



Department
of Health &
Social Care

*From Maria Caulfield MP
Parliamentary Under Secretary of State
Department of Health & Social Care*

*39 Victoria Street
London
SW1H 0EU*

27th November 2023

Dear Steve and Jane,

Thank you for your letter of 20th October to Steve Barclay. In your letter, you state that the Committee's Expert Panel is undertaking an independent evaluation of progress made against patient safety recommendations that the Government has accepted from independent inquiries and reviews made to it since 2010. I am replying as the Minister with responsibility for patient safety.

In line with your specific request, I am providing a list of key independent public inquiry and review recommendations pertaining to patient safety and whistleblowing in the NHS that the Government has accepted since 2010. The inquiries and reviews are listed below:

1. The Mid Staffordshire NHS Foundation Trust Public Inquiry (2013) (This review was conducted by Robert Francis who sits on the Expert Panel).
2. Berwick review into patient safety (2013)
3. The Morecambe Bay Investigation (2015)
4. Freedom to Speak Up: An independent review into creating an open and honest reporting culture in the NHS (2015). (This review was also conducted by Robert Francis)
5. Independent review into Liverpool Community Health NHS Trust (2018)
6. Kark review of the fit and proper persons test (2018)
7. The Independent Inquiry into issues raised by Paterson (2020)
8. The Independent Medicines and Medical Devices Safety Review (2020)
9. Independent investigation into the life and death of Elizabeth Dixon (2020)
10. Health and social care review: leadership for a collaborative and inclusive future ('Messenger Review') (2022)
11. The Independent Review of Maternity Services at the Shrewsbury and Telford Hospital NHS Trust (2022)
12. The Independent Investigation into Maternity and Neonatal Services at East Kent Hospitals NHS Foundation Trust (2022).

Regarding the Infected Blood Inquiry, which is not listed, the Government accepts that it must learn lessons from the infected blood scandal and we established the Inquiry to ascertain the truth of what happened. The Inquiry's final report is due in March 2024, and although recommendations have been made by the Inquiry, the Government must wait until the final report before being able to respond.

We also intend to publish our response to the independent rapid review into data on mental health inpatient settings shortly. The report was published in June and made

recommendations for improvements in the way local and national data is gathered and used to monitor and improve patient safety in mental health inpatient pathways.

We have not included the Gosport Independent Panel Report of 2018, as there were no specific recommendations. The role of the Panel was to establish facts about what happened at Gosport War Memorial Hospital rather than to make recommendations for policy and practice. Our response to the report of the Panel was published in November 2018 and set out plans and opportunities to improve the safety of care and to honour those who were so badly let down in Gosport.

Inquiries and reviews that the Government has commissioned have informed key patient safety initiatives that we've taken forward. This includes appointing the first Patient Safety Commissioner to be a champion for patients in promoting their views about the safety of medicines and medical devices, launching the Patient Safety Incident Response Framework which introduces a new national approach to all safety investigations and learning responses, establishing a network of over 1,000 Freedom to Speak Up Guardians across all Trusts supported by a National Guardian to promote speaking up across the NHS and introducing a legal duty of candour to ensure that providers are open and honest with patients when things go wrong with care.

Examples of other major patient safety initiatives that we have taken forward include the recent establishment of the Health Services Safety Investigations Body (HSSIB) as an independent body. HSSIB provides an unparalleled opportunity for investigations to have the greatest impact on patient safety and to be champion of changes in both safety culture and how safety is managed by health services.

However, I accept that recent investigations, such as the Ockenden report into Shrewsbury and Telford Hospital and the East Kent report, demonstrate a failure to learn from past incidents and that there is still more to do to improve care and safety as well as improving the quality of investigations where harm occurs. Major NHS safety failures undermine the good work being done elsewhere. It is why the Government is as committed as ever to action that will address underlying causes of avoidable harm in healthcare and support the entire system to improve culture and its approach to learning and continuous improvement in safety. This includes through the implementation of inquiry and review recommendations.

I hope that this response is helpful. The Department is happy to provide further input as the work of the Expert Panel progresses.

Yours sincerely,

A handwritten signature in blue ink, appearing to read 'Maria'.

MARIA CAULFIELD

Berwick review into patient safety (2013)

Professor Don Berwick was asked by the Prime Minister to carry out the review following the publication of the Francis Report into the breakdown of care at Mid Staffordshire Hospitals. The independent review was published on 6th August 2013 and made ten key recommendations in relation to advancing patient safety across healthcare.

Subject of accepted recommendation (pertaining to patient safety or whistleblowing)	Text of accepted recommendation
Patient safety	1. The NHS should continually and forever reduce patient harm by embracing wholeheartedly an ethic of learning
Patient safety	2. All leaders concerned with NHS healthcare – political, regulatory, governance, executive, clinical and advocacy – should place quality of care in general, and patient safety in particular, at the top of their priorities for investment, inquiry, improvement, regular reporting, encouragement and support
Patient safety	3. Patients and their carers should be present, powerful and involved at all levels of healthcare organisations from wards to the boards of Trusts
Patient safety	4. Government, Health Education England and NHS England should assure that sufficient staff are available to meet the NHS's needs now and in the future. Healthcare organisations should ensure that staff are present in appropriate numbers to provide safe care at all times and are well-supported.
Patient safety	5. Mastery of quality and patient safety sciences and practices should be part of initial preparation and lifelong education of all health care professionals, including managers and executives.
Patient safety	6. The NHS should become a learning organisation. Its leaders should create and support the capability for learning, and therefore change, at scale, within the NHS.
Patient safety	7. Transparency should be complete, timely and unequivocal. All data on quality and safety, whether assembled by government, organisations, or professional societies, should be shared in a timely fashion with all parties who want it, including, in accessible form, with the public.
Patient safety	8. All organisations should seek out the patient and carer voice as an essential asset in monitoring the safety and quality of care.
Patient safety	9. Supervisory and regulatory systems should be simple and clear. They should avoid diffusion of responsibility. They should be respectful of the goodwill and sound intention of the vast majority of staff. All incentives should point in the same direction.
Patient safety	10. We support responsive regulation of organisations, with a hierarchy of responses. Recourse to criminal sanctions should be extremely rare and should function primarily as a deterrent to wilful or reckless neglect or mistreatment.

Freedom to Speak Up Review (2015)

The review was commissioned by the Secretary of State in June 2014. Its purpose was to provide independent advice and recommendations on creating a more open and honest reporting culture in the NHS. The review was published in February 2015. The report made two overarching recommendations (**Recommendation 1:** All organisations which provide NHS healthcare and regulators should implement the Principles and Actions as set out in this report in line with the good practice described in this report. **Recommendation 2:** The Secretary of State should review at least annually the progress made in the implementation of these Principles and Actions and the performance of the NHS in handling concerns and the treatment of those who raise them, and report to Parliament.) The Department accepted the recommendations in principle and consulted on a package of measures to implement them, taking into account that the vast majority of the principles and actions (listed below) require implementation by local NHS healthcare providers, regulators and oversight bodies.

Subject of accepted recommendation (pertaining to patient safety or whistleblowing)	Text of accepted recommendation
Whistleblowing	1. Culture of safety: Every organisation involved in providing NHS healthcare, should actively foster a culture of safety and learning, in which all staff feel safe to raise concerns. Action 1.1: Boards should ensure that progress in creating and maintaining a safe learning culture is measured, monitored and published on a regular basis. Action 1.2: System regulators should regard departure from good practice, as identified in this report, as relevant to whether an organisation is safe and well-led
Whistleblowing	2. Culture of raising concerns: Raising concerns should be part of the normal routine business of any well led NHS organisation. Action 2.1: Every NHS organisation should have an integrated policy and a common procedure for employees to formally report incidents or raise concerns. In formulating that policy and procedure organisations should have regard to the descriptions of good practice in this report. Action 2.2: NHS England, NHS TDA and Monitor should produce a standard integrated policy and procedure for reporting incidents and raising concerns to support Action 2.1.
Whistleblowing	3. Culture free from bullying: Freedom to speak up about concerns depends on staff being able to work in a culture which is free from bullying and other oppressive behaviours. Action 3.1: Bullying of staff should consistently be considered, and be shown to be, unacceptable. All NHS organisations should be proactive in detecting and changing behaviours which amount, collectively or individually, to bullying or any form of deterrence against reporting incidents and raising concerns; and should have regard to the descriptions of good practice in this report.

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	Action 3.2: Regulators should consider evidence on the prevalence of bullying in an organisation as a factor in determining whether it is well-led. Action 3.3: Any evidence that bullying has been condoned or covered up should be taken into consideration when assessing whether someone is a fit and proper person to hold a post at director level in an NHS organisation.
Whistleblowing	4. Culture of visible leadership: All employers of NHS staff should demonstrate, through visible leadership at all levels in the organisation, that they welcome and encourage the raising of concerns by staff. Action 4.1: Employers should ensure and be able to demonstrate that staff have open access to senior leaders in order to raise concerns, informally and formally.
Whistleblowing	5. Culture of valuing staff: Employers should show that they value staff who raise concerns, and celebrate the benefits for patients and the public from the improvements made in response to the issues identified. Action 5.1: Boards should consider and implement ways in which the raising of concerns can be publicly celebrated.
Whistleblowing	6. Culture of reflective practice: There should be opportunities for all staff to engage in regular reflection of concerns in their work. Action 6.1: All NHS organisations should provide the resources, support and facilities to enable staff to engage in reflective practice with their colleagues and their teams.
Whistleblowing	7. Raising and reporting concerns: All NHS organisations should have structures to facilitate both informal and formal raising and resolution of concerns. Action 7.1: Staff should be encouraged to raise concerns informally and work together with colleagues to find solutions.

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	Action 7.2: All NHS organisations should have a clear process for recording all formal reports of incidents and concerns, and for sharing that record with the person who reported the matter, in line with the good practice in this report.
Whistleblowing	8. Investigations: When a formal concern has been raised, there should be prompt, swift, proportionate, fair and blame-free investigations to establish the facts. Action 8.1: All NHS organisations should devise and implement systems which enable such investigations to be undertaken, where appropriate by external investigators, and have regard to the good practice suggested in this report.
Whistleblowing	9. Mediation and dispute resolution: Consideration should be given at an early stage to the use of expert interventions to resolve conflicts, rebuild trust or support staff who have raised concerns. Action 9.1: All NHS organisations should have access to resources to deploy alternative dispute resolution techniques, including mediation and reconciliation to: • address unresolved disputes between staff or between staff and management as a result of or associated with a report raising a concern • repair trust and build constructive relationships.
Whistleblowing	10. Training: Every member of staff should receive training in their organisation's approach to raising concerns and in receiving and acting on them. Action 10.1: Every NHS organisation should provide training which complies with national standards, based on a curriculum devised jointly by HEE and NHS England in consultation with stakeholders. This should be in accordance with the good practice set out in this report.

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Whistleblowing	11. Support: All NHS organisations should ensure that there is a range of persons to whom concerns can be reported easily and without formality. They should also provide staff who raise concerns with ready access to mentoring, advocacy, advice and counselling. Action 11.1: The Boards of all NHS organisations should ensure that their procedures for raising concerns offer a variety of personnel, internal and external, to support staff who raise concerns including: a) a person (a ‘Freedom to Speak Up Guardian’) appointed by the organisation’s chief executive to act in a genuinely independent capacity b) a nominated non-executive director to receive reports of concerns directly from employees (or from the Freedom to Speak Up Guardian) and to make regular reports on concerns raised by staff and the organisation’s culture to the Board c) at least one nominated executive director to receive and handle concerns d) at least one nominated manager in each department to receive reports of concerns e) a nominated independent external organisation (such as the Whistleblowing Helpline) whom staff can approach for advice and support. Action 11.2: All NHS organisations should have access to resources to deploy counselling and other means of addressing stress and reducing the risk of resulting illness after staff have raised a concern. Action 11.3: NHS England, NHS TDA and Monitor should issue joint guidance setting out the support required for staff who have raised a concern and others involved.
Whistleblowing	12. Support to find alternative employment in the NHS: Where a NHS worker who has raised a concern cannot, as a result, continue in their current employment, the NHS should fulfil its moral obligation to offer support. Action 12.1: NHS England, the NHS Trust Development Authority and Monitor should jointly devise and establish a support scheme for NHS workers and

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	former NHS workers whose performance is sound who can demonstrate that they are having difficulty finding employment in the NHS as a result of having made protected disclosures. Action 12.1: All NHS organisations should actively support a scheme to help current and former NHS workers whose performance is sound to find alternative employment in the NHS.
Whistleblowing	13. Transparency: All NHS organisations should be transparent in the way they exercise their responsibilities in relation to the raising of concerns, including the use of settlement agreements. Action 13.1: All NHS organisations that are obliged to publish Quality Accounts or equivalent should include in them quantitative and qualitative data describing the number of formally reported concerns in addition to incident reports, the action taken in respect of them and feedback on the outcome. Action 13.2: All NHS organisations should be required to report to the National Learning and Reporting System (NLRS), or to the Independent National Officer described in Principle 15, their relevant regulators and their commissioners any formally reported concerns/public interest disclosures or incidences of disputed outcomes to investigations. NLRS or the Independent National Officer should publish regular reports on the performance of organisations with regard to the raising of and acting on public interest concerns; draw out themes that emerge from the reports; and identify good practice. Action 13.3: a) CEOs should personally review all settlement agreements made in an employment context that contain confidentiality clauses to satisfy themselves that such clauses are genuinely in the public interest. b) All such settlement agreements should be available for inspection by the CQC as part of their assessment of whether an organisation is well-led.

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	c) If confidentiality clauses are to be included in such settlement agreements for which Treasury approval is required, the trust should be required to demonstrate as part of the approval process that such clauses are in the public interest in that particular case. d) NHS TDA and Monitor should consider whether their role of reviewing such agreements should be delegated to the Independent National Officer recommended under Principle 15.
Whistleblowing	14. Accountability: Everyone should expect to be held accountable for adopting fair, honest and open behaviours and practices when raising or receiving and handling concerns. There should be personal and organisational accountability for: • poor practice in relation to encouraging the raising of concerns and responding to them • the victimisation of workers for making public interest disclosures • raising false concerns in bad faith or for personal benefit • acting with disrespect or other unreasonable behaviour when raising or responding to concerns • inappropriate use of confidentiality clauses. Action 14.1: Employers should ensure that staff who are responsible for, participate in, or permit such conduct are liable to appropriate and proportionate disciplinary processes. Action 14.2: Trust Boards, CQC, Monitor and the NHS TDA should have regard to any evidence of responsibility for, participation in or permitting such conduct in any assessment of whether a person is a fit and proper person to hold an appointment as a director or equivalent in accordance with the Health and Social Care Act 2008 [Regulated Activities] Regulations 2014 regulation 5. Action 14.3: All organisations associated with the provision, oversight or regulation of healthcare services should have regard to any evidence of poor conduct in relation to staff who have raised concerns when deciding whether it is appropriate to employ any person to a senior management or leadership position and whether the organisation is well-led

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Whistleblowing	15. External Review: There should be an Independent National Officer (INO) resourced jointly by national systems regulators and oversight bodies and authorised by them to carry out the functions described in this report, namely: - review the handling of concerns raised by NHS workers and/or the treatment of the person or people who spoke up, where there is cause for believing that this has not been in accordance with good practice • advise NHS organisations to take appropriate action where they have failed to follow good practice, or advise the relevant systems regulator to make a direction to that effect • act as a support for Freedom to Speak Up Guardians • provide national leadership on issues relating to raising concerns by NHS workers • offer guidance on good practice about handling concerns • publish reports on the activities of this office. Action 15.1: CQC, Monitor, NHS TDA, and NHS England should consider and consult on how such a post might jointly be created and resourced and submit proposals to the Secretary of State, as to how it might carry out these functions in respect of ongoing and future concerns.
Whistleblowing	16. Coordinated Regulatory Action: There should be coordinated action by national systems and professional regulators to enhance the protection of NHS workers making protected disclosures and of the public interest in the proper handling of concerns. Action 16.1: CQC, Monitor, NHS TDA in consultation with the Department of Health should work together to agree procedures and define the roles to be played by each in protecting workers who raise concerns in relation to regulated activity. Where necessary they should seek amendment of the regulations to enable this to happen. Action 16.2: Healthcare professional regulators should review their procedures and processes to ensure compliance with the good practice set out in this report and with this Principle.

