

Recommendations

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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 patients¹

- 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.

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 events² 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.

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 to 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.

- 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 validation⁴ 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.

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 clinicians 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.

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.

