests to proceed. Each trust should have in place a system for ensuring that this process is complied with.

101 Local research ethics committees should be re-formed as necessary so that they are capable of considering applications to undertake new and hitherto untried invasive clinical procedures.

102 Patients are always entitled to know the extent to which a procedure which they are about to undergo is innovative or experimental. They are also entitled to be informed about the experience of the clinician who is to carry out the procedure.

103 The Royal College of Surgeons of England should, in partnership with university medical schools and the NHS, be enabled to develop its unit for the training of surgeons, particularly in new techniques. It should also explore the question of whether there is an age beyond which surgeons, specifically in areas such as paediatric cardiac surgery, should not attempt new procedures or even should not continue in a particular field of surgery.

Discipline

104 In the exercise of their disciplinary function the professional regulatory bodies must adopt a more flexible approach towards what constitutes misconduct. They must deal with cases, as far as possible, at a local level and must have available a range of actions which both serve the interests of the public and the needs of the professional.

105 The need to involve the public in the various professional regulatory bodies applies as much to discipline as to all the other activities of these bodies (see Recommendation 42).

The safety of care

106 We support and endorse the broad framework of recommendations advocated in the report *'An Organisation with a Memory'* by the Chief Medical Officer's expert group on learning from adverse events in the NHS. The National Patient Safety Agency proposed as a consequence of that report should, like all other such bodies which contribute to the regulation of the safety and quality of healthcare, be independent of the NHS and the DoH.

107 Every effort should be made to create in the NHS an open and non-punitive environment in which it is safe to report and admit sentinel events.[3]

108 Major studies should, as a matter of priority, be carried out to investigate the extent and type of sentinel events in the NHS to establish a baseline against which improvements can be made and measured.

A national reporting system

109 There should a single, unified, accessible system for reporting and analysing sentinel events, with clear protocols indicating the categories of information which must be reported to a national database.

110 The national database of sentinel events should be managed by the National Patient Safety Agency, so as to ensure that a high degree of confidence is placed in the system by the public.

111 The National Patient Safety Agency, in the exercise of its function of surveillance of sentinel events, should be required to inform all trusts of the need for immediate action, in the light of occurrences reported to it. The Agency should also be required to publish regular reports on patterns of sentinel events and proposed remedial actions.

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[3] A sentinel event is defined as 'any unexplained occurrence involving death or serious physical or psychological injury, or the risk thereof'

112 *All* sentinel events should be subject to a form of structured analysis in the trust where they occur, which takes into account not only the conduct of individuals, but also the wider contributing factors within the organisation which may have given rise to the event.

Incentives to encourage the reporting of sentinel events

113 The reporting of sentinel events must be made as easy as possible, using all available means of communication (including a confidential telephone reporting line).

114 Members of staff in the NHS should receive immunity from disciplinary action by the employer or by a professional body if they report a sentinel event to the trust or to the national database within 48 hours, except where they themselves have committed a criminal offence.

115 Members of staff in the NHS who cover up or do not report a sentinel event may be subject to disciplinary action by their employer or by their professional body.

116 The opportunity should exist to report a sentinel event in confidence.

117 There should be a stipulation in every healthcare professional's contract that sentinel events must be reported, that reporting can be confidential, and that reporting within a specified time period will not attract disciplinary action.

118 The process of reporting of sentinel events should be integrated into every trust's internal communications, induction training and other staff training. Staff must know what is expected of them, to whom to report and what systems are in place to enable them to report.

The system of clinical negligence

119 In order to remove the disincentive to open reporting and the discussion of sentinel events represented by the clinical negligence system, this system should be abolished. It should be replaced by an alternative system for compensating those patients who suffer harm arising out of treatment from the NHS. An expert group should be established to advise on the appropriate method of compensation to be adopted.

Designing for safety

120 The proposed National Patient Safety Agency should, as a matter of urgency, bring together managers in the NHS, representatives of the pharmaceutical companies and manufacturers of medical equipment, members of the healthcare professions and the public, to seek to apply approaches based on engineering and design so as to reduce (and eliminate to the extent possible) the incidence of sentinel events.

Incorporating a concern for safety into systems and policies

121 At the level of individual trusts, an executive member of the board should have the responsibility for putting into operation the trust's strategy and policy on safety in clinical care. Further, a non-executive director should be given specific responsibility for providing leadership to the strategy and policy aimed at securing safety in clinical care.