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Whistleblowing	17. Recognition of organisations: CQC should recognise NHS organisations which show they have adopted and apply good practice in the support and protection of workers who raise concerns. Action 17.1: CQC should consider the good practice set out in this report when assessing how organisations handle staff concerns. Good practice should be viewed as a positive factor contributing to a good or outstanding rating as part of their well-led domain.
Whistleblowing	18. Students and Trainees: All principles in this report should be applied with necessary adaptations to education and training settings for students and trainees working towards a career in healthcare. Action 18.1: Professional regulators and Royal Colleges in conjunction with Health Education England should ensure that all students and trainees working towards a career in healthcare have access to policies, procedure and support compatible with the principles and good practice in this report. Action 18.2: All training for students and trainees working towards a career in healthcare should include training on raising and handling concerns.
Whistleblowing	19. Primary Care: All principles in this report should apply with necessary adaptations in primary care. Action 19.1: NHS England should include in its contractual terms for general/primary medical services standards for empowering and protecting staff to enable them to raise concerns freely, consistent with these Principles. Action 19.2: NHS England and all commissioned primary care services should ensure that each has a policy and procedures consistent with these Principles which identify appropriate external points of referral which are easily accessible for all primary care staff for support and to register a concern, in accordance with this report.

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	Action 19.3: In regulating registered primary care services CQC should have regard to these Principles and the extent to which services comply with them.
Whistleblowing	20. Legal protection should be enhanced Action 20.1: The Government should, having regard to the material contained in this report, again review the protection afforded to those who make protected disclosures, with a view to including discrimination in recruitment by employers (other than those to whom the disclosure relates) on grounds of having made that disclosure as a breach of either the Employment Rights Act 1996 or the Equality Act 2010. Action 20.2: The list of persons prescribed under the Employment Rights Act 1996 should be extended to include all relevant national oversight, commissioning, scrutiny and training bodies including NHS Protect, NHS England, NHS Clinical Commissioning Groups, Public Health England, Healthwatch England, local Healthwatch, Health Education England, Local Education and Training Boards and the Parliamentary and Health Services Ombudsman. Action 20.3: The Government should ensure that its proposal to widen the scope of the protection under the Employment Rights Act 1996 includes all students working towards a career in healthcare.

Health and social care review: leadership for a collaborative and inclusive Future ('Messenger Review')

The review was commissioned by the Secretary of State in October 2021. It was led by General Sir Gordon Messenger and focussed on the best ways to strengthen leadership and management across health and with its key interfaces with adult social care in England. The review was published in June 2022. It made seven recommendations to foster and replicate the best examples of leadership through improved training, career development and talent management, through embedding inclusive cultures and behaviours within health and care.

Subject of accepted recommendation (pertaining to patient safety or whistleblowing)	Text of accepted recommendation
Patient safety	1. Targeted interventions on collaborative leadership and organisational values, including a new, national entry-level induction for all who join health and social care.
Patient safety	2. Consistent management standards delivered through accredited training

Independent Medicines and Medical Devices Review (2020)

The Review was announced in February 2018. The review, which was chaired by Baroness Cumberlege, focused on how the health system responds when patients and their families raise concerns about the safety of treatments, specifically looking into cases of pelvic mesh, sodium valproate and hormone pregnancy tests (in this case Primodos). The review was published on 8 July 2020 and made 9 recommendations.

Subject of accepted recommendation (pertaining to patient safety or whistleblowing)	Text of accepted recommendation
Patient safety	Recommendation 2 The appointment of a Patient Safety Commissioner who would be an independent public leader with a statutory responsibility. The Commissioner would champion the value of listening to patients and promoting users' perspectives in seeking improvements to patient safety around the use of medicines and medical devices.
Patient safety	Recommendation 5 Networks of specialist centres should be set up to provide comprehensive treatment, care and advice for those affected by implanted mesh; and separately for those adversely affected by medications taken during pregnancy.
Patient safety	Recommendation 6 The MHRA needs substantial revision particularly in relation to adverse event reporting and medical device regulation. It needs to ensure that it engages more with patients and their outcomes. It needs to raise awareness of its public protection roles and to ensure that patients have an integral role in its work.
Patient safety	Recommendation 7 A central patient-identifiable database should be created by collecting key details of the implantation of all devices at the time of the operation. This can be linked to specifically created registers to research and audit the outcomes both in terms of the device safety and patient reported outcomes measures.
Patient safety	Recommendation 8 Transparency of payments made to clinicians needs to improve. The register of the General Medical Council (GMC) should be expanded to include a list of financial and non-pecuniary interests for all doctors, as well as doctors' particular clinical interests and their recognised and accredited specialisms. There should be mandatory reporting for the pharmaceutical and medical device industries of payments made to teaching hospitals, research institutions and individual clinicians.

Independent investigation into maternity and neonatal services in East Kent (2022)

The investigation into maternity and neonatal services at East Kent Hospitals University NHS Foundation Trust was commissioned in February 2020 following concerns raised about the quality and outcomes of these services. The investigation was led by Dr Bill Kirkup and published in October 2023. The report includes 5 recommendations. The Government accepted the recommendations in a Written Ministerial Statement on 7th March 2023. The recommendations which have been accepted are listed below.

Subject of accepted recommendation (pertaining to patient safety or whistleblowing)	Text of accepted recommendation
Patient safety	1. The prompt establishment of a Task Force with appropriate membership to drive the introduction of valid maternity and neonatal outcome measures capable of differentiating signals among noise to display significant trends and outliers, for mandatory national use.
Patient safety	2i. Those responsible for undergraduate, postgraduate and continuing clinical education be commissioned to report on how compassionate care can best be embedded into practice and sustained through lifelong learning. 2ii Relevant bodies, including royal colleges, professional regulators and employers, be commissioned to report on how the oversight and direction of clinicians can be improved, with nationally agreed standards of professional behaviour and appropriate sanctions for non-compliance.
Patient safety	3i. Relevant bodies, including RCOG, RCM and the Royal College of Paediatrics and Child Health, be charged with reporting on how teamworking in maternity and neonatal care can be improved, with particular reference to establishing common purpose, objectives and training from the outset. 3ii. Relevant bodies, including Health Education England, royal colleges and employers, be commissioned to report on the employment and training of junior doctors to improve support, teamworking and development.
Patient safety	4ii. Trusts be required to review their approach to reputation management and to ensuring there is proper representation of maternity care on their boards. 4iii. NHSE reconsiders its approach to poorly performing trusts, with particular reference to leadership.
Patient safety	5. That the trust: • accepts the reality of these findings. • acknowledges in full the unnecessary harm that has been caused. • embarks on a restorative process addressing the problems identified, in partnership with families, publicly and with external input.

Independent review of maternity services at the Shrewsbury and Telford Hospital NHS Trust (2022)

The review of maternity services at Shrewsbury and Telford Hospital NHS Trust was commissioned by the Secretary of State in summer 2017. The review was chaired by Donna Ockenden and published in March 2022. The report presented three asks to the SofS, 15 immediate and essential actions (IEAs) for the wider system and a further 94 local actions across the interim and final reports. The Government accepted all the recommendations.

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	Asks to the Secretary of State
Patient safety	1. The investment announced following our first report was welcomed. However to fund maternity and neonatal services appropriately requires a multi-year settlement to ensure the workforce is enabled to deliver consistently safe maternity and neonatal care across England.
Patient safety	2. The creation of a new working group, independent of the Maternity Transformation Programme with professional leadership to guide the implementation of the recommendations in this and other reports.
Patient safety	3. Recognition of the positive announcement on the creation of the Special Health Authority on maternity investigations and urge a timeliness to this work. Expectation that learning and service change from maternity incidents be introduced into clinical practice within six months of the incident occurring and that all investigations are independently chaired
	Immediate and Essential actions (those pertaining to patient safety or whistleblowing)
Patient Safety	4.The recommendations from the Health and Social Care Committee Report: The safety of maternity services in England must be implemented. We state that the Health and Social Care Select Committee view that a proportion of maternity budgets must be ring-fenced for training in every maternity unit should be implemented
Patient Safety	5. All trusts must maintain a clear escalation and mitigation policy where maternity staffing falls below the minimum staffing levels for all health professionals.
Patient Safety	6. Staff must be able to escalate concerns if necessary. There must be clear processes for ensuring that obstetric units are staffed by appropriately trained staff at all times. If not resident there must be clear guidelines for when a consultant obstetrician should attend.
Patient Safety	7. Trust boards must have oversight of the quality and performance of their maternity services. In all maternity services the Director of Midwifery and Clinical Director for obstetrics must be jointly operationally responsible and accountable for the maternity governance systems.
Patient Safety	8. Incident investigations must be meaningful for families and staff and lessons must be learned and implemented in practice in a timely manner.
Patient Safety	9. Nationally all maternal post-mortem examinations must be conducted by a pathologist who is an expert in maternal physiology and pregnancy related pathologies. In the case of a maternal death a joint review panel/investigation of all services involved in the care must include representation from all applicable hospitals/clinical settings
Patient Safety	10. Staff who work together must train together Staff should attend regular mandatory training and rotas. Job planning needs to ensure all staff can attend. Clinicians must not work on labour ward without appropriate regular CTG training and emergency skills training

Patient Safety	11. Local Maternity Systems, Maternal Medicine Networks and trusts must ensure that women have access to pre-conception care. Trusts must provide services for women with multiple pregnancy in line with national guidance Trusts must follow national guidance for managing women with diabetes and hypertension in pregnancy
Patient Safety	12. The LMNS, commissioners and trusts must work collaboratively to ensure systems are in place for the management of women at high risk of preterm birth. Trusts must implement NHS Saving Babies Lives Version 2 (2019)
Patient Safety	13. Women who choose birth outside a hospital setting must receive accurate advice with regards to transfer times to an obstetric unit should this be necessary. Centralised CTG monitoring systems should be mandatory in obstetric units
Patient Safety	14. In addition to routine inpatient obstetric anaesthesia follow-up, a pathway for outpatient postnatal anaesthetic follow-up must be available in every trust to address incidences of physical and psychological harm. Documentation of patient assessments and interactions by obstetric anaesthetists must improve. The determination of core datasets that must be recorded during every obstetric anaesthetic intervention would result in record-keeping that more accurately reflects events. Staffing shortages in obstetric anaesthesia must be highlighted and updated guidance for the planning and provision of safe obstetric anaesthesia services throughout England must be developed.
Patient Safety	15. Trusts must ensure that women readmitted to a postnatal ward and all unwell postnatal women have timely consultant review. Postnatal wards must be adequately staffed at all times
Patient Safety	17. There must be clear pathways of care for provision of neonatal care. This review endorses the recommendations from the Neonatal Critical Care Review (December 2019) to expand neonatal critical care, increase neonatal cot numbers, develop the workforce and enhance the experience of families. This work must now progress at pace.
Patient Safety	18. Care and consideration of the mental health and wellbeing of mothers, their partners and the family as a whole must be integral to all aspects of maternity service provision Maternity care providers must actively engage with the local community and those with lived experience, to deliver services that are informed by what women and their families say they need from their care
	Local actions (those pertaining to patient safety or whistleblowing)
	19. A thorough risk assessment must take place at the booking appointment and at every antenatal appointment to ensure that the plan of care remains appropriate
Patient Safety	20. All members of the maternity team must provide women with accurate and contemporaneous evidence-based information as per national guidance. This will ensure women can participate equally in all decision-making processes and make informed choices about their care. Women's choices following a shared decision-making process must be respected
Patient Safety	21. The maternity service at The Shrewsbury and Telford Hospital NHS Trust must appoint a dedicated Lead Midwife and Lead Obstetrician both with demonstrated expertise to focus on and champion the development and improvement of the practice of fetal monitoring. Both colleagues must have sufficient time and resource in order to carry out their duties.
Patient Safety	22. These leads must ensure that the service is compliant with the recommendations of Saving Babies Lives Care Bundle 2 (2019) and subsequent national guidelines. This additionally must include regional peer reviewed learning and assessment. These auditable recommendations must be considered by the

	Trust Board and as part of continued on-going oversight that has to be provided regionally by the Local Maternity System (LMS) and Clinical Commissioning Group
Patient Safety	23. Staff must use NICE Guidance (2017) on fetal monitoring for the management of all pregnancies and births in all settings. Any deviations from this guidance must be documented, agreed within a multidisciplinary framework and made available for audit and monitoring.
Patient Safety	24. The maternity department clinical governance structure and team must be appropriately resourced so that investigations of all cases with adverse outcomes take place in a timely manner
Patient Safety	25. The maternity department clinical governance structure must include a multidisciplinary team structure, trust risk representation, clear auditable systems of identification and review of cases of potential harm, adverse outcomes and serious incidents in line with the NHS England Serious Incident Framework 2015.
Patient Safety	26. Consultant obstetricians must be directly involved and lead in the management of all complex pregnancies and labour.
Patient Safety	27. There must be a minimum of twice daily consultant-led ward rounds and night shift of each 24-hour period. The ward round must include the labour ward coordinator and must be multidisciplinary. In addition the labour ward should have regular safety huddles and multidisciplinary handovers and in-situ simulation training.
Patient Safety	28. Complex cases in both the antenatal and postnatal wards need to be identified for consultant obstetric review on a daily basis
Patient Safety	29. The use of oxytocin to induce and/or augment labour must adhere to national guidelines and include appropriate and continued risk assessment in both first and second stage labour. Continuous CTG monitoring is mandatory if oxytocin infusion is used in labour and must continue throughout any additional procedure in labour
Patient Safety	32. The Trust must develop clear Standard Operational Procedures (SOP) for junior obstetric staff and midwives on when to involve the consultant obstetrician. There must be clear pathways for escalation to consultant obstetricians 24 hours a day, 7 days a week. Adherence to the SOP must be audited on an annual basis
Patient Safety	33. Women with pre-existing medical comorbidities must be seen in a timely manner by a multidisciplinary specialist team and an individual management plan formulated in agreement with the mother to be. This must include a pathway for referral to a specialist maternal medicine centre for consultation and/or continuation of care at an early stage of the pregnancy.
Patient Safety	34. There must be a named consultant with demonstrated expertise with overall responsibility for the care of high risk women during pregnancy, labour and birth and the post-natal period
Patient Safety	35. Obstetric anaesthetists are an integral part of the maternity team and must be considered as such. The maternity and anaesthetic service must ensure that obstetric anaesthetists are completely integrated into the maternity multidisciplinary team and must ensure attendance and active participation in relevant team meetings, audits, Serious Incident reviews, regular ward rounds and multidisciplinary training.
Patient Safety	36. Obstetric anaesthetists must be proactive and make positive contributions to team learning and the improvement of clinical standards. Where there is apparent disengagement from the maternity service the obstetric anaesthetists themselves must insist they are involved and not remain on the periphery, as the review team have observed in a number of cases reviewed.
Patient Safety	37. Obstetric anaesthetists and departments of anaesthesia must regularly review their current clinical guidelines to ensure they meet best practice standards in line with the national and local guidelines published by the RCoA and the OAA. Adherence to these by all obstetric anaesthetic staff working on labour ward and elsewhere, must be regularly audited. Any changes to clinical guidelines must be communicated and necessary training be provided to the midwifery and obstetric teams.

Patient Safety	38. Obstetric anaesthesia services at the Trust must develop or review the existing guidelines for escalation to the consultant on-call. This must include specific guidance for consultant attendance. Consultant anaesthetists covering labour ward or the wider maternity services must have sufficient clinical expertise and be easily contactable for all staff on delivery suite. The guidelines must be in keeping with national guidelines and ratified by the Anaesthetic and Obstetric Service with support from the Trust executive.
Patient Safety	39. The service must use current quality improvement methodology to audit and improve clinical performance of obstetric anaesthesia services in line with the recently published RCoA 2020 'Guidelines for Provision of Anaesthetic Services', section 7 'Obstetric Practice'.
Patient Safety	40. The Trust must ensure appropriately trained and appropriately senior/experienced anaesthetic staff participate in maternal incident investigations and that there is dissemination of learning from adverse events.
Patient Safety	41. The service must ensure mandatory and regular participation for all anaesthetic staff working on labour ward and the maternity services in multidisciplinary team training for frequent obstetric emergencies
Patient Safety	42. Medical and nursing notes must be combined; where they are kept separately there is the potential for important information not to be shared between all members of the clinical team. Daily clinical records, particularly for patients receiving intensive care, must be recorded using a structured format to ensure all important issues are addressed
Patient Safety	43. There must be clearly documented early consultation with a neonatal intensive care unit (often referred to as tertiary units) for all babies born on a local neonatal unit who require intensive care
Patient Safety	44. The neonatal unit should not undertake even short-term intensive care, (except while awaiting a neonatal transfer service), if they cannot make arrangements for 24 hour on-site, immediate availability at either tier 2, (a registrar grade doctor with training in neonatology or an advanced neonatal nurse practitioner) or tier 3, (a neonatal consultant), with sole duties on the neonatal unit
Patient Safety	45. There was some evidence of outdated neonatal practice at The Shrewsbury and Telford Hospital NHS Trust. Consultant neonatologists and ANNPs must have the opportunity of regular observational attachments at another neonatal intensive care unit
Patient Safety	46. Incidents must be graded appropriately, with the level of harm recorded as the level of harm the patient actually suffered and in line with the relevant incident framework.
Patient Safety	47. The Trust executive team must ensure an appropriate level of dedicated time and resources are allocated within job plans for midwives, obstetricians, neonatologists and anaesthetists to undertake incident investigations.
Patient Safety	48. All investigations must be undertaken by a multi-professional team of investigators and never by one individual or a single profession
Patient Safety	49. The use of HRCRs to investigate incidents must be abolished and correct processes, procedures and terminology must be used in line with the relevant Serious Incident Framework.
Patient Safety	50. Individuals clinically involved in an incident should input into the evidence gathering stage, but never form part of the team that investigates the incident.
Patient Safety	51. All SIs must be completed within the timeframe set out in the SI framework. Any SIs not meeting this timeline should be escalated to the Trust Board
Patient Safety	52. All members of the governance team who lead on incident investigations should attend regular appropriate training courses not less than three yearly. This should be included in local governance policy. These training courses must commence within the next 12 months
Patient Safety	53. The governance team must ensure their incident investigation reports are easier for families to understand, for example ensuring any medical terms are explained in lay terms as in HSIB investigation reports.
Patient Safety	54. Lessons from clinical incidents must inform delivery of the local multidisciplinary training plan
Patient Safety	55. The needs of those affected must be the primary concern during incident investigations. Patients and their families must be actively involved throughout the investigation process.

