Key recommendations made by the Francis Report	
The nature of standards	
13	Standards should be divided into: • Fundamental standards of minimum safety and quality – in respect of which non-compliance should not be tolerated. Failures leading to death or serious harm should remain offences for which prosecutions can be brought against organisations. There should be a defined set of duties to maintain and operate an effective system to ensure compliance; • Enhanced quality standards – such standards could set requirements higher than the fundamental standards but be discretionary matters for commissioning and subject to availability of resources; • Developmental standards which set out longer term goals for providers – these would focus on improvements in effectiveness and are more likely to be the focus of commissioners and progressive provider leadership than the regulator. All such standards would require regular review and modification.
Responsibility for setting standards	
17	The NHS Commissioning Board together with Clinical Commissioning Groups should devise enhanced quality standards designed to drive improvement in the health service. Failure to comply with such standards should be a matter for performance management by commissioners rather than the regulator, although the latter should be charged with enforcing the provision by providers of accurate information about compliance to the public.
Gaps between the understood functions of separate regulators	
19	There should be a single regulator dealing both with corporate governance, financial competence, viability and compliance with patient safety and quality standards for all trusts.
Responsibility for regulating and monitoring compliance	
20	The Care Quality Commission (CQC) should be responsible for policing the fundamental standards, through the development of its core outcomes, by specifying the indicators by which it intends to monitor compliance with those standards. It should be responsible not for directly policing compliance with any enhanced standards but for regulating the accuracy of information about compliance with them.

21	The regulator should have a duty to monitor the accuracy of information disseminated by providers and commissioners on compliance with standards and their compliance with the requirement of honest disclosure. The regulator must be willing to consider individual cases of gross failure as well as systemic causes for concern.
22	The National Institute for Health and Clinical Excellence should be commissioned to formulate standard procedures and practice designed to provide the practical means of compliance, and indicators by which compliance with both fundamental and enhanced standards can be measured. These measures should include both outcome and process based measures, and should as far as possible build on information already available within the system or on readily observable behaviour.
23	The measures formulated by the National Institute for Health and Clinical Excellence should include measures not only of clinical outcomes, but of the suitability and competence of staff, and the culture of organisations. The standard procedures and practice should include evidence-based tools or establishing what each service is likely to require as a minimum in terms of staff numbers and skill mix. This should include nursing staff on wards, as well as clinical staff. These tools should be created after appropriate input from specialties, professional organisations, and patient and public representatives, and consideration of the benefits and value for money of possible staff: patient ratios.
24	Compliance with regulatory fundamental standards must be capable so far as possible of being assessed by measures which are understood and accepted by the public and healthcare professionals.
25	It should be considered the duty of all specialty professional bodies, ideally together with the National Institute for Health and Clinical Excellence, to develop measures of outcome in relation to their work and to assist in the development of measures of standards compliance.
26	In policing compliance with standards, direct observation of practice, direct interaction with patients, carers and staff, and audit of records should take priority over monitoring and audit of policies and protocols. The regulatory system should retain the capacity to undertake in-depth investigations where these appear to be required.
27	The healthcare systems regulator should promote effective enforcement by: use of a low threshold of suspicion; no tolerance of non-compliance with fundamental standards; and allowing no place for favourable assumptions, unless there is evidence showing that suspicions are ill-founded or that deficiencies have been remedied. It requires a focus on identifying what is wrong, not on praising what is right.

Sanctions and interventions for non-compliance	
28	Zero tolerance: A service incapable of meeting fundamental standards should not be permitted to continue. Breach should result in regulatory consequences attributable to an organisation in the case of a system failure and to individual accountability where individual professionals are responsible. Where serious harm or death has resulted to a patient as a result of a breach of the fundamental standards, criminal liability should follow and failure to disclose breaches of these standards to the affected patient (or concerned relative) and a regulator should also attract regulatory consequences. Breaches not resulting in actual harm but which have exposed patients to a continuing risk of harm to which they would not otherwise have been exposed should also be regarded as unacceptable.
29	It should be an offence for death or serious injury to be caused to a patient by a breach of these regulatory requirements, or, in any other case of breach, where a warning notice in respect of the breach has been served and the notice has not been complied with. It should be a defence for the provider to prove that all reasonably practicable steps have been taken to prevent a breach, including having in place a prescribed system to prevent such a breach.
Interim Measures	
30	The healthcare regulator must be free to require or recommend immediate protective steps where there is reasonable cause to suspect a breach of fundamental standards, even if it has yet to reach a concluded view or acquire all the evidence. The test should be whether it has reasonable grounds in the public interest to make the interim requirement or recommendation.
31	Where aware of concerns that patient safety is at risk, Monitor and all other regulators of healthcare providers must have in place policies which ensure that they constantly review whether the need to protect patients requires use of their own powers of intervention to inform a decision whether or not to intervene, taking account of, but not being bound by, the views or actions of other regulators.
32	Where patient safety is believed on reasonable grounds to be at risk, Monitor and any other regulator should be obliged to take whatever action within their powers is necessary to protect patient safety. Such action should include, where necessary, temporary measures to ensure such protection while any investigation required to make a final determination is undertaken.
33	Insofar as healthcare regulators consider they do not possess any necessary interim powers, the Department of Health should consider introduction of the necessary amendments to legislation to provide such powers.