Care of an appropriate standard

122 One body should be responsible for co-ordinating *all* action relating to the setting, issuing and keeping under review of national clinical standards: this should be NICE, suitably structured so as to give it the necessary independence and authority.

123 Once the recommended system is in place, only NICE should be permitted to issue national clinical standards to the NHS. The DoH (as the headquarters of the NHS) while issuing, for example, National Service Frameworks and supplementary guidance, should not be able to rescind or detract from the standards issued by NICE.

124 NICE should pursue vigorously its current policy of involving as wide a community as possible, including the public, patients and carers, in the work to develop and keep under review clinical standards. In particular, the special expertise of the Royal Colleges and specialist professional associations should be harnessed and supported. Account should also be taken of the expertise of the senior management of the NHS.

125 National standards of clinical care should reflect the commitment to patient-centred care and thus in future be formulated from the perspective of the patient. The standards should address the quality of care that a patient with a given illness or condition is entitled to expect to receive from the NHS. The standards should take account of the best available evidence. The standards should include guidance on how promptly patients should get access to care. They should address the roles and responsibilities of the various healthcare professionals who will care for the patient. They should take account of the patient's journey from primary care, into the hospital system (if necessary), and back to primary and community care, and of the necessary facilities and equipment.

126 Such standards for clinical care as are established should distinguish clearly between those which are obligatory and must be observed, and those to which the NHS should aspire over time.

127 A timetable over the short, medium and long term should be published, and revised periodically, for the development of national clinical standards, so that the public may be consulted and kept aware of those areas of healthcare which are covered by such standards and those which will be covered in the future. Target dates should be set by which clinical standards will have been prepared for all major conditions and illnesses.

128 Resources, and any necessary statutory authority, must be made available to NICE to allow it to perform its role of developing, issuing and keeping under review national clinical standards.

129 Standards of clinical care which patients are entitled to expect to receive in the NHS should be made public.

Standards of care: NHS organisations

130 There must be a single, coherent, co-ordinated set of generic standards: that is, standards relating to the patient's experience and the systems for ensuring that care is safe and of good quality (for example corporate management, clinical governance, risk management, clinical audit, the management and support of staff, and the management of resources). Trusts must comply with these standards.

131 The current system of inspection of trusts and primary care trusts should be changed to become a system of validation[4] and periodic revalidation of these trusts. The system should be supportive and flexible. Its aim should be to promote continued improvement in the quality of care.

132 One body should be responsible for validating and re-validating NHS trusts and primary care trusts. This body should be CHI, suitably structured so as to give it the necessary independence and authority. Other bodies (for example the NHS Litigation Authority) which are currently concerned with setting and requiring compliance with those generic standards which should fall within the authority of CHI, should carry out their role in this respect under the authority of and answerable to CHI.

133 Validation and revalidation of trusts should be based upon compliance with the generic standards which relate to the patient's experience and the systems for ensuring that care is safe and of good quality.

134 The standards against which trusts are to be validated, and the results of the process of validation or revalidation, should be made public.

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[4] We choose the term 'validation' not only to mirror the process which healthcare professionals will have to undergo, but also to indicate that, while akin to licensing it contemplates more. Licensing tends to be thought of as a 'one-off event', whereas to us validation is a process. What makes validation akin to licensing is the element of permission to continue

135 Any organisation in the voluntary or private sector which provides services to NHS patients should be required to meet the standards for systems, facilities and staff which organisations in the NHS must meet. The aim should be that, wherever care is funded by the NHS, there is a single system of validation which indicates to the public that the organisation meets the necessary standards.

136 The validating body should have the power to withdraw, withhold or suspend a trust's validation if standards fall such as to threaten the quality of care or the safety of patients. Any trust or organisation whose validation may be affected in this way must be given the opportunity to take appropriate remedial action. It must then satisfy CHI that it has taken remedial action before its continued validation can be confirmed.

137 CHI should consider how it might work with the providers of those programmes of accreditation already adopted by a significant number of trusts. In the future, where required standards are met, CHI should accept as part of its validation process the accreditation obtained through these programmes.

138 The process of validation of trusts should, in time, be extended to cover discrete, identifiable services within trusts. This extension of validation should first be piloted and evaluated.

139 The pilot exercise for this form of validation should include children's acute hospital services and paediatric cardiac surgery.