Patient Safety	56. All feedback to families after an incident investigation has been conducted must be done in an open and transparent manner and conducted by senior members of the clinical leadership team, for example Director of Midwifery and consultant obstetrician meeting families together to ensure consistency and that information is in-line with the investigation report findings
Patient Safety	57. The maternity governance team must work with their Maternity Voices Partnership (MVP) to improve how families are contacted, invited and encouraged to be involved in incident investigations.
Patient Safety	58. There must be a robust process in place to ensure that all safety concerns raised by staff are investigated, with feedback given to the person raising the concern.
Patient Safety	59. The Trust must ensure that all staff are supported during incident investigations and consideration should be given to employing a clinical psychologist to support the maternity department going forwards.
Patient Safety	60. Complaint responses should be empathetic and kind in their nature. The local MVP must be involved in helping design and implement a complaints response template which is relevant and appropriate for maternity services
Patient Safety	61. Complaints themes and trends should be monitored at the maternity governance meeting, with actions to follow and shared with the MVP.
Patient Safety	62. All staff involved in preparing complaint responses must receive training in complaints handling.
Patient Safety	63. There must be midwifery and obstetric co-leads for audits.
Patient Safety	64. Audit meetings must be multidisciplinary in their attendance and all staff groups must be actively encouraged to attend, with attendance monitored.
Patient Safety	65. Any action that arises from a SI that involves a change in practice must be audited to ensure a change in practice has occurred
Patient Safety	66. Audits must demonstrate a systematic review against national/local standards ensuring recommendations address the identified deficiencies. Monitoring of actions must be conducted by the governance team
Patient Safety	67. Matters arising from clinical incidents must contribute to the annual audit plan.
Patient Safety	68. There must be midwifery and obstetric co-leads for developing guidelines.
Patient Safety	69. A process must be put in place to ensure guidelines are regularly kept up-to-date and amended as new national guidelines come into use.
Patient Safety	70. The Trust Board must review the progress of the maternity improvement and transformation plan every month.
Patient Safety	71. The maternity services senior leadership team must use appreciative inquiry to complete the National Maternity SelfAssessment235 Tool published in July 2021, to benchmark their services and governance structures against national standards and best practice guidance. They must provide a comprehensive report of their self-assessment, including any remedial plans which must be shared with the Trust Board.
Patient Safety	72. The Director of Midwifery must have direct oversight of all complaints and the final sign off of responsibility before submission to the Patient Experience team and the Chief Executive
Patient Safety	73. The Trust must adopt a consistent and systematic approach to risk assessment at booking and throughout pregnancy to ensure women are supported effectively and referred to specialist services where required.
Patient Safety	74. The Trust must have robust local guidance in place for the assessment of fetal growth. There must be training in symphysis fundal height (SFH) measurements and audit of the documentation of it, at least annually.
Patient Safety	75. Audits must be undertaken of babies born with fetal growth restriction to ensure guidance has been followed. These recommendations are part of the Saving Babies Lives Toolkit (2015 and 2019)

Patient Safety	76. The Trust must ensure parents receive appropriate information in all cases of fetal abnormality, including involvement of the wider multidisciplinary team 77. at the tertiary unit. Consideration must be given for birth in the tertiary centre as the best option in complex cases.
Patient Safety	78. Parents must be provided with all the relevant information, including the opportunity for a consultation at a tertiary unit in order to facilitate an informed choice. All discussions must be fully documented in the maternity records.
Patient Safety	79. The Trust must develop a robust pregnancy diabetes service that can accommodate timely reviews for women with pre-existing and gestational diabetes in pregnancy. This service must run on a weekly basis and have internal cover to permit staff holidays and study leave
Patient Safety	80. Staff working in maternity care at the Trust must be vigilant with regard to management of gestational hypertension in pregnancy. Hospital guidance must be updated to reflect national guidelines in a timely manner particularly when changes occur. Where there is deviation in local guidance from national guidance a comprehensive local risk assessment must be undertaken with the reasons for the deviation documented clearly in the guidance
Patient Safety	81. All patients with unplanned acute admissions to the antenatal ward, excluding women in early labour, must have a consultant review within 14 hours of admission (Seven Day Clinical Services NHSE 2017237). These consultant reviews must occur with a clearly documented plan recorded in the maternity record
Patient Safety	82. All women admitted for induction of labour, apart from those that are for post-dates, require a full clinical review prior to commencing the induction as recommended by the NICE Guidance Induction of Labour 2021.
Patient Safety	83. The Trust must strive to develop a safe environment and a culture where all staff are empowered to escalate to the correct person. They should use a standardised system of communication such as an SBAR239 to enable all staff to escalate and communicate their concerns.
Patient Safety	84. The Trust's escalation policy must be adhered to and highlighted on training days to all maternity staff
Patient Safety	85. The maternity service at the Trust must have a framework for categorising the level of risk for women awaiting transfer to the labour ward. Fetal monitoring must be performed depending on risk and at least once in every shift whilst the woman is on the ward
Patient Safety	86. The use of standardised computerised CTGs for antenatal care is recommended and has been highlighted by national documents such as Each Baby Counts and Saving Babies Lives. The Trust has used computerised CTGs since 2015 with local guidance to support its use. Processes must be in place to be able to escalate cases of concern quickly for obstetric review and likewise this must be reflected in appropriate decision making. Local mandatory electronic fetal monitoring training must include sharing local incidences for learning across the multi-professional team
Patient Safety	87. The labour ward coordinator must be the first point of referral and be proactive in role modelling the professional behaviours and personal values that are consistent with positive team working and providing timely support for midwives when asked or when abnormality in labour presents.
Patient Safety	88. The labour ward coordinator at the Trust must be supernumerary from labour care provision and provide the professional and operational link between midwifery and the most appropriately trained obstetrician.
Patient Safety	89. There must be a clear line of communication from the duty obstetrician and coordinating midwife to the supervising consultant at all times. Consultant support and on call availability are essential 24 hours per day, 7 days a week.
Patient Safety	90. Senior clinicians such as consultant obstetricians and band 7 coordinators must receive training in civility, human factors and leadership.
Whistleblowing	91. All clinicians at the Trust must work towards establishing a compassionate culture where staff learn together rather than apportioning blame. Staff must be encouraged to speak out when they have concerns about safe care
Patient Safety	92. Obstetricians must not assess fetal wellbeing with fetal blood sampling (FBS) in the presence of suspected fetal infection
Patient Safety	93. The Trust must provide protected time to ensure that all clinicians are able to continuously update their knowledge, skills and techniques relevant to their clinical work

Patient Safety	94. Midwives and obstetricians must undertake annual training on CTG interpretation taking into account the physiological basis for FHR changes and the impact of pre-existing antenatal and additional intrapartum risk factors
Patient Safety	95. Midwifery-led units must complete yearly operational risk assessments
Patient Safety	96. Midwifery-led units must undertake regular multidisciplinary team skill drills to correspond with the training needs analysis plan
Patient Safety	97. It is mandatory that all women are given written information with regards to the transfer time to the consultant obstetric unit when choosing an out-of-hospital birth. This information must be jointly developed and agreed between maternity services and the local ambulance trust.
Patient Safety	98. In view of the relatively high number of direct maternal deaths, the Trust's current mandatory multidisciplinary team training for common obstetric emergencies must be reviewed in partnership with a neighbouring tertiary unit to ensure they are fit for purpose. This outcome of the review and potential action plan for improvement must be monitored by the LMS
Patient Safety	99. The Trust's executive team must urgently address the deficiency in consultant anaesthetic staffing affecting daytime obstetric clinical work. Minimum consultant staffing must be in line with GPAS at all times. It is essential that sufficient consultant appointments are made to ensure adequate consultant cover for absences relating to annual, study and professional leave.
Patient Safety	100. The Trust's executive team must urgently address the impact of the shortfall of consultant anaesthetists on the out-of hours provision at the Princess Royal Hospital. Currently, one consultant anaesthetist provides out-off-hours support for all of the Trust's services. Staff appointments must be made to establish a separate consultant on-call rota for the intensive care unit as this will improve availability of consultant anaesthetist input to the maternity service
Patient Safety	101. The Trust's executive team must support the anaesthetic department to ensure that job planning facilitates the engagement of consultant anaesthetists in maternity governance activity, and all anaesthetists who cover obstetric anaesthesia in multidisciplinary maternity education and training as recommended by RCoA in 2020.
Patient Safety	102. The Trust's anaesthetists have responded to the first report with the development of a wide range of new and updated obstetric anaesthesia guidelines. Audit of compliance with these guidelines must now be undertaken to ensure evidence-based care is being embedded in day-to-day practice.
Patient Safety	103. The Trust's department of anaesthesia must reflect on how it will ensure learning and development based on incident reporting. After discussion within the department, written guidance must be provided to staff regarding events that require reporting.
Patient Safety	104. The Trust must ensure that there is a clearly documented, early consultation with a tertiary NICU for babies who require, or are anticipated to require, continuing intensive care. This must be the subject of regular audit
Patient Safety	106. The Trust must ensure that sufficient resources are available to provide safe neonatal medical or ANNP cover at all times commensurate with a unit of this size and designation, such that short term intensive care can be safely delivered, in consultation with a NICU.
Patient Safety	107. The number of neonatal nurses at the Trust who are "qualified-in-specialty" must be increased to the recommended level, by ensuring funding and access to appropriate training courses. Progress must be subject to annual review.
Patient Safety	108. The Trust must ensure that a woman's GP is given complete, accurate and timely, information when a woman experiences a perinatal loss, or any other serious adverse event during pregnancy, birth or postnatal continuum
Patient Safety	109. The Trust must ensure complete and accurate information is given to families after any poor obstetric outcome. The Trust must give families the option of receiving the governance reports, which must also be explained to them. Written summaries of any debrief meetings must also be sent to both the family and the GP
Patient Safety	110. The Trust must address as a matter of urgency the culture concerns highlighted through the staff voices initiative regarding poor staff behaviour and bullying, which remain apparent within the maternity service as illustrated by the results of the 2018 MatNeo culture survey

Whistle Blowing	111. Maternity care must be delivered by the Trust recognising that there will be an ongoing legacy of maternity related trauma within the local community, felt through generations of families.
Patient Safety	112. There must be dialogue with NHS England and Improvement and commissioners and the mental health trust and wider system locally, aiming to secure resources which reflect the ongoing consequences of such large scale adverse maternity experiences. Specifically this must ensure multi-year investment in the provision of specialist support for the mental health and wellbeing of women and their families in the local area

Report of the independent inquiry into the issues raised by Paterson (2020)

The non-statutory inquiry was commissioned by the Secretary of State in December 2017. It reviewed the circumstances surrounding Ian Paterson's malpractice and considered other past and current practices in the NHS and the independent sector. The inquiry aimed to learn lessons from these and made recommendations to improve the safety and quality of care provided to all patients. The review was published on 4 February 2020 and made 17 recommendations. In the government's response of December 2021, it accepted 15 recommendations.

Subject of accepted recommendation (pertaining to patient safety or whistleblowing)	Text of accepted recommendation
Patient safety	1. We recommend that there should be a single repository of the whole practice of consultants across England, setting out their practising privileges and other critical consultant performance data, for example, how many times a consultant has performed a particular procedure and how recently. This should be accessible and understandable to the public. It should be mandated for use by managers and healthcare professionals in both the NHS and independent sector.
Patient safety	2. We recommend that it should be standard practice that consultants in both the NHS and the independent sector should write to patients, outlining their condition and treatment, in simple language, and copy this letter to the patient's GP, rather than writing to the GP and sending a copy to the patient.
Patient safety	3. We recommend that CQC, as a matter of urgency, should assure itself that all hospital providers are complying effectively with up-to-date national guidance on MDT meetings, including in breast cancer care, and that patients are not at risk of harm due to non-compliance in this area.
Patient safety	4. We recommend that the University Hospitals Birmingham NHS Foundation Trust board should check that all patients of Paterson have been recalled, and to communicate with any who have not been seen.
Patient Safety	5. We recommend that Spire should check that all patients of Paterson have been recalled, and to communicate with any who have not been seen, and that they should check that they have been given an ongoing treatment plan in the same way that has been provided for patients in the NHS.
Patient safety	6. We recommend that a national framework or protocol, with guidance, is developed about how recall of patients should be managed and communicated. This framework or protocol should specify that the process is centred around the patient's needs, provide advice on how recall decisions are made, and advise what resource is required and how this might be provided. This should apply to both the independent sector and the NHS.
Patient safety	7. We recommend that the Government should ensure that the current system of regulation and the collaboration of the regulators serves patient safety as the top priority, given the ineffectiveness of the system identified in this Inquiry.
Patient safety	8. If the healthcare professional also works at another provider, any concerns about them should be communicated to that provider.

Independent investigation into the life and death of Elizabeth Dixon (2020)	
The Dixon Investigation was commissioned in June 2017 by the Secretary of State. The investigation, led by Dr Bill Kirkup, was tasked with investigating concerns about the death of 11-month old Elizabeth Dixon in 2001 while under the care of a private nursing agency commissioned by the local health authority. The investigation made 12 recommendation, 7 of which are pertaining to patient safety.	
Subject of accepted recommendation (pertaining to patient safety or whistleblowing)	Text of accepted recommendation
Patient safety	1. Hypertension (high blood pressure) in infants is a problem that is under-recognised and inconsistently managed, leading to significant complications. Its profile should be raised with clinicians; there should be a single standard set of charts showing the acceptable range at different ages and gestations; and a single protocol to reduce blood pressure safely. Blood pressure should be incorporated into a single early warning score to alert clinicians to deterioration in children in hospital.
Patient safety	2. Community care for patients with complex conditions or conditions requiring complex care must be properly planned, taking into account and specifying safety, effectiveness and patient experience. The presence of mental or physical disability must not be used to justify or excuse different standards of care.
Patient safety	3. Communication between clinicians, particularly when care is handed over from one team or unit to another, must be clear, include all relevant facts and use unambiguous terms. Terms such as palliative care and terminal care may be misleading and should be avoided
Patient safety	4. Training in clinical error, reactions to error and responding with honesty, investigation and learning should become part of the core curriculum for clinicians. Although it is true that curricula are already crowded with essential technical and scientific knowledge, it cannot be the case that no room can be found for training in the third leading cause of death in western health systems.
Patient safety	5. Clinical error, openly disclosed, investigated and learned from, must not be subject to blame. Conversely, there should be zero tolerance of cover up, deception and fabrication in any health care setting, not least in the aftermath of error.
Patient safety	6. Scrutiny of deaths should be robust enough to pick up instances of untoward death being passed off as expected. Despite changes to systems for child and adult deaths, concern remains that without independent review such cases may continue to occur. The introduction of medical examiners should be reviewed with a view to making them properly independent.

Patient safety	7. Local health service complaints systems are currently subject to change as part of wider reform of public sector complaints. Implementation of a better system of responding to complaints must be done in such a way as to ensure the integration of complaints into NHS clinical governance as a valuable source of information on safety, effectiveness and patient experience.
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Kark review into the effectiveness of the Fit and Proper Persons Test (2019)

In July 2018, then Minister of State for Health Steve Barclay commissioned Tom Kark QC to write a report and make recommendations in relation to the fit and proper persons test (FPPT) as it applied under Regulation 5 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. The review was published in February 2019 and made seven recommendations on how to improve the operation and effectiveness of Regulation 5.