34	Where a provider is under regulatory investigation, there should be some form of external performance management involvement to oversee any necessary interim arrangements for protecting the public.
Need to share information between regulators	
35	Sharing of intelligence between regulators needs to go further than sharing of existing concerns identified as risks. It should extend to all intelligence which when pieced together with that possessed by partner organisations may raise the level of concern. Work should be done on a template of the sort of information each organisation would find helpful.
Use of information for effective regulation	
36	A coordinated collection of accurate information about the performance of organisations must be available to providers, commissioners, regulators and the public, in as near real time as possible, and should be capable of use by regulators in assessing the risk of non-compliance. It must not only include statistics about outcomes, but must take advantage of all safety related information, including that capable of being derived from incidents, complaints and investigations.
Use of information about compliance by regulator from: Complaints	
38	The CQC should ensure as a matter of urgency that it has reliable access to all useful complaints information relevant to assessment of compliance with fundamental standards, and should actively seek this information out, probably via its local relationship managers. Any bureaucratic or legal obstacles to this should be removed.
39	The CQC should introduce a mandated return from providers about patterns of complaints, how they were dealt with and outcomes.
40	It is important that greater attention is paid to the narrative contained in, for instance, complaints data, as well as to the numbers.
Use of information about compliance by regulator from: Patient safety alerts	
41	Patient safety alerts The CQC should have a clear responsibility to review decisions not to comply with patient safety alerts and to oversee the effectiveness of any action required to implement them. Information-sharing with the CQC regarding patient safety alerts should continue following the transfer of the National Patient Safety Agency's functions in June 2012 to the NHS Commissioning Board.

Use of information about compliance by regulator from: Serious untoward incidents	
42	Strategic Health Authorities/their successors should, as a matter of routine, share information on serious untoward incidents with the CQC.
Use of information about compliance by regulator from: Media	
43	Those charged with oversight and regulatory roles in healthcare should monitor media reports about the organisations for which they have responsibility.
44	Any example of a serious incident or avoidable harm should trigger an examination by the CQC of how that was addressed by the provider and a requirement for the trust concerned to demonstrate that the learning to be derived has been successfully implemented.
Use of information about compliance by regulator from: Quality and risk profiles	
46	The Quality and Risk Profile should not be regarded as a potential substitute for active regulatory oversight by inspectors. It is important that this is explained carefully and clearly as and when the public are given access to the information.
Use of information about compliance by regulator from: Foundation trust governors, scrutiny committees	
47	The CQC should expand its work with overview and scrutiny committees and foundation trust governors as a valuable information resource. For example, it should further develop its current 'sounding board events'.
Enhancement of monitoring and the importance of inspection	
49	Routine and risk-related monitoring, as opposed to acceptance of self-declarations of compliance, is essential. The CQC should consider its monitoring in relation to the value to be obtained from: • The Quality and Risk Profile. • Quality Accounts. • Reports from Local Healthwatch. • New or existing peer review schemes. • Themed inspections.
50	The CQC should retain an emphasis on inspection as a central method of monitoring non-compliance.

51	The CQC should develop a specialist cadre of inspectors by thorough training in the principles of hospital care. Inspections of NHS hospital care providers should be led by such inspectors who should have the support of a team, including service user representatives, clinicians and any other specialism necessary because of particular concerns. Consideration should be given to applying the same principle to the independent sector, as well as to the NHS.
52	The CQC should consider whether inspections could be conducted in collaboration with other agencies, or whether they can take advantage of any peer review arrangements available.
CQC independence, strategy and culture	
53	Any change to the CQC's role should be by evolution – any temptation to abolish this organisation and create a new one must be avoided.
54	Where issues relating to regulatory action are discussed between the CQC and other agencies, these should be properly recorded to avoid any suggestion of inappropriate interference in the CQC's statutory role.
55	The CQC should review its processes as a whole to ensure that it is capable of delivering regulatory oversight and enforcement effectively, in accordance with the principles outlined in this report.
56	The leadership of the CQC should communicate clearly and persuasively its strategic direction to the public and to its staff, with a degree of clarity that may have been missing to date.
57	The CQC should undertake a formal evaluation of how it would detect and take action on the warning signs and other events giving cause for concern at the Trust described in this report, and in the report of the first inquiry, and open that evaluation for public scrutiny.
58	Patients, through their user group representatives, should be integrated into the structure of the CQC. It should consider whether there is a place for a patients' consultative council with which issues could be discussed to obtain a patient perspective directly.
59	Consideration should be given to the introduction of a category of nominated board members from representatives of the professions, for example, the Academy of Medical Royal Colleges, a representative of nursing and allied healthcare professionals, and patient representative groups.
Ensuring the utility of a health and safety function in a clinical setting	
87	The Health and Safety Executive is clearly not the right organisation to be focusing on healthcare. Either the CQC should be given power to prosecute 1974 Act offences or a new offence containing comparable provisions should be created under which the CQC has power to launch a prosecution.