140 Should the pilot exercise be successful, the category of discrete services which should be a priority for this form of validation are those specialist services which are currently funded or meet the criteria for funding by the National Specialist Commissioning Group (the successor to the Supra Regional Services Advisory Group).

141 For discrete services, whether specialist services or otherwise, to be validated trusts they must be able to demonstrate that all relevant aspects of the service can *currently* be met, rather than that the trust *aims* to develop so as to be able to do so at some point in the future. Trusts which do not meet the necessary standards to ensure the safety of patients and a good quality of care should not be permitted to offer, or continue to offer, the relevant service.

142 Where the interests of securing quality of care and the safety of patients require that there be only a small number of centres offering a specialist service, the requirements of quality and safety should prevail over considerations of ease of access. It is and should be the responsibility of the NHS to assist patients, and their families or carers, with the cost of transport and accommodation when they have to travel away from home to receive specialist services. Such support should not be the subject of a means test. (See further Recommendations 181 and 182 on specialist services for children.)

Monitoring standards and performance

Local monitoring

143 The process of clinical audit, which is now widely practised within trusts, should be at the core of a system of local monitoring of performance. Clinical audit should be multidisciplinary.

144 Clinical audit must be fully supported by trusts. They should ensure that healthcare professionals have access to the necessary time, facilities, advice and expertise in order to conduct audit effectively. All trusts should have a central clinical audit office which co-ordinates audit activity, provides advice and support for the audit process, and brings together the results of audit for the trust as a whole.

145 Clinical audit should be compulsory for all healthcare professionals providing clinical care and the requirement to participate in it should be included as part of the contract of employment.

National monitoring

146 The monitoring of clinical performance at a national level should be brought together and co-ordinated in one body: an independent Office for Information on Healthcare Performance. This Office should be part of CHI.

147 The Office for Information on Healthcare Performance should supplant the current fragmentation of approach through a programme of activities involving the co-ordination of the various national audits. In addition to its other responsibilities, the new system should provide a mechanism for surveillance whereby patterns of performance in the NHS which may warrant further scrutiny can be identified as early as possible.

Information systems

148 The current ‘dual’ system of collecting data in the NHS in separate administrative and multiple clinical systems is wasteful and anachronistic. A single approach to collecting data should be adopted, which clinicians can trust and use and from which information about both clinical and administrative performance can be derived.

149 Steps should be taken nationally and locally to build the confidence of clinicians in the data recorded in the Patient Administration Systems in trusts (which is subsequently aggregated nationally to form the Hospital Episode Statistics). Such steps should include the establishment by trusts of closer working arrangements between clincians and clinical coding staff.

150 The Hospital Episode Statistics database should be supported as a major national resource which can be used reliably, with care, to undertake the monitoring of a range of healthcare outcomes.

151 Systems for clinical audit and for monitoring performance rely on accurate and complete data. Competent staff, trained in clinical coding, and supported in their work are required: the status, training and professional qualifications of clinical coding staff should be improved.

152 The system of incentives and penalties to encourage trusts to provide complete and validated data of a high quality to the national database should be reviewed. Any new system must include reports of each trust's performance in terms of the quality and timeliness of the submission of data. The systems within a trust for producing data of a high quality, and its performance in returning such data in a timely manner to the national database, should be taken into account in the process of validating and revalidating the trust.

153 At national level, the indicators of performance should be comprehensible to the public as well as to healthcare professionals. They should be fewer and of high quality, rather than numerous but of questionable or variable quality.

154 The need to invest in world-class IT systems must be recognised so that the fundamental principles of data collection, validation and management can be observed: that data be collected only once; that the data be part and parcel of systems used to support healthcare professionals in their care of patients; and that trusts and teams of healthcare professionals receive feedback when data on their services are aggregated.

Publication of information about performance and standards

155 Patients and the public must be able to obtain information as to the relative performance of the trust and the services and consultant units within the trust.

156 As part of their Annual Reports trust boards should be required to report on the extent of their compliance with the national clinical standards. These reports should be made public and be made available to CHI.

Public involvement through empowerment

157 The involvement of the public in the NHS must be embedded in its structures: the perspectives of patients and of the public must be heard and taken into account wherever decisions affecting the provision of healthcare are made.