Subject of accepted recommendation (pertaining to patient safety or whistleblowing)	Text of accepted recommendation
Patient safety	1. All directors should meet specified standards of competence to sit on the board of any health-providing organisation. Where necessary, training should be available.
Patient safety	2. That a central database of directors should be created to hold relevant information about qualifications and history.

The Mid Staffordshire NHS Foundation Trust Public Inquiry (2013)

In June 2010, the Secretary of State for Health announced the establishment of a Public Inquiry into the serious failings in care and suffering of many patients at the Mid Staffordshire NHS Foundation Trust between January 2005 and March 2009. The report of the public inquiry by Robert Francis QC was published in February 2013. It made 290 recommendations. The Department published its response covering each of the recommendations in November 2013. The Department agreed to the overwhelming majority of recommendations (mostly in full, some in principle or in part) and rejected 9 recommendations (while accepting the intent behind them: 19, 61, 64, 137, 145, 183, 209, 212, 213).

Subject of accepted recommendation (pertaining to patient safety or whistleblowing)	Text of accepted recommendation
Patient safety	Recommendation 1 It is recommended that: • All commissioning, service provision regulatory and ancillary organisations in healthcare should consider the findings and recommendations of this report and decide how to apply them to their own work; • Each such organisation should announce at the earliest practicable time its decision on the extent to which it accepts the recommendations and what it intends to do to implement those accepted, and thereafter, on a regular basis but not less than once a year, publish in a report information regarding its progress in relation to its planned actions; • In addition to taking such steps for itself, the Department of Health should collate information about the decisions and actions generally and publish on a regular basis but not less than once a year the progress reported by other organisations; • The House of Commons Select Committee on Health should be invited to consider incorporating into its reviews of the performance of organisations accountable to Parliament a review of the decisions and actions they have taken with regard to the recommendations in this report
Patient safety	Recommendation 2 The NHS and all who work for it must adopt and demonstrate a shared culture in which the patient is the priority in everything done. This requires: • A common set of shared core values and standards shared throughout the system. • Leadership at all levels from ward to the top of the Department of Health, committed to and capable of involving all staff with those values and standards; • A system which recognises and applies the values of transparency, honesty and candour; • Freely available, useful, reliable and full information on attainment of the values and standards; • A tool or methodology such as a cultural barometer to measure the cultural health of all parts of the system.
Patient safety	Recommendation 3 The NHS Constitution should be the first reference point for all NHS patients and staff and should set out the system's common values, as well as the respective rights, legitimate expectation and obligations of patients.
Patient safety	Recommendation 4 The core values expressed in the NHS Constitution should be given priority of place and the overriding value should be that patients are put first, and everything done by the NHS and everyone associated with it should be informed by this ethos.

The Mid Staffordshire NHS Foundation Trust Public Inquiry (2013)

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Subject of accepted recommendation (pertaining to patient safety or whistleblowing)	Text of accepted recommendation
Patient safety	Recommendation 5 In reaching out to patients, consideration should be given to including expectations in the NHS Constitution that: • Staff put patients before themselves; • They will do everything in their power to protect patients from avoidable harm; • They will be honest and open with patients regardless of the consequences for themselves; • Where they are unable to provide the assistance a patient needs, they will direct them where possible to those who can do so; • They will apply the NHS values in all their work.
Patient safety	Recommendation 6 The handbook of the NHS Constitution should be revised to include a much more prominent reference to the NHS values and their significance.
Patient safety	Recommendation 7 All NHS staff should be required to enter into an express commitment to abide by the NHS values and the Constitution, both of which should be incorporated into the contracts of employment.
Patient safety	Recommendation 8 Contractors providing outsourced services should also be required to abide by these requirements and to ensure that staff employed by them for these purposes do so as well. These requirements could be included in the terms on which providers are commissioned to provide services.
Patient safety	Recommendation 9 The NHS Constitution should include reference to all the professional and managerial codes by which NHS staff are bound, including the Code of Conduct for NHS Managers.
Patient safety	Recommendation 10 The NHS Constitution should incorporate an expectation that staff will follow guidance and comply with standards relevant to their work, such as those produced by the National Institute for Health and Clinical Excellence and, where relevant, the Care Quality Commission, subject to any more specific requirements of their employers.
Patient safety	Recommendation 11

The Mid Staffordshire NHS Foundation Trust Public Inquiry (2013)

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Subject of accepted recommendation (pertaining to patient safety or whistleblowing)	Text of accepted recommendation
	Healthcare professionals should be prepared to contribute to the development of, and comply with, standard procedures in the areas in which they work. Their managers need to ensure that their employees comply with these requirements. Staff members affected by professional disagreement about procedures must be required to take the necessary corrective action, working with their medical or nursing director or line manager within the trust, with external support where necessary. Professional bodies should work on devising evidence-based standard procedures for as many interventions and pathways as possible.
Patient safety	Recommendation 12 Reporting of incidents of concern relevant to patient safety, compliance with fundamental standards or some higher requirement of the employer needs to be not only encouraged but insisted upon. Staff are entitled to receive feedback in relation to any report they make, including information about any action taken or reasons for not acting.
Patient safety	Recommendation 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. • Enhance 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.
Patient safety	Recommendation 14 In addition to the fundamental standards of service, the regulations should include generic requirements for a governance system designed to ensure compliance with fundamental standards, and the provision and publication of accurate information about compliance with the fundamental and enhanced standards.
Patient safety	Recommendation 15 All the required elements of governance should be brought together into one comprehensive standard. This should require not only evidence of a working system but also a demonstration that it is being used to good effect.

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Patient safety	Recommendation 16 The Government, through regulation, but after so far as possible achieving consensus between the public and professional representatives, should provide for the fundamental standards which should define outcomes for patients that must be avoided. These should be limited to those matters that it is universally accepted should be avoided for individual patients who are accepted for treatment by a healthcare provider.
Patient safety	Recommendation 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.
Patient safety	Recommendation 18 It is essential that professional bodies in which doctors and nurses have confidence are fully involved in the formulation and in the means of measuring compliance.
Patient safety	Recommendation 20 The Care Quality Commission 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.
Patient safety	Recommendation 21 The regulator should have a duty to monitor the accuracy of the 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.
Patient safety	Recommendation 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.
Patient safety	Recommendation 23

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	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 for 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 specialities, professional organisations, and patient and public representatives, and consideration of the benefits and value for money of possible staff:patient ratios.
Patient safety	Recommendation 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.
Patient safety	Recommendation 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.
Patient safety	Recommendation 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.
Patient safety	Recommendation 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.
Patient safety	Recommendation 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 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

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	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.
Patient safety	Recommendation 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 practical steps have been taken to prevent a breach, including having in place a prescribed system to prevent such a breach.
Patient safety	Recommendation 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.
Patient safety	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.
Patient safety	Recommendation 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.
Patient safety	Recommendation 33 Insofar as health regulators do not consider they possess any necessary interim powers, the Department of Health should consider the introduction of the necessary amendments to legislation to provide such powers.
Patient safety	Recommendation 34 Where a provider is under some form of regulatory investigation, there should be some form of external performance management involvement to oversee any necessary interim arrangements for protecting the public.
Patient safety	Recommendation 35

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	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 pierced 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.
Patient safety	Recommendation 36 A co-ordinated 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.
Patient safety	Recommendation 37 Trust Boards should provide, through quality accounts, and in nationally consistent format, full and accurate information about their compliance with each standard which applies to them. To the extent that it is not practical in a written report to set out detail, this should be made available via each trust's website. Reports should no longer be confined to reports on achievements as opposed to a fair representation of areas where compliance has not been achieved. A full account should be given of the methods used to obtain the information. To make or be party to a wilfully or recklessly false statement as to compliance with safety or essential standards in the required quality account should be made a criminal offence.
Patient safety	Recommendation 38 The Care Quality Commission 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 legal or bureaucratic obstacles to this should be removed.
Patient safety	Recommendation 39 The Care Quality Commission should introduce a mandated return from providers about patterns of complaints, how they were dealt with and outcomes.
Patient safety	Recommendation 40 It is important that greater attention is paid to the narrative contained in, for instance, complaints data, as well as to the numbers.
Patient safety	Recommendation 41

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	The Care Quality Commission 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 Care Quality Commission 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.
Patient safety	Recommendation 42 Strategic Health Authorities/their successors should, as a matter of routine, share information on serious untoward incidents with the Care Quality Commission.
Patient safety	Recommendation 43 Those charged with oversight and regulatory roles in healthcare should monitor media reports about the organisations for which they have responsibility.
Patient safety	Recommendation 44 Any example of a serious incident or avoidable harm should trigger an examination by the Care Quality Commission of how that was addressed by the provider and a requirement by the trust concerned to demonstrate that the learning to be derived has been successfully implemented.
Patient safety	Recommendation 45 The Care Quality Commission should be notified directly of upcoming healthcarerelated inquests, either by trusts or perhaps more usefully by coroners
Patient safety	Recommendation 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.
Patient safety	Recommendation 47 The Care Quality Commission 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'.
Patient safety	Recommendation 48 The Care Quality Commission should send a personal letter, via each registered body, to each Foundation Trust governor on appointment, inviting them to submit relevant information about any concerns to the Care Quality Commission.
Patient safety	Recommendation 49 Routine and risk-related monitoring, as opposed to acceptance of self-declarations of compliance, is essential. The Care Quality Commission should consider its monitoring in relation to the value to be obtained from:

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	• The Quality and Risk Profile; • Quality Accounts; • Reports from Local Healthwatch; • New or existing peer review schemes; • Themed inspections.
Patient safety	Recommendation 50 The Care Quality Commission should retain an emphasis on inspection as a central method of monitoring non-compliance.
Patient safety	Recommendation 51 The Care Quality Commission should develop a specialist cadre of inspectors by through 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 level 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.
Patient safety	Recommendation 52 The Care Quality Commission should consider whether inspections could be done in collaboration with other agencies, or whether they can take advantage of any peer review arrangements available.
Patient safety	Recommendation 53 Any change to the Care Quality Commission's role should be by evolution – any temptation to abolish this organisation and create a new one must be avoided.
Patient safety	Recommendation 54 Where regulatory issues are discussed between the Care Quality Commission and other agencies, these should be properly recorded to avoid any suggestion of inappropriate interference in the Care Quality Commission's statutory role.
Patient safety	Recommendation 55 The Care Quality Commission 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.
Patient safety	Recommendation 56

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	The leadership of the Care Quality Commission 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.
Patient safety	Recommendation 57 The Care Quality Commission 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.
Patient safety	Recommendation 58 Patients, through their user group representatives, should be integrated into the structure of the Care Quality Commission. 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.
Patient safety	Recommendation 59 Consideration should be given to the introduction of a category for 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.
Patient safety	Recommendation 60 The Secretary of State should consider transferring the functions of regulating the governance of healthcare providers and the fitness of persons to be directors, governors or equivalent persons from Monitor to the Care Quality Commission.
Patient safety	Recommendation 62 For as long as it retains responsibility for the regulation of FTs, Monitor should incorporate greater patient and public involvement into its own structures, to ensure this focus is always at the forefront of this work.
Patient safety	Recommendation 63 Monitor should publish all side letters and any rating issued to trusts as part of their authorisation or licence.
Patient safety	Recommendation 65 The NHS Trust Development Authority should develop a clear policy requiring proof of fitness for purpose in delivering the appropriate quality of care as a pre-condition to consideration for support for a Foundation Trust application.
Patient safety	Recommendation 66 The Department of Health, the NHS Trust Development Authority and Monitor should jointly review the stakeholder consultation process with a view to ensuring that;

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	• local stakeholder and public opinion is sought on the fitness of a potential applicant NHS Trust for Foundation Trust status and in particular on whether a potential applicant is delivering a sustainable service compliant with fundamental standards; • an accessible record of responses received is maintained; • the responses are made available for analysis on behalf of the Secretary of State, and, where an application is assessed by it, Monitor.
Patient safety	Recommendation 67 The NHS Trust Development Authority should develop a rigorous process for the assessment as well as the support of potential applicants for Foundation Trust status. The assessment must include as a priority focus a review of the standard of service delivered to patients, and the sustainability of a service at the required standard.
Patient safety	Recommendation 68 No NHS trust should be given support to make an application to Monitor unless, in addition to other criteria, the performance manager (the Strategic Health Authority cluster, the Department of Health team, or the NHS Trust Development Authority) is satisfied that the organisation currently meets Monitor's criteria for authorisation and that it is delivering a sustainable service which is, and will remain, safe for patients, and is compliant with at least fundamental standards.
Patient safety	Recommendation 69 The assessment criteria for authorisation should include a requirement that applicants demonstrate their ability to consistently meet fundamental patient safety and quality standards at the same time as complying with the financial and corporate governance requirements of a Foundation Trust.
	Recommendation 70 A duty of utmost good faith should be imposed on applicants for Foundation Trust status to disclose to the regulator any significant information material to the application and to ensure that any information is complete and accurate. This duty should continue throughout the application process, and thereafter in relation to the monitoring of compliance.
Patient safety	Recommendation 71 The Secretary of State's support for an application should not be given unless he is satisfied that the proposed applicant provides a service to patients which is, at the time of his consideration, safe, effective and compliant with all relevant standards, and that in his opinion it is reasonable to conclude that the proposed applicant will continue to be able to do so for the foreseeable future. In deciding whether he can be so satisfied, the Secretary of State should have regard to the required public consultation and should consult with the healthcare regulator.

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Patient safety	Recommendation 72 The assessment for an authorisation of applicant for Foundation Trust status should include a full physical inspection of its primary clinical areas as well as all wards to determine whether it is compliant with fundamental safety and quality standards.
Patient safety	Recommendation 73 The Department of Health's regular performance reviews of Monitor (and the Care Quality Commission) should include an examination of its relationship with the Department of Health and whether the appropriate degree of clarity of understanding of the scope of their respective responsibilities has been maintained.
Patient safety	Recommendation 74 Monitor and the Care Quality Commission should publish guidance for governors suggesting principles they expect them to follow in recognising their obligation to account to the public, and in particular in arranging for communication with the public served by the Foundation Trust and to be informed of the public's views about the services offered.
Patient safety	Recommendation 75 The Council of Governors and the board of each Foundation Trust should together consider how best to enhance the ability of the council to assist in maintaining compliance with its obligations and to represent the public interest. They should produce an agreed published description of the role of the governors and how it is planned that they perform it. Monitor and the Care Quality Commission should review these descriptions and promote what they regard as best practice.
Patient safety	Recommendation 76 Arrangements must be made to ensure that governors are accountable not just to the immediate membership but to the public at large – it is important that regular and constructive contact between governors and the public is maintained.
Patient safety	Recommendation 77 Monitor and the NHS Commissioning Board should review the resources and facilities made available for the training and development of governors to enhance their independence and ability to expose and challenge deficiencies in the quality of the Foundation Trust's services.
Patient safety	Recommendation 78

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	The Care Quality Commission and Monitor should consider how best to enable governors to have access to a similar advisory facility in relation to compliance with healthcare standards as will be available for compliance issues in relation to breach of a licence (pursuant to section 39A of the National Health Service Act 2006 as amended), or other ready access to external assistance.
Patient safety	Recommendation 79 There should be a requirement that all directors of all bodies registered by the Care Quality Commission as well as Monitor for Foundation Trusts are, and remain, fit and proper persons for the role. Such a test should include a requirement to comply with a prescribed code of conduct for directors.
Patient safety	Recommendation 80 A finding that a person is not a fit and proper person on the grounds of serious misconduct or incompetence should be a circumstance added to the list of disqualifications in the standard terms of a Foundation Trust's constitution.
Patient safety	Recommendation 81 Consideration should be given to including the criteria for fitness a minimum level of experience and/or training, while giving appropriate latitude for recognition of equivalence.
Patient safety	Recommendation 82 Provision should be made for regulatory intervention to require the removal or suspension from office after due process of a person whom the regulator is satisfied is not or is no longer a fit and proper person, regardless of whether the trust is in significant breach of its authorisation or licence.
Patient safety	Recommendation 83 If a 'fit and proper person test' is introduced as recommended, Monitor should issue guidance on the principles on which it would exercise its power to require the removal or suspension or disqualification of directors who did not fulfil it, and the procedure it would follow to ensure due process.
Patient safety	Recommendation 84 Where the contract of employment or appointment of an executive or non-executive is terminated in circumstances in which there are reasonable grounds for believing that he or she is not a fit person to hold such a post, licensed bodies should be obliged by the terms of their licence to report the matter to Monitor, the Care Quality Commission and the NHS Trust Development Authority.
Patient safety	Recommendation 85