Information sharing	
88	The information contained in reports for the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations should be made available to healthcare regulators through the serious untoward incident system in order to provide a check on the consistency of trusts' practice in reporting fatalities and other serious incidents.
89	Reports on serious untoward incidents involving death of or serious injury to patients or employees should be shared with the Health and Safety Executive.
95	As the interests of patient safety should prevail over the narrow litigation interest under which confidentiality or even privilege might be claimed over risk reports, consideration should also be given to allowing the CQC access to these reports.
National Patient Safety Agency functions	
98	Reporting to the National Reporting and Learning System of all significant adverse incidents not amounting to serious untoward incidents but involving harm to patients should be mandatory on the part of trusts.
99	The reporting system should be developed to make more information available from this source. Such reports are likely to be more informative than the corporate version where an incident has been properly reported, and invaluable where it has not been.
100	Individual reports of serious incidents which have not been otherwise reported should be shared with a regulator for investigation, as the receipt of such a report may be evidence that the mandatory system has not been complied with.
101	While it may be impracticable for the National Patient Safety Agency or its successor to have its own team of inspectors, it should be possible to organise for mutual peer review inspections or the inclusion in Patient Environment Action Team representatives from outside the organisation. Consideration could also be given to involvement from time to time of a representative of the CQC.
Transparency, use and sharing of information	
102	Data held by the National Patient Safety Agency or its successor should be open to analysis for a particular purpose, or others facilitated in that task.
103	The National Patient Safety Agency or its successor should regularly share information with Monitor.
104	The CQC should be enabled to exploit the potential of the safety information obtained by the National Patient Safety Agency or its successor to assist it in identifying areas for focusing its attention. There needs to be a better dialogue between the two organisations as to how they can assist each other.

Health Protection Agency – Coordination and publication of providers' information on healthcare associated infections	
106	106 The Health Protection Agency and its successor, should coordinate the collection, analysis and publication of information on each provider's performance in relation to healthcare associated infections, working with the Health and Social Care Information Centre.
Sharing concerns	
107	If the Health Protection Agency or its successor, or the relevant local director of public health or equivalent official, becomes concerned that a provider's management of healthcare associated infections is or may be inadequate to provide sufficient protection of patients or public safety, they should immediately inform all responsible commissioners, including the relevant regional office of the NHS Commissioning Board, the CQC and, where relevant, Monitor, of those concerns. Sharing of such information should not be regarded as an action of last resort. It should review its procedures to ensure clarity of responsibility for taking this action.
Effective complaints handling	
109	Methods of registering a comment or complaint must be readily accessible and easily understood. Multiple gateways need to be provided to patients, both during their treatment and after its conclusion, although all such methods should trigger a uniform process, generally led by the provider trust.
Lowering barriers	
110	Actual or intended litigation should not be a barrier to the processing or investigation of a complaint at any level. It may be prudent for parties in actual or potential litigation to agree to a stay of proceedings pending the outcome of the complaint, but the duties of the system to respond to complaints should be regarded as entirely separate from the considerations of litigation.
111	Provider organisations must constantly promote to the public their desire to receive and learn from comments and complaints; constant encouragement should be given to patients and other service users, individually and collectively, to share their comments and criticisms with the organisation.

112	Patient feedback which is not in the form of a complaint but which suggests cause for concern should be the subject of investigation and response of the same quality as a formal complaint, whether or not the informant has indicated a desire to have the matter dealt with as such.
Complaints handling	
114	Comments or complaints which describe events amounting to an adverse or serious untoward incident should trigger an investigation.
Investigations	
115	Arms-length independent investigation of a complaint should be initiated by the provider trust where any one of the following apply: • A complaint amounts to an allegation of a serious untoward incident; • Subject matter involving clinically related issues is not capable of resolution without an expert clinical opinion. • A complaint raises substantive issues of professional misconduct or the performance of senior managers. • A complaint involves issues about the nature and extent of the services commissioned.
Support for complainants	
116	Where meetings are held between complainants and trust representatives or investigators as part of the complaints process, advocates and advice should be readily available to all complainants who want those forms of support.
117	A facility should be available to Independent Complaints Advocacy Services advocates and their clients for access to expert advice in complicated cases.
Learning and information from complaints	
118	Subject to anonymisation, a summary of each upheld complaint relating to patient care, in terms agreed with the complainant, and the trust's response should be published on its website. In any case where the complainant or, if different, the patient, refuses to agree, or for some other reason publication of an upheld, clinically related complaint is not possible, the summary should be shared confidentially with the Commissioner and the CQC.