158 Organisations which are not part of the NHS but have an impact on it, such as Royal Colleges, the GMC, the Nursing and Midwifery Council and the body responsible for regulating the professions allied to medicine, must involve the public in their decision-making processes, as they affect the provision of healthcare by the NHS.

159 The processes for involving patients and the public in organisations in the NHS must be transparent and open to scrutiny: the annual report of every organisation in the NHS should include a section setting out how the public has been involved, and the effect of that involvement.

160 The public's involvement in the NHS should particularly be focused on the development and planning of healthcare services and on the operation and delivery of healthcare services, including the regulation of safety and quality, the competence of healthcare professionals, and the protection of vulnerable groups.

161 Proposals to establish Patients' Forums and Patients' Councils must allow for the involvement of the wider public and not be limited only to patients or to patients' groups. They must be seen as an addition to the process of involving patients and the public in the activities of the NHS, rather than as a substitute for it.

162 The mechanisms for the involvement of the public in the NHS should be routinely evaluated. These mechanisms should draw on the evidence of what works.

163 The process of public involvement must be properly supported, through for example, the provision of training and guidance.

164 Financial resources must be made available to enable members of the public to become involved in NHS organisations: this should include provision for payments to cover, for example, the costs of childcare, or loss of earnings.

165 The involvement of the public, particularly of patients, should not be limited to the representatives of patients' groups, or to those representing the interests of patients with a particular illness or condition: the NHS Modernisation Agency should advise the NHS on how to achieve the widest possible involvement of patients and the public in the NHS at local level.

166 Primary care trusts (and groups), given their capacity to influence the quality of care in hospitals, must involve patients and the public, for example through each PCG/T's Patient and Advocacy Liaison Service. They must make efforts systematically to gather views and feedback from patients. They must pay particular attention to involving their local community in decision-making about the commissioning of hospital services.

The care of children

Responsibility for children's services

167 A National Director for Children's Healthcare Services should be appointed to promote improvements in healthcare services provided for children.

168 Consideration should be given to the creation of an office of Children's Commissioner in England, with the role of promoting the rights of children in all areas of public policy and seeking improvements to the ways in which the needs of children are met. Healthcare would be one of the areas covered by such a commissioner. Were such an office to be created, we would see it as being in addition to, rather than in place of, our other recommendations about the need to improve the quality of leadership in children's healthcare services.[5]

169 The Cabinet Committee on Children and Young People's Services should specifically include in its remit matters to do with healthcare and health services for children and young people.

170 Each health authority and each primary care group or primary care trust should designate a senior member of staff who should have responsibility for commissioning children's healthcare services locally.

171 All trusts which provide services for children as well as adults, should have a designated executive member of the board whose responsibility it is to ensure that the interests of children are protected and that they are cared for in a paediatric environment by paediatrically trained staff.

Setting standards for children's healthcare services

172 The proposed National Service Framework (NSF) for children's healthcare services must be agreed and implemented as a matter of urgency.

173 The NSF should include a programme for the establishment of standards in all areas of children's acute hospital and healthcare services.

174 The NSF should set obligatory standards which must be observed, as well as standards to which children's services should aspire over time.

175 The NSF should include incentives for the improvement of children's healthcare services, with particular help being given to those trusts most in need.

176 The NSF must include plans for the regular publication of information about the quality and performance of children's healthcare services at national level, at the level of individual trusts, and of individual consultant units.

Planning the future of children's healthcare services

177 There must be much greater integration of primary, community, acute and specialist healthcare for children. The NSF should include strategic guidance to health authorities and trusts so that services in the future are better integrated and organised around the needs of children and their families.

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[5] One Panel member was of the definite opinion that an office of Children's Commissioner in England should be established to deal with any matter affecting the rights or welfare of children

178 Children's acute hospital services should ideally be located in a children's hospital, which should be physically as close as possible to an acute general hospital. This should be the preferred model for the future.

179 In the case of existing free-standing children's hospitals, particular attention must be given to ensuring that, through good management and organisation of care, children have access when needed to (a) facilities which may not routinely be found in a children's hospital and (b) specialists, the appointment of whom in a children's hospital could not be justified given the infrequent call on their services.

180 Consideration should be given to piloting the introduction of a system whereby children's hospitals take over the running of the children's acute and community services throughout a geographical area, building on the example of the Philadelphia Children's Hospital in the USA.