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	Monitor and the Care Quality Commission should produce guidance to NHS and Foundation Trusts on procedures to be followed in the event of an executive or non- executive director being found to have been guilty of serious failure in the performance of his or her office, and in particular with regard to the need to have regard to the public interest in protection of patients and maintenance of confidence in the NHS and the healthcare system.
Patient safety	Recommendation 86 A requirement should be imposed on Foundation Trusts to have in place an adequate programme for the training and continued development of directors.
Patient safety	Recommendation 87 The Health and Safety Executive is clearly not the right organisation to be focusing on healthcare. Either the Care Quality Commission should be given power to prosecute 1974 Act offences or a new offence containing comparable provisions should be created under which the Care Quality Commission has power to launch a prosecution.
Patient safety	Recommendation 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.
Patient safety	Recommendation 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.
Patient safety	Recommendation 90 In order to determine whether a case is so serious, either in terms of the breach of safety requirements or the consequences for any victims, that the public interest requires individuals or organisations to be brought to account for their failings, the Health and Safety Executive should obtain expert advice, as is done in the field of healthcare litigation and fitness to practise proceedings.
Patient safety	Recommendation 91 The Department of Health and NHS Commissioning Board should consider what steps are necessary to require all NHS providers, whether or not they remain members of the NHS Litigation Authority scheme, to have and to comply with risk management standards at least as rigorous as those required by the NHS Litigation Authority.
Patient safety	Recommendation 92

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	The financial incentives at levels below level 3 should be adjusted to maximise the motivation to reach level 3.
Patient safety	Recommendation 93 The NHS Litigation Authority should introduce requirements with regard to observance of the guidance to be produced in relation to staffing levels, and require trusts to have regard to evidence-based guidance and benchmarks where these exist and to demonstrate that effective risk assessments take place when changes to the numbers or skills of staff are under consideration. It should also consider how more outcome based standards could be designed to enhance the prospect of exploring deficiencies in risk management, such as occurred at the trust.
Patient safety	Recommendation 94 As some form of running record of the evidence reviewed must be retained on each claim in order for these reports to be produced, the NHS Litigation Authority should consider the development of a relatively simple database containing the same information.
Patient safety	Recommendation 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 Care Quality Commission access to these reports.
Patient safety	Recommendation 96 The NHS Litigation Authority should make more prominent in its publicity an explanation comprehensible to the general public of the limitations of its standards assessments and of the reliance which can be placed on them.
Patient safety	Recommendation 97 The National Patient Safety Agency's resources need to be well protected and defined. Consideration should be given to the transfer of this valuable function to a systems regulator.
Patient safety	Recommendation 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.
Patient safety	Recommendation 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.
Patient safety	Recommendation 100

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	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.
Patient safety	Recommendation 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 Care Quality Commission.
Patient safety	Recommendation 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.
Patient safety	Recommendation 103 The National Patient Safety Agency or its successor should regularly share information with Monitor.
Patient safety	Recommendation 104 The Care Quality Commission 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.
Patient safety	Recommendation 105 Consideration should be given to whether information from incident reports involving deaths in hospital could enhance consideration of the hospital standardised mortality ratio.
Patient safety	Recommendation 106 HPA and its successor, should co-ordinate 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.
Patient safety	Recommendation 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 Care Quality Commission

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	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.
Patient safety	Recommendation 108 Public Health England should review the support and training that health protection staff can offer to local authorities and other agencies in relation to local oversight of healthcare providers' infection control arrangements.
Patient safety	Recommendation 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.
Patient safety	Recommendation 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 consideration of litigation.
Patient safety	Recommendation 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.
Patient safety	Recommendation 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.
Patient safety	Recommendation 113 The recommendations and standards suggested in the Patients Association's peer review into complaints at the Mid Staffordshire NHS Foundation Trust should be reviewed and implemented in the NHS.
Patient safety	Recommendation 114 Comments or complaints which describe events amounting to a serious or untoward incident should trigger an investigation.
Patient safety	Recommendation 115 Arms length independent investigation of a complaint should be initiated by the provider trust where any one of the following apply:

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	• 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.
Patient safety	Recommendation 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.
Patient safety	Recommendation 117 A facility should be available to Independent Complaints Advocacy Services advocates and their clients for access to expert advice in complicated cases.
Patient safety	Recommendation 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 Care Quality Commission.
Patient safety	Recommendation 119 Overview and scrutiny committees and Local Healthwatch should have access to detailed information about complaints, although respect needs to be paid in this instance to the requirement of patient confidentiality.
Patient safety	Recommendation 120 Commissioners should require access to all complaints information as and when complaints are made, and should receive complaints and their outcomes on as near a real-time basis as possible. This means commissioners should be required by NHS Commissioning Board to undertake the support and oversight role of GPs in this area, and be given the resources to do so.
Patient safety	Recommendation 121 The Care Quality Commission 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.
Patient safety	Recommendation 122

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	Large-scale failures of clinical service are likely to have in common a need for: • Provision of prompt advice, counselling and support to very distressed and anxious members of the public; • Swift identification of persons of independence, authority and expertise to lead investigations and reviews; • A procedure for the recruitment of clinical and other experts to review cases; • A communications strategy to inform and reassure the public of the processes being adopted; • Clear lines of responsibility and accountability for the setting up and oversight of such reviews. Such events are of sufficient rarity and importance, and requiring of coordination of the activities of multiple organisations, that the primary responsibility should reside in the National Quality Board.
Patient safety	Recommendation 123 GPs need to undertake a monitoring role on behalf of their patients who receive acute hospital and other specialist services. They should be an independent, professionally qualified check on the quality of service, in particular in relation to an assessment of outcomes. They need to have internal systems enabling them to be aware of patterns of concern, so that they do not merely treat each case on its individual merits. They have a responsibility to all their patients to keep themselves informed of the standard of service available at various providers in order to make patients' choice reality. A GP's duty to a patient does not end on referral to hospital, but is a continuing relationship. They will need to take this continuing partnership with their patients seriously if they are to be successful commissioners.
Patient safety	Recommendation 124 The commissioner is entitled to and should, wherever it is possible to do so, apply a fundamental safety and quality standard in respect of each item of service it is commissioning. In relation to each such standard, it should agree a method of measuring compliance and redress for non-compliance. Commissioners should consider whether it would incentivise compliance by requiring redress for individual patients who have received substandard service to be offered by the provider. These must be consistent with fundamental standards enforceable by the Care Quality Commission.
Patient safety	Recommendation 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.
Patient safety	Recommendation 126

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	The NHS Commissioning Board and local commissioners should develop and oversee a code of practice for managing organisational transitions, to ensure the information conveyed is both candid and comprehensive. This code should cover both transitions between commissioners, for example as new clinical commissioning groups are formed, and guidance for commissioners on what they should expect to see in any organisational transitions among their providers.
Patient safety	Recommendation 127 The NHS Commissioning Board and local commissioners must be provided with the infrastructure and the support necessary to enable a proper scrutiny of its providers' services, based on sound commissioning contracts, while ensuring providers remain responsible and accountable for the services they provide.
Patient safety	Recommendation 128 Commissioners must have access to the wide range of experience and resources necessary to undertake a highly complex and technical task, including specialist clinical advice and procurement expertise. When groups are too small to acquire such support. they should collaborate with others to do so.
Patient safety	Recommendation 129 In selecting indicators and means of measuring compliance, the principal focus of commissioners should be on what is reasonably necessary to safeguard patients and to ensure that at least fundamental safety and quality standards are maintained. This requires close engagement with patients, past, present and potential, to ensure that their expectations and concerns are addressed.
Patient safety	Recommendation 130 Commissioners – not providers – should decide what they want provided. They need to take into account what can be provided, and for that purpose will have to consult clinicians both from potential providers and from elsewhere, and to be willing to receive proposals, but in the end it is the commissioner whose decision must prevail.
Patient safety	Recommendation 131 Commissioners need, wherever possible, to identify and make available alternative sources of provision. This may mean that commissioning has to be undertaken on behalf of consortia of commissioning groups to provide the negotiating weight necessary to achieve a negotiating balance of power with providers.
Patient safety	Recommendation 132 Commissioners must have the capacity to monitor the performance of every commissioning contract on a continuing basis during the contract period:

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	• Such monitoring may include requiring quality information generated by the provider. • Commissioners must also have the capacity to undertake their own (or independent) audits, inspections, and investigations. These should, where appropriate, include investigation of individual cases and reviews of groups of cases. • The possession of accurate, relevant, and useable information from which the safety and quality of a service can be ascertained is the vital key to effective commissioning, as it is to effective regulation. • Monitoring needs to embrace both compliance with the fundamental standards and with any enhanced standards adopted. In the case of the latter, they will be the only source of monitoring, leaving the healthcare regulator to focus on fundamental standards.
Patient safety	Recommendation 133 Commissioners should be entitled to intervene in the management of an individual complaint on behalf of a patient where it appears to them it is not being dealt with satisfactorily, while respecting the principle that it is the provider who has primary responsibility to process and respond to complaints about its services.
Patient safety	Recommendation 134 Consideration should be given to whether commissioners should be given responsibility for commissioning patients' advocates and support services for complaints against providers.
Patient safety	Recommendation 135 Commissioners should be accountable to their public for the scope and quality of services they commission. Acting on behalf of the public requires their full involvement and engagement: • There should be a membership system whereby eligible members of the public can be involved in and contribute to the work of the commissioners. • There should be lay members of the commissioners' board. • Commissioners should create and consult with patient forums and local representative groups. Individual members of the public (whether or not members) must have access to a consultative process so their views can be taken into account. • There should be regular surveys of patients and the public more generally. • Decision-making processes should be transparent: decision-making bodies should hold public meetings. Commissioners need to create and maintain a recognisable identity which becomes a familiar point of reference for the community.
Patient safety	Recommendation 136

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	Commissioners need to be recognisable public bodies, visibly acting on behalf of the public they serve and with a sufficient infrastructure of technical support. Effective local commissioning can only work with effective local monitoring, and that cannot be done without knowledgeable and skilled local personnel engaging with an informed public.
Patient safety	Recommendation 138 Commissioners should have contingency plans with regard to the protection of patients from harm, where it is found they are at risk from substandard or unsafe services.
	Recommendation 139 The first responsibility for any organisation charged with responsibility for performance management of a healthcare provider should be ensuring fundamental patient safety and quality standards are being met. Such an organisation must require convincing evidence to be available before accepting that such standards are being complied with.
Patient safety	Recommendation 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.
Patient safety	Recommendation 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.
	Recommendation 142 For an organisation to be effective in performance management, there must exist unambiguous lines of referral and information flows, so that the performance manager is not in ignorance of the reality.
Patient safety	Recommendation 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.
Patient safety	Recommendation 144

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	The NHS Commissioning Board should ensure the development of metrics on quality and outcomes of care for use by commissioners in managing the performance of providers, and retain oversight of these through its regional offices, if appropriate.
Patient safety	Recommendation 146 Local authorities should be required to pass over the centrally provide funds allocated to its Local Healthwatch, while requiring the latter to account for its stewardship of the money. Transparent respect for the independence of Local Healthwatch should not be allowed to inhibit a responsible local authority – or Healthwatch England as appropriate – intervening.
Patient safety	Recommendation 147 Guidance should be given to promote the coordination and cooperation between Local Healthwatch, Health and Wellbeing Boards, and local government scrutiny committees.
Patient safety	Recommendation 148 The complexities of the health service are such that proper training must be available to the leadership of Local Healthwatch as well as, when the occasion arises, expert advice.
Patient safety	Recommendation 149 Scrutiny committees should be provided with appropriate support to enable them to carry out their scrutiny role, including easily accessible guidance and benchmarks.
Patient safety	Recommendation 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.
Patient safety	Recommendation 151 MPs are advised to consider adopting some simple system for identifying trends in the complaints and information they received from constituents. They should also consider whether individual complaints imply concerns of wider significance than the impact on one individual patient.
Patient safety	Recommendation 152 Any organisation which in the course of a review, inspection or other performance of its duties, identifies concerns potentially relevant to the acceptability of training provided by a healthcare provider, must be required to inform the relevant training regulator of those concerns.

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Patient safety	Recommendation 153 The Secretary of State should by statutory instrument specify all medical education and training regulators as relevant bodies for the purpose of their statutory duty to cooperate. Information sharing between the deanery, commissioners, the General Medical Council, the Care Quality Commission and Monitor with regard to patient safety issues must be reviewed to ensure that each organisation is made aware of matters of concern relevant to their responsibilities.
Patient safety	Recommendation 154 The Care Quality Commission and Monitor should develop practices and procedures with training regulators and bodies responsible for the commissioning and oversight of medical training to coordinate their oversight of healthcare organisations which provide regulated training.
Patient safety	Recommendation 155 The General Medical Council should set out a standard requirement for routine visits to each local education provider, and programme in accordance with the following principles: • The Postgraduate Dean should be responsible for managing the process at the level of the Local Educational Training Board, as part of overall deanery functions • The Royal Colleges should be enlisted to support such visits and to provide the relevant specialist expertise where required. • There should be lay or patient representation on visits to ensure that patient interests are maintained as the priority. • Such visits should be informed by all other sources of information and, if relevant, coordinated with the work of Care Quality Commission and other forms of review. The Department of Health should provide appropriate resources to ensure that an effective programme of monitoring training by visits can be carried out. All healthcare organisations must be required to release healthcare professionals to support the visits programme. It should also be recognised that the benefits in professional development and dissemination of good practice are of significant value.
Patient safety	Recommendation 156 The system for approving and accrediting training placement providers and programmes should be configured to apply the principles set out above.

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Patient safety	Recommendation 157 The General Medical Council should set out a clear statement of what matters; deaneries are required to report to the General Medical Council either routinely or as they arise. Reports should include a description of all relevant activity and findings and not be limited to exceptional matters of perceived non-compliance with standards. Without a compelling and recorded reason, no professional in a training organisation interviewed by a regulator in the course of an investigation should be bound by a requirement of confidentiality not to report the existence of an investigation, and the concerns raised by or to the investigation with his own organisation.
Patient safety	Recommendation 158 The General Medical Council should amend its standards for undergraduate medical education to include a requirement that providers actively seek feedback from students and tutors on compliance by placement providers with minimum standards of patient safety and quality of care, and should generally place the highest priority on the safety of patients.
Patient safety	Recommendation 159 Surveys of medical students and trainees should be developed to optimise them as a source feedback of perceptions of the standards of care provided to patients. The General Medical Council should consult the Care Quality Commission in developing the survey and routinely share information obtained with healthcare regulators.
Patient safety	Recommendation 160 Proactive steps need to be taken to encourage openness on the part of trainees and to protect them from any adverse consequences in relation to raising concerns.
Patient safety	Recommendation 161 Training visits should make an important contribution to the protection of patients: • Obtaining information directly from trainees should remain a valuable source of information – but it should not be the only source of information used. • Visits to, and observation of, the actual training environment would enable visitors to detect poor practice from which both patients and trainees should be sheltered. • The opportunity can be taken to share and disseminate good practice with trainees and management. Visits of this nature will encourage the transparency that is so vital to the preservation of minimum standards.