121	The CQC should have a means of ready access to information about the most serious complaints. Their local inspectors should be charged with informing themselves of such complaints and the detail underlying them.
Responsibility for requiring and monitoring delivery of enhanced standards	
125	In addition to their duties with regard to the fundamental standards, commissioners should be enabled to promote improvement by requiring compliance with enhanced standards or development towards higher standards. They can incentivise such improvements either financially or by other means designed to enhance the reputation and standing of clinicians and the organisations for which they work.
Intervention and sanctions for substandard or unsafe services	
137	Commissioners should have powers of intervention where substandard or unsafe services are being provided, including requiring the substitution of staff or other measures necessary to protect patients from the risk of harm. In the provision of the commissioned services, such powers should be aligned with similar powers of the regulators so that both commissioners and regulators can act jointly, but with the proviso that either can act alone if the other declines to do so. The powers should include the ability to order a provider to stop provision of a service.
Performance managers working constructively with regulators	
140	Where concerns are raised that such standards are not being complied with, a performance management organisation should share, wherever possible, all relevant information with the relevant regulator, including information about its judgement as to the safety of patients of the healthcare provider.
Taking responsibility for quality	
141	Any differences of judgement as to immediate safety concerns between a performance manager and a regulator should be discussed between them and resolved where possible, but each should recognise its retained individual responsibility to take whatever action within its power is necessary in the interests of patient safety.

Clear metrics on quality	
143	Metrics need to be established which are relevant to the quality of care and patient safety across the service, to allow norms to be established so that outliers or progression to poor performance can be identified and accepted as needing to be fixed.
Inspection powers	
150	Scrutiny committees should have powers to inspect providers, rather than relying on local patient involvement structures to carry out this role, or should actively work with those structures to trigger and follow up inspections where appropriate, rather than receiving reports without comment or suggestions for action.
Role of the Department of Health and the National Quality Board	
169	The Department of Health, through the National Quality Board, should ensure that procedures are put in place for facilitating the identification of patient safety issues by training regulators and cooperation between them and healthcare systems regulators.
Registration of healthcare support workers	
209	A registration system should be created under which no unregistered person should be permitted to provide for reward direct physical care to patients currently under the care and treatment of a registered nurse or a registered doctor (or who are dependent on such care by reason of disability and/or infirmity) in a hospital or care home setting. The system should apply to healthcare support workers, whether they are working for the NHS or independent healthcare providers, in the community, for agencies or as independent agents. (Exemptions should be made for persons caring for members of their own family or those with whom they have a genuine social relationship.)
A regulator as an alternative	
219	An alternative option to enforcing compliance with a management code of conduct, with the risk of disqualification, would be to set up an independent professional regulator. The need for this would be greater if it were thought appropriate to extend a regulatory requirement to a wider range of managers and leaders. The proportionality of such a step could be better assessed after reviewing the experience of a licensing provision for directors.

Regulatory oversight of quality accounts	
251	The CQC and/or Monitor should keep the accuracy, fairness and balance of quality accounts under review and should be enabled to require corrections to be issued where appropriate. In the event of an organisation failing to take that action, the regulator should be able to issue its own statement of correction.
Access to data	
252	Access to data It is important that the appropriate steps are taken to enable properly anonymised data to be used for managerial and regulatory purposes.
Access to quality and risk profile	
253	The information behind the quality and risk profile – as well as the ratings and methodology – should be placed in the public domain, as far as is consistent with maintaining any legitimate confidentiality of such information, together with appropriate explanations to enable the public to understand the limitations of this tool.
Role of the Health and Social Care Information Centre	
257	The Information Centre should be tasked with the independent collection, analysis, publication and oversight of healthcare information in England, or, with the agreement of the devolved governments, the United Kingdom. The information functions previously held by the National Patient Safety Agency should be transferred to the NHS Information Centre if made independent.
258	The Information Centre should continue to develop and maintain learning, standards and consensus with regard to information methodologies, with particular reference to comparative performance statistics.
Impact assessments before structural change	
287	The Department of Health should together with healthcare systems regulators take the lead in developing through obtaining consensus between the public and healthcare professionals, a coherent, and easily accessible structure for the development and implementation of values, fundamental, enhanced and developmental standards as recommended in this report.