181 *Specialist* services for children should be organised so as to provide the best available staff and facilities, thus providing the best possible opportunity for good outcomes. Advice should be sought from experts on the appropriate number of patients to be treated to achieve good outcomes. In planning and organising specialist services, the requirements of quality and safety should prevail over considerations of ease of access.

182 Where *specialist* services for children are concentrated in a small number of trusts spread throughout England, these trusts should establish Family Support Funds to help families to meet the costs arising from travelling and staying away from home. The Funds should be administered flexibly and should not be limited to those on income support or with low incomes.

183 After completion of a pilot exercise, all trusts which provide acute hospital services for children should be subject to a process of validation to ensure that they have appropriate child- and family-centred policies, staff, and facilities to provide a good standard of care for children. Trusts which are not so validated should not, save in emergencies, provide acute hospital services for children.

The staffing of children's healthcare services

184 Children should always (save in exceptional circumstances, such as emergencies) be cared for in a paediatric environment, and always by healthcare professionals who hold a recognised qualification in caring for children. This is especially so in relation to paediatric intensive care.

185 The 1991 standards for the numbers of paediatrically qualified nurses required at any given time should serve as the minimum standard and should apply where children are treated (save in emergencies). The standards should be reviewed as a matter of urgency to take account of changing patterns in the provision of acute healthcare services.

186 All surgeons who operate on children, including those who also operate on adults, must undergo training in the care of children and obtain a recognised professional qualification in the care of children. As matter of priority, the GMC, the body responsible for the revalidation of doctors, should agree with the Royal College of Surgeons of England the appropriate number and range of procedures which surgeons who operate on children must undertake in order to retain their validation. This will have consequences for the way in which general surgery for children is organised.

Communication between healthcare professionals, children and their parents or carers

187 Parents should ordinarily be recognised as experts in the care of their children, and when their children are in need of healthcare, parents should ordinarily be fully involved in that care.

188 Parents of very young children have particular knowledge of their child. This knowledge must be valued and taken into account in the process of caring for the child, unless there is good reason to do otherwise.

189 Children's questions about their care must be answered truthfully and clearly.

190 Healthcare professionals intending to care for children should be trained in the particular skills necessary to communicate with parents and with children.

191 Healthcare professionals should be honest and truthful with parents in discussing their child's condition, possible treatment and the possible outcome.

Healthcare services and treatment for children with congenital heart disease

192 National standards should be developed, as a matter of priority, for all aspects of the care and treatment of children with congenital heart disease (CHD). The standards should address diagnosis, surgical and other treatments, and continuing care. They should include standards for primary and social care, as well as for hospital care. The standards should also address the needs of those with CHD who grow into adulthood.

193 With regard to paediatric cardiac surgery, the standards should stipulate the minimum number of procedures which must be performed in a hospital over a given period of time in order to have the best opportunity of achieving good outcomes for children. PCS must not be undertaken in hospitals which do not meet the minimum number of procedures. Considerations of ease of access to a hospital should not be taken into account in determining whether PCS should be undertaken at that hospital.

194 With regard to those surgeons who undertake paediatric cardiac surgery, although not stipulating the number of operating sessions sufficient to maintain competence, it may be that four sessions a week should be the minimum number required. Agreement on this should be reached as a matter of urgency after appropriate consultation.

195 With regard to the very particular circumstances of open-heart surgery on very young children (including neo-nates and infants), we stipulate that the following standard should apply unless, within six months of the publication of this Report, this standard is varied by the DoH having taken the advice of relevant experts: there must, in any unit providing open-heart surgery on very young children, be two surgeons trained in paediatric surgery who must each undertake between 40 and 50 open-heart operations a year.

196 The national standards should stipulate that children with CHD who undergo any form of interventional procedure must be cared for in a paediatric environment. This means that all healthcare professionals who care for these children must be trained and qualified in paediatric care. It also means that children must be cared for in a setting with facilities and equipment designed for children. There must also be access on the same site as where any surgery is performed to a paediatric intensive care unit, supported by trained intensivists.

197 Surgical services for children with very rare congenital heart conditions, such as Truncus Arteriosus, or involving procedures undertaken very rarely, should only be performed in a maximum of two units, validated as such on the advice of experts. Such arrangements should be subject to periodic review.

198 An investigation should be conducted as a matter of urgency to ensure that PCS is not currently being carried out where the low volume of patients or other factors make it unsafe to perform such surgery.