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Patient safety	Recommendation 162 The General Medical Council should in the course of its review of its standards and regulatory process ensure that the system of medical training and education maintains as its first priority the safety of patients. It should also ensure that providers of clinical placements are unable to take on students or trainees in areas which do not comply with fundamental patient safety and quality standards. Regulators and deaneries should exercise their own independent judgement as to whether such standards have been achieved and if at any stage concerns relating to patient safety are raised, they must take appropriate action to ensure these concerns are properly addressed.
Patient safety	Recommendation 163 The General Medical Council's system of reviewing the acceptability of the provision of training by healthcare providers must include a review of the sufficiency of the numbers and skills of available staff for the provision of training and to ensure patient safety in the course of training.
Patient safety	Recommendation 164 The Department of Health and the General Medical Council should review whether the resources available for regulating Approved Practice Setting are adequate and, if not, make arrangements for the provision of the same. Consideration should be given to empowering the General Medical Council to charge organisations a fee for approval.
Patient safety	Recommendation 165 The General Medical Council should immediately review its approved practice settings criteria with a view to recognition of the priority to be given to protecting patients and the public.
Patient safety	Recommendation 166 The General Medical Council should in consultation with patient interest groups and the public immediately review its procedures for assuring compliance with its approved practice settings criteria with a view in particular to provision for active exchange of relevant information with the healthcare systems regulator, coordination of monitoring processes with others required for medical education and training, and receipt of relevant information from registered practitioners of their current experience in approved practice settings approved establishments.
Patient safety	Recommendation 167 The Department of Health and General Medical Council should review the powers available to the General Medical Council in support of assessment and monitoring of approved practice settings establishments with a view to ensuring that the General Medical Council (or if considered more appropriate, the

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	healthcare systems regulator), has the power to inspect establishments, either itself or by an appointed entity on its behalf, and to require the production of relevant information.
Patient safety	Recommendation 168 The Department of Health and the General Medical Council should consider making the necessary statutory (and regulatory changes) to incorporate the approved practice settings scheme into the regulatory framework for post graduate training.
Patient safety	Recommendation 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.
Patient safety	Recommendation 170 Health Education England should have a medically qualified director of medical education and a lay patient representative on its board.
Patient safety	Recommendation 171 All Local Education and Training Boards should have a post of medically qualified postgraduate dean responsible for all aspects of postgraduate medical education.
Patient safety	Recommendation 172 The Government should consider urgently the introduction of a common requirement of proficiency in communication in the English language with patients and other persons providing healthcare to the standard required for a registered medical practitioner to assume professional responsibility for medical treatment of an Englishspeaking patient.
Patient safety	Recommendation 173 Every healthcare organisation and everyone working for them must be honest, open and truthful in all their dealings with patients and the public, and organisational and personal interests must never be allowed to outweigh the duty to be honest, open and truthful.
Patient safety	Recommendation 174 Where death or serious harm has been or may have been caused to a patient by an act or omission of the organisation or its staff, the patient (or any lawfully entitled personal representative or other authorised person) should be informed of the incident, given full disclosure of the surrounding circumstances and be offered an appropriate level of support, whether or not the patient or representative has asked for this information.
Patient safety	Recommendation 175

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	Full and truthful answers must be given to any question reasonably asked about his or her past or intended treatment by a patient (or, if deceased, to any lawfully entitled personal representative).
Patient safety	Recommendation 176 Any statement made to a regulator or a commissioner in the course of its statutory duties must be completely truthful and not misleading by omission.
Patient safety	Recommendation 177 Any public statement made by a healthcare organisation about its performance must be truthful and not misleading by omission.
Patient safety	Recommendation 178 The NHS Constitution should be revised to reflect the changes recommended with regard to a duty of openness, transparency and candour, and all organisations should review their contracts of employment, policies and guidance to ensure that, where relevant, they expressly include and are consistent with above principles and these recommendations.
Patient safety	Recommendation 179 'Gagging clauses' or non disparagement clauses should be prohibited in the policies and contracts of all healthcare organisations, regulators and commissioners; insofar as they seek, or appear, to limit bona fide disclosure in relation to public interest issues of patient safety and care.
Patient safety	Recommendation 180 Guidance and policies should be reviewed to ensure that they will lead to compliance with Being Open, the guidance published by the National Patient Safety Agency.
Patient safety	Recommendation 181 A statutory obligation should be imposed to observe a duty of candour: • On healthcare providers who believe or suspect that treatment or care provided by it to a patient has caused death or serious injury to a patient to inform that patient or other duly authorised person as soon as is practicable of that fact and thereafter to provide such information and explanation as the patient reasonably may request; • On registered medical practitioners and registered nurses and other registered professionals who believe or suspect that treatment or care provided to a patient by or on behalf of any healthcare provider by which they are employed has caused death or serious injury to the patient to report their belief or suspicion to their employer as soon as is reasonably practicable.

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	The provision of information in compliance with this requirement should not of itself be evidence or an admission of any civil or criminal liability, but non-compliance with the statutory duty should entitle the patient to a remedy.
Patient safety	Recommendation 182 There should be a statutory duty on all directors of healthcare organisations to be truthful in any information given to a healthcare regulator or commissioner, either personally or on behalf of the organisation, where given in compliance with a statutory obligation on the organisation to provide it.
Patient safety	Recommendation 184 Observance of the duty should be policed by the Care Quality Commission, which should have powers to prosecute in the last resort in cases of serial non-compliance or serious and wilful deception. The Care Quality Commission should be supported by monitoring undertaken by commissioners and others.
Patient safety	Recommendation 185 There should be an increased focus in nurse training, education and professional development on the practical requirements of delivering compassionate care in addition to the theory. A system which ensures the delivery of proper standards of nursing requires: • Selection of recruits to the profession who evidence the: • Possession of the appropriate values, attitudes and behaviours; • Ability and motivation to enable them to put the welfare of others above their own interest; • Drive to maintain, develop and improve their own standards and abilities; • Intellectual achievements to enable them to acquire through training the necessary technical skills: • Training and experience in delivery of compassionate care; • Leadership which constantly reinforces values and standards of compassionate care; • Involvement in, and responsibility for, the planning and delivery of compassionate care; • Constant support and incentivisation which values nurses and the work they do through: • Recognition of achievement; • Regular, comprehensive feedback on performance and concerns; • Encouraging them to report concerns and to give priority to patient well-being.
Patient safety	Recommendation 186

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	Nursing training should be reviewed so that sufficient practical elements are incorporated to ensure that a consistent standard is achieved by all trainees throughout the country. This requires national standards.
Patient safety	Recommendation 187 There should be a national entry-level requirement that student nurses spend a minimum period of time, at least three months, working on the direct care of patients under the supervision of a registered nurse. Such experience should include direct care of patients, ideally including the elderly, and involve hands-on physical care. Satisfactory completion of this direct care experience should be a pre-condition to continuation in nurse training. Supervised work of this type as a healthcare support worker should be allowed to count as an equivalent. An alternative would be to require candidates for qualification for registration to undertake a minimum period of work in an approved healthcare support worker post involving the delivery of such care.
Patient safety	Recommendation 188 The Nursing and Midwifery Council working with universities, should consider the introduction of an aptitude test to be undertaken by aspirant registered nurses at entry into the profession, exploring, in particular, candidates' attitudes towards caring, compassion and other necessary professional values.
Patient safety	Recommendation 189 The Nursing and Midwifery Council and other professional and academic bodies should work towards a common qualification assessment/examination.
Patient safety	Recommendation 190 There should be national training standards for qualification as a registered nurse to ensure that newly qualified nurses are competent to deliver a consistent standard of the fundamental aspects of compassionate care.
Patient safety	Recommendation 191 Healthcare employers recruiting nursing staff, whether qualified or unqualified, should assess candidates' values, attitudes and behaviours towards the well-being of patients and their basic care needs, and care providers should be required to do so by commissioning and regulatory requirements.
Patient safety	Recommendation 192 The Department of Health and the Nursing and Midwifery Council should introduce the concept of a Responsible Officer for nursing, appointed by and accountable to, the Nursing and Midwifery Council.
Patient safety	Recommendation 193

The Mid Staffordshire NHS Foundation Trust Public Inquiry (2013)

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Subject of accepted recommendation (pertaining to patient safety or whistleblowing)	Text of accepted recommendation
	Without introducing a revalidation scheme immediately, the Nursing and Midwifery Council should introduce common minimum standards for appraisal and support with which responsible officers would be obliged to comply. They could be required to report to the Nursing and Midwifery Council on their performance on a regular basis.
Patient safety	Recommendation 194 As part of a mandatory annual performance appraisal, each Nurse, regardless of workplace setting, should be required to demonstrate in their annual learning portfolio an up-to-date knowledge of nursing practice and its implementation. Alongside developmental requirements, this should contain documented evidence of recognised training undertaken, including wider relevant learning. It should also demonstrate commitment, compassion and caring for patients, evidence by feedback from patients and families on the care provided by the nurse. This portfolio and each annual appraisal should be made available to the Nursing and Midwifery Council, if requested, as part of a nurse's revalidation process. At the end of each annual assessment, the appraisal and portfolio should be signed by the nurse as being an accurate and true reflection and be countersigned by their appraising manager as being such.
Patient safety	Recommendation 195 Ward nurse managers should operate in a supervisory capacity, and not be officebound or expected to double up, except in emergencies as part of the nursing provision on the ward. They should know about the care plans relating to every patient on his or her ward. They should make themselves visible to patients and staff alike, and be available to discuss concerns with all, including relatives. Critically, they should work alongside staff as a role model and mentor, developing clinical competencies and leadership skills within the team. As a corollary, they would monitor performance and deliver training and/or feedback as appropriate, including a robust annual appraisal.
Patient safety	Recommendation 196 The Knowledge and Skills Framework should be reviewed with a view to giving explicit recognition to nurses' demonstrations of commitment to patient care and, in particular, to the priority to be accorded to dignity and respect, and their acquisition of leadership skills.
Patient safety	Recommendation 197 Training and continuing professional development for nurses should include leadership training at every level from student to director. A resource for nurse leadership training should be made available for all NHS healthcare provider organisations that should be required under commissioning arrangements by those buying healthcare services to arrange such training for appropriate staff.
Patient safety	Recommendation 198

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	Healthcare providers should be encouraged by incentives to develop and deploy reliable and transparent measures of the cultural health of front-line nursing workplaces and teams, which build on the experience and feedback of nursing staff using a robust methodology, such as the 'cultural barometer'.
Patient safety	Recommendation 199 Each patient should be allocated for each shift a named key nurse responsible for coordinating the provision of the care needs for each allocated patient. The named key nurse on duty should, whenever possible, be present at every interaction between a doctor and an allocated patient.
Patient safety	Recommendation 200 Consideration should be given to the creation of a status of Registered Older Person's Nurse.
Patient safety	Recommendation 201 The Royal College of Nursing should consider whether it should formally divide its 'Royal College' functions and its employee representative/trade union functions and its employee representative/trade union functions between two bodies rather than behind internal 'Chinese walls'.
Patient safety	Recommendation 202 Recognition of the importance of nursing representation at provider level should be given by ensuring that adequate time is allowed for staff to undertake this role, and employers and unions must regularly review the adequacy of the arrangements in this regard.
Patient safety	Recommendation 203 A forum for all directors of nursing from both NHS and independent sector organisations should be formed to provide a means of coordinating the leadership of the nursing profession.
Patient safety	Recommendation 204 All healthcare providers and commissioning organisations should be required to have at least one executive director who is a registered nurse, and should be encouraged to consider recruiting nurses as non-executive directors.
Patient safety	Recommendation 205 Commissioning arrangements should require the boards of provider organisations to seek and record the advice of its nursing director on the impact on the quality of care and patient safety of any proposed major change to nurse staffing arrangements or provision facilities, and to record whether they accepted or rejected the advice, in the latter case recording its reasons for doing so.
Patient safety	Recommendation 206

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	The effectiveness of the newly positioned office of Chief Nursing Officer should be kept under review to ensure the maintenance of a recognised leading representative of the nursing profession as a whole, able and empowered to give independent professional advice to the Government on nursing issues of equivalent authority to that provided by the Chief Medical Officer.
Patient safety	Recommendation 207 There should be a uniform description of healthcare support workers, with the relationship with currently registered nurses made clear by the title.
Patient safety	Recommendation 208 Commissioning arrangements should require provider organisations to ensure by means of identity labels and uniforms that a healthcare support worker is easily distinguishable from that of a registered nurse.
Patient safety	Recommendation 210 There should be a national code of conduct for healthcare support workers.
Patient safety	Recommendation 211 There should be a common set of national standards for the education and training of healthcare support workers.
Patient safety	Recommendation 214 A leadership staff college or training system, whether centralised or regional, should be created to: provide common professional training in management and leadership to potential senior staff; promote healthcare leadership and management as a profession; administer an accreditation scheme to enhance eligibility for consideration for such roles; promote and research best leadership practice in healthcare.
	Recommendation 215 A common code of ethics, standards and conduct for senior board-level healthcare leaders and managers should be produced and steps taken to oblige all such staff to comply with the code and their employers to enforce it.
Patient safety	Recommendation 216 The leadership framework should be improved by increasing the emphasis given to patient safety in the thinking of all in the health service. This could be done by, for example, creating a separate domain for managing safety, or by defining the service to be delivered as a safe and effective service.
Patient safety	Recommendation 217 A list should be drawn up of all the qualities generally considered necessary for a good and effective leader. This in turn could inform a list of competences a leader would be expected to have.

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Patient safety	Recommendation 218 Serious non-compliance with the code, and in particular, non-compliance leading to actual or potential harm to patients, should render board-level leaders and managers liable to be found not to be fit and proper persons to hold such positions by a fair and proportionate procedure, with the effect of disqualifying them from holding such positions in future.
Patient safety	Recommendation 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.
Patient safety	Recommendation 220 A training facility could provide the route through which an accreditation scheme could be organised. Although this might be a voluntary scheme, at least initially, the objective should be to require all leadership posts to be filled by persons who experience some shared training and obtain the relevant accreditation, enhancing the spread of the common culture and providing the basis for a regulatory regime.
Patient safety	Recommendation 221 Consideration should be given to ensuring that there is regulatory oversight of the competence and compliance with appropriate standards by the boards of health service bodies which are not Foundation Trusts, of equivalent rigour to that applied to Foundation Trusts.
Patient safety	Recommendation 222 The General Medical Council should have a clear policy about the circumstances in which a generic complaint or report ought to be made to it, enabling a more proactive approach to monitoring fitness to practise.
Patient safety	Recommendation 223 If the General Medical Council is to be effective in looking into generic complaints and information it will probably need either greater resources, or better cooperation with the Care Quality Commission and other organisations such as the Royal Colleges to ensure that it is provided with the appropriate information.
Patient safety	Recommendation 224 Steps must be taken to systematise the exchange of information between the Royal Colleges and the General Medical Council, and to issue guidance for use by employers of doctors to the same effect.

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Patient safety	Recommendation 225 The General Medical Council should have regard to the possibility of commissioning peer reviews pursuant to section 35 of the Medical Act 1983 where concerns are raised in a generic way, in order to be advised whether there are individual concerns. Such reviews could be jointly commissioned with the Care Quality Commission in appropriate cases.
Patient safety	Recommendation 226 To act as an effective regulator of nurse managers and leaders, as well as more front-line nurses, the Nursing and Midwifery Council needs to be equipped to look at systemic concerns as well as individual ones. It must be enabled to work closely with the systems regulators and to share their information and analyses on the working of systems in organisations in which nurses are active. It should not have to wait until a disaster has occurred to intervene with its fitness to practise procedures. Full access to the Care Quality Commission information in particular is vital.
Patient safety	Recommendation 227 The Nursing and Midwifery Council needs to have its own internal capacity to assess systems and launch its own proactive investigations where it becomes aware of concerns which may give rise to nursing fitness to practise issues. It may decide to seek the cooperation of the Care Quality Commission, but as an independent regulator it must be empowered to act on its own if it considers it necessary in the public interest. This will require resources in terms of appropriately expert staff, data systems and finance. Given the power of the registrar to refer cases without a formal third party complaint, it would not appear that a change of regulation is necessary, but this should be reviewed.
Patient safety	Recommendation 228 It is of concern that the administration of the Nursing and Midwifery Council, which has not been examined by this Inquiry, is still found by other reviews to be wanting. It is imperative in the public interest that this is remedied urgently. Without doing so, there is a danger that the regulatory gap between the Nursing and Midwifery Council and the Care Quality Commission will widen rather than narrow.
Patient safety	Recommendation 229 It is highly desirable that the Nursing and Midwifery Council introduces a system of revalidation similar to that of the General Medical Council, as a means of reinforcing the status and competence of registered nurses, as well as providing additional protection to the public. It is essential that the Nursing and Midwifery Council has the resources and the administrative and leadership skills to ensure that this does not detract from its existing core function of regulating fitness to practise of registered nurses.
Patient safety	Recommendation 230

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	The profile of the Nursing and Midwifery Council needs to be raised with the public, who are the prime and most valuable source of information about the conduct of nurses. All patients should be informed, by those providing treatment or care, of the existence and role of the Nursing and Midwifery Council, together with contact details. The Nursing and Midwifery Council itself needs to undertake more by way of public promotion of its functions.
Patient safety	Recommendation 231 It is essential that, so far as practicable, Nursing and Midwifery Council procedures do not obstruct the progress of internal disciplinary action in providers. In most cases it should be possible, through cooperation, to allow both to proceed in parallel. This may require a review of employment disciplinary procedures, to make it clear that the employer is entitled to proceed even if there are pending Nursing and Midwifery Council proceedings.
Patient safety	Recommendation 232 The Nursing and Midwifery Council could consider a concept of employment liaison officers, similar to that of the General Medical Council, to provide support to directors of nursing. If this is impractical, a support network of senior nurse leaders will have to be engaged in filling this gap.
Patient safety	Recommendation 233 While both the General Medical Council and the Nursing and Midwifery Council have highly informative internet sites, both need to ensure that patients and other service users are made aware at the point of service provision of their existence, their role and their contact details.
Patient safety	Recommendation 234 Both the General Medical Council and Nursing and Midwifery Council must develop closer working relationships with the Care Quality Commission – in many cases there should be joint working to minimise the time taken to resolve issues and maximise the protection afforded to the public.
Patient safety	Recommendation 235 The Professional Standards Authority for Health and Social Care (PSA) (formerly the Council for Healthcare Regulatory Excellence), together with the regulators under its supervision, should seek to devise procedures for dealing consistently and in the public interest with cases arising out of the same event or series of events but involving professionals regulated by more than one body. While it would require new regulations, consideration should be given to the possibility of moving towards a common independent tribunal to determine fitness to practise issues and sanctions across the healthcare professional field.
Patient safety	Recommendation 236 Hospitals should review whether to reinstate the practice of identifying a senior clinician who is in charge of a patient's case, so that patients and their supporters are clear who is in overall charge of a patient's care.

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Patient safety	Recommendation 237 There needs to be effective teamwork between all the different disciplines and services that together provide the collective care often required by an elderly patient; the contribution of cleaners, maintenance staff, and catering staff also needs to be recognised and valued.
Patient safety	Recommendation 238 Regular interaction and engagement between nurses and patients and those close to them should be systematised through regular ward rounds: • All staff need to be enabled to interact constructively, in a helpful and friendly fashion, with patients and visitors. • Where possible, wards should have areas where more mobile patients and their visitors can meet in relative privacy and comfort without disturbing other patients. • The NHS should develop a greater willingness to communicate by email with relatives. • The currently common practice of summary discharge letters followed up some time later with more substantive ones should be reconsidered. • Information about an older patient's condition, progress and care and discharge plans should be available and shared with that patient and, where appropriate, those close to them, who must be included in the therapeutic partnership to which all patients are entitled.
Patient safety	Recommendation 239 The care offered by a hospital should not end merely because the patient has surrendered a bed – it should never be acceptable for patients to be discharged in the middle of the night, still less so at any time without absolute assurance that a patient in need of care will receive it on arrival at the planned destination. Discharge areas in hospital need to be properly staffed and provide continued care to the patient.
Patient safety	Recommendation 240 All staff and visitors need to be reminded to comply with hygiene requirements. Any member of staff, however junior, should be encouraged to remind anyone, however senior, of these.
Patient safety	Recommendation 241 The arrangements and best practice for providing food and drink to elderly patients require constant review, monitoring and implementation.
Patient safety	Recommendation 242 In the absence of automatic checking and prompting, the process of the administration of medication needs to be overseen by the nurse in charge of the ward, or his/her nominated delegate. A frequent check needs to be done to ensure that all patients have received what they have been prescribed and what they need. This is particularly the case when patients are moved from one ward to another, or they are returned to the ward after treatment.

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Patient safety	Recommendation 243 The recording of routine observations on the ward should, where possible, be done automatically as they are taken, with results being immediately accessible to all staff electronically in a form enabling progress to be monitored and interpreted. If this cannot be done, there needs to be a system whereby ward leaders and named nurses are responsible for ensuring that the observations are carried out and recorded.
Patient safety	Recommendation 244 There is a need for all to accept common information practices, and to feed performance information into shared databases for monitoring purposes. The following principles should be applied in considering the introduction of electronic patient information systems: • Patients need to be granted user friendly, real time and retrospective access to read their records, and a facility to enter comments. They should be enabled to have a copy of records in a form useable by them, if they wish to have one. If possible, the summary care record should be made accessible in this way. • Systems should be designed to include prompts and defaults where these will contribute to safe and effective care, and to accurate recording of information on first entry. • Systems should include a facility to alert supervisors where actions which might be expected have not occurred, or where likely inaccuracies have been entered. • Systems should, where practicable and proportionate, be capable of collecting performance management and audit information automatically, appropriately anonymised direct from entries, to avoid unnecessary duplication of input. • Systems must be designed by healthcare professionals in partnership with patient groups to secure maximum professional and patient engagement in ensuring accuracy, utility and relevance, both to the needs of the individual patients and collective professional, managerial and regulatory requirements. Systems must be capable of reflecting changing needs and local requirements over and above nationally required minimum standards.
Patient safety	Recommendation 245 Each provider organisation should have a board level member with responsibility for information.
Patient safety	Recommendation 246 Department of Health/the NHS Commissioning Board/regulators should ensure that provider organisations publish in their annual quality accounts information in a common form to enable comparisons to be made between organisations, to include a minimum of prescribed information about their

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	compliance with fundamental and other standards, their proposals for the rectification of any non-compliance and statistics on mortality and other outcomes. Quality accounts should be required to contain the observations of commissioners, overview and scrutiny committees, and Local Healthwatch.
Patient safety	Recommendation 247 Healthcare providers should be required to lodge their quality accounts with all organisations commissioning services from them, Local Healthwatch, and all systems regulators.
Patient safety	Recommendation 248 Healthcare providers should be required to have their quality accounts independently audited. Auditors should be given a wider remit enabling them to use their professional judgement in examining the reliability of all statements in the accounts.
Patient safety	Recommendation 249 Each quality account should be accompanied by a declaration signed by all directors in office at the date of the account certifying that they believe the contents of the account to be true, or alternatively a statement of explanation as to the reason any such director is unable or has refused to sign such a declaration.
Patient safety	Recommendation 250 It should be a criminal offence for a director to sign a declaration of belief that the contents of a quality account are true if it contains a misstatement of fact concerning an item of prescribed information which he/she does not have reason to believe is true at the time of making the declaration.
Patient safety	Recommendation 251 The Care Quality Commission 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.
Patient safety	Recommendation 252 It is important that the appropriate steps are taken to enable properly anonymised data to be used for managerial and regulatory purposes.
Patient safety	Recommendation 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.

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Patient safety	Recommendation 254 While there are likely to be many different gateways offered through which patient and public comments can be made, to avoid confusion, it would be helpful for there to be consistency across the country in methods of access, and for the output to be published in a manner allowing fair and informed comparison between organisations.
Patient safety	Recommendation 255 Results and analysis of patient feedback including qualitative information need to be made available to all stakeholders in as near 'real time' as possible, even if later adjustments have to be made.
Patient safety	Recommendation 256 A proactive system for following up patients shortly after discharge would not only be good 'customer service', it would probably provide a wider range of responses and feedback on their care.
Patient safety	Recommendation 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.
Patient safety	Recommendation 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.
Patient safety	Recommendation 259 The Information Centre, in consultation with the Department of Health, the NHS Commissioning Board and the Parliamentary and Health Service Ombudsman, should develop a means of publishing more detailed breakdowns of clinically related complaints
Patient safety	Recommendation 260 The standards applied to statistical information about serious untoward incidents should be the same as for any other healthcare information and in particular the principles around transparency and accessibility. It would, therefore, be desirable for the data to be supplied to, and processed by, the Information Centre and, through them, made publicly available in the same way as other quality related information.
Patient safety	Recommendation 261

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	The Information Centre should be enabled to undertake more detailed statistical analysis of its own than currently appears to be the case.
Patient safety	Recommendation 262 All healthcare provider organisations, in conjunction with their healthcare professionals, should develop and maintain systems which give them: • Effective real-time information on the performance of each of their services against patient safety and minimum quality standards; • Effective real-time information of the performance of each of their consultants and specialist teams in relation to mortality, morbidity, outcome and patient satisfaction. In doing so, they should have regard, in relation to each service, to best practice for information management of that service as evidenced by recommendations of the Information Centre, and recommendations of specialist organisations such as the medical Royal Colleges. The information derived from such systems should, to the extent practicable, be published and in any event made available in full to commissioners and regulators, on request, and with appropriate explanation, and to the extent that is relevant to individual patients, to assist in choice of treatment.
Patient safety	Recommendation 263 It must be recognised to be the professional duty of all healthcare professionals to collaborate in the provision of information required for such statistics on the efficacy of treatment in specialties.
Patient safety	Recommendation 264 In the case of each specialty, a programme of development for statistics on the efficacy of treatment should be prepared, published, and subjected to regular review.
Patient safety	Recommendation 265 The Department of Health, the Information Centre and the Care Quality Commission should engage with each representative specialty organisation in order to consider how best to develop comparative statistics on the efficacy of treatment in that specialty, for publication and use in performance oversight, revalidation, and the promotion of patient knowledge and choice.
Patient safety	Recommendation 266 In designing the methodology for such statistics and their presentation, the Department of Health, the Information Centre, the Care Quality Commission and the specialty organisations should seek and have regard to the views of patient groups and the public about the information needed by them.

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Patient safety	Recommendation 267 All such statistics should be made available online and accessible through provider websites, as well as other gateways such as the Care Quality Commission.
Patient safety	Recommendation 268 Resources must be allocated to and by provider organisations to enable the relevant data to be collected and forwarded to the relevant central registry.
Patient safety	Recommendation 269 The only practical way of ensuring reasonable accuracy is vigilant auditing at local level of the data put into the system. This is important work, which must be continued and where possible improved.
Patient safety	Recommendation 270 There is a need for a review by the Department of Health, the Information Centre and the UK Statistics Authority of the patient outcome statistics, including hospital mortality and other outcome indicators. In particular, there could be benefit from consideration of the extent to which these statistics can be published in a form more readily useable by the public.
Patient safety	Recommendation 271 To the extent that summary hospital-level mortality indicators are not already recognised as national or official statistics, the Department of Health and the Health and Social Care Information Centre should work towards establishing such status for them or any successor hospital mortality figures, and other patient outcome statistics, including reports showing provider-level detail.
Patient safety	Recommendation 272 There is a demonstrable need for an accreditation system to be available for healthcare-relevant statistical methodologies. The power to create an accreditation scheme has been included in the Health and Social Care Act 2012, it should be used as soon as practicable.
Patient safety	Recommendation 273 The terms of authorisation, licensing and registration and any relevant guidance should oblige healthcare providers to provide all relevant information to enable the coroner to perform his function, unless a director is personally satisfied that withholding the information is justified in the public interest.
Patient safety	Recommendation 274 There is an urgent need for unequivocal guidance to be given to trusts and their legal advisers and those handling disclosure of information to coroners, patients and families, as to the priority to be given to openness over any perceived material interest.

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Patient safety	Recommendation 275 It is of considerable importance that independent medical examiners are independent of the organisation whose patients' deaths are being scrutinised.
Patient safety	Recommendation 276 Sufficient numbers of independent medical examiners need to be appointed and resourced to ensure that they can give proper attention to the workload.
Patient safety	Recommendation 277 National guidance should set out standard methodologies for approaching the certification of the cause of death to ensure, so far as possible, that similar approaches are universal.
Patient safety	Recommendation 278 It should be a routine part of an independent medical examiners role to seek out and consider any serious untoward incidents or adverse incident reports relating to the deceased, to ensure that all circumstances are taken into account whether or not referred to in the medical records.
Patient safety	Recommendation 279 So far as is practicable, the responsibility for certifying the cause of death should be undertaken and fulfilled by the consultant, or another senior and fully qualified clinician in charge of a patient's case or treatment.
Patient safety/whistleblowing	Recommendation 280 Both the bereaved family and the certifying doctor should be asked whether they have any concerns about the death or the circumstances surrounding it, and guidance should be given to hospital staff encouraging them to raise any concerns they may have with the independent medical examiner.
Patient safety	Recommendation 281 It is important that independent medical examiners and any others having to approach families for this purpose have careful training in how to undertake this sensitive task in a manner least likely to cause additional and unnecessary distress.
Patient safety	Recommendation 282 Coroners should send copies of relevant Rule 43 reports to the Care Quality Commission.
Patient safety	Recommendation 283 Guidance should be developed for coroners' offices about whom to approach in gathering information about whether to hold an inquest into the death of a patient. This should include contact with the patient's family.

The Mid Staffordshire NHS Foundation Trust Public Inquiry (2013)

In June 2010, the Secretary of State for Health announced the establishment of a Public Inquiry into the serious failings in care and suffering of many patients at the Mid Staffordshire NHS Foundation Trust between January 2005 and March 2009. The report of the public inquiry by Robert Francis QC was published in February 2013. It made 290 recommendations. The Department published its response covering each of the recommendations in November 2013. The Department agreed to the overwhelming majority of recommendations (mostly in full, some in principle or in part) and rejected 9 recommendations (while accepting the intent behind them: 19, 61, 64, 137, 145, 183, 209, 212, 213).

Subject of accepted recommendation (pertaining to patient safety or whistleblowing)	Text of accepted recommendation
Patient safety	Recommendation 284 The Lord Chancellor should issue guidance as to the criteria to be adopted in the appointment of assistant deputy coroners.
Patient safety	Recommendation 285 The Chief Coroner should issue guidance on how to avoid the appearance of bias when assistant deputy coroners are associated with a party in a case.
Patient safety	Recommendation 286 Impact and risk assessments should be made public, and debated publicly, before a proposal for any major structural change to the healthcare system is accepted. Such assessments should cover at least the following issues: • What is the precise issue or concern in respect of which change is necessary? • Can the policy objective identified be achieved by modifications within the existing structure? • How are the successful aspects of the existing system to be incorporated and continued in the new system? • How are the existing skills which are relevant to the new system to be transferred to it? • How is the existing corporate and individual knowledge base to be preserved, transferred and exploited? • How is flexibility to meet new circumstances and to respond to experience built into the new system to avoid the need for further structural change? • How are necessary functions to be performed effectively during any transitional period? • What are the respective risks and benefits to service users and the public and, in particular, are there any risks to safety or welfare?
Patient safety	Recommendation 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.
Patient safety	Recommendation 288 The Department of Health should ensure that there is senior clinical involvement in all policy decisions which may impact on patient safety and well-being.
Patient safety	Recommendation 289

The Mid Staffordshire NHS Foundation Trust Public Inquiry (2013)

In June 2010, the Secretary of State for Health announced the establishment of a Public Inquiry into the serious failings in care and suffering of many patients at the Mid Staffordshire NHS Foundation Trust between January 2005 and March 2009. The report of the public inquiry by Robert Francis QC was published in February 2013. It made 290 recommendations. The Department published its response covering each of the recommendations in November 2013. The Department agreed to the overwhelming majority of recommendations (mostly in full, some in principle or in part) and rejected 9 recommendations (while accepting the intent behind them: 19, 61, 64, 137,145,183,209,212,213).

Subject of accepted recommendation (pertaining to patient safety or whistleblowing)	Text of accepted recommendation
	Department of Health officials need to connect more to the NHS by visits, and most importantly by personal contact with those who have suffered poor experiences. The Department of Health could also be assisted in its work by involving patient/service user representatives through some form of consultative forum within the Department.
Patient safety	Recommendation 290 The Department of Health should promote a shared positive culture by setting an example in its statements by being open about deficiencies, ensuring those harmed have a remedy, and making information publicly available about performance at the most detailed level possible.

The Morecambe Bay Investigation report by Dr Bill Kirkup (2015)

The Morecambe Bay Investigation was commissioned by the Secretary of State in September 2013. It reviewed the management, delivery and outcomes of care provided by the maternity and neonatal services at the University Hospitals of Morecambe Bay NHS Foundation Trust. The investigation was chaired by Dr Bill Kirkup CBE and published in March 2015. The report contains 44 recommendations; 18 are aimed at the Trust (1-18 below) and 26 are aimed at the wider NHS (19-44). All the recommendations were accepted or accepted in principle.

Subject of accepted recommendation (pertaining to patient safety or whistleblowing)	Text of accepted recommendation
Recommendations for the Trust	
Patient Safety	1. The University Hospitals of Morecambe Bay NHS Foundation Trust should formally admit the extent and nature of the problems that have previously occurred, and should apologise to those patients and relatives affected, not only for the avoidable damage caused but also for the length of time it has taken to bring them to light and the previous failures to act. This should begin immediately with the response to this Report
Patient Safety	2. The University Hospitals of Morecambe Bay NHS Foundation Trust should review the skills, knowledge, competencies and professional duties of care of all obstetric, paediatric, midwifery and neonatal nursing staff, and other staff caring for critically ill patients in anaesthetics and intensive and high dependency care, against all relevant guidance from professional and regulatory bodies. This review should be completed by June 2015, and identify requirements for additional training, development and, where necessary, a period of experience elsewhere.
Patient Safety	3. The University Hospitals of Morecambe Bay NHS Foundation Trust should draw up plans to deliver the training and development of staff identified as a result of the review of maternity, neonatal and other staff, and should identify opportunities to broaden staff experience in other units, including by secondment and by supernumerary practice. These should be in place in time for June 2015.
Patient Safety	4. Following completion of additional training or experience where necessary, the University Hospitals of Morecambe Bay NHS Foundation Trust should identify requirements for continuing professional development of staff and link this explicitly with professional requirements including revalidation. This should be completed by September 2015.
Patient Safety	5. The University Hospitals of Morecambe Bay NHS Foundation Trust should identify and develop measures that will promote effective multidisciplinary team-working, in particular between paediatricians, obstetricians, midwives and neonatal staff. These measures should include, but not be limited to, joint training sessions, clinical, policy and management meetings and staff development activities. Attendance at designated events must be compulsory within terms of employment. These measures should be identified by April 2015 and begun by June 2015.
Patient Safety	6. The University Hospitals of Morecambe Bay NHS Foundation Trust should draw up a protocol for risk assessment in maternity services, setting out clearly: who should be offered the option of delivery at Furness General Hospital and who should not; who will carry out this assessment against which criteria; and how this will be discussed with pregnant women and families. The protocol should involve all relevant staff groups, including midwives, paediatricians, obstetricians and those in the receiving units within the region. The Trust should ensure that individual decisions on delivery are clearly recorded as part of the plan of care, including what risk factors may trigger escalation of care, and that all Trust staff are aware that they should not vary decisions without a documented risk assessment. This should be completed by June 2015

Patient Safety	7. The University Hospitals of Morecambe Bay NHS Foundation Trust should audit the operation of maternity and paediatric services, to ensure that they follow risk assessment protocols on place of delivery, transfers and management of care, and that effective multidisciplinary care operates without inflexible demarcations between professional groups. This should be in place by September 2015.
Patient Safety	8. The University Hospitals of Morecambe Bay NHS Foundation Trust should identify a recruitment and retention strategy aimed at achieving a balanced and sustainable workforce with the requisite skills and experience. This should include, but not be limited to, seeking links with one or more other centre(s) to encourage development of specialist and/or academic practice whilst offering opportunities in generalist practice in the Trust; in addition, opportunities for flexible working to maximise the advantages of close proximity to South Lakeland should be sought. Development of the strategy should be completed by January 2016.
Patient Safety	9. The University Hospitals of Morecambe Bay NHS Foundation Trust should identify an approach to developing better joint working between its main hospital sites, including the development and operation of common policies, systems and standards. Whilst we do not believe that the introduction of extensive split-site responsibilities for clinical staff will do much other than lead to time wasted in travelling, we do consider that, as part of this approach, flexibility should be built into working responsibilities to provide temporary solutions to short-term staffing problems. This approach should be begun by September 2015
Patient Safety	10. The University Hospitals of Morecambe Bay NHS Foundation Trust should seek to forge links with a partner Trust, so that both can benefit from opportunities for learning, mentoring, secondment, staff development and sharing approaches to problems. This arrangement is promoted and sometimes facilitated by Monitor as 'buddying' and we endorse the approach under these circumstances. This could involve the same centre identified as part of the recruitment and retention strategy. If a suitable partner is forthcoming, this arrangement should be begun by September 2015
Patient Safety/ Whistleblowing	11. The University Hospitals of Morecambe Bay NHS Foundation Trust should identify and implement a programme to raise awareness of incident reporting, including requirements, benefits and processes. The Trust should also review its policy of openness and honesty in line with the duty of candour of professional staff, and incorporate into the programme compliance with the refreshed policy. This should be begun with maternity staff by April 2015 and rolled out to other staff by April 2016.
Patient Safety	12. The University Hospitals of Morecambe Bay NHS Foundation Trust should review the structures, processes and staff involved in investigating incidents, carrying out root cause analyses, reporting results and disseminating learning from incidents, identifying any residual conflicts of interest and requirements for additional training. The Trust should ensure that robust documentation is used, based on a recognised system, and that Board reports include details of how services have been improved in response. The review should include the provision of appropriate arrangements for staff debriefing and support following a serious incident. This should be begun with maternity units by April 2015 and rolled out across the Trust by April 2016
Patient Safety	13. The University Hospitals of Morecambe Bay NHS Foundation Trust should review the structures, processes and staff involved in responding to complaints, and introduce measures to promote the use of complaints as a source of improvement and reduce defensive 'closed' responses to complainants. The Trust should increase public and patient involvement in resolving complaints, in the case of maternity services through the Maternity Services Liaison Committee. This should be completed, and the improvements demonstrated at an open Board meeting, by December 2015
Patient Safety	14. The University Hospitals of Morecambe Bay NHS Foundation Trust should review arrangements for clinical leadership in obstetrics, paediatrics and midwifery, to ensure that the right people are in place with appropriate skills and support. The Trust has implemented change at executive level, but this needs to be carried through to the levels below. All staff with defined responsibilities for clinical leadership should show evidence of attendance at appropriate training and development events. This review should be commenced by April 2015

Patient Safety	15. The University Hospitals of Morecambe Bay NHS Foundation Trust should continue to prioritise the work commenced in response to the review of governance systems already carried out, including clinical governance, so that the Board has adequate assurance of the quality of care provided by the Trust's services. This work is already underway with the facilitation of Monitor, and we would not seek to vary or add to it, which would serve only to detract from implementation. We do, however, recommend that a full audit of implementation be undertaken before this is signed off as completed
Patient Safety	16. As part of the governance systems work, we consider that the University Hospitals of Morecambe Bay NHS Foundation Trust should ensure that middle managers, senior managers and non-executives have the requisite clarity over roles and responsibilities in relation to quality, and it should provide appropriate guidance and where necessary training. This should be completed by December 2015
Patient Safety	17. The University Hospitals of Morecambe Bay NHS Foundation Trust should identify options, with a view to implementation as soon as practicable, to improve the physical environment of the delivery suite at Furness General Hospital, including particularly access to operating theatres, an improved ability to observe and respond to all women in labour and en suite facilities; arrangements for post-operative care of women also need to be reviewed. Plans should be in place by December 2015 and completed by December 2017
Patient Safety	18. All of the previous recommendations should be implemented with the involvement of Clinical Commissioning Groups, and where necessary, the Care Quality Commission and Monitor. In the particular circumstances surrounding the University Hospitals of Morecambe Bay NHS Foundation Trust, NHS England should oversee the process, provide the necessary support, and ensure that all parties remain committed to the outcome, through an agreed plan with the Care Quality Commission, Monitor and the Clinical Commissioning Groups.
Recommendations for the wider NHS	
Patient safety	19. In light of the evidence we have heard during the Investigation, we consider that the professional regulatory bodies should review the findings of this Report in detail with a view to investigating further the conduct of registrants involved in the care of patients during the time period of this Investigation.
Patient safety	20. Clear standards should be drawn up for incident reporting and investigation in maternity services. These should include the mandatory reporting and investigation as serious incidents of maternal deaths, late and intrapartum stillbirths and unexpected neonatal deaths. We believe that there is a strong case to include a requirement that investigation of these incidents be subject to a standardised process, which includes input from and feedback to families, and independent, multidisciplinary peer review, and should certainly be framed to exclude conflicts of interest between staff. We recommend that this build on national work already begun on how such a process would work. Action: the Care Quality Commission, NHS England, the Department of Health.
Patient safety	21. We commend the introduction of the duty of candour for all NHS professionals. This should be extended to include the involvement of patients and relatives in the investigation of serious incidents, both to provide evidence that may otherwise be lacking and to receive personal feedback on the results.
Patient safety / Whistleblowing	22. We recommend that a duty should be placed on all NHS Boards to report openly the findings of any external investigation into clinical services, governance or other aspects of the operation of the Trust, including prompt notification of relevant external bodies such as the Care Quality Commission and Monitor. The Care Quality Commission should develop a system to disseminate learning from investigations to other Trusts.
Whistleblowing	23. We commend the introduction of a clear national policy on whistleblowing. As well as protecting the interests of whistleblowers, we recommend that this is implemented in a way that ensures that a systematic and proportionate response is made by Trusts to concerns identified.
Patient safety	24. Professional regulatory bodies should clarify and reinforce the duty of professional staff to report concerns about clinical services, particularly where these relate to patient safety, and the mechanism to do so. Failure to report concerns should be regarded as a lapse from professional standards.

Patient safety	25. Clear national standards should be drawn up setting out the professional duties and expectations of clinical leads at all levels, including, but not limited to, clinical directors, clinical leads, heads of service, medical directors, nurse directors. Trusts should provide evidence to the Care Quality Commission, as part of their processes, of appropriate policies and training to ensure that standards are met. Action: NHS England, the Care Quality Commission, the General Medical Council, the Nursing and Midwifery Council, all Trusts.
Patient safety	26. Clear national standards should be drawn up setting out the responsibilities for clinical quality of other managers, including executive directors, middle managers and nonexecutives. All Trusts should provide evidence to the Care Quality Commission, as part of their processes, of appropriate policies and training to ensure that standards are met. Action: NHS England, the Care Quality Commission, all Trusts.
Patient Safety	27. The Local Supervising Authority system for midwives was ineffectual at detecting manifest problems at the University Hospitals of Morecambe Bay NHS Foundation Trust, not only in individual failures of care but also with the systems to investigate them. As with complaints, our remit was not to examine the operation of the system nationally; however, the nature of the failures and the recent King's Fund review (Midwifery regulation in the United Kingdom) lead us to suppose that this is not unique to this Trust, although there were specific problems there that exacerbated the more systematic concern. We believe that an urgent response is required to the King's Fund findings, with effective reform of the system
Patient safety	28. We considered carefully the effectiveness of separating organisationally the regulation of quality by the Care Quality Commission from the regulation of finance and performance by Monitor, given the close inter-relationship between Trust decisions in each area. However, we were persuaded that there is more to be gained than lost by keeping regulation separated in this way, not least that decisions on safety are not perceived to be biased by their financial implications. The close links, however, require a carefully coordinated approach, and we recommend that the organisations draw up a memorandum of understanding specifying roles, relationships and communication.
Patient safety	29. The relationship between the investigation of individual complaints and the investigation of the systemic problems that they exemplify gave us cause for concern, in particular the breakdown in communication between the Care Quality Commission and the Parliamentary and Health Service Ombudsman over necessary action and follow-up. We recommend that a memorandum of understanding be drawn up clearly specifying roles, responsibilities, communication and follow-up, including explicitly agreed actions where issues overlap.
Patient safety	30. The division of responsibilities between the Care Quality Commission and other parts of the NHS for oversight of service quality and the implementation of measures to correct patient safety failures was not clear, and we are concerned that potential ambiguity persists. We recommend that NHS England draw up a protocol that clearly sets out the responsibilities for all parts of the oversight system, including itself, in conjunction with the other relevant bodies; the starting point should be that one body, the Care Quality Commission, takes prime responsibility.
Patient safety	31. The cumulative impact of new policies and processes, particularly the perceived pressure to achieve Foundation Trust status, together with organisational reconfiguration, placed significant pressure on the management capacity of the University Hospitals of Morecambe Bay NHS Foundation Trust to deliver against changing requirements whilst maintaining day-to-day needs, including safeguarding patient safety. Whilst we do not absolve Trusts from responsibility for prioritising limited capability safely and effectively, we recommend that the Department of Health should review how it carries out impact assessments of new policies to identify the risks as well as the resources and time required.
Patient safety	32. There is no mechanism to scrutinise perinatal deaths or maternal deaths independently, to identify patient safety concerns and to provide early warning of adverse trends. This shortcoming has been clearly identified in relation to adult deaths by Dame Janet Smith in her review of the Shipman deaths but is in our view no less applicable to maternal and perinatal deaths, and should have raised concerns in the University Hospitals of Morecambe Bay NHS Foundation Trust before they eventually became evident. Legislative preparations have already been made to implement a system based on medical examiners, as effectively used in other countries, and pilot schemes have apparently proved effective. We cannot understand why this has not already been implemented in full and recommend that steps are taken to do so without delay.

Patient safety	33. There should be a national review of the provision of maternity care and paediatrics in challenging circumstances, including areas that are rural, difficult to recruit to, or isolated. This should identify the requirements to sustain safe services under these conditions. In conjunction, a national protocol should be drawn up that defines the types of unit required in different settings and the levels of care that it is appropriate to offer in them.
Patient Safety	34. The challenge of providing healthcare in areas that are rural, difficult to recruit to or isolated is not restricted to maternity care and paediatrics. We recommend that NHS England consider the wisdom of extending the review of requirements to sustain safe provision to other services. This is an area lacking in good-quality research yet it affects many regions of England, Wales and Scotland. This should be seen as providing an opportunity to develop and promote a positive way of working in remote and rural environments.
Patient Safety	35. Given that the systematic review of deaths by medical examiners should be in place, as above, we recommend that this system be extended to stillbirths as well as neonatal deaths, thereby ensuring that appropriate recommendations are made to coroners concerning the occasional need for inquests in individual cases, including deaths following neonatal transfer.
Patient Safety	36. We further recommend that all external reviews of suspected service failures be registered with the Care Quality Commission and Monitor, and that the Care Quality Commission develops a system to collate learning from reviews and disseminate it to other Trusts. Action: the Care Quality Commission, Monitor.
Patient Safety	37. We believe that the educational opportunities afforded by smaller units, particularly in delivering a broad range of care with a high personal level of responsibility, have been insufficiently recognised and exploited. We recommend that a review be carried out of the opportunities and challenges to assist such units in promoting services and the benefits to larger units of linking with them. Action: Health Education England, the Royal College of Obstetricians and Gynaecologists, the Royal College of Paediatrics and Child Health, the Royal College of Midwives.
Patient Safety	38. A national protocol should be drawn up setting out the duties of all Trusts and their staff in relation to inquests. This should include, but not be limited to, the avoidance of attempts to 'fend off' inquests, a mandatory requirement not to coach staff or provide 'model answers', the need to avoid collusion between staff on lines to take, and the inappropriateness of relying on coronial processes or expert opinions provided to coroners to substitute for incident investigation.
Patient Safety	39. The NHS complaints system in the University Hospitals of Morecambe Bay NHS Foundation Trust failed relatives at almost every turn. Although it was not within our remit to examine the operation of the NHS complaints system nationally, both the nature of the failures and persistent comment from elsewhere lead us to suppose that this is not unique to this Trust. We believe that a fundamental review of the NHS complaints system is required, with particular reference to strengthening local resolution and improving its timeliness, introducing external scrutiny of local resolution and reducing reliance on the Parliamentary and Health Service Ombudsman to intervene in unresolved complaints.
Patient Safety	40. Mortality recording of perinatal deaths is not sufficiently systematic, with failures to record properly at individual unit level and to account routinely for neonatal deaths of transferred babies by place of birth. This is of added significance when maternity units rely inappropriately on headline mortality figures to reassure others that all is well. We recommend that recording systems are reviewed and plans brought forward to improve systematic recording and tracking of perinatal deaths. This should build on the work of national audits such as MBRRACE-UK, and include the provision of comparative information to Trusts.
Patient Safety	41. This Investigation was hampered at the outset by the lack of an established framework covering such matters as access to documents, the duty of staff and former staff to cooperate, and the legal basis for handling evidence. These obstacles were overcome, but the need to do this from scratch each time an investigation of this format is set up is unnecessarily time-consuming. We believe that this is an effective investigation format that is capable of getting to the bottom of significant service and organisational problems without the need for a much more expensive, time-consuming and disruptive public inquiry. This being so, we believe that there is considerable merit in establishing a proper framework, if necessary statutory, on which future

	investigations could be promptly established. This would include setting out the arrangements necessary to maintain independence and work effectively and efficiently, as well as clarifying responsibilities of current and former health service staff to cooperate.
Patient Safety	42. We were concerned by the ad hoc nature and variable quality of the numerous external reviews of services that were carried out at the University Hospitals of Morecambe Bay NHS Foundation Trust. We recommend that systematic guidance be drawn up setting out an appropriate framework for external reviews and professional responsibilities in undertaking them. Action: the Academy of Medical Royal Colleges, the Royal College of Nursing, the Royal College of Midwives.
Patient Safety	43. We strongly endorse the emphasis placed on the quality of NHS services that began with the Darzi review, High Quality Care for All, and gathered importance with the response to the events at the Mid Staffordshire NHS Foundation Trust. Our findings confirm that this was necessary and must not be lost. We are concerned that the scale of recent NHS reconfiguration could result in new organisations and post-holders losing the focus on this priority. We recommend that the importance of putting quality first is re-emphasised and local arrangements reviewed to identify any need for personal or organisational development, including amongst clinical leadership in commissioning organisations.
Patient Safety	44. Organisational change that alters or transfers responsibilities and accountability carries significant risk, which can be mitigated only if well managed. We recommend that an explicit protocol be drawn up setting out how such processes will be managed in future. This must include systems to secure retention of both electronic and paper documents against future need, as well as ensuring a clearly defined transition of responsibilities and accountability.

Independent review into Liverpool Community Health NHS Trust (2018)	
Dr Bill Kirkup was asked by the Minister for Health (Ben Gummer) in May 2016 to examine the widespread healthcare failings by Liverpool Community Health NHS Trust (LCH) from November 2010 to December 2014. The independent review published on 8 th February 2018 and made 7 recommendations in relation to advancing patient safety in the NHS. Government accepted all recommendations made by the Chair.	
Subject of accepted recommendation (pertaining to patient safety or whistleblowing)	Text of accepted recommendation
Patient safety	1. Reconfigured LCH services should be reviewed after a year to ensure that the services are now safe and effective.
Patient safety	2. Health services in HMP Liverpool should be subject to urgent review to ensure that future arrangements are fit for purpose and will be effectively monitored.
Patient safety	3. NHS England should review the arrangements for commissioning prison health services nationally to ensure that these are safe and effective.